

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 IPR2018-01055
Patent No. 9,370,631

**DECLARATION OF CHARLES E. CLEMENS IN SUPPORT OF PATENT
OWNER'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 9,370,631**

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. 9,370,631 ("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. 8,936,631 (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*, 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. 8,936,631 and supporting exhibits;
- b. Expert Declaration of S. David Piper and supporting exhibits;
- c. Deposition transcript of S. David Piper, dated January 25, 2018;
- d. U.S. Patent No. 8,936,631 (the “’631 Patent”) (Petition Ex. 1001);
- e. French Patent Application No. 03/05858;

- f. International Application No. PCT/FR2004/001189;
- g. File History of U.S. Patent No. 8,936,631;
- h. U.S. Patent No. 8,936,177 (the “177 Patent);
- i. International Publication No. WO 00/59806 (“Allsop”) (Petition, Ex. 1006);
- j. U.S. Patent No. 6,283,365 (“Bason”) (Petition, Ex. 1007);
- k. European Patent No. EP 0480488 (“Marelli”) (Petition, Ex. 1008);
- l. U.S. Patent No. 3,205,863 (“Rhoades”) (Petition, Ex. 1009);
- m. Stein, S., *Advances in Metered Dose Inhaler Technology: Hardware Development*, 15 AAPS PHARMSCITECH 326, 330 (2014) (Ex. 2008);
- n. 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);
- o. Stuart, A., *More Than Just a Dose Counter*, 46 INNOVATIONS IN PHARMACEUTICAL TECHNOLOGY 40 (Ex. 2010);
- p. 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).

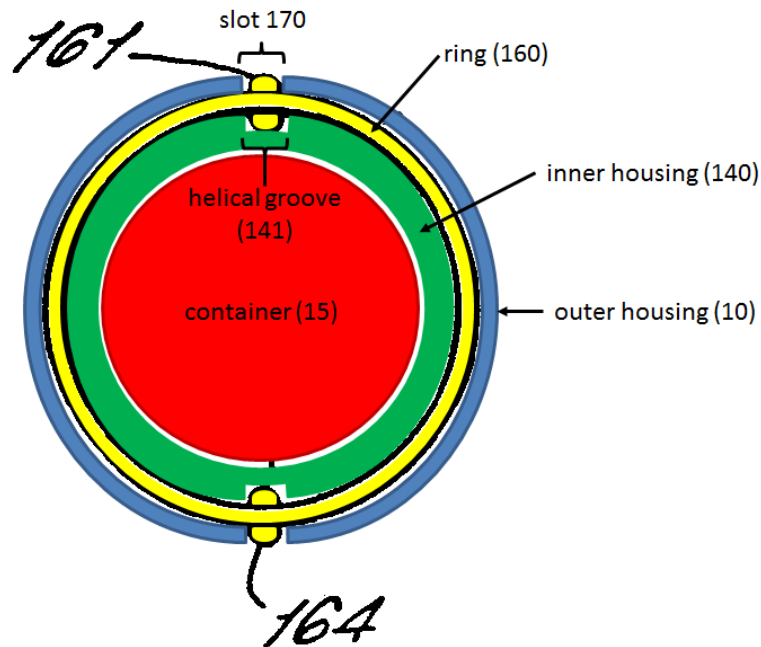
- q. Stein, S. et al., *The History of Therapeutic Aerosols: A Chronical Review*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278812/> (Ex. 2016).
- r. Newman, S., *Principles of Metered-Dose Inhaler Design*, 50 RESPIRATORY CARE 1177 (2005) (Ex. 2017).
- s. Malloy, R., PLASTIC PART DESIGN FOR INJECTION MOLDING 88, 99 (1994) (Ex. 2018)
- t. Deposition of S.D. Piper (Jan 25, 2019) (Ex. 2019).
- u. *The Kids Should See This*, available at <https://thekidshouldseethis.com/post/how-does-a-retractable-ballpoint-click-pen-work> (Ex. 2020).

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 ‘631 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.



