Birch Stewart Kolasch Birch LLP

# A review of the analogous art test:

## *Sanofi v. Mylan*, No. 21-1981 (Fed. Cir. May 9, 2023)

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# Outline

- Procedural history of the case
- Discussion of the invention and challenged claims
- PTAB final written decision
- Appeal to Federal Circuit
- Discussion of law of analogous art in prosecution
- Takeaways

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# Procedural History

- Mylan filed an *inter partes review* (IPR) against claims 1-18 of U.S. Patent RE47,614 owned by Sanofi
  - Mylan asserted that each of claims 1-18, as a whole, would have been obvious from the combined teachings of Burren, Venezia, and De Gennes
- Final written decision found claims obvious
- Sanofi appealed to Federal Circuit

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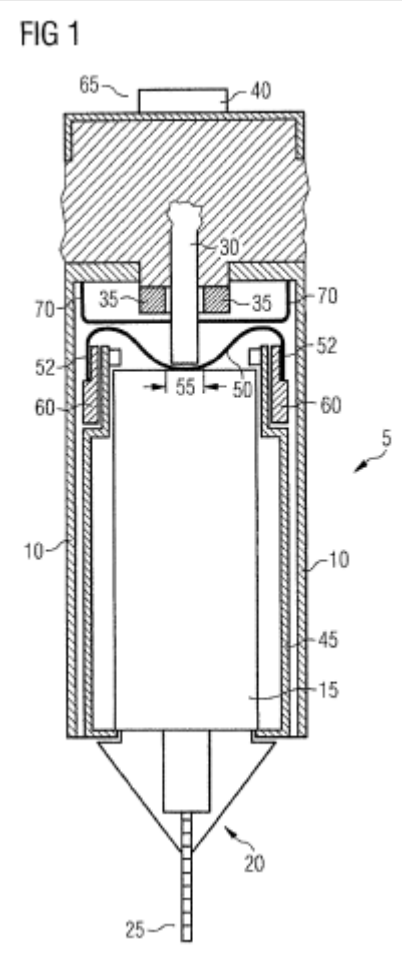
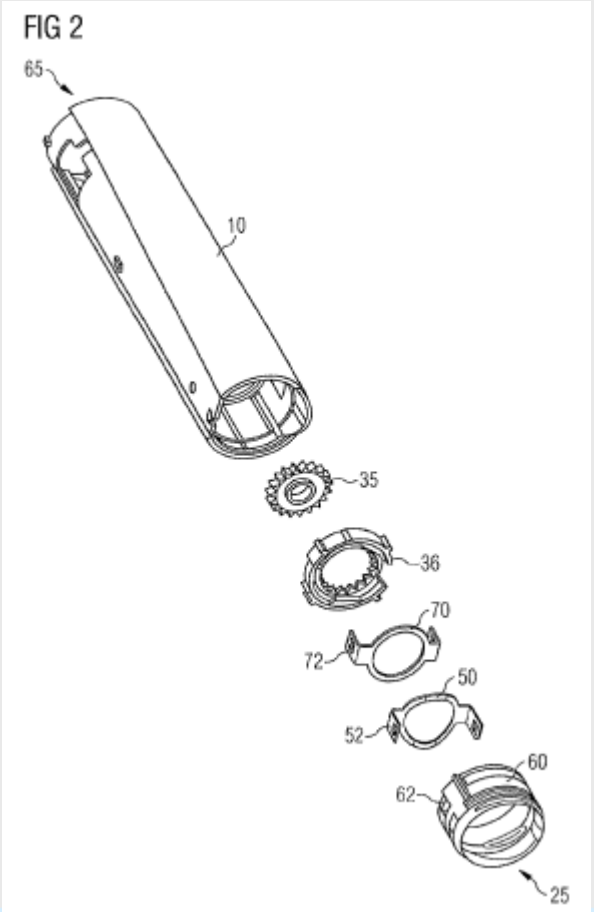
# The Invention (US RE47,614E)

- Medical devices known as pen injectors
  - compact mechanical devices which permit patients to self-inject with measured doses of a drug
- most commonly injected drugs
  - Insulin
  - Epi-pen

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# Examples of other Commercial products



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# Background

- Mylan has an authorized generic EpiPen

**As part of Mylan's actions to enhance access to epinephrine auto-injectors,** the company has introduced the first authorized generic (AG) for EpiPen® Auto-Injector. Epinephrine auto-injectors are used for the emergency treatment of a life-threatening allergic reaction (anaphylaxis). With epinephrine auto-injectors, the stability of the medication and maintenance of quality of the delivery device is critical given the nature of the condition it is intended to treat. Patients are encouraged to work with their healthcare professional to determine the best option for them.

