

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M Company, Merck & Co., Inc. and Merck Sharp & Dohme Corp.,
Petitioners

v.

Aptar France S.A.S.,
Patent Owner

Case IPR2018-01054
Patent No. 8,936,177

**DECLARATION OF CHARLES E. CLEMENS IN SUPPORT OF PATENT
OWNER'S RESPONSE TO PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 8,936,177**

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| Ex. 2021 3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp., v. Aptar France SAS IPR2018-01054 |
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I, Charles E. Clemens, declare as follows:

I. Introduction

1. I have been asked to evaluate and assess certain information in connection with Aptar's Response to 3M Company, Merck & Co., Inc. and Merck Sharp & Dohme Corp.'s (collectively, "Petitioners") petition for *inter partes* review of U.S. Patent No. 8,936,177 ("the Petition"). All of the opinions and conclusions found in this declaration are my own.

2. I make this declaration as a supplement to my original Declaration in Support of Patent Owner's Preliminary Response to Petition for *Inter Partes* Review of U.S. Patent No. 8,936,177 (Ex. 2005). The entirety of that declaration is incorporated herein by reference.

II. Compensation

3. I am being compensated for my work at my normal consulting rate of \$500/hour for time spent in connection with this matter. My compensation is not contingent on the results of my work or on the testimony I provide.

III. Qualifications and Experience

4. I have over 38 years of experience as an engineer, executive, and consultant in the medical device industry.

5. In 1979, I obtained a Bachelor of Science degree in Mechanical Engineering from San Diego State University.

6. From 1981 to 1995, I worked at IVAC Corporation (now CareFusion, a subsidiary of Becton Dickinson), a company that pioneered intravenous medication delivery systems. During my time at IVAC, I worked in multiple roles, including as a product designer, engineering manager, and technical director for the largest medication delivery system program the company had ever attempted, which resulted in launching the product in both the US and European markets. My work at IVAC involved design, development, marketing, launch, and manufacturing of numerous drug delivery devices and vital sign monitoring systems. My design and development work at IVAC lead to the filing of five patents on which I was a named inventor. The focus of my work was in both durable and disposable products utilizing small mechanisms, plastic injection molded parts produced in quantities of millions, and precision assembly of parts to achieve high production quality and functional reliability. In 1990, I established and managed training for specialized design tools for Design for Manufacturing and Assembly (DFMA), a design process intended for optimizing assemblies and part count for small plastic devices produced in high quantities.

7. From 1995 to the present, I have been operating a medical device design and development consulting company as the Founder and Principal Consultant. My consulting company focuses on developing innovative medical device products and bringing them to market. During this time I have worked

extensively on dozens of medical device designs across many clients in the areas of (a) respiratory care devices such as personal inhalers, (b) liquid medication delivery devices, including intravenous (“IV”) systems and injectors, (c) hemodialysis and other blood handling systems, and (d) in-vitro diagnostic systems.

8. As a consultant, I have performed design, analyses, prototyping, and testing activities of numerous inhalation products. Between 1995 and 1998, I played a significant role in the development of a partial liquid ventilation system for the treatment of Infant and Adult Respiratory Distress Syndrome, including designing and building Clinical Trial systems credited with saving infant lives. Between 1999 and 2000, I developed a patented low cost, injection molded, high performance aerosol generator for use in inhaler products for Aerogen Incorporated. In 2003, I developed aerosol quality testing systems and directed computational fluid dynamic analysis of a small inhaler product indicated for therapeutic inhaled nicotine delivery for InJet Digital Aerosols. Between 2004 and 2012, I assisted several companies in various inhaler product design projects, such as design reviews, risk analyses, and design verification testing. This work was performed for companies such as Dura Pharmaceuticals (2004), KOS Pharmaceuticals BAI (2006), and General Pharm Partners (2012).

9. I am identified as an inventor on 10 issued patents and 6 applications in the field of medical devices, including small mechanisms, plastic injection molding and assembly, patient medication delivery devices, and fluidic control devices.

10. I have worked and am familiar with hundreds of plastic medical device assemblies and mechanisms throughout my career and have significant experience with medication delivery systems, including MDI-type devices. Further, I have analyzed many injector devices utilizing small plastic dose counting mechanisms.

11. My professional background and technical qualifications are reflected in my *curriculum vitae*, which is attached as Exhibit 2006.

IV. Materials Considered

12. In arriving at the opinions set forth in this declaration, I relied on the following materials:

- a. Petition for *Inter Partes* Review of U.S. Patent No. 8,936,177 and supporting exhibits;
- b. Expert Declaration of S. David Piper and supporting exhibits;
- c. U.S. Patent No. 8,936,177 (the “177 Patent”) (Petition Ex. 1001);
- d. File History of U.S. Patent No. 8,936,177;
- e. U.S. Patent No. 6,283,365 (“Bason”) (Petition, Ex. 1005);

- f. British Patent GB 1317315 (“Elliott”) (Petition, Ex. 1006);
- g. U.S. Patent No. 3,205,863 (“Rhoades”) (Petition, Ex. 1007);
- h. Stein, S., *Advances in Metered Dose Inhaler Technology: Hardware Development*, 15 AAPS PHARMSCITECH 326, 330 (2014) (Ex. 2008);
- i. Sander, N., et al., *Dose counting and the use of pressurized metered-dose inhalers: running on empty*, 97 ANNALS OF ALLERGY, ASTHMA & IMMUNOLOGY 34 (2006) (Ex. 2009);
- j. Stuart, A., *More Than Just a Dose Counter*, 46 INNOVATIONS IN PHARMACEUTICAL TECHNOLOGY 40 (Ex. 2010);
- k. Henry, A.R., *The Role of Statistical Tolerance Analysis Tools in Dose Counter Optimization*, available at <http://multimedia.3m.com/mws/media/1159495O/statistical-tolerance-analysis-tools-in-dose-counters.pdf> (Ex. 2011).
- l. Stein, S. et al., *The History of Therapeutic Aerosols: A Chronical Review*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278812/> (Ex. 2016).
- m. Newman, S., *Principles of Metered-Dose Inhaler Design*, 50 RESPIRATORY CARE 1177 (2005) (Ex. 2017).
- n. Malloy, R., PLASTIC PART DESIGN FOR INJECTION MOLDING 88, 99 (1994) (Ex. 2018).

o. *The Kids Should See This*, available at <https://thekidshouldseethis.com/post/how-does-a-retractable-ballpoint-click-pen-work> (Ex. 2020).

p. Deposition of S.D. Piper (Jan. 25, 2019) (Ex. 2019).

V. Person of Ordinary Skill in the Art

13. I understand that a person of ordinary skill in the art (“POSA”) is a person who is presumed to have known the relevant art at the time of the invention.

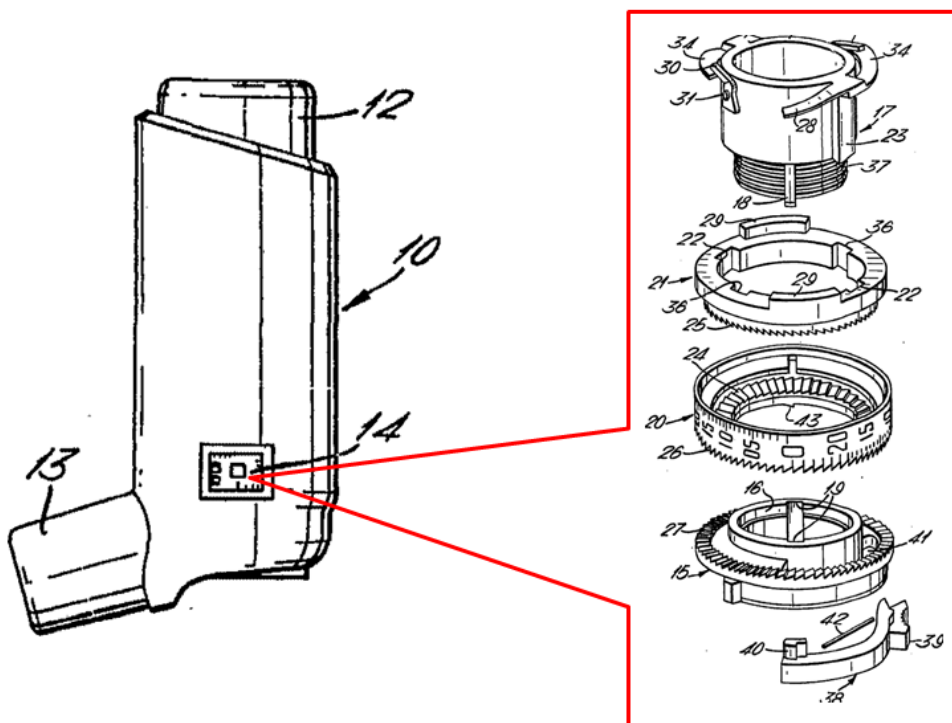
14. I understand that Petitioners have proposed that a person of ordinary skill in the art “at the time of the alleged invention of the ’177 patent would have had a bachelor’s degree in industrial design, mechanical engineering or a related discipline and at least three to five years of industry experience in the design or manufacture of mechanical devices, or equivalent experience, education, or both.”

