Trials@uspto.gov
571-272-7822

Paper 39
Date: March 26, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

IPR2019-01657
Patent RE47,614 E

Before RICHARD H. MARSCHALL, JASON W. MELVIN, and SEAN P. O'HANLON, *Administrative Patent Judges*.

O'HANLON, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)
Denying in Part and Dismissing in Part Petitioner's Motion to Exclude
37 C.F.R. § 42.64(c)

I. INTRODUCTION

A. Background

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 1–18 ("the challenged claims") of U.S. Patent No. RE47,614 E (Ex. 1001, "the '614 patent"). Paper 3 ("Pet."), 1. Sanofi-Aventis Deutschland GmbH ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). On April 2, 2020, we instituted an *inter partes* review of the challenged claims on all grounds raised in the Petition. Paper 9 ("Institution Decision" or "Inst. Dec.").

Subsequent to institution, Patent Owner filed a Patent Owner Response (Paper 14, "PO Resp."), Petitioner filed a Reply to the Patent Owner Response (Paper 21, "Pet. Reply"), and Patent Owner filed a Sur-reply to Petitioner's Reply (Paper 28, "PO Sur-reply"). An oral hearing was held on January 13, 2021. A transcript of the hearing has been entered into the record. Paper 38 ("Tr.").

In our Scheduling Order, we notified the parties that "any arguments for patentability not raised in the [Patent Owner] response will be deemed waived." *See* Paper 10, 8; *see also* Patent Trial and Appeal Board Consolidated Trial Practice Guide 66 (Nov. 2019) ("The patent owner response . . . should identify all the involved claims that are believed to be patentable and state the basis for that belief.").[1]

For the reasons that follow, we conclude that Petitioner has proven by a preponderance of the evidence that claims 1–18 of the '614 patent are unpatentable.

[1] *Available at* https://www.uspto.gov/TrialPracticeGuideConsolidated.

B. Real Parties in Interest

Petitioner identifies the following entities as real parties in interest: "Mylan Pharmaceuticals Inc., Mylan Inc., and BGP Products Operations GmbH (all Viatris Inc. subsidiaries); Biocon Ltd., Biocon Biologics India Ltd., and Biocon Sdn. Bhd., Malaysia; and Becton, Dickinson and Company." Paper 36, 2.

Patent Owner states that it is its sole real party in interest. Paper 5, 2.

C. Related Matters

The parties do not identify any district court litigation involving the '614 patent. Pet. 2; Paper 36, 2. Patent Owner notes that it has filed a continuation patent application claiming priority to the application resulting in the '614 patent. Paper 5, 2.

D. The Challenged Patent

The '614 patent discloses "a drug delivery device and a method of manufacturing a drug delivery device." Ex. 1001, 1:26–27. Figures 1 and 5 show illustrative views of the drug delivery device and a spring washer component thereof, respectively, and are reproduced below:

FIG 1

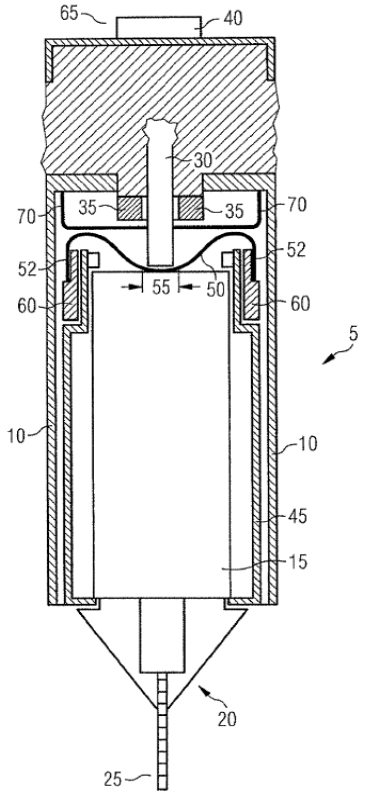


FIG 5

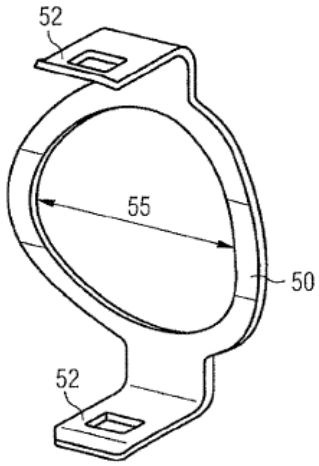


Figure 1 shows, in cross-section, a side view of an exemplary drug delivery device. *Id.* at 3:65–67. Figure 5 shows a spring washer used in the drug delivery device. *Id.* at 4:9–10. Drug delivery device 5, which may be a pen-type device, includes housing 10 in which cartridge 15 containing a medical product is located. *Id.* at 4:17–27. Cartridge retaining member 45 is releasably secured to the housing, such as via a threaded connection, and retains the cartridge within the drug delivery device. *Id.* at 4:30–34, 6:12–14. Spring washer 50 is arranged within the housing to exert a force on the cartridge in the distal direction, thereby securing the cartridge against movement with respect to the cartridge retaining member and housing. *Id.* at 5:10–15.

The spring washer includes fixing elements 52 that extend axially and allow the spring washer to be fixed to the housing, directly or through sleeve 60, or to the cartridge retaining member. Ex. 1001, 5:25–34, 6:44–46. The fixing elements can be snap-fit onto holding means provided on the sleeve. *Id.* at 5:34–35, 7:14–20. In this manner, the spring washer is constrained against axial or rotational movement with respect to the housing. *Id.* at 5:35–53.

The spring washer is curved in the axial or radial directions. Ex. 1001, 7:46–47. When the cartridge retaining member (and the cartridge contained therein) is mounted to the housing, such as by screwing it into the sleeve, the cartridge moves into abutment with the spring washer. *Id.* at 6:17–26. This deflects the spring washer proximally, loading the spring washer such that it exerts a distal force on the cartridge. *Id.* Further washer 70 can be included to limit the proximal deflection of the spring washer. *Id.* at 6:47–60.

The drug contained within the cartridge is dispensed by moving piston rod 30 distally, causing a piston contained within the cartridge to move distally and dispense a dose of the drug. Ex. 1001, 4:38–45. The spring washer includes opening 55 to allow the piston to pass through the spring washer. *Id.* at 5:20–24.

E. The Challenged Claims

Petitioner challenges claims 1–18 of the ’614 patent. Pet. 1, 4. Claims 1 and 16–18 are independent. Claim 1 is illustrative of the challenged claims and 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.

Ex. 1001, 8:2–14.

F. Asserted Ground of Unpatentability

The Petition relies on the following prior art references:

Name	Reference	Exhibit
Burren	US 2007/0021718 A1, published Jan. 25, 2007	1006
Venezia	US 2,882,901, issued Apr. 21, 1959	1007
de Gennes	US 4,144,957, issued Mar. 20, 1979	1008

Petitioner asserts the following ground of unpatentability:

Claims Challenged	35 U.S.C. §	References
1–18	103(a)[2]	Burren, Venezia, de Gennes

Pet. 4. Petitioner submits two declarations of Arthur G. Erdman, Ph.D., (Exs. 1004, 1038, collectively "the Erdman Declarations") in support of its

[2] The application resulting in the '614 patent was filed prior to the date when the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), took effect. Thus, we refer to the pre-AIA version of section 103. For the same reason, we refer to the per-AIA version of section 112 below.

contentions. Patent Owner submits a declaration of Mr. Gordon D. Row (Ex. 2001) in support of its Response.

II. ANALYSIS

A. Principles of Law

To prevail in its challenge to Patent Owner's claims, Petitioner must demonstrate by a preponderance of the evidence that the claims challenged in the Petition are unpatentable. 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2019). This burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time of the invention to a person having ordinary skill in the art. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness.[3] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

[3] The parties have not directed us to any such objective evidence.

B. Level of Ordinary Skill in the Art

Petitioner contends that a person having ordinary skill in the art at the time of the invention ("POSA") "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" and that such a person "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." Pet. 11 (citing Ex. 1004 ¶¶ 36–41).

Patent Owner contends a person having ordinary skill in the art at the time of the invention "would have had at least a bachelor's degree in mechanical engineering or a related field with approximately two years of experience with medical device design and manufacturing." PO Resp. 10 (citing Ex. 2001 ¶ 13).

The parties do not identify, and we do not discern, any material difference between the parties' proposed definitions. Based on the record before us, we adopt Petitioner's proposed definition of the level of ordinary skill, as it addresses subject matter at issue in this Decision (spring elements and fastening structures). We note that we would reach the same conclusions under either proposed standard. We further note that both proposed definitions are consistent with the problems addressed in the '614 patent and the asserted prior art.

C. Claim Construction

In an *inter partes* review, claims are construed using the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b), including construing the claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b). Thus, we apply the claim construction standard as set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Claim terms are generally given their ordinary and customary meaning as would be understood by one with ordinary skill in the art in the context of the specification, the prosecution history, other claims, and even extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Phillips*, 415 F.3d at 1312–17. Usually, the specification is dispositive, and it is the single best guide to the meaning of a disputed term. *Id.* at 1315.

When a claim term does not include the word "means," a rebuttable presumption that the term is not drafted in means-plus-function language pursuant to 35 U.S.C. § 112, ¶ 6, can be overcome "if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (en banc in relevant part) (quotation marks and internal citations omitted). If the presumption is overcome, "[a]pplication of § 112, ¶ 6 requires identification of the structure in the specification which performs

the recited function," but does not permit "incorporation of structure from the written description beyond that necessary to perform the claimed function." *Micro Chem., Inc., v. Great Plains Chem. Co.*, 194 F.3d 1250, 1257–58 (Fed. Cir. 1999).

Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

1. Applicability of Means-Plus-Function Construction

Petitioner argues that "[t]he claim terms should be given their ordinary and customary meaning, consistent with the specification," but proposes constructions for "cartridge retaining member" and "fixing elements" "[i]n case these terms are construed as means-plus-function limitations." Pet. 12–14.

In the Institution Decision, we determined that the presumption against application of § 112, ¶ 6 had not been overcome and that express construction of "cartridge retaining member" and "fixing elements" was not necessary. Inst. Dec. 9–10. We also "direct[ed] the parties to address whether 'cartridge retaining member' and 'fixing elements' should be construed as means-plus-function limitations per § 112, ¶ 6." *Id.* at 10. Patent Owner argues that the claims should not be interpreted as containing means-plus-function limitations. PO Resp. 6–7. Petitioner appears to agree. *See* Pet. Reply 4–5 (arguing that Patent Owner "has waived any argument applying a narrower means-plus-function reading").