## Branded Products vs. Authorized Generics (AG)

According to the U.S. Food and Drug Administration (FDA), generic drugs are equivalent to brand drugs in terms of dosage, safety, strength, quality, the way they work and the way they are administered. An AG is a brand-name prescription drug – already approved by FDA – and marketed as a generic under a private label. The AG is sold and distributed as a generic product. Unlike a standard generic, an AG has identical inactive ingredients to the branded product. The FDA approval of the branded product as safe and effective applies to the AG, as well.

### Mylan's Authorized Generic for EpiPen® Auto-Injector

| | |
|---|---|
| FORMULATION | Identical to brand |
| DEVICE | Identical to brand; sold as two-pack |
| DOSAGE | 0.3 mg and 0.15 mg |
| DISTRIBUTION | Retail Pharmacy, Wholesaler, Patient Access Program |
| LABEL | The label is the same as the brand name (EpiPen®) but does not include the brand name. There are no changes to the administration instructions. |
| APPROVAL PROCESS | The AG falls under Mylan's current New Drug Application for EpiPen Auto-Injector as an annual reportable notification. The AG does not require an Abbreviated New Drug Application. |

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# Background

- Sanofi also markets AUVI-Q as an EpiPen alternative


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# Background

- Prior antitrust litigation between Sanofi and Mylan with Sanofi alleging Mylan used anticompetitive practices to market its popular epinephrine autoinjector EpiPen, specifically interfering with the launch of its more “consumer-friendly” Auvi-Q
  - Alleged that Mylan used restrictive rebates and other tactics that amount to a violation of the Sherman Act prong barring monopolization

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# Background

- Sanofi lost at 10th Circuit, with court holding that Sanofi failed to present an issue of monopolization
- Sanofi appealed to the U.S. Supreme Court, but denied cert in April 2023
- Separately, Mylan is also apart of a larger multidistrict litigation that includes claims from consumers alleging they paid higher prices because Mylan delayed generic versions of EpiPen
  - 2009: price of two EpiPens was ~ $100
  - 2013: ~$265
  - 2015: ~$461
  - 2016: ~$609

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# The Invention (US RE47,614E)

The invention claimed is:

**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.

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# The Invention (US RE47,614E)

16. A method of manufacturing a drug delivery device comprising:

providing a housing with a proximal end and a distal end,

providing a cartridge adapted to accommodate a drug,

providing a cartridge retaining member adapted to retain the cartridge and be releasably secured to the housing,

arranging a spring washer within the housing and

releasably securing the cartridge retaining member to the housing, thereby loading the spring washer so as to exert a force on the cartridge and to secure the cartridge against displacement 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.

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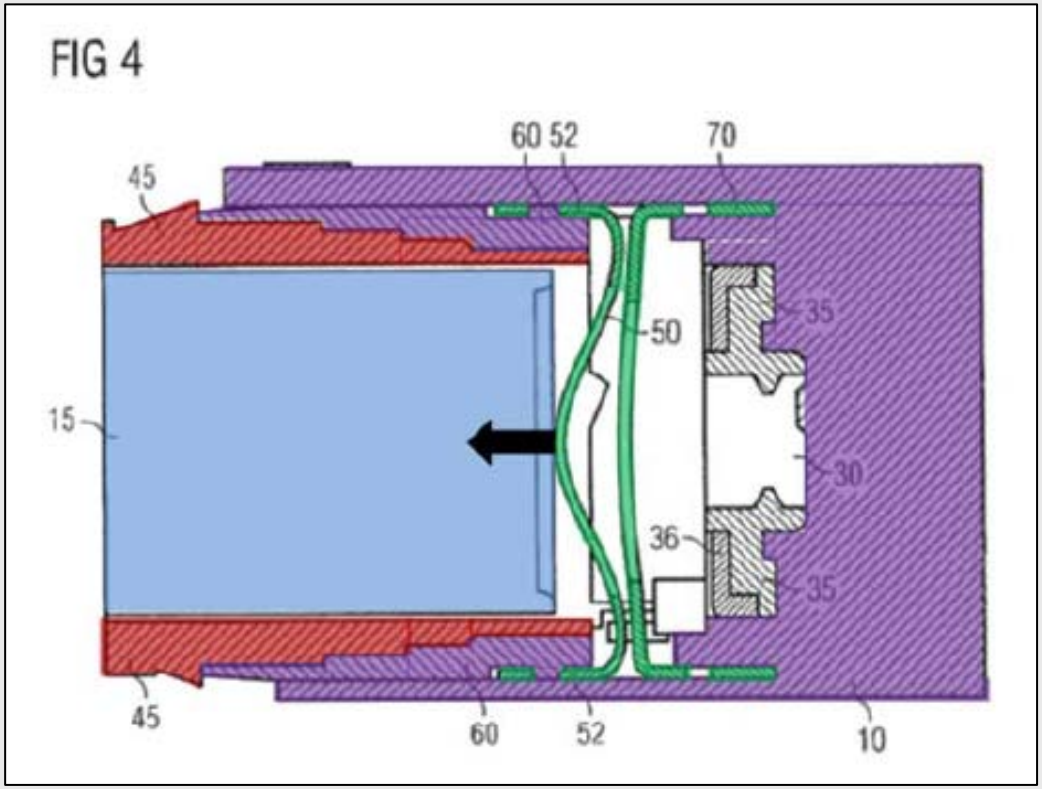
# PTAB Challenge: The Invention