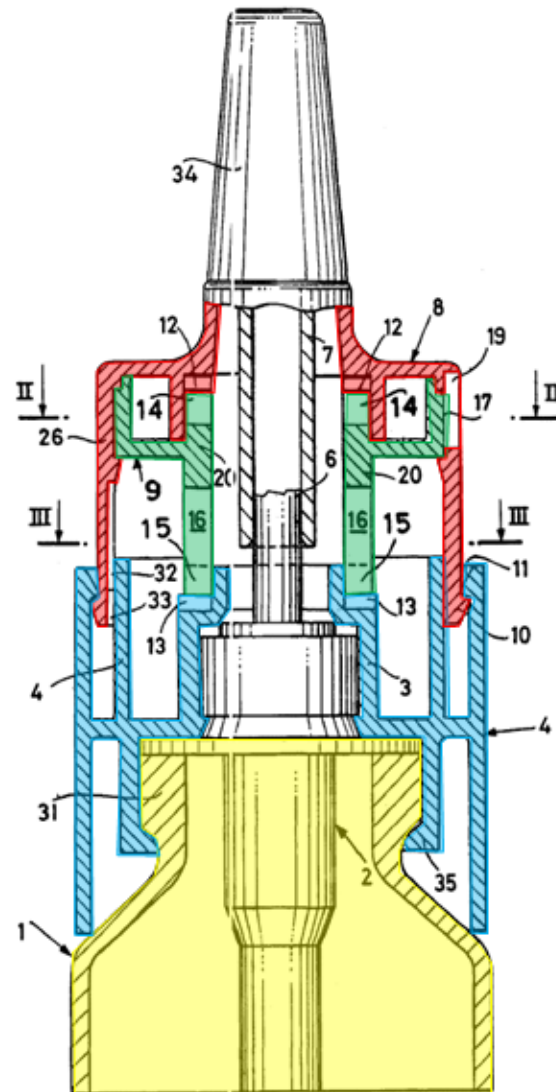
Ex. 1006 at Fig. 7 (annotated).

18. The dose counter mechanism in Allsop operates by a user depressing the canister 15 directly, which causes the inner housing 140 to rotate on its axis. Ex. 1006 at 9:3-11. As a result, ring 160 is guided downwards vertically by the pins 161 and 162 in helical grooves 141 and slots 170, respectively. Ex. 1006 at 9:12-17. The movement of pin 161 in groove 170 along the series of dosage markings 172 that are displayed on the outside of the housing 10 is what indicates to a user how many doses are left in the container 15. Ex. 1006 at 9:12-17.

B. Marelli (EP 0480488)

19. Marelli discloses a “dose counting device for a distributor of doses of fluid products,” particularly, “nasal distributors.” Ex. 1008, 1:3-7. An annotated

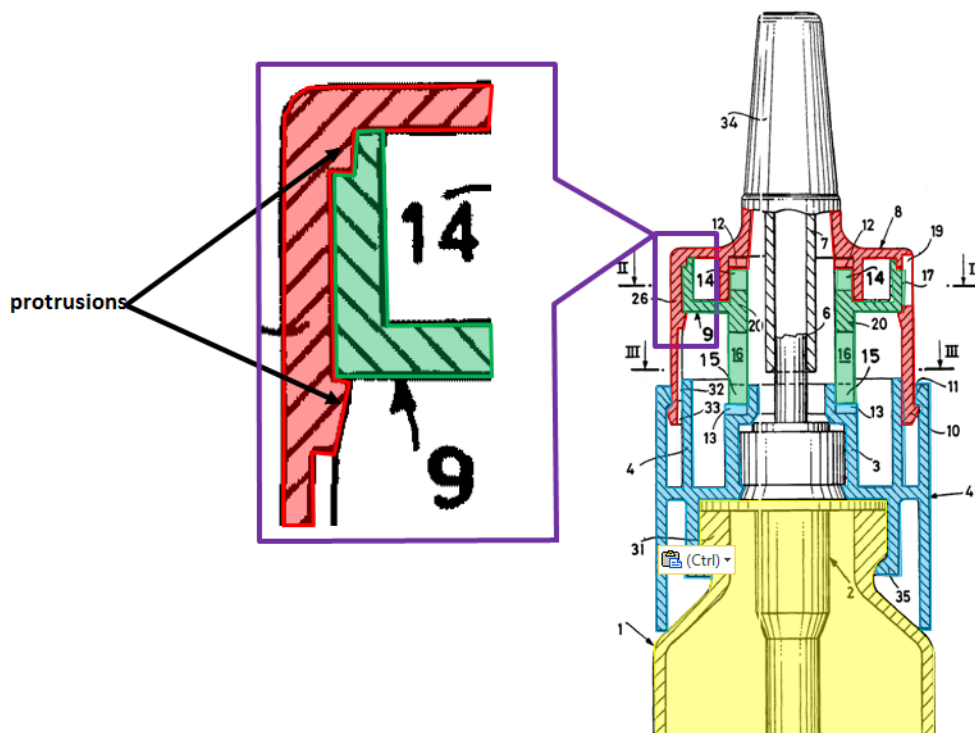
depiction of the device appears below, with the nasal 8 in red, the rotating element 9 in green, the ring nut 4 in blue, and container 1 in yellow.