We reaffirm our determination that the presumption against application of § 112, ¶ 6 has not been overcome. Neither "cartridge retaining member" nor "fixing elements" recites the word "means," and, therefore, there is a presumption that the terms are not drafted in means-plus-function format. *Williamson*, 792 F.3d at 1349. Additionally, there is no argument or record evidence, proposed by either party, to support the construction of these terms under § 112, ¶ 6. *See Zeroclick LLC v. Apple Inc.*, 891 F.3d 1003, 1007–08 (Fed. Cir. 2018) (determining that, because a party asserting a means-plus-function claim construction provided no evidentiary support for its assertion, that party failed to carry its burden of rebutting the presumption against the application of § 112, ¶ 6). Therefore, the presumption against application of § 112, ¶ 6 is unrebutted. Accordingly, we do not interpret any claim term to contain means-plus-function limitations.

2. Fixing Element

Patent Owner argues that "fixing element" should be construed as "a structure that secures by attachment." PO Resp. 7, 10. In support of this construction, Patent Owner contrasts the function of a fixing element with that of a positioning device. *Id.* at 8–9.

Petitioner replies by arguing that the '614 patent neither provides an express definition of "fixing element" nor supports Patent Owner's proposed construction. Pet. Reply 9–11. According to Petitioner, the "core problem" with Patent Owner's proposed construction is that, "in [the '614 patent], 'fixing' permits some movement," but the '614 patent "provides no guidance on how much movement is permitted before 'fixing' ceases to be 'fixing'." *Id.* at 11. "[The '614 patent] expressly permits axial movement of the fixing

elements during spring loading." *Id.* (citing Ex. 1001, 5:38–40). Petitioner argues that the '614 patent "treats positioning elements and fixing elements as broadly overlapping classes of structures." *Id.* (citing Ex. 1038 ¶ 12).

Patent Owner replies that it "never asserted that a fixing element needs to 'bar any movement at all in all directions.'" PO Sur-reply 2 (citing Pet. Reply 11). Patent Owner reiterates its contention that a "fixing element" should be construed as "a structure that secures by attachment." *Id.* at 2–3, 5, 6.

Independent claims 1, 16, and 17 require the fixing elements of the spring washer to be "configured to axially and rotationally fix the spring washer relative to the housing." Ex. 1001, 8:12–14, 9:9–11, 10:1–3. Independent claim 18 similarly requires the fixing element be "configured to fix the spring washer from movement with respect to the housing." *Id.* at 10:11–13. Thus, the claim language itself precludes movement of the fixing elements with respect to the housing.

Additionally, the '614 patent explains that movement of the spring element is allowed, even with the fixing elements fixed to the housing: "Of course, axial movement of the spring washer 50 for *loading the spring washe*r or during *relaxing of the spring washer* is allowed." Ex. 1001, 5:38–40 (emphases added); *see also id.* at 5:25–26 ("The spring washer 50 is fixed to the housing 10 in order to allow for the force to be exerted on the cartridge 15."). This movement noted by Petitioner is spring flexion, not movement of the fixing elements. Continuing, the '614 patent states, "However, the region(s) in which the spring washer 50 is fixed to the housing 10, e.g. fixing elements 52, preferably do not rotate and/or do not move axially during operation of the drug delivery device." *Id.* at 5:40–43.

Rather, "[s]leeve member 60 and/or spring washer 50 is expediently secured against rotational and/or axial movement with respect to the housing." *Id.* at 5:35–38.

Patent Owner's proposed construction is consistent with the Specification and the ordinary and customary meaning. As discussed above, the Specification of the '614 patent describes that the fixing elements are fixed, or secured, to the housing such that they do not move relative to the housing. *See* Ex. 2004, 3 (defining fix to mean "to make or become firm, stable, or secure" and "to attach or place permanently"); Ex. 2005, 3 (defining fix to mean "fasten (something) securely in a particular place or position"); Ex. 2006, 3 (defining fix to mean "to make firm, stable, or secure" and "to fasten or attach firmly"); *see also CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("Sensibly enough, our precedents show that dictionary definitions may establish a claim term's ordinary meaning." (citations omitted)). Thus, we adopt Patent Owner's proposed construction that "fixing element" means "a structure that secures by attachment." PO Resp. 10.

D. Overview of the Prior Art

1. Burren

Burren discloses "devices for dispensing, injecting or delivering substances, and to methods of making and using such devices." Ex. 1006 ¶ 2. Figures 1 and 2 show illustrative views of the injecting device and a spring component thereof, respectively, and are reproduced below:

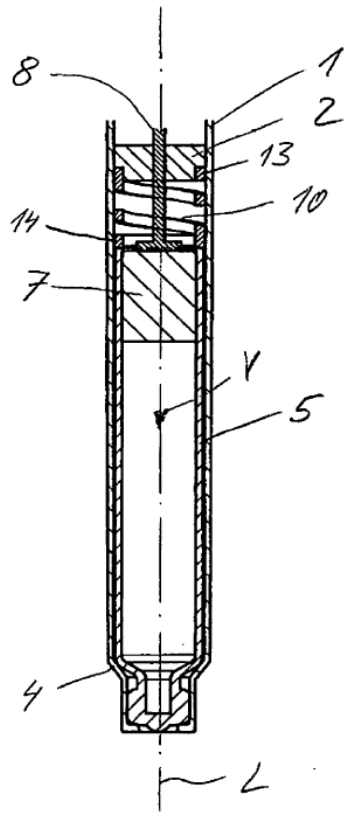


Fig. 1

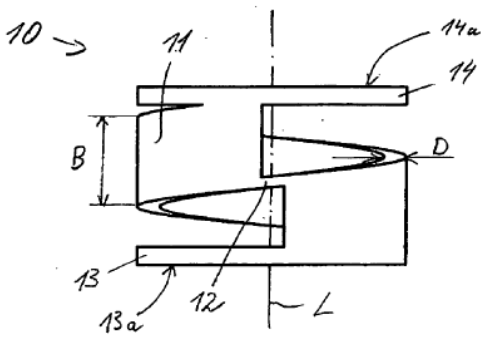


Fig. 2

Figure 1 shows, in cross-section, a distal portion of an injection device. *Id.* ¶ 18. Figure 2 shows a spring used in the injection device. *Id.* ¶ 19. The injection device, which may be an injection pen, includes housing 1, insert 2, container 5 (which is filled with a liquid medicament), plunger 7, driving member 8, and spring 10. *Id.* ¶¶ 22–23. In this first embodiment ("embodiment one"), the housing is illustrated as being a single component. *Id.* at Fig. 1; *see also id.* ¶ 22 ("The injection device has a longitudinally extending, sleeve-type housing 1 comprising one or more parts."). In a second embodiment ("embodiment two"), the housing is provided in two parts that are connected together. *Id.* ¶ 31, Fig. 4.

The spring includes positioning devices 13, 14 on either end thereof. Ex. 1006 ¶ 24. Spring end faces 13a, 14a constitute support surfaces, by means of which the spring is supported on the container and the insert solely by contact pressure. *Id.* In this manner, the spring biases the container against stop 4, which may be a part joined to, carried by, or in the housing, and acts as an abutment contact for the container. *Id.* ¶ 23. The spring "may be a tension spring, flexion spring or torsion 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.

2. Venezia

Venezia discloses a hypodermic syringe assembly. Ex. 1007, 1:15–17. Figures 2 and 6 show illustrative views of the assembly and a washer component thereof, respectively, and are reproduced below:

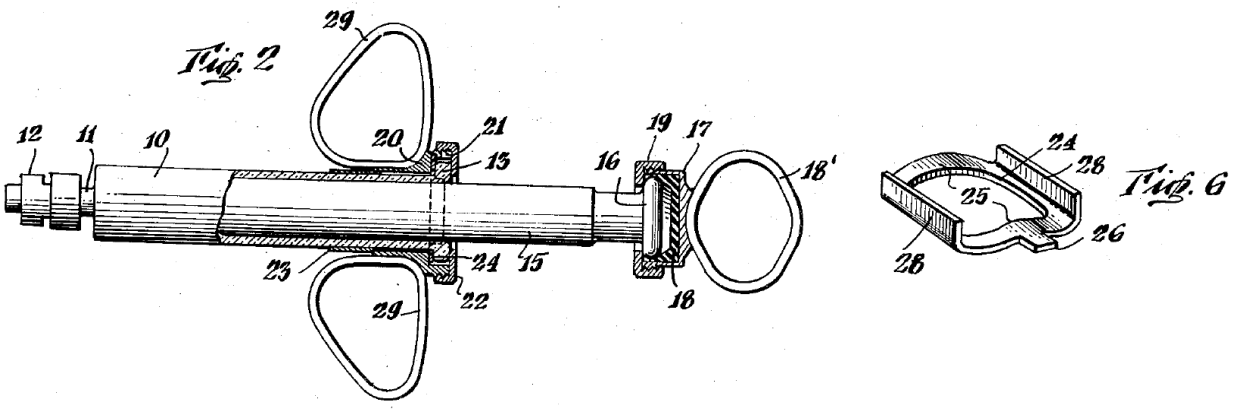


Figure 2 shows, in partial cross-section, a longitudinal view of the syringe assembly. *Id.* at 1:43–45. Figure 6 shows a perspective view of a washer used in the syringe. *Id.* at 1:54–55, 2:53–54. The syringe includes barrel 10 having flange 13 at a proximal end thereof. *Id.* at 1:56–65. Collar 20 includes distal fingers 23 that grip the barrel. *Id.* at 2:38–49. The collar

includes flange 21 at its proximal end. *Id.* at 2:30–33. The collar flange is cup-shaped to accommodate washer 24. *Id.* at 2:58–60. Ring 22 is threaded onto the collar flange. *Id.* at 2:33–34, 3:11–14. As the ring is tightened onto the collar, bulged portions 25 of the washer bear with increasing resistance against the end face of the barrel flange. *Id.* at 3:15–17. The washer includes tongue 26 that fits into opening 27 in the collar flange to prevent the washer from turning relative to the collar. *Id.* at 2:63–65, 3:19–20. The washer further includes extensions 28 that engage flattened side portions 14 of the barrel flange to prevent the barrel from turning relative to the washer. *Id.* at 1:61–65, 3:17–19. With the collar thus locked in place relative to the barrel, a physician or technician may grasp and manipulate the syringe to dispense liquid medicament via finger-accommodating rings 29 projecting from the collar, even while wearing rubber gloves. *Id.* at 1:20–25, 3:20–22, 3:33–37.