15. I am a POSA according to Petitioners’ proposed definition.

VI. Alleged Prior Art Asserted by Petitioners

A. Elliott (Great Britain Patent No. 1317315)

16. Elliott discloses a counter for use in small, handheld devices. Ex. 1006 at 1:20-23. The Elliott counter consists of a number of components that include the housing 17, drive member 21, number wheel 21, base 15, and aerosol can/vial 12. Ex. 1006 at Sheet 1.

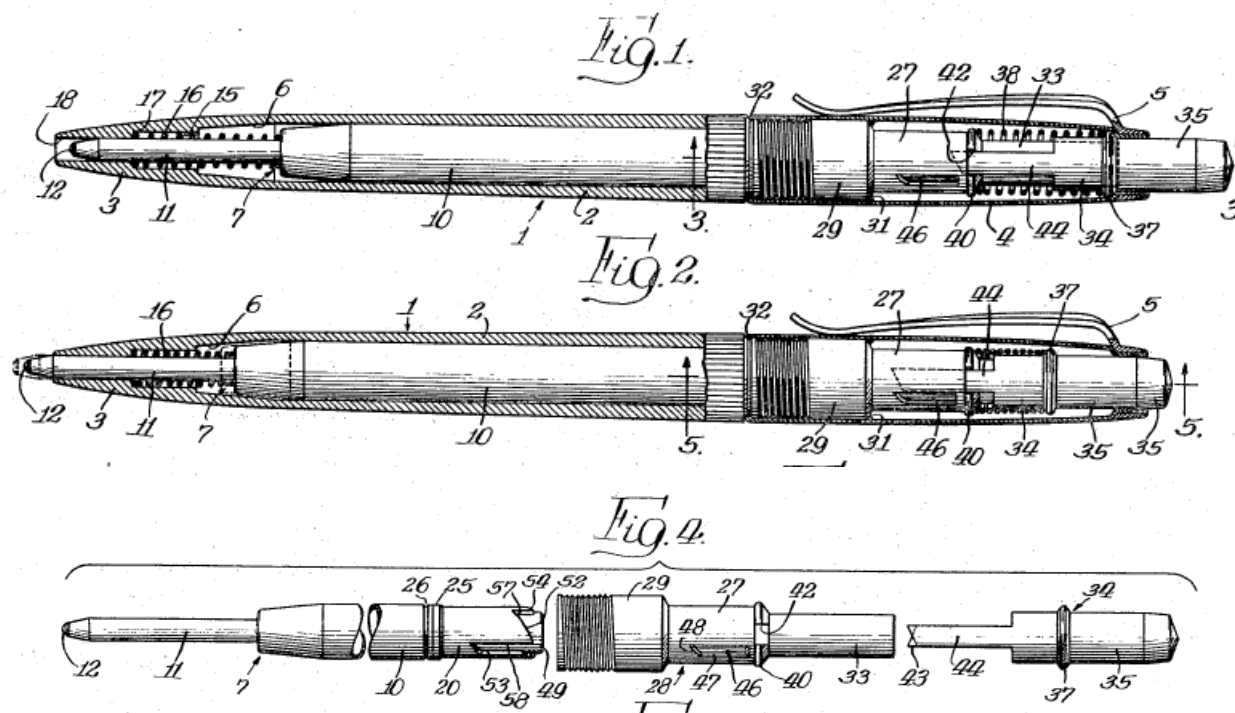


17. Elliott discloses a simple press-and-release mechanism. To actuate the device, the patient presses down once on the canister, and the medication is released from mouthpiece 13. Ex. 1006 at 2:66-90. Elliott's counting components are biased to engage with one another under the force of the fixed base 15, bell cranks 30, and leaf spring 28. Ex. 1006 at Fig 1, 2:47-53. Elliott does not teach a cap for enclosing the inhaler.

B. Rhoades (U.S. Patent No. 3,205,863)

18. Rhoades (U.S. Patent No. 3,205,863) discloses a retractable ball point pen. Rhoades relates to "ball point writing instruments . . . having a projecting and retracting mechanism operated by a push button for alternatively moving the writing point between an exposed, writing position and a concealed, non-writing

position.” Ex. 1009 at 1:09-14. Depicted below are sectional views of Rhoades’s device with the writing point-and-cartridge unit in the retracted position and in the projected position, respectively, as well as an exploded view of Rhoades’ internal components. Ex. 1009 at Figs. 1, 2, 4.

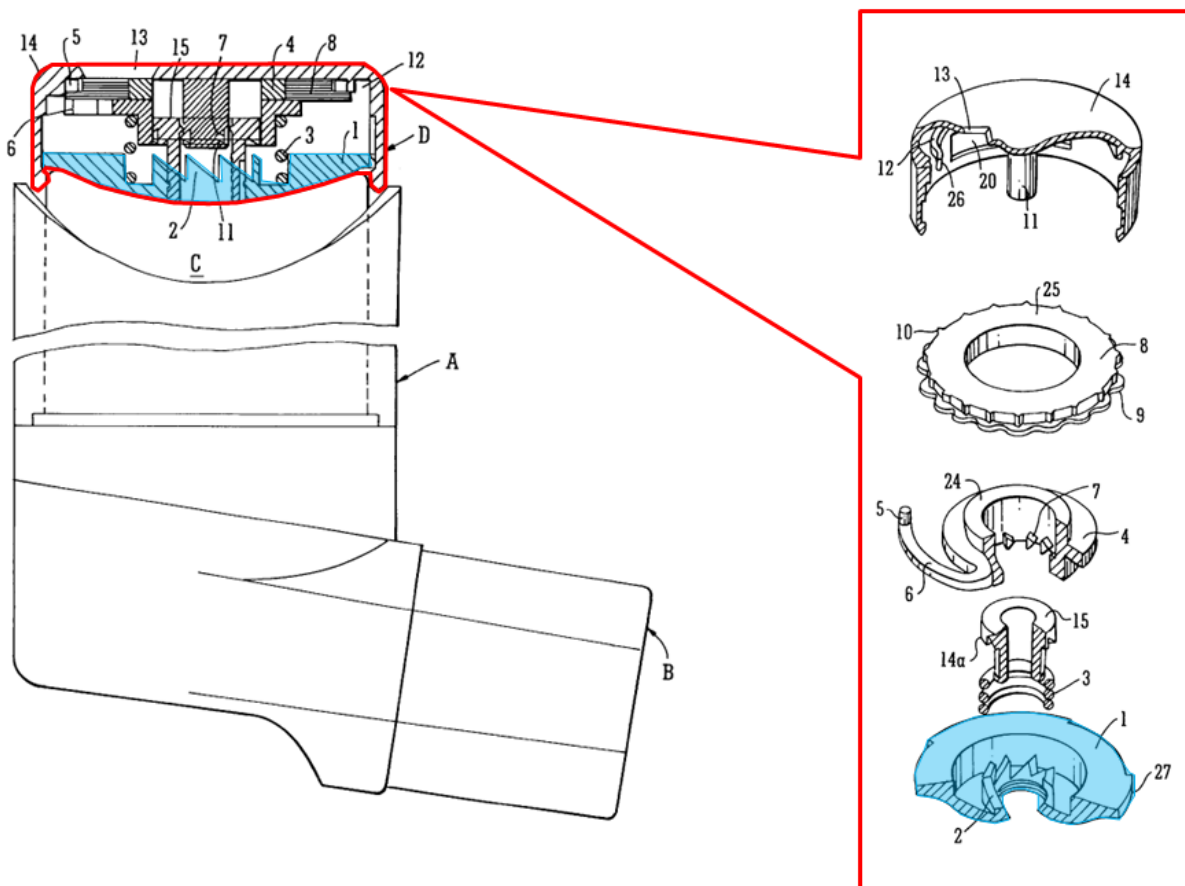


19. The cam body 20 is secured to the rear end of ink reservoir 10. Ex. 1009 at 3:49-56. “The cam body 20 is rotatably and slidably disposed within a tubular central portion 27 of a stationary guide member 28 so as to in effect be ‘floating’ therein.” Ex. 1009 at 3:65-67. The plunger 34 and push button 35 interact with the cam body 20 and are biased upward by a return spring 38. Ex. 1009 at 3:74-4:7. Depression of push button 35 brings the plunger 34 into successive engagement with surfaces 50, 52, 54, and 55 of cam body 20. Ex. 1009

at 4:22-28. Rhoades is maintained in a projected position when cam surfaces 50 and 52 are engaged with stop members 45 and 46, and in a retracted position when cam surfaces 54 and 55 are engaged with bottom surfaces 51 and 53. Ex. 1009 at 5:15-28.