The claimed drug-delivery device has four main components:

(1) a housing **10 (purple)** for housing internal components of the device;
(2) a cartridge containing medicine **15 (blue)** ;
(3) a cartridge retaining member **15 (red)** for retaining the cartridge; and
(4) a spring washer **50 and 70 (green)** for biasing the cartridge against the cartridge-retaining member to secure it against movement, where the spring washer includes at least two fixing elements to fix it relative to the housing

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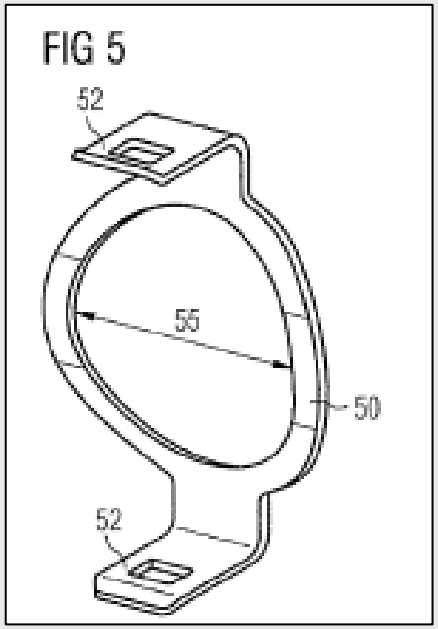
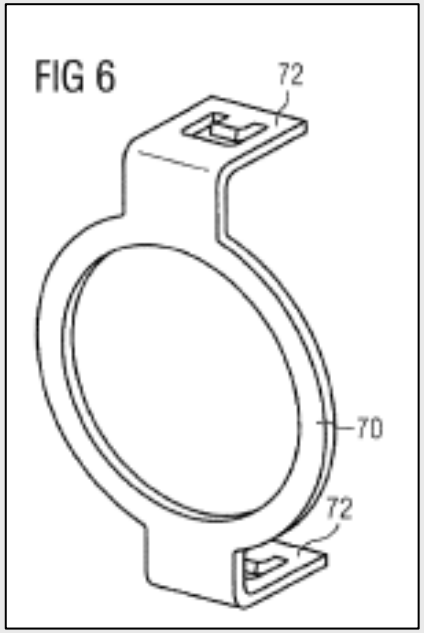
# PTAB Challenge: The Invention

In a drug delivery device of this kind movement of the cartridge with respect to the housing and/or the cartridge retaining member is reduced or even avoided on account of the spring washer, which exerts the force on the cartridge. The spring washer can reduce play between cartridge and housing and/or between cartridge and cartridge retaining member. This is, for example, particularly advantageous when cartridges with different lengths are to be used in the drug delivery device. Thus, the drug delivery device may be a reusable device. Manufacturing tolerances in cartridge lengths can thus be compensated by means of the spring washer. Consequently, during operation of the drug delivery device, axial movement of the cartridge in the cartridge retaining member can be reduced or even prevented and dose accuracy can be increased. The spring washer allows securing the cartridge within the cartridge retaining member without requiring much space. Consequently a very compact drug delivery device can be formed.