3. de Gennes

de Gennes discloses self-centering clutch release bearings. Ex. 1008, 1:5–6. Figures 2 and 5 show illustrative views of the release bearing and a cover component thereof, respectively, and are reproduced below:

FIG. 2

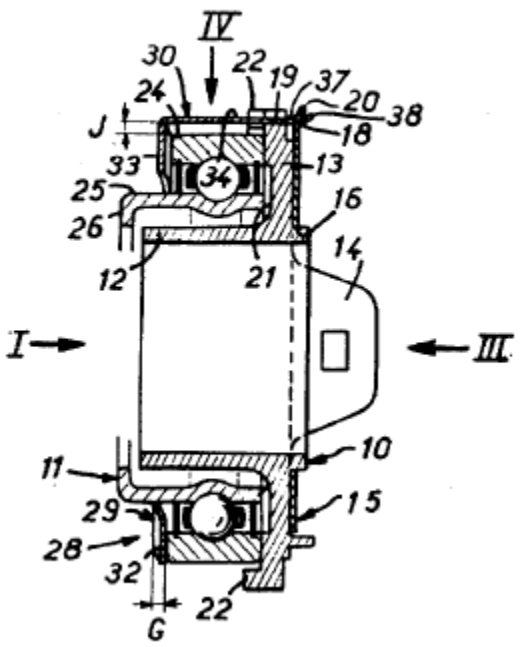


FIG. 5

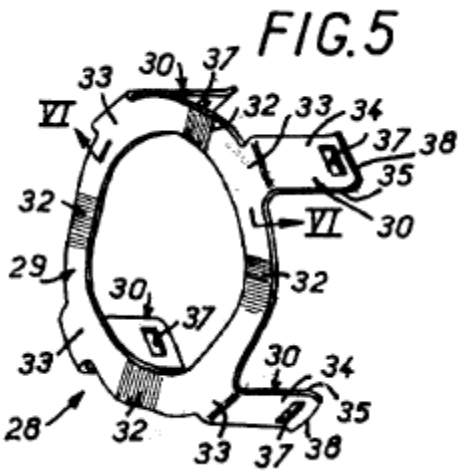


Figure 2 shows, in cross-section, a side view of a clutch bearing. *Id.* at 2:43–44. Figure 5 shows a perspective view of a cover of the clutch bearing. *Id.* at 2:49–50. The clutch bearing includes operating element 10 and drive element 11. *Id.* at 3:8–16. The operating element is subjected to the action of a displacement control means (not shown) and includes annular transverse support flange 13. *Id.* at 3:8–23. Reinforcement plate 15 lines the rear face of the flange. *Id.* at 3:30–32. The drive element includes ball bearings positioned between outer race 24 and inner race 25. *Id.* at 3:56–64. Support edge 26 of the inner race is configured to bear against the clutch release device. *Id.* at 3:65–68; *see also id.* at 3:13–16.

Cover 28 fastens the operating element to the drive element. Ex. 1008, 4:1–4. The cover includes transverse wall 29 having support zones 32 that bear against the drive element outer race. *Id.* at 4:4–9, 4:17–23. The support zones are resiliently deformable undulations that elastically

press the outer race against the operating element flange. *Id.* at 4:45–54, 5:13–22. The cover further includes peripheral skirt 30 having a number of legs 34 that extend axially from the transverse wall. *Id.* at 4:25–29. Each leg includes a cutout 37 adapted to engage respective claws 20 of the reinforcement plate. *Id.* at 4:38–40.

The clutch bearing is assembled by bringing free ends 38 of the cover legs into position facing radial extensions 18 of the reinforcing plate. Ex. 1008, 4:60–63. The cover is then pushed axially such that the cover legs contact the claws and are elastically deformed around the claws. *Id.* at 4:63–68. After passing the claws, the legs then return to their elastic configuration, with the claws positioned within the leg cutouts. *Id.* at 4:68–5:2.

E. The Challenge

Petitioner argues that claims 1–18 would have been obvious over Burren, Venezia, and de Gennes. Pet. 24–69. In support of its showing, Petitioner relies upon the Erdman Declarations. *Id.* (citing Ex. 1004). We have reviewed the parties' briefs and the evidence of record. For the reasons set forth below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–18 would have been obvious in view of Burren, Venezia, and de Gennes.

1. Patent Owner's Non-Analogous Art Argument as to de Gennes

Patent Owner argues that the Petition's reliance on de Gennes is improper because the reference is not analogous to the invention claimed in the '614 patent. PO Resp. 21–36.

A reference qualifies as prior art for a determination under § 103 when it is analogous to the claimed invention. *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992).

> Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

In re Bigio, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (citing *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986)).

> The Supreme Court's decision in [*KSR*] directs us to construe the scope of analogous art broadly, stating that "*familiar items may have obvious uses beyond their primary purposes*, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle." [*KSR*, 550 U.S.] at 402 (emphasis added).

Wyers v. Master Lock Co., 616 F.3d 1231, 1238 (Fed. Cir. 2010).

Patent Owner argues that de Gennes is not analogous art because it is not in the same field of endeavor as the '614 patent and is not pertinent to a problem with which the '614 patent is involved. PO Resp. 21–36. Petitioner concedes that de Gennes is not in the same field of endeavor as the '614 patent. *See, e.g.*, Pet. Reply 20 ("That de Gennes is from the automotive field is irrelevant because the problem being solved—adding legs to a spring washer—is not unique to cars or injector pens."); Tr. 18, 5–8 ("We're not saying that automotive art, for example, are identical to medical device art."). Thus, our analysis focuses on the second prong of the analogous art test.

"A reference is reasonably pertinent if . . . it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *Clay*, 966 F.2d at 659. "If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection." *Id.* In other words, "familiar items may have obvious uses beyond their primary purposes." *KSR*, 550 U.S. at 402.

Regarding the second prong of the analogous art test, Patent Owner identifies a singular problem: "[t]o secure a cartridge against movement within a housing." PO Resp. 25 (citing Ex. 2001 ¶¶ 70–72), 26–27. Patent Owner argues that, in contrast, "the problem addressed by de Gennes's cover (and device in general) is to allow for radial movement of an operating element with respect to a drive element within a self-centering clutch bearing." *Id.* at 28 (citing Ex. 2001 ¶ 73).

Initially, we note that a reference is analogous if it is reasonably pertinent to at least one of the problems faced by the inventors. *See Donner Tech., LLC v. Pro Stage Gear, LLC*, 979 F.3d 1353, 1361 (Fed. Cir. 2020) ("[I]f the two references have 'pertinent similarities' such that [the asserted reference] is reasonably pertinent to *one or more of the problems* to which the [challenged] patent pertains, then [the asserted reference] is analogous art." (emphasis added)).

The '614 patent describes its objective as a drug delivery device that "allows for improved operability with respect to dosage control and/or improved reproducibility of the dosage in connection with different cartridges." Ex. 1001, 1:51–55. The '614 patent explains that this objective

is achieved by a component that exerts a force on the cartridge to secure the cartridge against movement relative to a cartridge retaining member. *Id.* at 1:59–67, 2:10–15. Due to application of this force, "axial movement of the cartridge in the cartridge retaining member can be reduced or even prevented and dose accuracy can be increased." *Id.* at 2:12–15. The '614 patent further discloses that using a spring washer as the biasing component is beneficial because a spring washer is compact and does not require "much space." *Id.* at 2:15–18. The spring washer is arranged within the housing to exert a force on the cartridge in the distal direction, thereby securing the cartridge against movement with respect to the cartridge retaining member and housing. *Id.* at 5:10–15.

Thus, we agree with Patent Owner's assertion that one problem the inventors of the '614 patent faced was securing the cartridge against axial movement within a housing. *See* PO Resp. 25; *see also* Ex. 2001 ¶¶ 71–72 (presenting similar definitions of the problem). However, Patent Owner defines the problem too narrowly. "[T]he reasonable-pertinence analysis must be carried out through the lens of a [person having ordinary skill in the art] who is considering turning to art outside her field of endeavor." *Donner*, 979 F.3d at 1360. "Such a[n artisan]—resigned to considering art outside her field of endeavor—would thus not identify the problems so narrowly so as to rule out all such art." *Id.* Patent Owner's definition of the inventors' problem improperly focuses on the specific components of its drug delivery device, effectively precluding consideration of references outside the '614 patent's field of endeavor.

Petitioner defines the problem as "axial[] fixation and support of two components relative to one another." Pet. 23 (citing Ex. 1004 ¶ 73);[4] *see also* PO Resp. 34 (identifying the same as the problem identified by Petitioner). We agree that this definition properly defines the aforementioned problem faced by the inventors of the '614 patent without limiting the problem to the inventors' field of endeavor. Petitioner's definition is substantially the same as Patent Owner's but refers to generic terminology rather than components specific to the '614 patent, thereby allowing consideration of fields outside of the '614 patent's field of endeavor.

de Gennes addresses this problem. de Gennes discloses a self-centering clutch release bearing and notes that one important requirement for this type of bearing is for the front wall of its cover to "constitute the axially-directed resilient means provided for urging the drive element in the direction of the transverse flange of the operating element." Ex. 1008, 1:5–55. To this end, de Gennes's cover 28 includes transverse wall 29 having support zones 32 that bear against the drive element outer race 24. *Id.* at 4:4–9, 4:17–23. The support zones are resiliently deformable undulations that elastically press the outer race against the operating element flange 13. *Id.* at 4:45–54, 5:13–22; *see also* Ex. 1004 ¶ 73 (defining a

[4] Although Petitioner and Petitioner's declarant refer to Burren when identifying a problem (*see* Pet. 23; Ex. 1004 ¶ 73; *see also* PO Sur-reply 17–19), the defined problem is also relevant to the '614 patent, especially given that the '614 patent acknowledges that Burren's spring performs the same function (that is, solves a same problem) as the '614 patent. *See* Ex. 1001, 1:38–42 (acknowledging that Burren's "spring may serve as compensation for longitudinal tolerances in order to support a medical container in an injection device").

problem addressed by de Gennes as "to axially fix and support two components—drive element 11 and operating element 10—relative to one another"). The cover is fixed relative to the drive element via legs 34 extending from peripheral skirt 30. Ex. 1008, 4:25–29. Each leg includes a cutout 37 adapted to engage respective claws 20 of reinforcement plate 15. *Id.* at 4:38–40.

Thus, de Gennes is reasonably pertinent to axially fixing two components relative towards each other, a problem addressed by the inventors of the '614 patent. Accordingly, de Gennes is analogous to the '614 patent.

2. Independent Claims 1 and 16–18

Petitioner relies on Burren to disclose a drug delivery device substantially as claimed and relies on Venezia and de Gennes to teach additional disclosures of a spring washer having fixing elements. Pet. 26–50. Petitioner addresses all of the independent claims (claims 1 and 16–18) collectively. *Id.* Patent Owner likewise addresses the independent claims collectively. *See generally* PO Resp. Claim 1 recites a drug delivery device. Ex. 1001, 8:2–14. Claim 16 recites of method of manufacturing a drug delivery device by providing and arranging the components of claim 1. *Id.* at 8:64–9:11. Claim 17 recites a drug delivery device and is identical to claim 1 with the sole exception that the cartridge retaining member is secured to the housing but does not require the cartridge retaining member to be releasably secured to the housing as in claim 1. *Id.* at 9:12–10:3. Claim 18 recites a drug delivery device that is substantially similar to claim 17, but further recites that the fixing elements allow the axial loading

of the spring washer. *Id.* at 10:4–18. Our analysis below focuses on claim 1, but applies equally to the other independent claims.

a. Housing

Claim 1 recites "a housing with a proximal end and a distal end." Ex. 1001, 8:3. Claims 16–18 contain similar recitations. *Id.* at 8:66, 9:13, 10:5. Petitioner argues that Burren's housing 1 of embodiment one and proximal housing portion 3 of embodiment two correspond to the recited housing. Pet. 28. Patent Owner does not contest this aspect of the Petition.