C. Bason (U.S. Patent No. 6,283,685)

20. Bason (U.S. Patent No. 6,283,685) discloses an indicator device “adapted to serve as a dose counter for [MDIs].” Ex. 1005, 1:3-5, 2:16-19. The Bason dose counter D (outlined in red below) comprises a base 1 (highlighted in blue), central bush 14, rings 4 and 8, and cap 14. Ex. 1005, Figs. 1, 3 (annotated).



21. In Bason, the base 1 of the dose counter D is “bonded” to the canister, which allows the base 1 and central bush 15 to stay in a “fixed position” throughout the activation of the inhaler. Ex. 1005 at 2:16-23. When the cap is depressed, the rings 4 and 8 are also depressed and engage with the “fixed” teeth on the base 1. Ex. 1005 at 3:15-22. For rings 4 and 8 to rotate, they must press down and slide against the surface of the base’s “fixed” teeth. Ex. 1005 at 3:15-22. The “fixed,” non-rotatable nature of the base 1 is important and necessary for the dose counter D to work properly. Ex. 1005 at 2:20-27. If the base could rotate, or if the canister C could rotate (which would allow the base 1 to rotate), then the rings 4 and 8 would not interact with the base’s fixed teeth correctly, and the dose counter would not function. Ex. 1005 at 1:32-44.

VII. Ground 1: Claims 1, 2, 3, 9 and 21 of the ’177 Patent Are Not Obvious Under 35 U.S.C. § 103 over Elliott in View of Rhoades

22. Petitioners assert that claims 1, 2-3, 9, and 21 are obvious over Elliott in view of Rhoades. It is my opinion as a person of ordinary skill in the art that claims 1, 2, 3, 9, and 21 are not obvious over Elliott in view of Rhoades.

A. Modification of Elliott in View of Rhoades

23. Petitioners assert that a person of ordinary skill in the art would have been motivated to incorporate “the known *Rhoades* mechanism into the *Elliott* inhaler to reach the claimed invention.” However, Petitioners’ description of the modification of Elliott in view of Rhoades does not contain adequate description of

the design concept that shows the structure and operation of the device and how it would function, or that the combination practices the limitations of claims 1, 2, 3, 9, and 21 of the '177 Patent.

24. Petitioners' description of the Elliott and Rhoades combination is contained at pages 34 through 36 of the Petition. It states that the combination is a simple substitution of the Rhoades mechanism into the Elliott inhaler. After Elliott's number wheel and drive member are removed, (1) the cam body 20 of Rhoades is incorporated below the canister; (2) the stop members of Rhoades would have been molded directly onto Elliott's inhaler body; and (3) the canister would sit on a component "analogous" to the Rhoades plunger having fingers 43 and 44. Finally, Petitioners suggest that the Rhoades cam body could have easily been modified to include the displayable dose values.

25. The problem with this conclusory description is that Petitioners do not describe how a person of ordinary skill in the art would have substituted the Rhoades components for the Elliott components in a way that ensures operability of the device and interoperability between the components. Petitioners do not indicate how the cam body could be mounted to the inhaler or modified to include numerals. Nor do Petitioners explain how the cam body, stop members, or fingers would interact now that they are placed in different locations in Elliott. Petitioners

also do not explain how the push cap is assembled or how it functions with the other components of the inhaler.

B. Claim 1 of the '177 Patent Is Not Rendered Obvious over Elliott in view of Rhoades

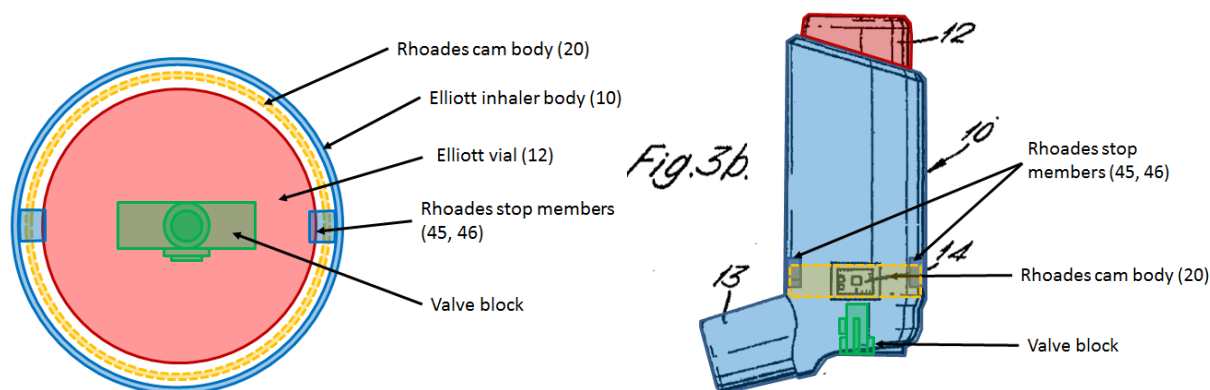
26. It is my opinion as a person of ordinary skill in the art that claim 1 of the '177 Patent is not rendered obvious over Elliott in view of Rhoades.

1. “a stationary body (1) including at least one stationary gear (110, 122)”

27. I understand that a patent is invalid as obvious under 35 U.S.C. § 103 if the differences between the subject matter sought to be patented and the prior art are such that the subject matter would have been obvious at the time the invention was made to a person having ordinary skill in the art. Whether a patent is obvious is based on the review of the following factors: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the art, and (4) any relevant objective considerations, such as commercial success and the licensing of the patents. I also understand that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.

28. Claim 1 of the '177 Patent requires “a stationary body (1) including at least one stationary gear (110, 122).” Petitioners’ proposed combination of Elliott and Rhoades do not render this claim element obvious.

29. Petitioners state that “it would have been obvious to a POSA to incorporate the unitary stop members of the *Rhoades* stationary body into the *Elliott* inhaler body when substituting the *Rhoades* mechanism into *Elliott*.” Molding stop members onto Elliott’s inhaler body would create internal protrusions into the interior of the inhaler body which ultimately must rest below the canister but above the valve block, which mounts the drug canister. Petitioners’ proposed modifications to Elliott would render the device inoperable.



30. Assembly of the device must occur through the open top of the inhaler. Each component included in Petitioners’ proposed combination would be inserted through the top of the inhaler during assembly. Once the stop members (shown in blue above) are molded onto the body and protrude into the cavity of the inhaler body, there could be no further assembly of the device. This is because at

least the cam body (shown in yellow) would not be able to be inserted past the stop members down into the lower portion of the inhaler as Petitioners describe.

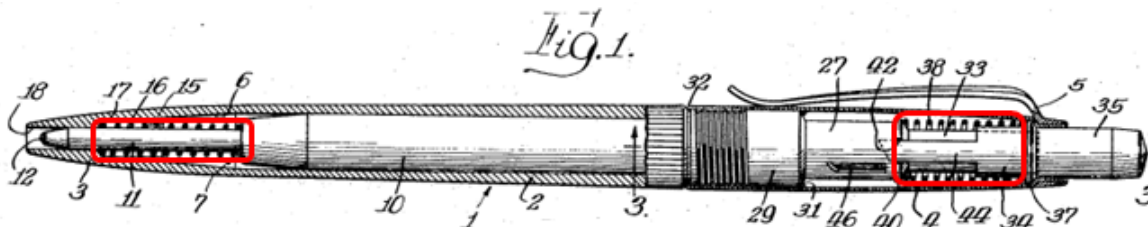
31. Additionally, there is no practical tooling design that could create molded undercut features with the required functional angled bottom surface on the inside diameter of the inhaler body and above the valve block mounting (shown in green) so as not to interfere with the inhalation flow path. Ex. 2018 at 99. Because molding stop members onto the interior of Elliott's inhaler body would make assembly of the device impossible, a POSA would not have modified Elliott in view of Rhoades. To the extent Petitioners argue that complex and expensive tooling techniques or incorporating additional parts may address these issues, such measures render this combination more complex, more expensive, and unpredictable.