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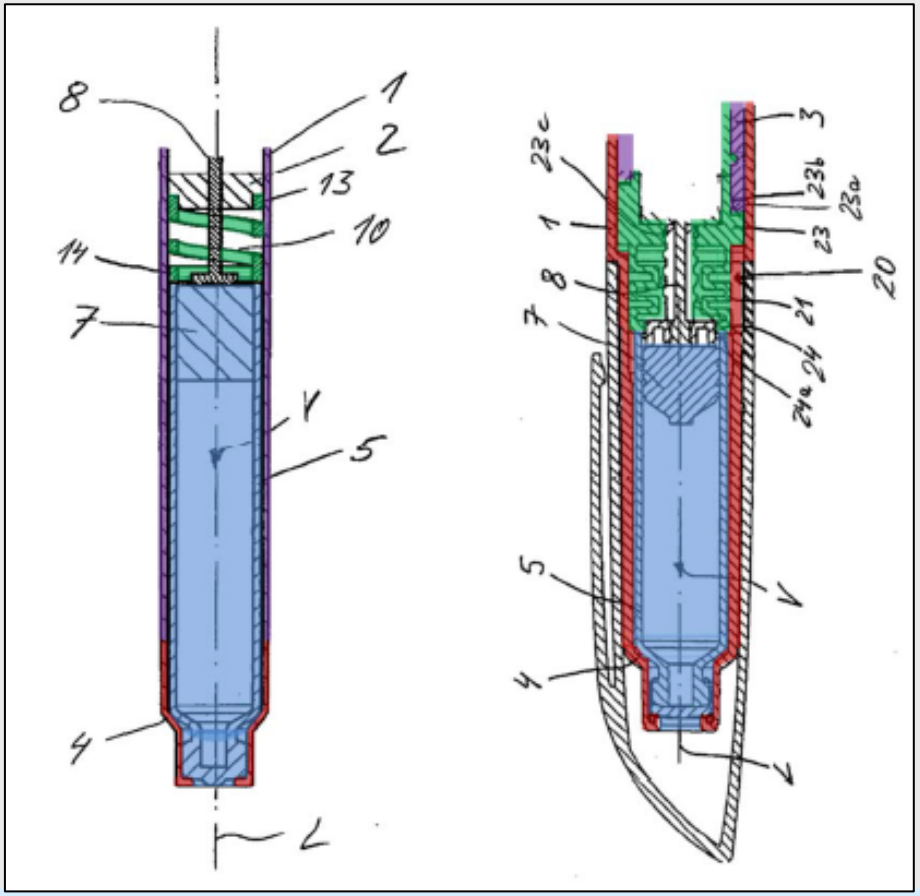
# PTAB Challenge: The Prior Art




Burren discloses injection pens having four *similar components* that perform the *same functions*:

(1) housing **1 (purple)** or proximal housing portion **2 (purple)** for housing internal components of the device;

(2) container **5 (blue)** containing medicine;

(3) stop **4 (red)** or distal housing portion **1 (red)** for retaining the container; and

(4) spring **10 (green)** or spring **20 (green)** for biasing the container against the stop or distal housing portion to secure it against movement, where the springs have positioning devices for fixing the springs relative to the housing

***The springs in Burren are a "coil spring" and "spring bellows," rather than a "spring washer."***

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# PTAB Challenge

- Burren does not teach a “spring washer” having “at least two fixing elements” for axially and rotationally fixing the washer relative to the housing
- “Nevertheless, a POSA would have had reason to use (1) a spring washer as a compensating spring for securing a cartridge against axial movement within a drug-delivery device like Burren’s, and (2) at least two fixing elements to axially and rotationally fix the spring washer within the device.”
- Secondary references (1) Venezia and (2) De Gennes demonstrate the well-understood and common use of a spring washer to accomplish a “compensating” function similar to that of Burren’s device