Burren discloses that in embodiment one its "injection device has a longitudinally extending, sleeve-type housing 1 comprising one or more parts" and, in embodiment two, "[t]he housing . . . 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." Ex. 1006 ¶¶ 22, 31. Thus, Burren supports Petitioner's contentions.

b. Cartridge

Claim 1 recites "a cartridge adapted to accommodate a drug." Ex. 1001, 8:4. Claims 16–18 contain similar recitations. *Id.* at 8:67, 9:14, 10:6. Petitioner argues that Burren's container 5 corresponds to the recited cartridge for both embodiments. Pet. 29–30. Patent Owner does not contest this aspect of the Petition.

Burren discloses that its injection device includes "container 5, for example a glass ampoule, which is filled with a liquid medicament, for example insulin." Ex. 1006 ¶ 22; *see also id.* ¶ 31 (regarding embodiment two). Thus, Burren supports Petitioner's contentions.

c. Retaining Member

Claim 1 recites "a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member releasably secured to the housing." Ex. 1001, 8:5–7. Claims 16–18 contain similar recitations.[5] *Id.* at 9:1–2, 9:15–17, 10:7–9. Petitioner argues that Burren's stop 4 corresponds to the recited retaining member. Pet. 31–34. Regarding embodiment one, Petitioner argues that "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.'" *Id.* at 32–33 (quoting Ex. 1006 ¶ 23) (alteration in original). Regarding embodiment two, Petitioner notes that stop 4 is part of distal housing portion 1. *Id.* at 33 (citing Ex. 1006 ¶ 31, Fig. 4). Petitioner also argues that it would have been obvious to a person of ordinary skill in the art to couple Burren's stop to the housing in a releasable manner to facilitate cartridge replacement. *Id.* at 34 (citing Ex. 1006 ¶ 116). Patent Owner does not contest this aspect of the Petition.

Burren discloses that "the container 5 is supported by means of an abutment contact on the housing 1" and that "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." Ex. 1006 ¶ 23; *see also id.* at Fig. 4 (illustrating embodiment two with stop 4 being a component of distal housing portion 1). Petitioner's declarant testifies that "a person of ordinary

[5] As noted above, claim 17 recites a drug delivery device comprising a cartridge retaining member that is secured to the housing but does not require the cartridge retaining member to be releasably secured to the housing. Ex. 1001, 9:15–17.

skill would have understood Burren as suggesting a 'cartridge retaining member' that is provided as a part separate from the housing (for example, as a separate stop or distal housing portion) for retaining a portion of, or the entire, container." Ex. 1004 ¶ 115. Petitioner's declarant testifies that "Burren contemplates that the injection pen may be a device that 'can be repeatedly re-used,'" and "[a] person of ordinary skill would have found it apparent that, to allow a user to remove an emptied container from the device, the stop and/or distal housing portion should be releasably secured to the housing." *Id.* ¶ 116 (citing Ex. 1004 ¶ 29).

Accordingly, for the foregoing reasons, Burren and the evidence of record support Petitioner's contentions.

d. Spring Washer

Claim 1 recites "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." Ex. 1001, 8:8–11. Claims 16–18 contain similar recitations. *Id.* at 9:3–8, 9:18–21, 10:10–12. Petitioner notes that Burren discloses "spring 10, formed as a coil spring," for embodiment one and "spring 20, in the form of a spring bellows," for embodiment two and argues that, "[i]n both embodiments, the springs are 'arranged within the housing.'" Pet. 39. Petitioner acknowledges that in both of Burren's embodiments the springs are not spring washers, but argues that "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'" and that "a POSA would have understood a spring washer to be a type of plate spring." *Id.* at 40 (quoting Ex. 1006 ¶ 16; citing Ex 1004 ¶ 125).

Petitioner relies on Venezia to teach use of washer 24 in a drug delivery device. Pet. 41–42. Petitioner likens Venezia's collar 20 to the recited housing, barrel 10 to the recited cartridge, and ring 22 to the recited retaining member, and argues that washer 24 is disposed between barrel flange 13 and the collar "[t]o prevent movement of barrel 10 within collar 20." *Id.* at 41 (citing Ex. 1007, 2:45–60, Figs. 3, 4, 6; Ex. 1004 ¶ 127). Petitioner notes that Venezia's washer includes bulged zones 25 and argues that "[w]hen ring 22 is threaded onto flange 21, flange 13 presses against bulged zones 25, 'loading' the spring washer. . . . 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." *Id.* at 41–42 (citing Ex. 1007, 3:11–17; Ex 1004 ¶ 127).

Petitioner relies on de Gennes to teach cover 28, which Petitioner describes as being "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." Pet. 42 (citing Ex. 1008, 4:1–8, 4:17–23, 4:45–51, 5:13–22, Figs. 5, 15; Ex. 1004 ¶ 128).

Petitioner argues that "a POSA would have found it obvious to replace the springs illustrated in Burren with a spring washer, like those taught by Venezia and [d]e Gennes, to provide the same compensating function for securing a cartridge against movement within an injection pen." Pet. 43 (citing Ex. 1004 ¶ 129).

Patent Owner argues that, in Burren's embodiment two, the spring is not arranged within the housing. PO Resp. 16–19. "As such, Burren's second embodiment lacks an element required by each challenged claim

making reliance on that embodiment deficient as a matter of law." *Id.* at 18 (citations omitted). Patent Owner presents a copy of Burren's Figure 4, annotated to illustrate "[s]pring 20 positioned below proximal housing portion 3." *Id.*

Petitioner faults Patent Owner's annotation of Burren's Figure 4 and argues that "[r]etaining mechanism 23b indisputably 'latches in the recess of the housing portion 3.'" Pet. Reply 7 (citing PO Resp. 18). Petitioner argues that Patent Owner has not established that the claim language requires the entire spring to be located within the housing. *Id.*

As noted above, for Burren's embodiment two, Petitioner argues that Burren discloses "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." Pet. 39 (citing Ex. 1006 ¶¶ 31–34, Fig. 4; Ex. 1004 ¶ 122). Burren discloses that it is spring element 21 that is the bellows: "[T]he spring element 21 is of a meandering shape with several portions extending alternately in the forward drive direction V and transversely thereto. This results in a spring bellows, the spring action of which can be likened to that of flexible arms connected in series." Ex. 1006 ¶ 32. Indeed, Petitioner's declarant acknowledges that it is the spring element 21 that acts as a compensating spring. Ex. 1004 ¶ 122. However, instead of explaining how Burren's bellows component is arranged within the housing, Petitioner argues that a different component, retaining mechanism 23b, is partially arranged within proximal housing portion 3. Pet. Reply 7. This inconsistency fails to explain with requisite particularity how the Petitioner-defined compensating spring (spring element 21) is arranged within the Petitioner-defined housing (proximal housing portion 3).

Moreover, as we noted in the Institution Decision, "spring element 21 is illustrated as being within distal housing portion 1 rather than within the proximal housing portion." Inst. Dec. 22–23 (citing Ex. 1006, Fig. 4).

Petitioner has not shown sufficiently how Burren's embodiment two discloses a spring arranged within the housing. Petitioner's reliance on Venezia and de Gennes does not remedy this deficiency. *See* Pet. 41–43. Thus, on this record, Petitioner has not shown by a preponderance of the evidence that the challenged claims would have been obvious based on Burren's embodiment two combined with the other asserted references.

Patent Owner makes several arguments regarding Petitioner's reliance on de Gennes. PO Resp. 37–47. First, Patent Owner argues that the function of Burren's spring is to bias container 5 away from insert 2, and because de Gennes's cover could not bias components away from each other, it is not a suitable replacement for Burren's spring. PO Resp. 37–42 (citing Ex. 1006 ¶¶ 23–24, Fig. 1; Ex. 1008, 4:11–16, 4:55–60, 5:3–22, Fig. 2; Ex. 2001 ¶¶ 83–90; Pet. 36, 40, 55).

Petitioner replies that the Petition does not suggest bodily incorporating de Gennes's cover into Burren's injection device. Pet. Reply 17. Rather, de Gennes "was used as an answer to Burren's suggestion of providing a spring with legs." *Id.* (citing Ex. 1038 ¶ 17).

Patent Owner replies that, in the Reply, Petitioner improperly attempts to shift the arguments in the Petition to rely more heavily on Burren. PO Sur-reply 20–21.

We disagree with Patent Owner's assertion that the purpose of Burren's spring is to bias "the insert 2 and container 5[] away from each other." PO Resp. 37. Burren explains that the purpose of its spring is to

accommodate containers of various lengths to abut against the stop. Ex. 1006 ¶¶ 3, 23. Indeed, the '614 patent describes Burren as performing this compensation. Ex. 1001, 1:38–42. Patent Owner's declarant cites to a portion of Burren's disclosure to support Patent Owner's argument. Ex. 2001 ¶ 83 ("Burren's injection device includes a spring 10 that 'bridges a space left free between the container 5 and the insert 2' to bias the container 5 away from the insert 2." (quoting Ex. 1006 ¶ 23)). However, Mr. Row omits a very relevant portion of this sentence: "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*." Ex. 1006 ¶ 23 (emphasis added). Thus, Burren uses its spring in the same manner as the '614 patent's spring to compensate for longitudinal tolerances by exerting a force on the container in the distal direction. *See, e.g.*, Ex. 1001, 1:38–42.

Nor do we agree with Patent Owner's assertion that the Reply improperly shifts the arguments made in the Petition. Petitioner argues in the Petition that Burren suggests use of a spring washer. Pet. 62 (citing Ex. 1006 ¶ 16; Ex. 1004 ¶ 85).

Next, Patent Owner argues that de Gennes's cover would not work within Burren's device because with the cover oriented so that legs 34 engage Burren's insert 2, the cover would not function to bias the container towards the stop because "the anchoring zones 33 of the cover 28 would contact the container 5." PO Resp. 42–44 (citing Ex. 1006 ¶¶ 17, 23, Fig. 1; Ex. 1008, 4:17–24, 4:45–54, 5:33–36, Fig. 5; Ex. 2001 ¶¶ 91–96; Pet. 55–56). We understand Patent Owner to argue that support zones 32 of

de Gennes's cover 28 would not contact Burren's container 5. *See* Ex. 2001 ¶¶ 95–96.