Ex. 1008 at Fig. 1 (annotated).

20. Actuation of the device is accomplished by depression of nasal 8 relative to ring nut 4. Ex. 1008 at 4:26-38. Actuation causes fluid product to be expelled from valve 2 of container 1 where it is delivered out of protrusion 34 into

a user's nostril. Ex. 1008 at 3:9-25, 34-38. When a user depresses nasal 8 (in red), rotating element 9 (in green), which is affixed between the nasal 8 and the ring nut 4 as held in place by abutting protrusions on the interior of the nasal 8, is also depressed the same, fixed distance because it is retained within nasal 8 by the protrusions (shown below).



Ex. 1008 at Fig. 1 (annotated).

21. The device counts doses via rotating element 9, with teeth 12 and 13 using upper parts 14 and lower parts 15 of a circumferential succession of small elastically flexible legs 16. Ex. 1008 at 3:39-46. Depression of the nasal 8 (and element 9) draws teeth 12 towards teeth 13, compressing flexible legs 16 and causing upper part 14 to be elastically urged from tooth 21 to adjacent tooth 24.

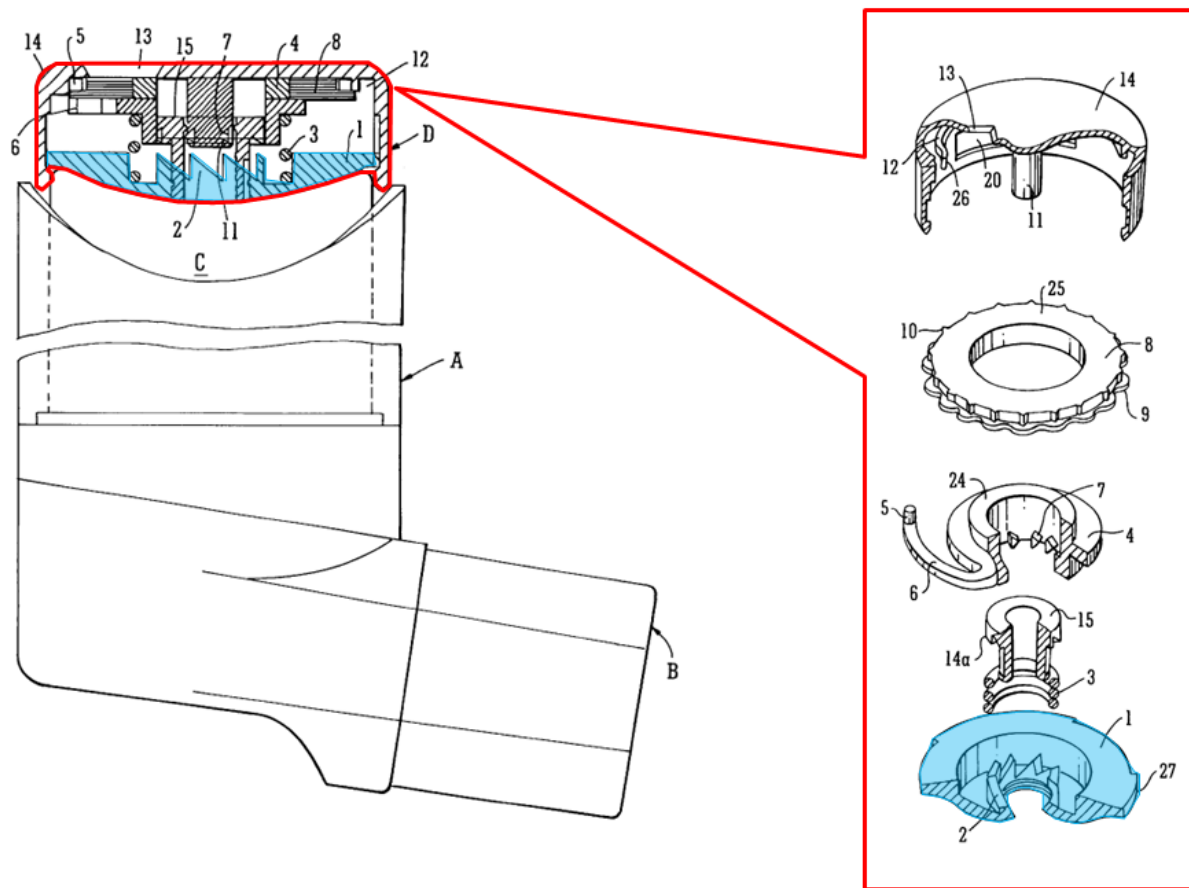
Ex. 1008 at 4:9-30. Release of the nasal 8 draws teeth 12 back away from teeth 13, causing lower part 15 to be elastically urged from tooth 22 to adjacent tooth 25.