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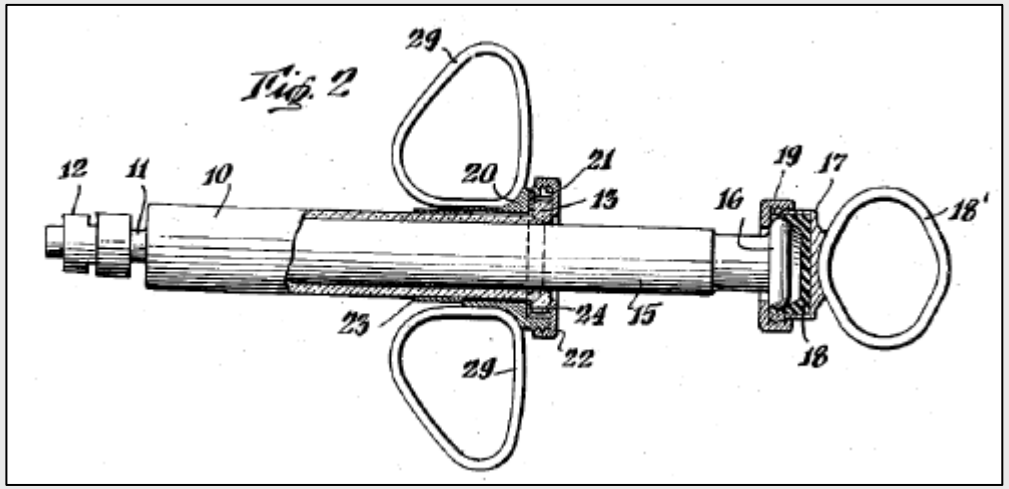
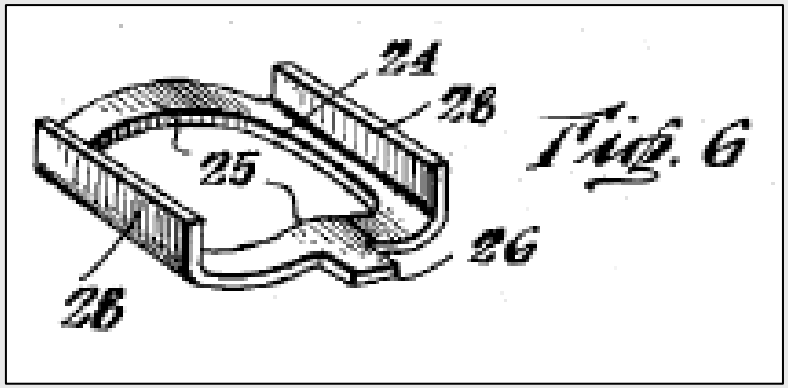
# PTAB Challenge

Venezia is directed to a hypodermic syringe




Venezia discloses a spring washer in the hypodermic syringe to secure a component against axial movement

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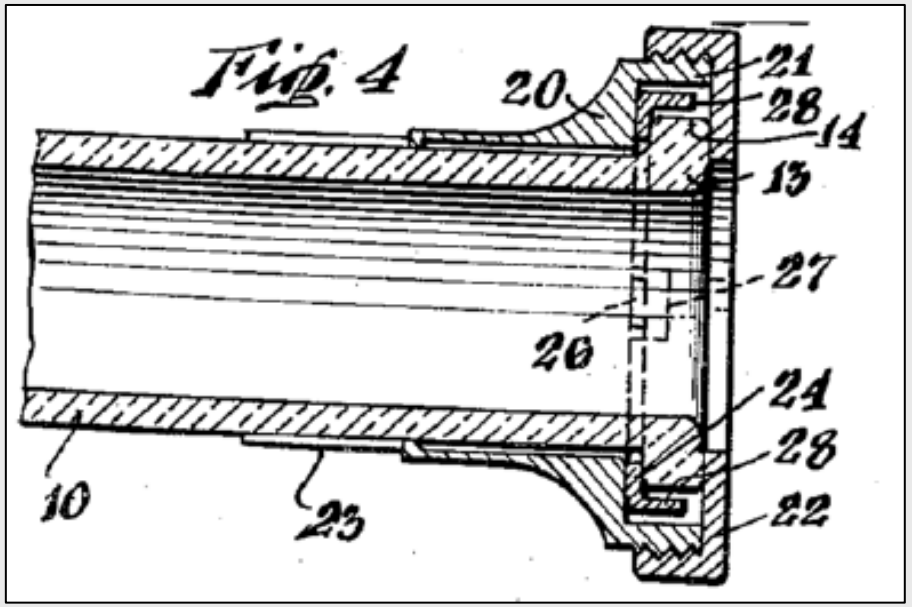
# PTAB Challenge

- Venezia also discloses:
- an attachment for joining barrel **10** (analogous to a “cartridge”) to plunger
- the attachment includes collar **20** (analogous to a “housing”) having threaded flange **21** onto which flanged ring **22** (analogous to a “cartridge retaining member”) is releasably mounted.
- Flanged ring **22** receives flange **13** of the barrel and, when the flanged ring is threaded onto threaded flange **21**, flange **13** is housed within collar **20**