Petitioner replies that a person having ordinary skill in the art "would readily understand that the specific clutch cover would not be lifted intact from de Gennes and substituted into Burren's pen. Pet. Reply 17. According to Petitioner, it would have been a simple matter for a skilled artisan to position the legs and the support zones of de Gennes's cover in the appropriate directions. Pet. Reply 18 (citing Ex. 1006 ¶¶ 3, 13, 23; Ex. 1038 ¶¶ 20–21).

The arguments advanced by Patent Owner and Patent Owner's declarant are premised on de Gennes's cover being positioned within Burren's pen without modification. However, it is well settled that "[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference . . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citations omitted). "[W]e do not ignore the modifications that one skilled in the art would make to a device borrowed from the prior art." *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1382 (Fed. Cir. 2007) (citing *Optivus Tech., Inc. v. Ion Beam Applications, S.A.*, 469 F.3d 978, 989–90 (Fed. Cir. 2006)). "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421. To this end, we credit the testimony of Petitioner's declarant, who testifies that reversing the direction in which support zones 32 extend away from anchoring zones 33 would have been obvious. *See* Ex. 1038 ¶ 21 (defining "a basic concept of springs that would have been readily appreciated by

those of ordinary skill: in order to push a component against (or even away from) another, the spring (such as a spring washer) should be formed so that its biasing force is applied in the desired direction"). We credit this testimony and agree that a person of ordinary skill would alter the direction in which the support zones extend away from the anchoring zones so as to exert their biasing force in the desired direction.

Finally, Patent Owner argues that the only basis for Petitioner's reliance on de Gennes is hindsight. PO Resp. 45–47; PO Sur-Reply 23. According to Patent Owner, "[Petitioner's] selection of de Gennes's clutch bearing cover 28 is not based on any functional description of the cover 28 or particular improvement that the clutch bearing cover 28 would have provided to a drug delivery device." PO Resp. 45.

Petitioner counters that "Burren plainly teaches that the spring biases the container distally, which would be ample guidance to one with actual skill." Pet. Reply 18 (citing Ex. 1006 ¶¶ 3, 13, 23; Ex. 1038 ¶¶ 20–21). "Burren (rather than [the '614 patent]) provides the impetus to look at springs with legs." *Id.* at 22. We agree.

As noted by Petitioner, Burren discloses that its spring can be in the form of a "plate spring" or "a spring with legs." Ex. 1006 ¶ 16. The spring "biases the container 5 against the stop 4." *Id.* at ¶ 23. In a similar manner, de Gennes's cover 28 includes support zones 32 that are "formed by the median portion of an axially resiliently deformable undulation." Ex. 1008, 4:45–54. "[D]ue 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 . . . ." *Id.* at 5:13–22. The cover also includes

legs 34 by which the cover is attached to the bearing. *Id.* at 4:55–5:2. Accordingly, we agree that the references of record, rather than the '614 patent, suggest the combination asserted by Petitioner.

Venezia discloses placing washer 24 within the cup-shaped rear portion of collar flange 21 such that the washer is intermediate collar 20 and ring 22. Ex. 1007, 2:58–60, 3:3–5, Fig. 3. Ring 22 is threaded onto the collar flange and, as the ring is tightened onto the collar, bulged portions 25 of the washer bear with increasing resistance against the end face of the barrel flange. *Id.* at 3:11–17. In this manner, the collar, ring, and barrel 10 are held together firmly. *Id.* at 3:24–26. Petitioner's declarant testifies that this tightening of the ring onto the collar against the force of the washer loads the washer. Ex. 1004 ¶ 127 (citing Ex. 1007, 3:11–17).

With respect to Burren's embodiment one, for the reasons set forth above, the combination of Burren, Venezia, and de Gennes supports Petitioner's contentions.

e. Fixing Elements

Claim 1 recites "wherein the spring washer has at least two fixing elements configured to axially and rotationally fix the spring washer relative to the housing." Ex. 1001, 8:12–14. Claims 16–18 contain similar recitations. *Id.* at 9:9–11, 10:1–3, 10:12–16. Petitioner argues that positioning device 13 of Burren's spring 10 is a fixing element "that fastens spring 10 indirectly to the housing" via insert 2 and that positioning device 23 of Burren's spring 20 includes retaining mechanism 23b that "holds the spring via 'a latched or snap-fit connection with' proximal housing portion 3." Pet. 45–46 (citing Ex. 1006 ¶¶ 23–24, 33, Figs. 1–4; Ex. 1004 ¶¶ 132–134). Petitioner acknowledges that "Burren illustrates

springs having only one positioning device, or 'fixing element,'" and relies on Venezia and de Gennes to teach the use of multiple fixing elements. *Id.* at 47.

Regarding Venezia, Petitioner argues that tongue 26 "projects into an opening formed in flange 21 . . . and forms a 'spline and recess structure' to fix, at least rotationally, washer 24 to collar 20." Pet. 47 (citing Ex. 1004 ¶ 136; Ex. 1007, 2:63–65, 3:8–10, 3:19–20, Figs. 3, 5–6). Continuing, Petitioner asserts that

> 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. 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. Moreover, the POSA would have recognized the value of providing at least two tongues to prevent tilting of the spring washer during use.

Id. at 47–48 (citing Ex. 1004 ¶ 137).

Regarding de Gennes, Petitioner argues that legs 34 of cover 28 "snap-fit over corresponding fastening claws 20 provided on reinforcement plate 15" and that "a POSA would have understood the legs taught by [d]e Gennes w[ere] 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." Pet. 48 (citing Ex. 1008, 4:11–16, 4:30–40, 4:55–5:12, 7:26–39, Figs. 2, 4, 15; Ex. 1004 ¶ 138). Petitioner notes that its declarant testifies that "the POSA would have understood that the snap-fit connection illustrated in [d]e 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 Ex. 1004 ¶ 139).

Patent Owner makes two arguments regarding Petitioner's reliance on Venezia. PO Resp. 49–66. First, Patent Owner argues Venezia's tongue 26 merely rests loosely within opening 27, and thus is not a fixing element. PO Resp. 50–51 (citing Ex. 2001 ¶¶ 106–109). According to Patent Owner, incorporating Venezia's washer into Burren's device as set forth in the Petition would not axially fix the washer to the housing. *Id.* at 51–58 (citing Ex. 2001 ¶¶ 111–117).

Petitioner replies that Venezia's tongue provides axial fixing in at least one direction. Pet. Reply 15.

Patent Owner replies that Petitioner "fails to explain how Venezia's tongue 26 would function to 'axially and rotationally fix' a spring washer relative to Burren's housing." PO Sur-reply 12. We agree.

Venezia discloses that "[t]he tongue . . . extends through opening 27 to thus provide a spline and recess structure" and "[b]ody 24 may not turn because of tongue 26 preventing this." Ex. 1007, 3:8–10, 3:19–20. Petitioner states that this arrangement will "fix, at least rotationally, washer 24 to collar 20." Pet. 47. Petitioner then asserts that such a "slot-fit connection" would result "in both axial and rotational fixation." *Id.* at 48 (citing Ex. 1004 ¶ 137). Petitioner's declarant testifies that a person of ordinary skill in the art would understand that Venezia's tongue and opening arrangement could be incorporated into Burren's injection pen "through, for example, a slot-fit connection (in other words, a radially-extending protrusion fitted into a corresponding slot provided directly or indirectly on

the housing), which would result in both axial and rotational fixation of the spring washer relative to the housing." Ex. 1004 ¶ 137.

Neither Petitioner nor Petitioner's declarant provides adequate support for the contention that this structure would prevent axial movement of Venezia's washer when incorporated into Burren's device with the tongue positioned within a slot. In his second declaration, Petitioner's declarant opines that an axially-limited slot disclosed by the '614 patent or Venezia's collar 20 could prevent axial movement of the tongue within a slot. Ex. 1038 ¶ 26. The Petition, however, does not contemplate incorporating either of these features into Burren's modified device—nor would it be appropriate to rely on the disclosure of the '614 patent in such manner. Accordingly, Venezia does not support Petitioner's contentions.

Next, Patent Owner argues that neither the Petition nor Petitioner's declarant explains adequately why it would be beneficial to add a second tongue to Venezia's washer when incorporating it into Burren's device. PO Resp. 59–60. Patent Owner argues that Petitioner's rationale of preventing tilting is unavailing because tilting would already be prevented when the washer is clamped between Burren's insert 2 and container 5. *Id.* at 61. Patent Owner argues that Petitioner's reliance on Burren's discussion of preventing tilting is misplaced, as Burren's discussion addresses providing an even application of force to the container so the container does not tilt. *Id.* at 61–63 (citing Ex. 1006 ¶ 30). Patent Owner argues that Petitioner's rationale is further flawed because providing a second tongue on Venezia's washer would not prevent tilting of the washer. *Id.* at 63–66.

Petitioner replies that Patent Owner has not explained how a second fixing element provides a new and unexpected result, and, thus, the

duplication of parts would have been obvious. Pet. Reply 16 (citing *In re Harza*, 274 F.2d 669, 671 (CCPA 1960)).

Patent Owner replies that adding a second tongue "is not 'the mere duplication of parts' but rather, a modification (addition of a second tongue) to an already existing part (Venezia's washer)." PO Sur-reply 16.

We agree that Petitioner does not explain adequately how a second tongue would prevent tilting of the washer, as the tongue could rotate even with two tongues. *See, e.g.*, PO Resp. 64 (presenting a modified version of Venezia's Figure 6 to include two tongues as suggested by Petitioner's declarant (*see* Ex. 1004 ¶ 92) and annotated to illustrate rotation about an axis formed by two tongues). Nor are we persuaded by Petitioner's duplication of parts rationale, which was not advanced in the Petition and which does not explain how tilting would be prevented. We further agree that Petitioner does not provide an adequate explanation as to why a second tongue would be beneficial.

Petitioner has not shown sufficiently how Venezia's tongue would be configured to axially fix the washer within Burren's housing or why it would have been obvious to include two such tongues. *See* Pet. 47–48. Thus, on this record, the combination of Burren and Venezia does not support Petitioner's contentions.

As to de Gennes, however, we reach a difference conclusion. de Gennes discloses that its cover 28 is positioned to urge outer race 24 of drive element 11 against operating element 10 by elastically deforming legs 34 around fastening claws 20 and letting the legs return to the elastic position with the claws positioned within the leg cutouts. Ex. 1008, 4:60–5:2. Petitioner's declarant testifies that a "person of ordinary skill

would have understood that the snap-fit connection, for instance, was a common way of fixing a component to another part and would have readily understood its applicability to fixing a similar spring washer within the housing of a drug-delivery device." Ex. 1004 ¶ 139 (citation omitted). Thus, de Gennes and the evidence of record support Petitioner's contentions.