2. **“a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir”**

32. Claim 1 of the '177 Patent requires “a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir.” Petitioners' proposed combination of Elliott and Rhoades do not render this claim element obvious.

33. First, Petitioners state that Elliott's number wheel satisfies the counter element limitation of claim 1. However, in my review of Petitioners' proposed combination of Elliott and Rhoades as a person of ordinary skill in the art, it is clear that Elliott's number wheel is not present in the combination. Because the number wheel is absent from the combination, it cannot meet the claimed "counter element."

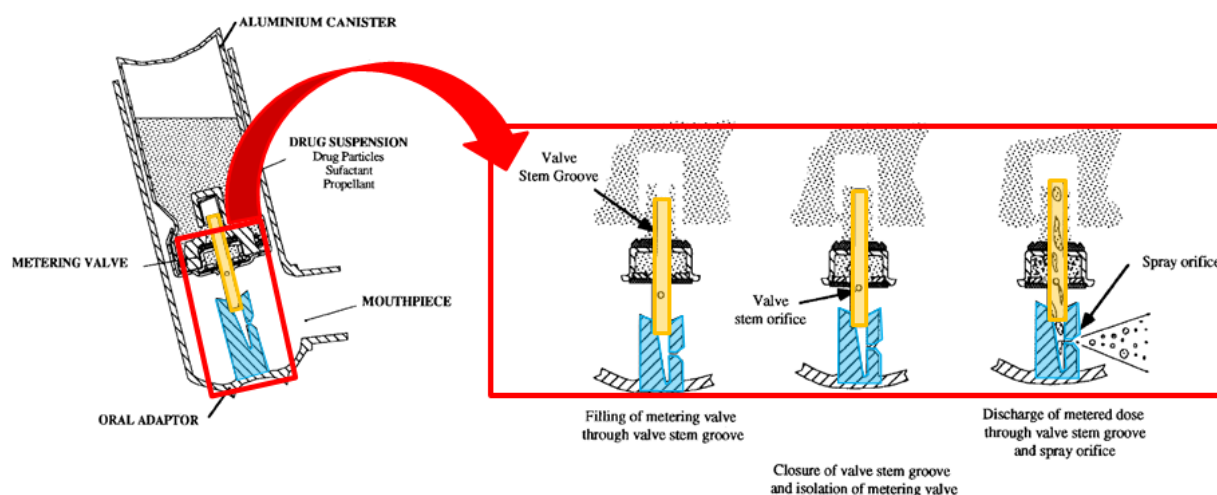
34. Second, Petitioners point to the Rhoades cam body, stating that it would have been obvious for a person of ordinary skill in the art to incorporate Rhoades's mechanism of converting axial motion to rotational motion into the Elliott inhaler below the Elliott vial. Both Elliott and Rhoades require bias forces to keep all of the components in contact with one another. In Elliott, it is a fixed base, bell crank, and leaf spring. In Rhoades, it is a set of return springs 16 and 38. Petitioners do not describe how the bias necessary for the components of the Elliott/Rhoades combination to engage one another would be accomplished. If the components are not biased together, nothing forces the cam body to rotate as is required by the claim.



35. If Elliott's bell crank, leaf spring, and fixed base are used to accomplish the bias, Petitioners do not describe where the bell crank, leaf spring, and base would be located in the proposed combination, or how the bell crank, leaf spring, and base would interact with the cam body, plunger, and stop members of Rhoades to allegedly accomplish the claim elements of the '177 Patent.

36. If Rhoades's springs are included in the combination, Petitioners do not describe where the springs would be located or how they would interact with the inhaler. If Petitioners had proposed including the Rhoades spring in the Elliott inhaler, it is not described how the upper Rhoades spring would bias the analogous plunger with fingers against the cam body and at the same time be anchored to the Inhaler body ID and not interfere with safe operation of the drug canister. As for the lower spring, an inhaler operates to dispense medication by including a valve receptacle at the bottom of the inhaler. When at rest, the valve stem mounts firmly in the valve seat so as not to be disturbed during operation. When the canister is depressed, the valve stem receives a dose of medicine from the metering valve. The medicine travels down the valve stem, into the valve seat, and out through the spray orifice. The metering valve, valve stem, valve seat, and spray orifice have tightly controlled dimensions and tolerances adopted from years of optimizing in order to interact with precision to dispense medication accurately. If a spring had been placed around and grounded to the top of the valve stem in an attempt to bias

the cam body from below, up against the stop members, the spring would interfere with proper placement of the valve stem in the valve seat and the metered dose of medication would not be properly discharged through the valve seat's spray orifice. If the spring was placed around the valve seat, the spring would obstruct the spray orifice, and the medication would not be properly dispensed.