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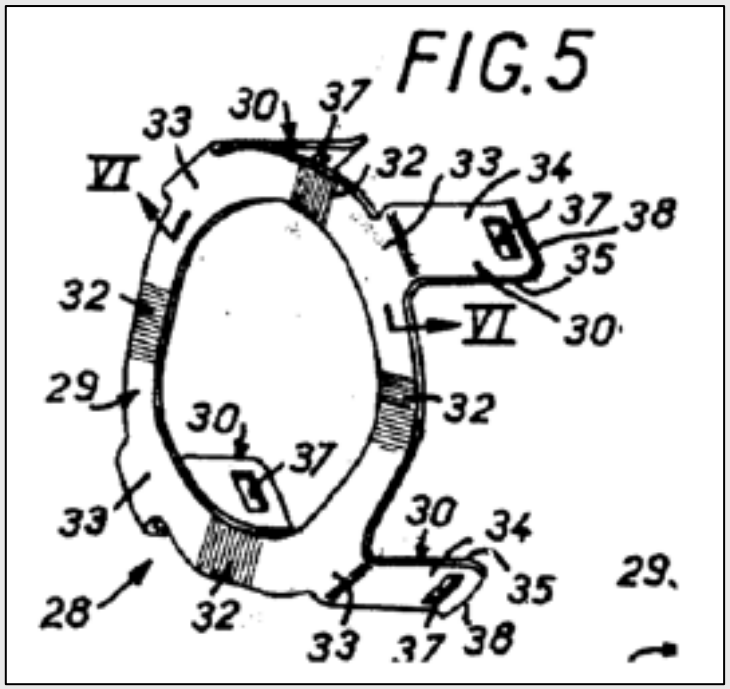
# PTAB Challenge

- De Gennes describes a cover 28 “suitable for axially fastening together [an] operating element 10 and [a] drive element 11.”
- The cover is a spring washer with alternating resilient support zones 32 that bear on the drive element.
- De Gennes uses “snap-fit engagement grips” to secure the spring washer.

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# PTAB Challenge

The present invention relates generally to "self-centering" clutch release bearings which comprise an operating element intended to be subjected to the action of a displacement control means and having a transverse annular plate or flange sometimes known as a cage, a drive element intended to act on the release device of a clutch under the action of the operating element, and having radially an omnidirectional latitude of movement in relation to the operating element to provide the self-centering action, axially-directed resilient means urging the drive element in the direction of the transverse plate of the operating element, and a cover which fastens together the operating element, the drive element, and the resilient means.

- De Gennes is directed to clutch releases *for automotive applications*
- De Gennes discloses use of spring washers to bias and fix components in mechanical systems.
- De Gennes discloses axially securing two components, a drive element and an operating element, relative to one another to prevent movement—and does so through the use of a spring washer to bias the drive element into abutting contact with the operating element.

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# PTAB Challenge

- Mylan's argument:
  - given POSAs' familiarity with general spring mechanics and manufacturing and their widespread use for securing components, a POSA would have considered devices like De Gennes, which also incorporates a biasing element, like a spring washer, for a similar function
  - A POSA would have had a reasonable expectation of success in using a spring washer having at least two fixing elements as a compensating spring in an injection pen like Burren's.

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# Sanofi's Patent Owner Response

1. De Gennes Is Non-Analogous Art to the Claimed invention
2. De Gennes's Cover Performs a Different Function Than the Spring of Burren and Does Not Suggest a Suitable Replacement 37
3. De Gennes's Cover Would Not Have Functioned Properly in Burren's Injection Device in the Proposed Combination
4. Selection of de Gennes based on Visual Similarity Between the Patent's Figure 5 and de Gennes's Figure 5 Is Hindsight and Not a Valid Reason to Combine
5. Claim 18: de Gennes's cover Would Not Have Allowed Axial Loading Within Burren's Device
6. …

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# Case Law of Analogous Art

- When prior art is being used against a patent (or patent application), the prior art must be *analogous* to the claimed invention
- Threshold inquiry
- 35 U.S.C. § 103 limits patents to claimed subject matter that would have been nonobvious to a "person of ordinary skill in the art" at the time of filing
- "person of ordinary skill in the art" has ordinary creativity and is aware of all prior art in his field of endeavor, and prior art that is relevant to the problem solved by the invention

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# Case Law of Non-Analogous Art

- 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))

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# Case Law of Non-Analogous Art

- 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)).

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# Sanofi's Patent Owner Response

- Sanofi argued that de Gennes relates to cars and not drug delivery devices or medical devices, such that a person of ordinary skill in the art "would not have considered a clutch bearing to be within the same field of endeavor."
- Sanofi argued that de Gennes is not "reasonably pertinent" to the '614 patent's problem, which their expert framed as "secur[ing] a cartridge against movement within a housing."

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# PTAB final written decision

- Regarding the second prong of the analogous art test, Sanofi identified a singular problem: “[t]o secure a cartridge against movement within a housing.”
- Sanofi argued 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.”
- Board found this problem to be too narrow

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# PTAB final written decision

- Mylan identified the problem as “axial[] fixation and support of two components relative to one another.”