Accordingly, for the foregoing reasons, the combination of Burren and de Gennes support Petitioner's contentions.

f. Axial Loading

Claim 18 recites "where the fixing elements allow axial loading of the spring washer when the cartridge retaining member is secured to the housing." Ex. 1001, 10:16–18. Petitioner argues that because the asserted fixing elements of Venezia and de Gennes are fixed relative to the respective asserted housings, "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.'" Pet. 50 (citing Ex 1004 ¶ 144).

Patent Owner argues that the Petition does not explain how de Gennes's cover would be arranged within Burren's housing to provide the recited axial loading. PO Resp. 47–49. Specifically, Patent Owner argues that the Petition is silent regarding how de Gennes's legs would be received within Burren's device. *Id.* at 48.

Petitioner replies that a skilled artisan would have known how to attach de Gennes's cover in the same manner as Burren's retaining member 23b attaches bellows spring 20. Pet. Reply 18–19 (citing Ex. 1038 ¶ 24; *KSR*, 550 U.S. at 417).

As explained above, a skilled artisan would have reversed the displacement of de Gennes's support zones 32 to extend distally such that

they engage and are axially loaded by the cartridge. This would result in de Gennes's legs 34 extending towards Burren's stop 2. Patent Owner acknowledges that, "[i]n the Petition, [Petitioner] proposes that the legs 34 of de Gennes's cover 28 would have secured to Burren's device by affixing to insert 2." PO Resp. 42–43 (citing Pet. 55–56). Thus, as acknowledged by Patent Owner, Petitioner provides an adequate explanation as to how de Gennes's cover would be incorporated into Burren's device to allow the recited axial loading of support zones 32.

Accordingly, for the foregoing reasons, Venezia and de Gennes support Petitioner's contentions.

g. Rationale to Combine

Petitioner argues that "both Venezia and [d]e Gennes demonstrate the well-understood and common use of a spring washer to accomplish a 'compensating' function similar to that of Burren's device." Pet. 61 (citing Ex. 1004 ¶¶ 80–83). Petitioner argues that Burren suggests use of a spring washer (*id.* at 62 (citing Ex. 1006 ¶ 16; Ex. 1004 ¶ 85)) and that use of a spring washer in place of Burren's coil and bellows springs would satisfy Burren's design features of "(1) short spring-path compactness, (2) even spring-force distribution, and (3) minimal sliding surfaces." *Id.* (citing Ex. 1004 ¶ 85).

Petitioner argues that "Burren . . . identifies several functions that would have suggested to the POSA to use fixing elements like those of Venezia and [d]e Gennes to axially and rotationally fix the washer," including "(1) to anchor the washer; (2) to prevent tilting; and (3) to minimize wear." Pet. 64 (citing Ex. 1004 ¶ 90). Petitioner argues that

Venezia's slot-fit feature and de Gennes's snap-fit connection would have achieved these objectives. *Id.* at 64–66.

Petitioner argues that a "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." Pet. 67 (citing Ex. 1004 ¶ 97). "Making such adaptions to device-specific washers was considered a routine task by those skilled in the art." *Id.* (citing Ex. 1004 ¶ 97). Thus, Petitioner argues, "a POSA would have had a reasonable expectation of success in using spring washers having fixing elements like those of Venezia and [d]e Gennes." *Id.* at 66 (citing Ex. 1004 ¶ 95).

Patent Owner argues that Petitioner's rationales for including a spring washer in Burren's device are flawed. PO Resp. 66–71. Patent Owner notes the three rationales set forth in the Petition and argues that Petitioner "fails to demonstrate that the spring washers of Venezia and de Gennes have improved characteristics over Burren's spring 10 with respect to these factors," given that "Burren expressly discloses that the spring 10 proposed by Burren already achieves these functions without need for further modification." *Id.* at 67 (citing Ex. 1006 ¶¶ 17, 30; Ex. 2001 ¶¶ 150–163). Patent Owner argues that Petitioner fails to present evidence adequate to support its contention that "Venezia's washer or de Gennes's cover (when resized to fit within Burren's device) are capable of a 1-5 mm deflection." *Id.* at 68. Patent Owner argues that "the spring-force distribution of Venezia's washer and de Gennes's cover is less even than Burren's existing spring 10." *Id.* at 69 (citing Ex. 2001 ¶¶ 155–157).

Petitioner replies that "Burren itself provides the rationale to modify" and discloses variants to its springs, including "a plate spring optionally with legs." Pet. Reply 23. According to Petitioner, these "variants . . . were so obvious that merely listing them was sufficient guidance to those in the art." *Id.* at 23 (citing Ex. 1038 ¶¶ 32–34). Petitioner argues that Patent Owner's declarant "agreed that a POSA would have been 'keenly aware of' the factors necessary in selecting an appropriate spring." *Id.* at 24 (citing Ex. 1036, 122:12–20; Ex. 1038 ¶¶ 32, 34, 36–37).

Patent Owner replies that, in its Reply, Petitioner improperly attempts to shift the arguments in the Petition to rely more heavily on Burren. PO Sur-reply 8–11. For example, Patent Owner asserts that the Reply newly contends that "Burren itself provides the rationale to modify." *Id.* at 8–9 (citing Pet. Reply 23). Patent Owner argues that the Petition does not set forth enough detail as to how Burren's device is to be modified to accommodate the springs of Venezia and de Gennes. *Id.* at 24.

We disagree with Patent Owner's characterization of the rationale set forth in the Petition. As noted above, Petitioner argues in the Petition that Burren suggests use of a spring washer. Pet. 62 (citing Ex. 1006 ¶ 16; Ex. 1004 ¶ 85). Petitioner further argues that use of a spring washer in place of Burren's coil and bellows springs would satisfy Burren's design features. *Id.* at 62–63.

Nor are we persuaded that the Petition fails because it does not demonstrate that the spring washers of Venezia and de Gennes have improved characteristics over Burren's spring 10. As explained above, the test for obviousness "is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *Keller*, 642 F.2d at 425.

Petitioner explains persuasively why an ordinarily skilled artisan would have incorporated de Gennes's cover into Burren's injection pen. *See, e.g.*, Pet. 62–64 (citing Ex. 1004 ¶¶ 86–89).

Patent Owner argues that Petitioner's rationales for including fixing elements in Burren's device are flawed. PO Resp. 71–75. Patent Owner argues that de Gennes's cover does not function in the same manner as Burren's spring and Venezia's tongue 26 would not perform the functions asserted by Petitioner. *Id.*

Petitioner replies that a skilled artisan would not bodily incorporate de Gennes's cover into Burren's device; rather, de Gennes was used "as an answer to Burren's suggestion of providing a spring with legs." Pet. Reply 17 (citing Ex. 1038 ¶ 17).

As noted above, de Gennes discloses that its cover 28 is positioned to urge outer race 24 of drive element 11 against operating element 10 by elastically deforming legs 34 around fastening claws 20 and letting the legs return to the elastic position with the claws positioned within the leg cutouts. Ex. 1008, 4:60–5:2. Petitioner's declarant testifies that a "person of ordinary skill would have understood that the snap-fit connection, for instance, was a common way of fixing a component to another part and would have readily understood its applicability to fixing a similar spring washer within the housing of a drug-delivery device." Ex. 1004 ¶ 139 (citation omitted). We find this evidence persuasive to explain why and how an ordinarily skilled artisan would have incorporated de Gennes's cover into Burren's injection pen.

h. Conclusion

Accordingly, for the reasons set forth above, we are persuaded by Petitioner's showing that Burren, Venezia, and de Gennes render obvious independent claims 1 and 16–18.

3. Dependent Claims 2–15

We have reviewed the parties' briefs and evidence of record and determine that Petitioner has shown, by a preponderance of the evidence, that dependent claims 2–15 would have been obvious in view of Burren, Venezia, and de Gennes.

Claim 2 depends directly from claim 1 and recites "wherein the spring washer is biased so as to exert the force on the cartridge in the distal direction." Ex. 1001, 8:15–17. Petitioner argues that Burren's springs bias the container and that a person having ordinary skill in the art would substitute a spring washer in place of Burren's spring so as to "exert a biasing force in the same direction to secure the cartridge against movement." Pet. 51 (citing Ex. 1004 ¶ 146). Patent Owner does not contest this aspect of the Petition. As discussed in § II.E.2.d above, a person having ordinary skill would alter the direction in which de Gennes's support zones extend away from the anchoring zones so as to exert their biasing force in the desired direction. Thus, we find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

Claim 3 depends directly from claim 1 and recites "wherein the spring washer is secured against axial movement with respect to the housing." Ex. 1001, 8:18–20. Petitioner argues that "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." Pet. 51 (citing Ex. 1004 ¶ 147). Patent Owner does not contest this aspect of the Petition. As discussed in § II.E.2.e above, we are persuaded by Petitioner's arguments that de Gennes teaches the use of fixing elements to fix its cover within Burren's housing. Thus, we find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

> Claim 4 depends directly from claim 1 and recites,
>
> wherein the drug delivery device comprises a piston rod for dispensing a dose of the drug from the device when the piston rod is driven in the distal direction and wherein the spring washer comprises an opening, the opening being arranged so as to allow the piston rod to run through the opening.

Ex. 1001, 8:21–26. Petitioner maps Burren's plunger rod 8 to the recited piston rod and argues that springs disclosed by all of the asserted references have openings through which the plunger rod would move axially to dispense medicament. Pet. 52 (citing Ex. 1004 ¶¶ 148–149; Ex. 1006 ¶¶ 22, 26, Figs. 1–4; Ex. 1007, 2:60–63, Figs. 2, 5–6; Ex. 1008. Figs. 5, 15). Patent Owner does not contest this aspect of the Petition. Burren discloses that distal movement of the plunger rod urges driving element 7 in forward drive direction V to dispense medicament from container 5. Ex. 1006 ¶ 22. In order for this to occur, the plunger rod necessarily passes through the spring. *See id.* at Fig. 1; *see also id.* ¶ 22 (disclosing that "[t]he plunger rod 8 extends through the insert 2"). Petitioner's declarant testifies that a person having ordinary skill in the art would know that a spring washer used in place of Burren's spring "should include an opening sufficient to allow movement of the plunger rod for dispensing medicine from the container."