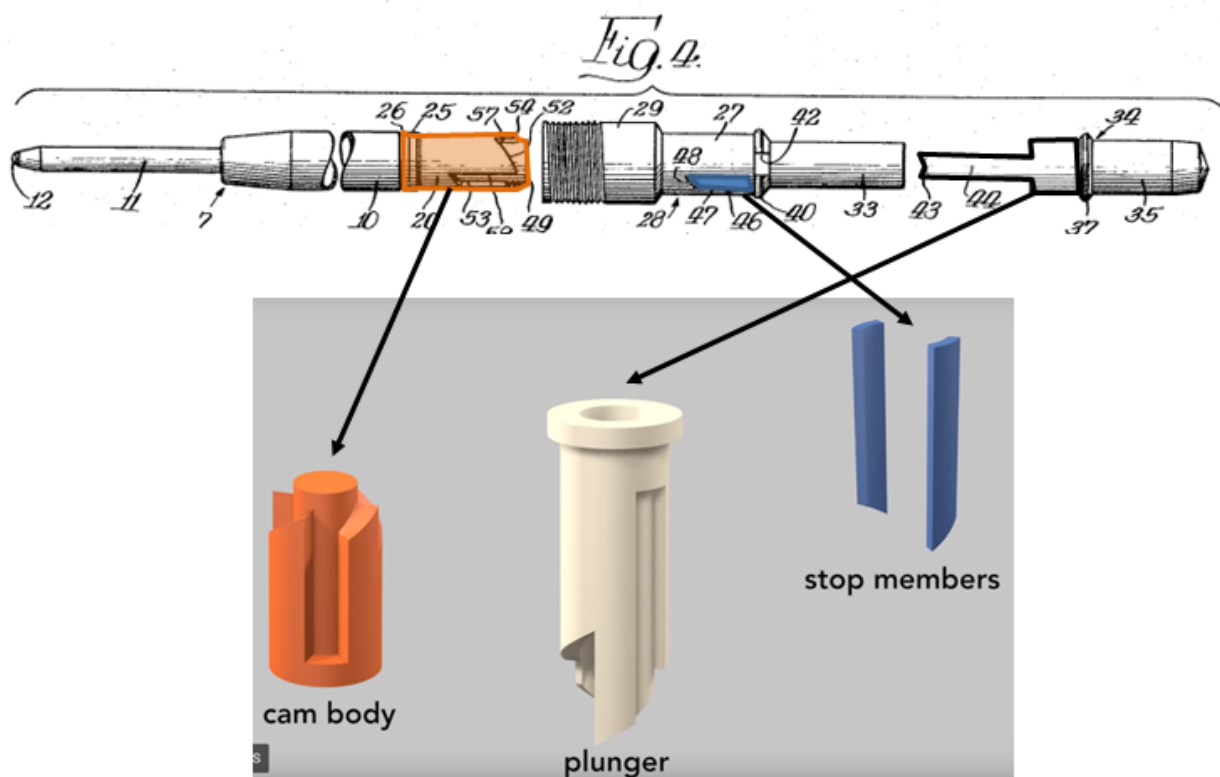


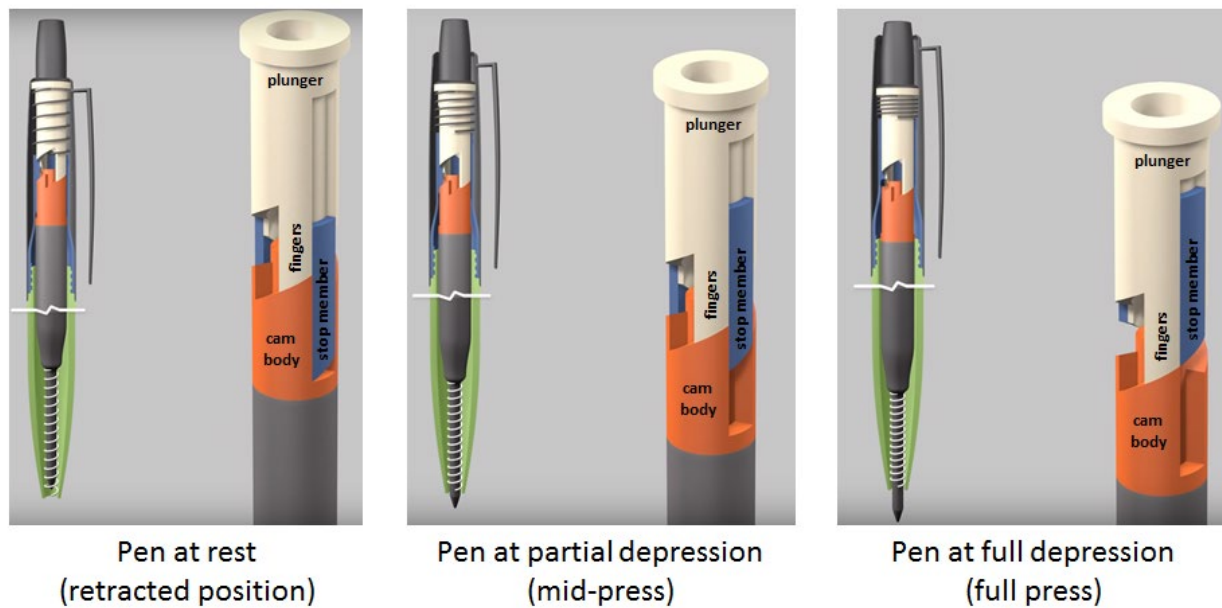
3. **“wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke”**

37. Claim 1 of the '177 Patent requires “wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform

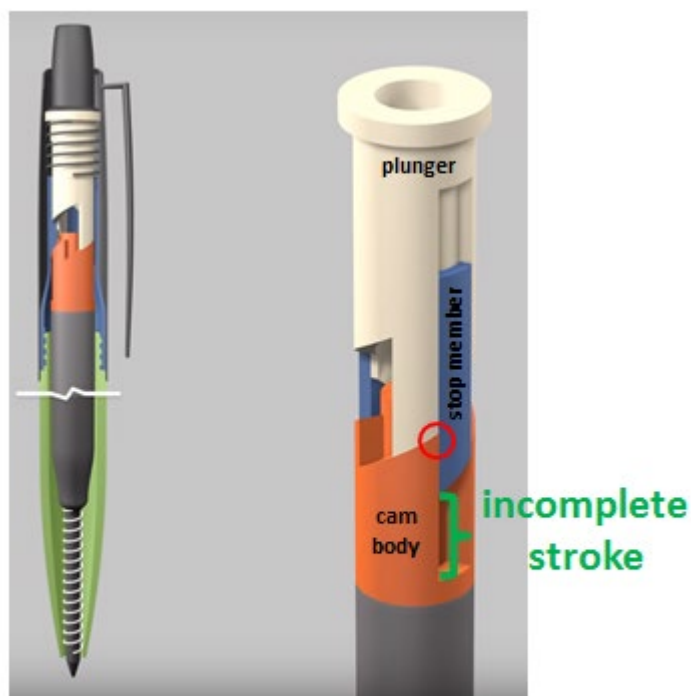
a complete actuation stroke.” Petitioners’ proposed combination of Elliott and Rhoades do not render this claim element obvious.

38. Petitioners state that the Rhoades cam body 20 “will rotate even if fingers 43, 44 [of plunger] are not depressed all of the way.” However, the plunger must be fully depressed before the cam body will rotate; a partial depression will not suffice. The illustration below shows the pen and its internal components at rest, mid-press, and fully depressed. The orange cam body is Rhoades cam body 20, the white plunger corresponds to Rhoades tubular plunger 34, and the blue stop members are Rhoades stop members 45 and 46.



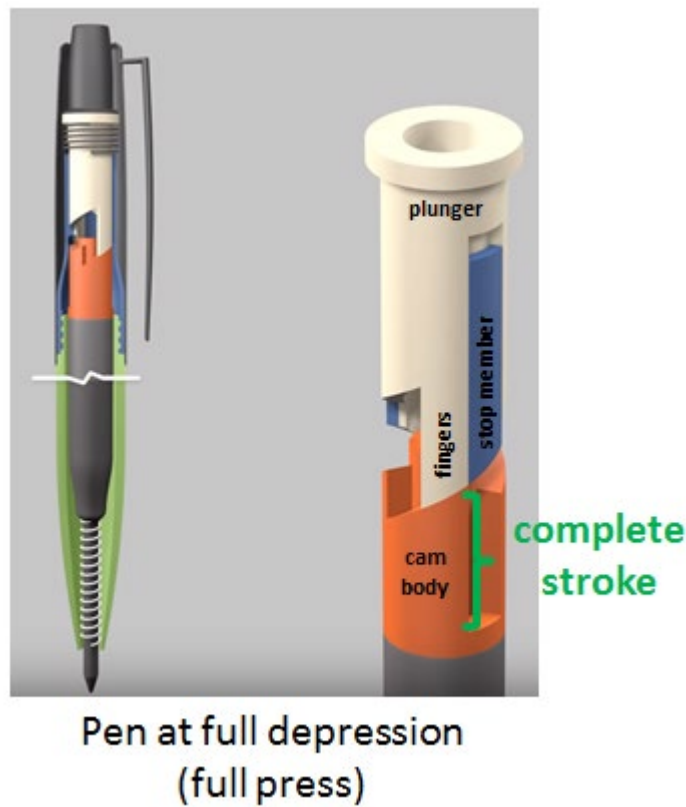


39. At rest, the stop member is fully engaged in the groove of the cam body. Rotation is not possible, as the stop member prevents any rotation. At mid-press, the stop member is still partially in the cam body's groove, so again, the cam body cannot rotate. During the predetermined incomplete actuation stroke shown in green below, the stop member prevents the cam body from rotating as the stop member still has not risen above the upper corner of the cam body's groove (highlighted in a red circle). If the plunger is released now, the cam body will not rotate and the dose expended during this partial depression will not be counted.



Pen at partial depression
(mid-press)

40. Only once the plunger is fully depressed (i.e., a complete actuation stroke) will the cam body rotate as shown below.



41. As a result, the dose indicator device is not actuated once the dispenser performs a predetermined incomplete actuation stroke as required by the claims. In sum, the pen must go from the retracted position to the extended position to allegedly dispense a dose. For this to happen, the plunger must be depressed all the way. Anything less than a full depression results in the pen tip going back to the retracted position, and the cam body does not turn to count the dose. For this reason, the Elliott/Rhoades combination does not teach this claim element.

C. Claim 2 of the '177 Patent Is Not Rendered Obvious over Elliott in view of Rhoades

42. I understand that a dependent claim is not rendered obvious if claim limitations within the independent claim are not rendered obvious. Therefore, because claim 1 is not rendered obvious over the Elliott/Rhoades combination, neither is claim 2.

43. Additionally, Petitioners state that a person of ordinary skill in the art would have known to design the height of the cam faces, stop members, and teeth so that the point of the incomplete return stroke correlates to the point of chamber refilling. Petitioners do not describe how the height of the teeth could be “designed . . . to cause chamber refilling to occur after” the valve has been sufficiently released. Petitioners also do not describe how these modifications could have been made to the components of Elliott and Rhoades while also (1) maintaining interoperability of all of the device’s components, (2) ensuring that the medication is dispensed properly, or (3) achieving these goals within the small tolerance stack of an MDI. This is particularly problematic where, as here, even small design changes could cause unpredictable results.