Ex. 1008 at 4:30-36. Displacement of parts 14 and 15 into the next adjacent positions on teeth 12 and 13, respectively, moves intermediate part 20 of flexible legs 16 forward by one position. Ex. 1008 at 4:36-39. The lateral movement of intermediate part 20 causes element 9 to rotate, which features numerical index 17.

Ex. 1008 at 4:39-48. In this way, the flexible legs 16 interact with the teeth 12 on nasal 8 and with teeth 13 on ring nut 4 to cause rotating element 9 to rotate and progress to the next dose value. Ex. 1008 at 4:22-48.

C. Bason (U.S. Patent No. 6,283,365)

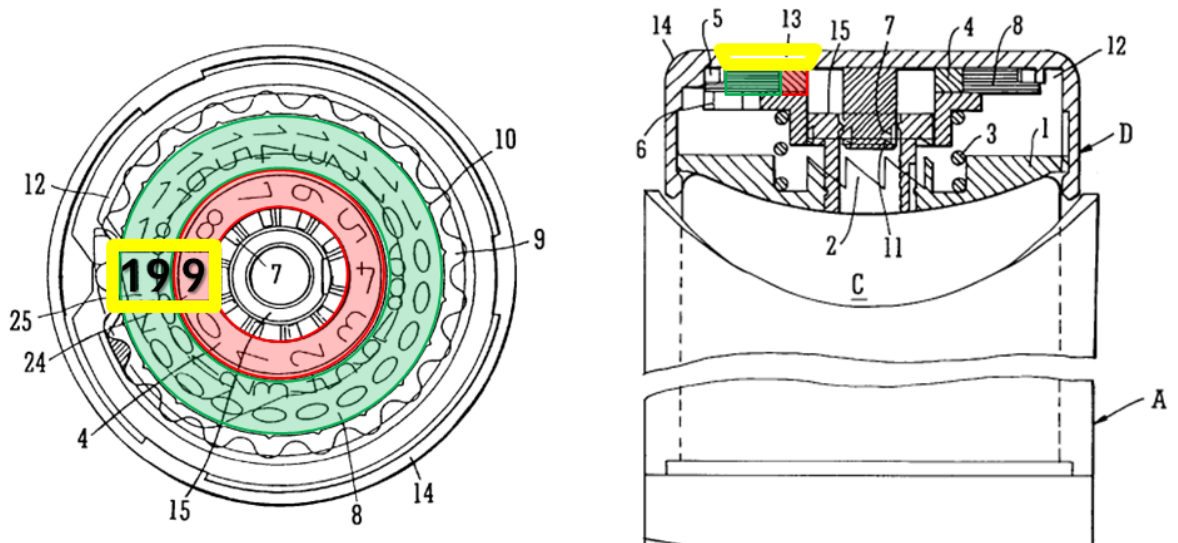
22. Bason (U.S. Patent No. 6,283,685) discloses an indicator device “adapted to serve as a dose counter for [MDIs].” Ex. 1007, 1:3-5, 2:16-19. The Bason dose counter D (outlined in red below) comprises a base 1 (highlighted in blue), central bush 15, rings 4 and 8, and cap 14. Ex. 1007, Figs. 1, 3.