Ex. 1004 ¶ 149. Thus, we find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

Claim 5 depends directly from claim 1 and recites "wherein the spring washer is curved in an axial direction." Ex. 1001, 8:27–29. Petitioner argues that the asserted spring washers of de Gennes and Venezia contain such curvature. Pet. 52–53 (citing Ex. 1004 ¶ 151; Ex. 1007, 2:53–58, 3:15–17, Fig. 6; Ex. 1008, 4:17–23, 4:45–51, 5:35–36, Figs. 5–6). Petitioner's declarant testifies that "axial deflection of these curved portions causes the spring washer to exert the biasing force necessary to secure a component." Ex. 1004 ¶ 151 (citing Ex. 1007, 2:53–58, 3:15–17; Ex. 1008, 4:45–51, 5:35–36). Patent Owner does not contest this aspect of the Petition. de Gennes's cover 28 contains support zones 32 in the form of resiliently deformable undulations that elastically press the outer race against the operating element flange. Ex. 1008, 4:45–54, 5:13–22. Venezia's washer 24 includes bulged portions 25 used for a similar purpose. Ex. 1007, 3:11–17. Thus, we find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

Claim 6 depends directly from claim 1 and recites "wherein the spring washer is a Belleville type spring washer." Ex. 1001, 8:30–31. Petitioner argues that a person having ordinary skill in the art would have been well-aware of Belleville washers and viewed them as appropriate for use in Burren's injection pen. Pet. 53–54 (citing Ex. 1004 ¶¶ 152–153; Ex. 1020, 801–02, 854–61; Ex. 1023, 221–22). Petitioner argues that such an artisan would have fixed a Bellevue washer using fixing elements like those taught by Venezia and de Gennes. *Id.* at 54 (citing Ex. 1004 ¶ 153). Patent Owner does not contest this aspect of the Petition. Petitioner's declarant testifies

that Belleville washers were known and that "a person of ordinary skill would have appreciated that the small-deflection, compact-space of an injection device like Burren's would be an appropriate application for a Belleville washer." Ex. 1004 ¶ 152 (citing Ex. 1006 ¶ 17). We find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

Claim 7 depends directly from claim 1 and recites "wherein the spring washer is fixed to a threaded sleeve member of the housing." Ex. 1001, 8:32–34. Claim 8 depends directly from claim 1 and recites "wherein the spring washer being fixed to the housing comprises the spring washer fixed to a threaded sleeve member of the housing and the threaded sleeve member fixed to the housing." *Id.* at 8:35–39. Petitioner maps Burren's insert 2 to the recited sleeve member and argues that Burren suggests the insert may be a threaded component and that it, instead of the spring, could be threaded for engagement with plunger rod 8. Pet. 54–56 (citing Ex. 1004 ¶¶ 155–157; Ex. 1006 ¶¶ 15, 22–23, 34, Fig. 1). Patent Owner does not contest this aspect of the Petition. Burren discloses that its insert 2 is secured in housing 1 so that it cannot move axially. Ex. 1006 ¶ 22. Plunger rod 8 extends through the insert. *Id.* Burren discloses that the plunger may be threaded for dose metering. *Id.* ¶ 15. Burren explicitly discloses the threaded plunger may engage with the spring of embodiment two. *Id.* ¶ 34. Petitioner's declarant testifies that, instead, the insert could be threaded for engagement with the plunger rod and that this modification would have been obvious to a person having ordinary skill in the art. Ex. 1004 ¶ 157. Thus, we find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

Claim 9 depends directly from claim 1 and recites "wherein the at least two fixing elements comprise two oppositely disposed fixing elements which extend in the axial direction." Ex. 1001, 8:40–42. Petitioner argues that de Gennes's cover includes four axially-extending legs 34, with each leg being disposed opposite of another leg, and that a person having ordinary skill in the art would retain this configuration when incorporating the cover into Burren's injection pen. Pet. 56–57 (citing Ex. 1004 ¶ 159; Ex. 1008, 4:25–29, 5:3–4, 5:30–32, Figs. 5, 15).

Patent Owner notes that the Petition relies only on Burren and de Gennes regarding claim 9, and, therefore, should we deem de Gennes not to be analogous art, the Petition does not otherwise challenge this claim. PO Resp. 75–76. Petitioner acknowledges that the Petition only "cites de Gennes for th[e] element" recited in claim 9. Pet. Reply 24.

de Gennes discloses that its legs 34 "extend axially from the transverse wall of the cover" and "alternate circumferentially with gaps 35." Ex. 1008, 4:25–29; *see also id.* at Fig. 5. The legs are configured to engage claws 20 on reinforcement plate 15, the claws being positioned at four diagonally opposite points on the reinforcing plate. *Id.* at 3:42–51, 4:55–5:2. Petitioner's declarant testifies that this arrangement of legs 34 would be retained to provide even and stable support for the spring washer. Ex. 1004 ¶ 159. Thus, we find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

Claim 10 depends directly from claim 1 and recites "wherein the at least two fixing elements are further configured as positioning elements, which keep the spring washer in a determined orientation." Ex. 1001, 8:43–46. Petitioner argues that the asserted fixing elements of de Gennes

and Venezia "would axially and rotationally fix a spring washer when installed within a Burren-type injection pen," and, thus, such fixing elements are also positioning elements. Pet. 57 (citing Ex. 1001, 5:44–53; Ex. 1004 ¶ 160). Patent Owner does not contest this aspect of the Petition. As discussed in § II.E.2.e above, we are persuaded by Petitioner's arguments that de Gennes teaches the use of fixing elements to fix its cover within Burren's housing. Thus, we find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

Claim 11 depends directly from claim 1 and additionally recites "a further washer, the further washer being arranged on the proximal side of the spring washer." Ex. 1001, 8:47–49. Petitioner argues that "Burren expressly contemplates the use of 'several spring elements or components' in a single drug-delivery device" and "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." Pet. 57–58 (citing Ex. 1004 ¶ 161; citing Ex. 1006 ¶ 16). Petitioner argues that it would have been obvious to include a second washer in Burren's injection pen "for securing a cartridge in order to, for example, establish a desired deflection profile of the spring washer over a given load range." *Id.* at 58 (citing Ex. 1004 ¶ 162). Patent Owner does not contest this aspect of the Petition. Petitioner's declarant testifies that the spring-stacking arrangement described by Petitioner would be "desirable for compensating purposes given the small distances needed to compensate for manufacturing tolerances and the need for forces sufficient to axially hold the cartridge against the cartridge-retaining member." Ex. 1004 ¶ 162; *see also id.* ¶ 55 (testifying that spring stacking was a common, well-understood technique

for adjusting deflection). We credit the testimony of Petitioner's declarant and find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

Claim 12 depends indirectly from claim 1 through claim 11 and recites "wherein the further washer is a disk washer or a further spring washer having a higher strength as compared to the spring washer." Ex. 1001, 8:50–53. Claim 13 depends indirectly from claim 1 through claim 11 and recites "wherein the further washer is arranged to limit the loading distance of the spring washer." *Id.* at 8:54–56. Claim 14 depends indirectly from claim 1 through claim 11 and recites "wherein the further washer is arranged to limit deformation of the spring washer to elastic deformation." *Id.* at 8:57–59. Petitioner argues that, when fine-tuning a stacked spring arrangement, a person having ordinary skill in the art would position a spring having a higher strength on the proximal side of the spring washer to act as a backstop by limiting the loading distance of the spring washer. Pet. 58–59 (citing Ex. 1004 ¶¶ 163–164). Patent Owner does not contest this aspect of the Petition. Petitioner's declarant testifies that a person having ordinary skill in the art "would have been aware that, with a higher strength, the amount of deformation of the spring washer at higher loads would lessen," which would "limit the loading distance of the spring washer." Ex. 1004 ¶ 163. Such limiting would "be beneficial in preserving the elasticity, and thus the biasing function, of the spring washer (i.e., prevent failure due to high loads)." *Id.* We credit the testimony of Petitioner's declarant and find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

Claim 15 depends indirectly from claim 1 through claim 11 and recites "wherein the further washer is curved in an axial direction so as to correspond to a curvature of the spring washer." Ex. 1001, 8:60–63. Petitioner argues that the recited orientation is known as stacking springs "in series" and a person having ordinary skill in the art would have considered and predictably implemented such a stacked spring system. Pet. 60 (citing Ex. 1004 ¶ 165). Patent Owner does not contest this aspect of the Petition. Petitioner's declarant testifies that the spring-stacking arrangement described by Petitioner "would have been understood to allow for greater loads over a smaller deflection, which would have been viewed as desirable for compensating purposes in a drug-delivery device." Ex. 1004 ¶ 165. We credit the testimony of Petitioner's declarant and find that the cited references and evidence of record support Petitioner's contentions, which we adopt.

F. Petitioner's Motion to Exclude Evidence

Petitioner filed a Motion to Exclude Exhibits 2001, 2002, 2003, 2004, 2005, 2006, 2008, 2009, 2011, 2012, 2013, and 2014. Paper 33 ("Pet. Mot."). Patent Owner opposed the Motion. Paper 35 ("PO Opp."). Petitioner filed a Reply in support of the Motion. Paper 37 ("Pet. Reply to Opp.").

The party moving to exclude evidence bears the burden of proof to establish that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence ("FRE"). *See* 37 C.F.R. §§ 42.20(c), 42.62(a). For the reasons discussed below, Petitioner's Motion is *denied in part and dismissed in part*.

1. Exhibit 2001

Petitioner moves to exclude the declaration testimony of Patent Owner's declarant, Mr. Row, (Ex. 2001) under FRE 702, 703, and 705. Pet. Mot. 2–3. According to Petitioner, Mr. Row's "declaration does not provide sufficient facts or data, is not the product of reliable principles or methods, and has not applied the proper principles to the facts of this proceeding." *Id.* at 2. "In addition, the declaration does not disclose the underlying facts and data, and does not set forth the basis of Mr. Row's opinions." *Id.* Petitioner argues that "[l]arge portions of [Exhibit] 2001, specifically including ¶¶15-38 and 48-52, provide narrative with no citation or other identified basis." *Id.* Under FRE 105, Petitioner also argues that, if admitted, the scope of Mr. Row's declaration "should be restricted to the purpose for which it was originally submitted." *Id.* at 3 (citing *Huddleston v. United States*, 485 U.S. 681, 691–92 (1988)).

Patent Owner argues that the Motion should be denied as "procedurally improper" because Petitioner's objections to Mr. Row's declaration "lack the 'sufficient particularity' required by the Board's rules." PO Opp. 1 (citing 37 C.F.R. § 42.64(b)(1)). Patent Owner argues that "[t]he declaration provides an extensive factual predicate and reasoned basis for Mr. Row's conclusions on [Petitioner's] inadequate obviousness grounds." PO Opp. 2–3. Patent Owner argues that Mr. Row is qualified to provide expert testimony in the field of drug delivery devices and that his testimony is based on the evidence of record and his personal knowledge. *Id.* at 3–4. Patent Owner argues that Petitioner's request that the scope of the declaration be restricted "is not grounds for excluding any portion of Mr. Row's declaration." *Id.* at 5.

Petitioner replies by clarifying that its challenge to Mr. Row's declaration testimony "is not to his credentials, but to his methods." Pet. Reply to Opp. 1. "The question is not whether Mr. Row has an appropriate background to be an expert, but whether he can give consistent, candid testimony on the same topic throughout his testimony." *Id.* at 3.