- The Board agreed that Mylan’s definition of the problem “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.”

- “*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*.”

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# PTAB final written decision

- Therefore, de Gennes *is analogous art* to the invention
- Burren in combination with Venezia does not render the challenged claims of the ’614 patent unpatentable. However, Burren in combination with Venezia and de Gennes does render the challenged claims unpatentable because, among other things, the “snap-fit connection” of de Gennes taught the “fixing elements” of the ’614 patent
- Holding: Mylan has shown by a preponderance of the evidence that claims 1–18 would have been obvious in view of Burren, Venezia, and de Gennes

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# Appeal to Federal Circuit – Sanofi's position

- Sanofi argues that the Board "altered and extended Mylan's deficient showing" by analyzing whether de Gennes constitutes analogous art to the '614 patent when Mylan only presented its arguments with respect to Burren
- Argued the Board cannot "raise, address, and decide unpatentability theories never presented by the petitioner and not supported by record evidence."
- Argued the Board "adopted Mylan's problem statement derived from Burren and then worked backward to relate that problem to the '614 patent," which led the Board to a "legally erroneous conclusion that lacks substantial evidence."

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# Appeal to Federal Circuit – Mylan's position

- Mylan argues its petition permitted the Board to evaluate de Gennes as analogous art because there is no functional difference between the problem of Burren and the problem of the '614 patent
- Mylan argued Sanofi raises "a distinction without a difference" because "[t]he evidence and arguments underlying the Board's findings—whether linked to Burren or [the '614 patent]— remained the same."
- Argued the Board "relied on substantial evidence to find Mylan's definition of the 'problem' more appropriately defined the scope of analogous art."

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# Appeal to Federal Circuit –Decision

- In evaluating whether a reference is analogous, “we have consistently held that a patent challenger must compare the reference to the challenged patent.”
- The purpose of the analogous art test is to examine whether a reference can be considered as prior art to the challenged patent in the first place.
- Disagreed with Mylan’s reliance on two cases (Mandel Bros., Inc. v. Wallace, 335 U.S. 291,295–96 (1948), and In re Mariani, 177 F.2d 293, 294–96 (CCPA 1949)) to argue it is proper to compare *a reference to other references* for analogous art purposes.

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# Appeal to Federal Circuit - Decision

- Mylan's arguments would allow a challenger to focus on the problems of alleged prior art references while ignoring the problems of the challenged patent.
- Even if a reference is analogous to one problem considered in another reference, it does not necessarily follow that the reference would be analogous to the problems of the challenged patent
- As we explain, Mylan's arguments as to Burren are insufficient to carry its burden because they do not address the '614 patent

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# Appeal to Federal Circuit - Decision

- Mylan's expert stated that "although De Gennes is concerned with a clutch bearing, it addresses a problem analogous to that addressed in *Burren*."
- When asked during oral argument before the Board as to which "problem" should be examined for the analogous art test, Mylan's counsel stated "[i]t doesn't really matter" and that "the problem to be solved . . . Is really identical[ly] presented between Burren and [the '614 patent]. They're both interested in solving the same issue and that is on the Burren side accommodating various cartridge lengths and on the [the '614 patent] side identifying the cartridges."

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# Non-analogous art and prosecution

- If facing a rejection under 35 USC § 103 during prosecution, an argument that the art is non-analogous can be pursued to rebut the combination of references

- May be a rare argument to make, but this may be technical area dependent

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# Non-analogous art and prosecution

- MPEP § 2141.01(a) provides guidance for Examiners regarding analogous, or non-analogous art

- Breaks down by technical area in the MPEP

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# Non-analogous art and prosecution

- **Chemical Arts MPEP § 2141.01(a)(III)**
  - Examples of analogous art in the chemical arts include: *Ex parte Bland,* 3 USPQ2d 1103 (Bd. Pat App. & Inter. 1986) (Claims were drawn to a particulate composition useful as a preservative for an animal foodstuff (or a method of inhibiting fungus growth in an animal foodstuff therewith) comprising verxite having absorbed thereon propionic acid. *All references were concerned with absorbing biologically active materials on carriers, and therefore the teachings in each of the various references would have been pertinent to the problems in the other references and the invention at hand*.)