44. As a result, the Elliott/Rhoades combination as described by Petitioners does not teach the limitations of claim 2.

D. Claims 3, 9, and 21 of the '177 Patent Are Not Rendered Obvious over Elliott in view of Rhoades

45. Because claim 1 is not rendered obvious over the Elliott/Rhoades combination, neither are dependent claims 3, 9, and 21.

E. A POSA Would Not Have Been Motivated to Combine Elliott with Rhoades

46. I have been informed that to establish obviousness, one must identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. I do not believe that a person of ordinary skill in the art would have been motivated or encouraged to combine Elliott with Rhoades at the time of the invention of the '177 Patent.

47. First, Rhoades is not analogous art. I have been informed that, in order for a reference to be proper for use in an obviousness challenge under 35 U.S.C. § 103, the reference must be analogous art to the claimed invention. I understand that prior art is analogous when it is (1) from the same field of endeavor or (2) reasonably pertinent to the particular problem the inventor was trying to solve. A reference is reasonably pertinent if it is one which logically would have commended itself to an inventor's attention in considering his or her problem. To determine if art is analogous, one should look to the purposes of both the invention and the prior art. If a prior art reference and the claimed invention have a same purpose, the reference relates to the same problem.

48. The stated purpose of the '177 Patent is to "provide a fluid dispenser including a dose indicator device that prevents any risk of under-counting, i.e. that guarantees that the *indicator device is **actuated*** [counted] each time liquid is dispensed by the fluid dispenser." (Emphasis and parenthetical added.)

49. Rhoades discloses a projecting and retracting ball point pen. The mechanism of Rhoades does not include any means for counting. Rhoades's stated purpose is to "provide a ball point writing instrument having an improved push button operated projecting and retracting mechanism."

50. The projecting and retracting mechanism disclosed in Rhoades is functionally specialized and very different from the actuation of a metered dose inhaler ("MDI"). A video describing the operation of the pen disclosed in Rhoades (and identifying Rhoades by patent number) indicated that the pen was designed by a team of sixty-six people. *See* Ex. 2020, *The Kids Should See This*, available at <https://thekidshouldseethis.com/post/how-does-a-retractable-ballpoint-click-pen-work-at-3:44>). These highly optimized mechanisms are unique for their purpose (requiring 60 people to create) and are not easily modified or interchanged for other purposes. For example, Rhoades teaches a pen tip that projects outside the pen housing upon the user's first press of the push button. The pen tip remains projected outside the pen housing at rest. When the user presses the push button again, the pen tip is retracted inside the pen housing, where it remains at rest. In summary, Rhoades describes a two-press pen mechanism, one to extend the pen tip for writing, and a second to retract the pen tip for storage. Rhoades does not teach or suggest any need for precise and accurate counting and coordination in

dispensing the ink out of the reservoir at all. In fact, the Rhoades purpose completely ignores the amount of liquid ink in the reservoir.

51. In contrast, the mechanism of actuation of an MDI is precisely designed to deliver a specific amount of medication to a patient's lungs atomized to respirable aerosol from the inside of the inhaler housing and is additionally highly sensitive to the accurate indication of the amount of liquid medication remaining in the reservoir. The MDI includes a canister filled with pressurized medication and a valve stem for dispensing the medication out of the canister. The valve stem mounts vertically in a nozzle block in the inhaler. The nozzle block is highly engineered to convert pressurized liquid medication inside the canister to droplets when it exits at high speed. The liquid is forced through a nozzle orifice, which allows liquid droplets to form and spray outwards to a fluid dynamically designed air path and mouthpiece during a patient's inhalation. The size of the droplets formed and the drug percentage in the carrier liquid must be designed to be inhaled by the patient, allowing the patient to receive the proper dosage of medication. *See* Ex. 2008 (Stein, S., *Advances in Metered Dose Inhaler Technology: Hardware Development*, 15 AAPS PHARMSciTECH 326, 330 (Apr. 2014)). When the patient breathes in the droplets through the mouthpiece, they begin to evaporate so they can shrink to a size that is most likely to deposit correctly in the patient's lungs. If this process is not precisely executed, one of two things can happen. First, the

droplets may be too small and will be exhaled by the patient. As a second alternative, the droplets may be too large, in which case the droplets will land somewhere in the patient's mouth and render the medication useless. This design is very complex. Unlike Rhoades, the medication in an MDI must be dispensed from inside the inhaler housing and from a fixed mounting, or the improper droplet composition will render the drug ineffective.

52. For at least these reasons, a person of ordinary skill in the art seeking to design a dose indicator device that prevents any risk of undercounting would not have looked to Rhoades's disclosure of an ink pen.

53. Petitioners cite U.S. Patent No. 5,234,970 ("Ambrosio"), which discloses a dosing device for administering powdered medication. In Ambrosio, the patentee discusses prior art U.K. Patent No. 2,165,159 ("Auvinent"), which discloses that a device for rotating the rod is an indexing mechanism much like that of a ball-point pen. Ambrosio expressly teaches away from the mechanism disclosed in Auvinent. Ambrosio states that "because of the cup-like arrangement of this patent, adhesion can occur along the walls of each depression, *which is disadvantageous from a delivery viewpoint.*" A person of ordinary skill in the art with knowledge of Ambrosio and/or Auvinent would not have been motivated to incorporate a ball-point pen mechanism into a precision dosing device, such as an MDI.

54. U.S. Patent No. 7,090,662 (“Wimpenny”) was cited by Petitioners for its discussion of the “ball point pen principle” disclosed in prior art patent DE 3,814,023. Wimpenny states that the ball point pen mechanism “does not address the problem of incorrect dose setting by the user.”

55. For at least these reasons, it is my understanding that Rhoades is not reasonably pertinent to the particular problem of preventing dose undercounting that is at the heart of the ’177 Patent. A person of ordinary skill in the art seeking to design a dose indicator device that prevents any risk of undercounting thus would not have looked to Rhoades’s disclosure of an ink pen.

56. Additionally, Petitioners describe that the combination of Elliott and Rhoades would result in an inhaler that is extendable and retractable like a pen. As described in detail below, this departure from historic, typical MDI operation, which requires only one depression by a user to dispense the medication, would be very confusing to users and highly undesirable.

57. Petitioners point to the FDA’s guidance to avoid undercounting as providing motivation to “coordinat[e] the valve travel length to the tolerances of the mechanical components of the dose counter so that the dose counter would actuate (*i.e.*, count) before the fluid was dispensed.” I disagree that the FDA’s guidance to avoid undercounting would have provided motivation to a person of ordinary skill in the art to implement any specific design solution to ensure

accurate dose counting. But, in so arguing, Petitioners concede that a person of ordinary skill in the art would have had to redesign and make improvements by coordinating tolerances of the stop members with the tolerances of the valve travel and refilling features to decrease the possibility of undercounting. Petitioners do not describe how a person of ordinary skill in the art could have achieved this coordination, what tests they would have run, or how they could have a reasonable expectation of success in doing so.

58. Second, a person of ordinary skill in the art would not have been motivated to combine Elliott and Rhoades because the mechanism disclosed in Rhoades does not provide the precision required for an MDI.

59. For example, an MDI requires precise functionality to ensure that the accurate amount of medication is dispensed in each dose. As described above, for example, the atomization of the medication requires a particular design so as to create droplets that are the correct size. Petitioners fail to explain how their combinations are accomplished with non-precision components like those of an ink pen.

60. In addition, an MDI requires execution and coordination of multiple functions within a very small travel distance. For example, the travel distance of actuation of an MDI with a dose indicator device must accurately and repeatedly permit (1) delivery of the dose of medication; (2) refill of the valve's metering

chamber; and (3) engagement of an accurate counting mechanism so as to allow the count to progress. See Ex. 2011 (<http://multimedia.3m.com/mws/media/1159495O/statistical-tolerance-analysis-tools-in-dose-counters.pdf>). Each of the above functions must be accomplished when the user presses down on the inhaler and the medication canister moves up and down, typically traveling only a few millimeters in distance.

61. In contrast, the ball-point pen disclosed in Rhoades is not designed to be a precision-engineered plastic device. Indeed, Rhoades discloses a travel distance which is much larger than that of any traditional MDI. The pen disclosed in Rhoades functions simplistically with wide physical tolerances. These design characteristics are consistent with the Petitioners' assertion that an ink pen can be manufactured in higher volumes at a low cost. Additionally, the pen's function—which is to facilitate writing and maintain the ink reservoir in a retracted state when not in use—is not critical and does not require the same kind of precision as a drug delivery device. Indeed, Rhoades expressly teaches away from use of “close manufacturing tolerances.” Rhoades at 8:6-16.