Ex. 1007 at Figs. 1, 3 (annotated).

23. The dose counter assembles as follows. Base 1 of the dose counter D features an annular cavity housing a spring 3, with central bush 15 “in fixed position” on top of base 1, and base 1 itself bonded to canister C. Ex. 1007 at 2:16-27. Ring 4 is circumferentially assembled around central bush 15 such that teeth 7 are moveable between teeth 2 and teeth 14a. Ex. 1007 at 2:28-38. Ring 8 is “concentrically disposed above and around” ring 4. Ex. 1007 at 2:43-48. Cap 14 covers all of the aforementioned components. Ex. 1007 at 2:48-65. Bason’s dose values are visible through window 13. Ex. 1007 at 2:66-3:1. Because

Bason's dose values are featured on the upper faces 24 and 25 of the rotational rings 4 and 8, the window 13 must be positioned on top surface of the cap 14 in order for a user to be able to progressively view them (shown in yellow below).



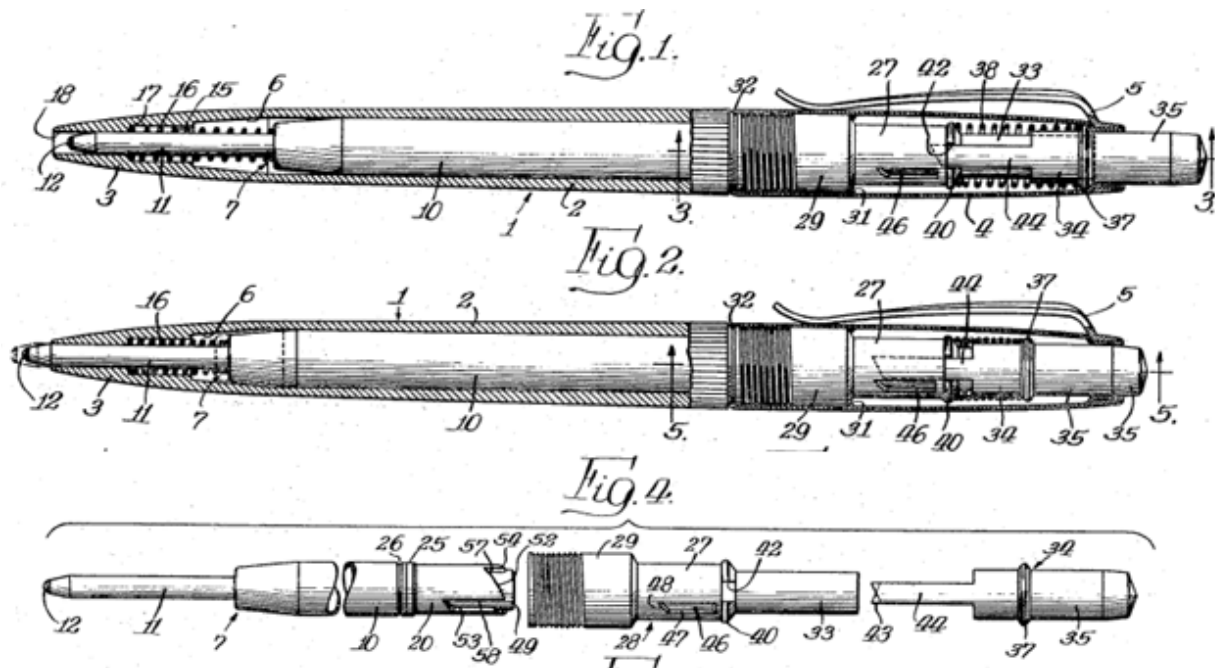
Ex. 1007 at Figs. 1, 4 (annotated).

24. The dose counter actuates by depressing the cap 14 so that the sides of the cap recess down into the inhaler housing. Depression of cap 14 depresses rings 4 and 8 and causes teeth 7 to engage with the “fixed” teeth 2 on the base 1, urging ring 4 to rotate. Ex. 1007 at 3:15-22. Upon release of the cap, teeth 7 return upwards to engage with teeth 14a of bush 15 to complete the rotational movement of the ring 4. Ex. 1007 at 3:18-22. “Each of these rotational movements represents one half of a complete movement of the ring 4 so that the number visible through window 13 will change by one point for a complete

depression and release of the cap.” Ex. 1007 at 3:22-26. For rings 4 and 8 to rotate, teeth 7 must press down and slide against the surface of the base’s “fixed” teeth 2, and must return upwards to interact with teeth 14a of bush 15. Ex. 1007 at 3:15-26. Bonding the base to the canister C thus allows the base 1 with teeth 2 and central bush 15 with teeth 14a to stay in a “fixed position” throughout the activation of the inhaler. Ex. 1007 at 2:16-23. The “fixed,” non-rotatable nature of the base 1 is important and necessary for the dose counter D to work properly. Ex. 1007 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 fixed teeth correctly, and the dose counter would not function. Ex. 1007 at 1:32-44.