Initially, we find Patent Owner's procedural arguments unavailing. *See* PO Opp. 1–2. In its Objection to Evidence (Paper 18, "Pet. Obj."), Petitioner cited to the same basis for the same paragraphs of Mr. Row's declaration as are cited in the Motion. *Compare* Pet. Mot. 2 (citing Ex. 2001 ¶¶ 15–38, 48–52), *with* Pet. Obj. 1 (citing same). Thus, Petitioner's objections sufficiently preserved and identified the grounds for the objection as required by our rules. Petitioner's objections also identified with requisite particularity the paragraphs of Mr. Row's declaration to permit Patent Owner to consider correction via supplemental evidence.

Turning to the merits of Petitioner's motion, whether Mr. Row's opinions are conclusory or are not adequately based on objective evidence goes to the weight we should accord to his testimony. As appropriate, we have explained above the weight that we accord the allegedly objectionable testimony by Mr. Row. Thus, we deny Petitioner's motion to exclude the identified paragraphs of Mr. Row's declaration (Ex. 2001).

Nor are we persuaded that we should restrict the scope of Mr. Row's declaration. As noted by Petitioner, "[t]he rules do not provide additional opportunities to object to additional uses of the exhibit." Pet. Mot. 3. Moreover, because the decision here is rendered by the panel, as opposed to a jury, there is little risk that the testimony to which Petitioner objects will confuse or mislead the panel. *See Corning Inc. v. DSM IP Assets B.V.*,

IPR2013-00053, Paper 66 at 19 (PTAB May 1, 2014) (routine decision)[6] ("Similar to a district court in a bench trial, the Board, sitting as a non-jury tribunal with administrative expertise, is well-positioned to determine and assign appropriate weight to the evidence presented."); *see also Huddleston*, 485 U.S. at 691–92 (discussing unduly prejudicial evidence and explaining that FRE 105 "provides that the trial court shall, upon request, instruct the jury that the similar acts evidence is to be considered only for the proper purpose for which it was admitted").

2. Exhibits 2002–2006

Exhibits 2002–2006 present definitions of "washer" and "fix." Petitioner moves to exclude the dictionary definitions presented in Exhibits 2002–2006 under FRE 402 and 403 as being irrelevant. Pet. Mot. 4–5. Petitioner argues that Patent Owner has not shown that the definitions presented in these exhibits are applicable to the pen injectors and the definitions address only a subset of the claim terms (for example, "washer" instead of "spring washer"). *Id.*; *see also* Pet. Reply to Opp. 3–4. Petitioner also repeats its request for restriction. Pet. Mot. 6.

Patent Owner argues that the Motion is procedurally deficient and that the probative value of the definitions outweighs the potential of unfair prejudice. PO Opp. 5–8.

The Federal Circuit has approved the use of dictionaries for guidance in claim construction, "so long as the extrinsic evidence does not contradict the meaning otherwise apparent from the intrinsic record." *Helmsderfer v.*

[6] A "routine decision" of the Board is a decision that has not been designated as precedential or informative.

Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1382 (Fed. Cir. 2008); *see also Comaper Corp. v. Antec, Inc.*, 596 F.3d 1343, 1348 (Fed. Cir. 2010) (approving of "consult[ing] a general dictionary definition of [a] word for guidance" in determining ordinary meaning); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1325 (Fed. Cir. 2008) ("[O]ur decisions, including *Phillips*, do not preclude the use of general dictionary definitions as an aid to claim construction." (citation omitted)).

Patent Owner relies on dictionary definitions in this case as evidence of the meaning of terms in the patent claims to a person of ordinary skill. *See, e.g.*, PO Resp. 45; Ex. 2001 ¶ 101. In light of these circumstances, we do not find compelling Petitioner's argument that we should exclude these exhibits.

For the same reasons as discussed above, we are not persuaded by Petitioner's request for restriction or Patent Owner's procedural arguments.

3. Exhibits 2008 and 2009

Each of Exhibits 2008 and 2009 is a copy of the declaration of Petitioner's declarant, Dr. Erdman, (Ex. 1004) with "page 45 annotated during deposition." PO Resp. iii. Petitioner moves to exclude Exhibits 2008 and 2009 under FRE 402 and 403 as being irrelevant and unfairly prejudicial. Pet. Mot. 6–7. Petitioner notes that these exhibits are not cited in Patent Owner's Response and that it objected to these exhibits during Dr. Erdman's deposition, and posits that Patent Owner may have entered these exhibits to produce evidence for a different proceeding. *Id.*; *see also* Pet. Reply to Opp. 4–5. Petitioner clarifies that it "does not seek expungement, just formal exclusion from consideration." Pet. Reply to Opp. 5. Petitioner also repeats its request for restriction. Pet. Mot. 7.

Patent Owner argues that public policy disfavors excluding these exhibits. PO Opp. 8.

Exhibits 2008 and 2009 are copies of Dr. Erdman's declaration that Patent Owner's counsel annotated during the deposition of Dr. Erdman. *See* PO Resp. iii; Ex. 2010, 74–81 (transcript of Dr. Erdman's deposition). The exhibits are annotated at page 45 to include arrows added by Patent Owner's counsel to facilitate identification of components of Burren's embodiments for discussion during the deposition. Ex. 2010, 74–81; Ex. 2008, 45 (annotated to include two arrows); Ex. 2009, 45 (annotated to include three arrows). Petitioner does not explain persuasively why these exhibits are irrelevant or prejudicial. To the contrary, these exhibits facilitate understanding of Dr. Erdman's deposition transcript. We further note that we do not rely on the materials Petitioner seeks to exclude in making our conclusions in this case, so we dismiss as moot this aspect of Petitioner's Motion.

Additionally, for the same reasons as discussed above, we are not persuaded by Petitioner's request for restriction.

4. Exhibits 2011 and 2012

Exhibit 2011 is a "[v]ideo demonstrating [h]ow a [c]lutch [r]elease [b]earing [w]orks" and Exhibit 2012 is a "[v]ideo explaining a [c]lutch [r]elease [b]earing." PO Resp. iii. Petitioner moves to exclude Exhibits 2011 and 2012 under FRE 402 and 403 as being irrelevant and unfairly prejudicial. Pet. Mot. 7–8. Petitioner argues that "[t]he operation of a clutch bearing is irrelevant to any argument [Petitioner] has made." *Id.* at 7; *see also* Pet. Reply to Opp. 5. Petitioner also repeats its request for restriction. Pet. Mot. 8.

Patent Owner argues that "the scope and content of the prior art are fundamental to evaluating a proffered case of obviousness" and Exhibits 2011 and 2012 are "relevant to understanding how the device disclosed by de Gennes operates." PO Opp. 8–9.

As noted above, the nature of our proceedings, in which the same panel that decides admissibility also serves as the fact-finder, disfavors exclusion in these circumstance. *See Corning*, IPR2013-00053, Paper 66 at 19. Moreover, because we do not rely on the materials Petitioner seeks to exclude in making our conclusions in this case, we dismiss as moot this aspect of Petitioner's Motion.

Additionally, for the same reasons as discussed above, we are not persuaded by Petitioner's request for restriction.

5. Exhibits 2013 and 2014

Exhibits 2013 and 2014 are publications of priority applications relied upon by the '614 patent. PO Opp. 9; Ex. 1001, codes (30), (64). Petitioner moves to exclude Exhibits 2013 and 2014 under FRE 402 and 403 as being irrelevant and cumulative. Pet. Mot. 8–9; *see also* Pet. Reply to Opp. 4–5. Petitioner also repeats its request for restriction. Pet. Mot. 9.

Patent Owner argues that Exhibits 2013 and 2014 were "cited in the written description discussion of [its] Motion to Amend." PO Opp. 9. Patent Owner argues that public policy disfavors excluding these exhibits. *Id.*

As noted above, the nature of our proceedings, in which the same panel that decides admissibility also serves as the fact-finder, disfavors exclusion in these circumstance. *See Corning*, IPR2013-00053, Paper 66 at 19. Moreover, because we do not rely on the materials Petitioner seeks to

exclude in making our conclusions in this case, we dismiss as moot this aspect of Petitioner's Motion.

Additionally, for the same reasons as discussed above, we are not persuaded by Petitioner's request for restriction.

G. Patent Owner's Contingent Motion to Amend

Patent Owner filed a Contingent Motion to Amend in which it requested that we provide preliminary guidance concerning the Motion. Paper 15, 2. We issued Preliminary Guidance per Patent Owner's request. Paper 27. Subsequently, Patent Owner withdrew its Motion to Amend. Paper 29. Accordingly, there is no motion to amend for us to consider.

H. Patent Owner's Constitutional Argument

Patent Owner argues that, "for purposes of preserving [certain] issues, [Patent Owner] asserts that any future final written decisions that may be rendered by the Board will be unconstitutional for violation of the Appointments Clause" of the U.S. Constitution. PO Resp. 76 (citing *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), *cert. granted sub nom. United States v. Arthrex, Inc.*, 2020 WL 6037206 (Oct. 13, 2020)). Patent Owner further "asserts that institution decisions, and preliminary guidance on amendments, are also unconstitutional for violation of the Appointments Clause." *Id.* at 76–77.

We are bound by the Federal Circuit's decision in *Arthrex*, which addressed these issues. *See* 941 F.3d at 1337 ("This as-applied severance . . . cures the constitutional violation . . . ."), 1340 ("[W]e see no constitutional infirmity in the institution decision as the statute clearly

bestows such authority on the Director pursuant to 35 U.S.C. § 314."); *see also Arthrex, Inc. v. Smith & Nephew, Inc.*, 953 F.3d 760, 764 (Fed. Cir. 2020) (Moore, J., concurring in denial of rehearing) ("Because the APJs were constitutionally appointed as of the implementation of the severance, *inter partes* review decisions going forward were no longer rendered by unconstitutional panels."). Accordingly, we do not consider this issue any further.

III. CONCLUSION[7]

For the foregoing reasons, claims 1–18 of the '614 patent have been shown to be unpatentable. In summary,

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–18	103(a)	Burren, Venezia, de Gennes	1–18	

[7] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

IV. ORDER

Accordingly, it is

ORDERED that claims 1–18 of the '614 patent are determined to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is *denied in part and dismissed in part*; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

For PETITIONER:

Richard Torczon
Tasha Thomas
Douglas Carsten
Wendy L. Devine
WILSON SONSINI GOODRICH & ROSATI PC
rtorczon@wsgr.com
tthomas@wsgr.com
dcarsten@wsgr.com
wdevine@wsgr.com
4838-4909-4087@mail.vault.netdocuments.com

For PATENT OWNER:

W. Karl Renner
John S. Goetz
Joshua A. Griswold
Matthew S. Colvin
Kenneth W. Darby, Jr.
FISH & RICHARDSON P.C.
IPR28328-0015IP1@fr.com
PTABInbound@fr.com