62. A person of ordinary skill in the art attempting to achieve the mechanism of action of a dose indicator device—including coordination of drug expulsion upon actuation, refill of the metering chamber, and timed completion of the counting—in such a short distance would have known that the mechanism

required precision and very small tolerances, smaller than that of an ink pen. As the travel distance and coordination of the mechanism of a retracting ink pen is substantially longer and less precise, a person of ordinary skill in the art would not have been motivated to combine the MDI disclosed in Elliott with the ball-point pen disclosed in Rhoades. Petitioners do not describe how a person of ordinary skill in the art would have achieved the requisite reengineering or why they would have been motivated to do so.

63. Third, a person of ordinary skill in the art would not be motivated to combine Elliott and Rhoades because Rhoades teaches a constantly projected dispensing position of the dispenser means fully outside of the housing and a constantly retracted position of this dispenser means fully inside of the housing, as described in Figures 8 through 11. Indeed, an express purpose of Rhoades is to “provide a ball point writing instrument having an improved push button operated projecting and retracting mechanism which operates upon successive full depressions of the push button to propel the writing point into exposed writing position projecting from the barrel and to retract the writing point into concealed non-writing position within the barrel, respectively.” Rhoades at 1:18-25. If Elliott was modified in view of Rhoades as Petitioners suggest, when the inhaler is in the constantly projected position, the fluid reservoir valve and valve atomizing block would dispense medicine outside of the MDI mouthpiece nozzle housing. As

described above, the medication in an MDI must be dispensed inside the fluid dynamically designed mouthpiece to achieve functional atomization and ensure the drug is inhaled correctly and accurately delivered to the lungs. Thus, a person of ordinary skill in the art would not have been motivated to modify Elliott in view of Rhoades.

64. Fourth, a person of ordinary skill in the art would not be motivated to combine Elliott and Rhoades because the Rhoades mechanism, which results in axial projection of the pen tip outside the pen housing upon the user's press of the push button, would physically jam the dispensing valve into the interior side wall of the mouthpiece nozzle. Unlike Rhoades, which discloses the pen design along a single axis, MDIs are angled to allow ergonomic access to the patient's mouth. Rhoades's single-axis mechanism does not permit projection outside the angled mouthpiece of an MDI. In this case, the medicine would not be accurately dispensed to the patient, if at all, defeating the express purpose of the '177 Patent.

65. Lastly, a person of ordinary skill in the art would not be motivated to combine Elliott and Rhoades because Rhoades teaches that a user must depress the push button twice and effect four separate movements or actions to operate the pen. First, the user depresses push button 35 to fully project the pen tip, and the force of the spring pushes it back in the other direction to its projected rest position. These are the first two movements or actions. To bring the pen back to its

retracted rest position, the user must depress the push button fully again, and it again travels in the opposite direction to the retracted rest position.

66. It is impractical and inconsistent with traditional MDI use to require a user to depress the inhaler twice and effect four separate movements or actions to dispense medicine and then retract the fluid reservoir, all while maintaining accurate dosing. This departure from historic, typical MDI operation would be highly undesirable because it (1) diverges from a patient's typical experience; (2) may compromise the accuracy of timed delivery of the medication with respect to patient respiration; and (3) may result in patient misuse. A person of ordinary skill in the art would understand that a patient would likely expect an MDI to operate as a "simple press-and-release inhaler like the one depicted in Elliott," as Petitioners describe. Leaving the valve extended outside of the housing at rest may exert undue extended pressure on the valve components, expose critical nozzle orifice features to physical damage, dirt, and debris, and may compromise accurate delivery of the medication. Further, Petitioners' proposal would require a patient to remember to reset the valve before every use, which complicates the patient's operation of the device and may lead to misuse. In the case of a rescue inhaler, which can be used to deliver life-saving medicine in acute situations, requiring the patient to depress the inhaler before use may hinder the patient's ability to receive the medication when he or she needs it.

67. Alternatively, Petitioners assert that a person of ordinary skill in the art would have made a “simple and predictable” modification to the cam surfaces of cam body 20 if he or she wanted to “incorporate the *Rhoades* mechanism into a simple depress-and-release inhaler like the one depicted in *Elliott*.” As an initial matter, Petitioners main argument here is that Elliott should be modified to be like Rhoades and include the Rhoades cam body. Since that combination has numerous obvious complications, Petitioners change course and suggest that Rhoades (the design that was to improve Elliott) be modified like (the purportedly inferior) Elliott. Rather than two gears with separate heights, Petitioners assert that a person of ordinary skill in the art would have used a single row of teeth, all of the same height, and separately incorporate a second row of teeth of the same height to interact with the stop members. But Petitioners offer no explanation of how this modification would be effectuated and function to solve the problems that the ’177 patent solved, how such modification is simple or predictable, or why a person of ordinary skill in the art would have been motivated to make this modification.

68. A person of ordinary skill in the art would not have looked to Rhoades in improving the MDI disclosed in Elliott. A person of ordinary skill in the art would have had no reasonable expectation of success in doing so for the reasons described above.

VIII. Ground 1: Claims 1, 2, 3, 9 and 21 of the '177 Patent Are Not Obvious Under 35 U.S.C. § 103 over Bason in View of Rhoades

69. Petitioners also assert that claims 1, 2-3, 9, and 21 are obvious over Bason in view of Rhoades. It is my opinion as a person of ordinary skill in the art that claims 1, 2, 3, 9, and 21 are not obvious over Bason in view of Rhoades.

A. Modification of Bason in View of Rhoades

70. Petitioners assert that a person of ordinary skill in the art would have been motivated to incorporate “the entire *Rhoades* mechanism into *Bason*.” However, Petitioners’ description of the modification of Bason in view of Rhoades does not contain sufficient description of the design concept that shows the structure and operation of the device and how it would function, or that the combination practices the limitations of claims 1, 2, 3, 9, and 21 of the '177 Patent.

71. Petitioners’ description of the Bason and Rhoades combination is contained at pages 58 through 60 of the Petition. It states that the combination is a simple substitution of the Rhoades mechanism into the Bason inhaler. To make this substitution a POSA purportedly would have (1) bonded the cam body 20 of Rhoades facing upwards to the canister at the top of the inhaler; (2) the outer housing of Bason would correspond to Rhoades’s guide member 28 and would extend slightly; (3) the stop members of Rhoades would have been molded directly onto Bason’s inhaler body; and (4) the Bason cap would have included fingers 43 and 44. Finally, Petitioners suggest that the Rhoades cam body could have easily

been modified to include the displayable dose values. Petitioners include no figures describing how the modification would have been constructed.

72. The problem with this conclusory description is that Petitioners do not describe how a person of ordinary skill in the art would have substituted the Rhoades components for the Elliott components in a way that ensures operability of the device and interoperability between the components. Petitioners do not indicate how the cam body could be modified to include readable numerals. Nor do Petitioners explain how the cam body, stop members, or fingers would interact now that they are placed in different locations in Bason. Petitioners also do not explain how the push cap is assembled or how it functions with the other components of the inhaler.

B. Claim 1 of the '177 Patent Is Not Rendered Obvious over Bason in view of Rhoades

73. It is my opinion as a person of ordinary skill in the art that claim 1 of the '177 Patent is not rendered obvious over Bason in view of Rhoades.

- 1. “a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir”.**

74. Claim 1 of the '177 Patent requires “a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or

that remain to be dispensed from said reservoir.” Petitioners’ proposed combination of Bason and Rhoades does not render this claim element obvious.

75. Petitioners identify two components in the Bason/Rhoades combination as invalidating this claim element: (1) Bason ring 4 and (2) Rhoades cam body 20. Neither component teaches this claim element. Bason ring 4 cannot not meet this claim element because Bason ring 4 is not present in the asserted Bason/Rhoades combination. As I understand the Bason/Rhoades combination described by Petitioners, Bason ring 4 is removed and replaced by the Rhoades cam body. Petition at 56-59. Since Bason ring 4 is absent from the Bason/Rhoades combination, it cannot form the basis of invalidity for this claim element.