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# Non-analogous art and prosecution

- **Mechanical arts MPEP § 2141.01(a)(IV)**
- Examples of analogous art in the mechanical arts include: *Stevenson v. Int'l Trade Comm.,* 612 F.2d 546, 550, 204 USPQ 276, 280 (CCPA 1979) (“In a simple mechanical invention a broad spectrum of prior art must be explored and it is reasonable to permit inquiry into other areas where one of ordinary skill in the art would be aware that similar problems exist.”).
- *In re Bigio,* 381 F.3d 1320, 1325-26, 72 USPQ2d 1209, 1211-12 (Fed. Cir. 2004). The patent application claimed a "hair brush" having a specific bristle configuration. The Board affirmed the examiner’s rejection of the claims as being obvious in view of prior art patents disclosing toothbrushes.

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# Non-analogous art and prosecution

- **Electrical arts MPEP § 2141.01(a)(V)**
- *Medtronic, Inc. v. Cardiac Pacemakers,* 721 F.2d 1563, 220 USPQ 97 (Fed. Cir. 1983) (Patent claims were drawn to a cardiac pacemaker which comprised, among other components, a runaway inhibitor means for preventing a pacemaker malfunction from causing pulses to be applied at too high a frequency rate. Two references disclosed circuits used in high power, high frequency devices which inhibited the runaway of pulses from a pulse source. The court held that one of ordinary skill in the pacemaker designer art faced with a rate-limiting problem would look to the solutions of others faced with rate limiting problems, and therefore the references were in an analogous art.).

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# Non-analogous art and prosecution

- “Relevant field of endeavor” test
- Examiner should consider “explanations of the invention’s subject matter in the patent application, including the embodiments, function, and structure of the claimed invention.”
- Primary focus is on what the reference discloses.
- Examiner must consider the disclosure of each reference “in view of the ‘the reality of the circumstances.’”
- Circumstances are to be weighed “from the vantage point of the common sense likely to be exerted by one of ordinary skill in the art in assessing the scope of the endeavor.”

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# Non-analogous art and prosecution

- “Reasonably pertinent” test
- Examiner should consider the problem faced by the inventor in specification.
- Reference must “logically have commended itself to an inventor's attention in considering his problem.”
- An inventor is not expected to have been aware of all prior art outside of the field of endeavor.
- A reference outside of the field of endeavor is reasonably pertinent if a person of ordinary skill would have consulted it and applied its teachings when faced with the problem that the inventor was trying to solve.

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# Non-analogous art and prosecution

- Turns on how the problem to be solved is perceived.
- If the problem to be solved is viewed in a narrow or constrained way, and such a view is not consistent with the specification, the scope of available prior art may be inappropriately limited.
- It may be necessary for the examiner to explain why an inventor seeking to solve the identified problem would have looked to the reference in an attempt to find a solution to the problem, *i.e.*, factual reasons why the prior art is pertinent to the identified problem.

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# Real Example from Prosecution

Applicant submits that Reb is nonanalogous art to the present invention, and therefore, the present invention is not obvious over Reb. Turning to the first test, Reb relates to a drug delivery method rather than battery. Therefore, Reb is not from the same field of endeavor as the present invention. Turning to the second test, Reb is also not reasonably pertinent to the particular problem with which the present inventors are involved. For instance, the claimed invention is concerned with producing a binder for a secondary battery electrode which suppresses the deformation of the electrode structure even when the volume change of the silicon-based active material that occurs as charging/discharging proceeds, and improves the conductivity of the electrode (paragraph [0008] of the present specification).

In contrast, Reb is concerned with optimizing microspheres as dual embolization agents and drug delivery agents where the microspheres contain a contrast agent (see paragraphs [0008] and [0009]). The microspheres may contain PVA copolymers as one of a broad listing of polymer materials (see paragraph [0013]). Therefore, Reb is non-analogous art that should not be relied upon in the outstanding obviousness rejection.

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# Takeaways and Strategies

- Always review art applied in a rejection to determine whether the art is analogous to the *claimed invention*
- If there may be an argument that the art is non-analogous, apply the two part test under MPEP § 2141.01(a)
- Argument will usually turn on the second prong of the test (whether the reference still is reasonably pertinent to the particular problem face by claimed invention)
- Focus on the problem being solved, and how broadly (or narrowly) the problem can be defined
  - Examiner will argue the problem broadly
  - You want a narrower construction of the problem

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# Takeaways and Strategies

- Review the art applied for teachings specific to their problem being solved, and why their rationale would not be applicable to claimed invention
- Conduct an interview with the Examiner to gauge their response to the argument
- If an Examiner is applying a non-analogous art reference, there is a good chance that there was nothing in the relevant art that might teach the feature

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# Thank you!

Questions: email me at hbureau@bskb.com

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