76. The Rhoades cam body also does not meet this claim element. Bason describes the base and related components as being in a “fixed position” ([0012]) and having “fixed” teeth ([0020]). The base does not rotate. The “fixed,” non-rotatable nature of the base is critical for its teeth to interact with the ring properly. If the Rhoades cam body is “bonded” in the same manner expressed in Bason, the Rhoades cam body likewise cannot rotate. If Petitioners suggest otherwise in their Reply, Bason teaches away from the proposed modification or requiring the “bonded” cam body to rotate. The Rhoades cam body is not “displaceable axially **and in rotation**” as required by this claim element.

77. Even if the cam body was capable of rotation, bonding the Rhoades cam body 20 to the drug canister would render the device inoperable for its intended purpose. If the cam body was capable of rotation as Petitioners suggest, the canister would also rotate while the device is actuated. This would cause frictional wear on the sealing surfaces between the valve stem and valve block and would preclude the medication from being properly dispensed. *See* Ex. 2008 at 330-31; Newman, S., *Principles of Metered-Dose Inhaler Design*, 50 RESPIRATORY CARE 1177 (2005). Not only would this render the device inoperable for its intended purpose of dispensing medication, but it would create a substantial safety hazard for the patient, who may not receive life-saving medicine when it is needed. A POSA would not be motivated to modify Bason in a way that resulted in a canister that rotated during actuation.

78. Petitioners state that further modifications could be made to the Bason/Rhoades combination to display the dose values as claimed. Petitioners argue that it would be obvious to (1) add dose values along the Rhoades cam body, and (2) include a window through which the doses could be viewed. This is not a trivial modification because, as described by Petitioners, the Rhoades mechanism would orient the cam body into two different positions during a single inhalation. Petitioners and their expert do not describe how the dose values included on the cam body would be viewable by a patient in both the extended and retracted

positions. Petitioners also do not describe how the intricate functional mechanical connections between counting rings 4 and 5 and cap 14 (including features 5, 6, 9, 10, 12, and 26 that are necessary for the device to count) are incorporated on the cam body of the new combination. The structural modifications Petitioners propose would require significant reworking of the systems disclosed in Bason and Rhoades.

79. Petitioners do not identify or explain how the modified Bason cap with Rhoades plunger fingers will be spring biased against the Rhoades cam body bonded to the drug canister.

80. Petitioners also do not identify or illuminate how the cam body now bonded to the canister is spring biased from below and against the stop members now integrally molded to the inside diameter of the Bason inhaler body.

81. Petitioners fail to recognize that the stop members of Rhoades cannot be practically molded to Bason's inhaler body because a major "undercut" feature would be created in the molded part and thus could not be removed off the tool after it was molded.

82. Even if the stop members of Rhoades could be molded to the inhaler body (through expensive complicated tooling or additional parts,) the Rhoades cam body (now bonded to the drug canister) could not be assembled past the inwardly

projecting stop members, rendering the combination incapable of providing its intended functionality.

83. Petitioners have not shown that the Bason/Rhoades combination discloses this claim element.

2. **“wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.”**

84. Claim 1 of the '177 Patent requires ““wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.” Petitioners’ proposed combination of Bason and Rhoades do not render this claim element obvious.

85. Petitioners first point to Bason’s rings as teaching this claim element. But, as described in Paragraphs 70-72 above, the Bason ring 4 is removed and replaced with the Rhoades cam body to create the Bason/Rhoades combination. Bason’s ring 8 and numerous other parts making up the counting functionality of Bason were not identified or described by Petitioners as part of the combination.

Petitioners cannot prove this element is disclosed in the Bason/Rhoades combination by citing to components that are not present in the combination.

86. Petitioners also state that Rhoades teaches this claim element. However, Rhoades's cam body 20 is bonded to the ink reservoir in the Bason/Rhoades combination. The cam body cannot be said to "cooperate[]" with the ink reservoir as required by the claim; rather, they act as one piece. Moreover, as described in Section VII.B.3 above, Rhoades does not teach an incomplete actuation stroke and, thus, cannot satisfy this claim element.

C. Claim 2 of the '177 Patent Is Not Rendered Obvious over Bason in view of Rhoades

87. I understand that a dependent claim is not rendered obvious if claim limitations within the independent claim are not rendered obvious. Therefore, because claim 1 is not rendered obvious over the Bason/Rhoades combination, neither is claim 2.

88. Additionally, as with the Rhoades/Elliott combination, Petitioners point solely to their prior discussion of Rhoades's cam body as preventing the fluid from being expelled again until the dispenser has completed a predetermined incomplete return stroke. However, Rhoades's cam body is not a dose indicator device. *See* Paragraphs 34-36. Rhoades's cam body does not cooperate with the fluid reservoir. *See* Paragraph 86. Rhoades's cam body does not prevent fluid from being expelled until the dispenser has completed a predetermined incomplete

return stroke. *See* Paragraph 43. As a result, the Bason/Rhoades combination as described by Petitioners does not teach the limitations of claim 2.

D. Claims 3, 9, and 21 of the '177 Patent Are Not Rendered Obvious over Bason in view of Rhoades

89. Because claim 1 is not rendered obvious over the Bason/Rhoades combination, neither are dependent claims 3, 9, and 21.

E. A POSA Would Not Have Been Motivated to Combine Bason with Rhoades

90. I do not believe that a person of ordinary skill in the art would have been motivated or encouraged to combine Bason with Rhoades at the time of the invention of the '177 Patent. For all of the reasons described in paragraphs 42-68 above, Rhoades is not analogous art, and a person of ordinary skill in the art would not have looked to Rhoades in improving the MDI disclosed in Bason. A person of ordinary skill in the art would have had no reasonable expectation of success in doing so for the reasons described above.

91. A POSA would not have considered a non-analogous Rhoades design to be a significant enough economic improvement over a Bason design with inexpensive injection molded parts and already sensitive to economic needs. This is especially true given that the Rhoades design did not provide any function to count actual ink removal from its reservoir. Further, the Bason design already

reflected the FDA's recommendation for dose counting, therefore a POSA would not have been motivated to improve it in view of Rhoades.

92. In addition, as described above, Petitioners assert that in modifying Bason in view of Rhoades, a person of ordinary skill in the art would have incorporated Rhoades's cam body 20 "facing upward and bonded to the base of the canister, at the top of the inhaler." If the cam body is bonded to the base of the canister, then the whole unit must rotate together as the inhaler is actuated. Rotation of the canister during actuation is a significant departure from traditional and approved inhaler operation, which would likely cause wear on the valve stem and nozzle block and would affect the delivery of a proper drug dose as described in Paragraph 77 above. Petitioners do not describe why a person of ordinary skill in the art would have been motivated to modify Bason as they describe in spite of these risks. Nor do Petitioners describe how a person of ordinary skill in the art would have accounted for rotation of the canister and valve stem in optimizing delivery of the drug. In my experience, I am not familiar with a metered dose inhaler that includes a drug canister that rotates upon actuation.

IX. Secondary Considerations of Non-Obviousness

93. For nearly fifty years before the invention of the dose indicator device as claimed in the '177 Patent, there was no method by which a patient could accurately determine how many doses remained in his or her MDI. As a result,

patients were left to guess how many doses were left in their MDIs and had only two practical options: (1) throw away an MDI that still contained medicine or (2) use an MDI that may be empty of medicine and risk not receiving the correct drug dose. Competitors in the industry at the time of the invention of the '177 Patent were aware of this problem, and yet were unable to create a satisfactory solution.

94. Despite the proliferation of inferior MDIs for many years, drug makers (including Petitioners), failed to create an accurate MDI dose counter. Indeed, although the FDA issued draft guidance in 2001, the FDA's final Guidance for Industry was issued in March 2003, two months before Aptar filed its French application disclosing the groundbreaking technology of the '177 Patent. And MDIs had been available for nearly fifty years before the final Guidance was issued. The '177 Patent therefore clearly addressed the long-felt need in the industry for an accurate dose counter that avoided undercounting.

95. In my opinion, a person of ordinary skill in the art would not have combined Elliott with Rhoades or Bason with Rhoades. And if a person of skill in the art were lead to these combinations, it is only through the benefit of the '177 Patent's teaching and using hindsight to reconstruct such combinations. If the combinations Petitioner suggests were actually obvious to a person of ordinary skill in the art, I believe someone involved in development of MDIs would have

made the combinations in the many years before the invention of the '177 Patent.
No one successfully combined these features until the invention of the '177 Patent.

I declare under penalty of perjury under the laws of the United States of America and the State of California that the foregoing is true and correct.

Dated: February 13, 2019

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

Charles E. Clemens