D. Rhoades (U.S. Patent No. 3,205,836)

25. Rhoades discloses a ball point pen “having a projecting and retracting mechanism” used “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’ 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 2:44-55.



Ex. 1009 at Figs. 1, 2, and 4.

26. 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. 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.

VII. Ground 1: Claims 1-4 of the ‘631 Patent Are Not Anticipated by Allsop

27. Petitioners assert that claims 1-4 of the ‘631 patent are anticipated by Allsop. It is my opinion as a person of ordinary skill in the art that claims 1-4 are not anticipated by Allsop.

A. Claims 1 and 3 of the ‘631 Patent Are Not Anticipated by Allsop

28. It is my opinion as a person of ordinary skill in the art that claims 1 and 3 of the ‘631 Patent are not anticipated by Allsop.

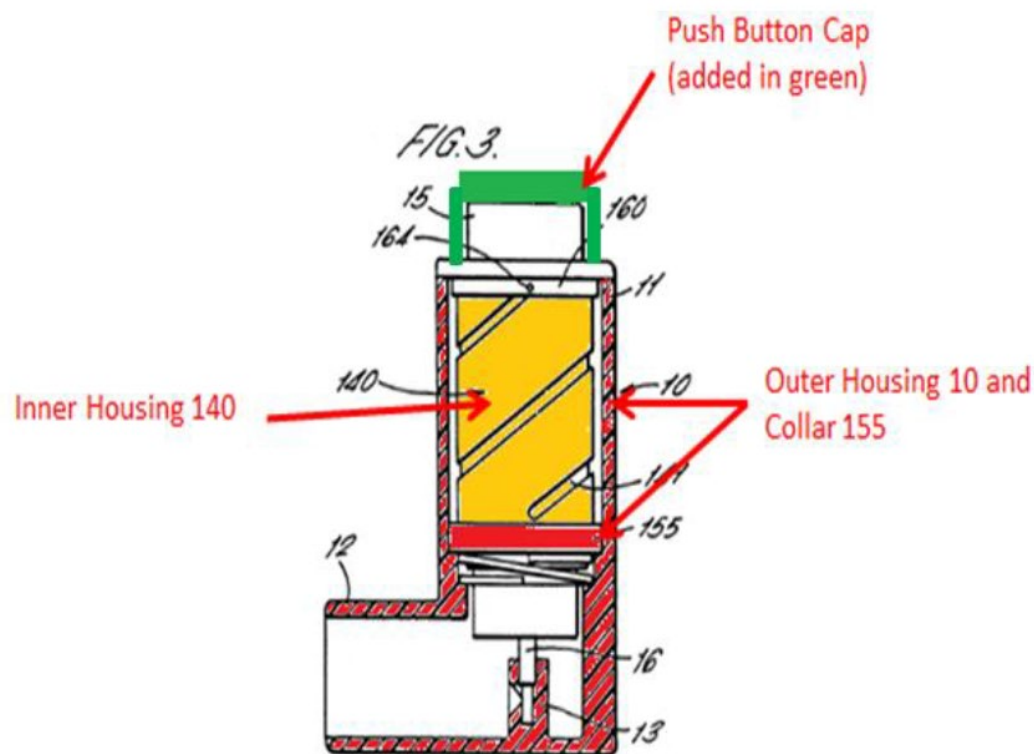
1. “a first member that is displaceable axially relative to said stationary body”

29. Claims 1 and 3 of the ‘613 Patent require “a first member that is displaceable axially relative to said stationary body.” Allsop does not disclose components that meet this claim description.

30. Petitioners state that Allsop’s “push-button cap” is the claimed first member and suggest that it “could be depressed axially, moving the canister axially.” This is incorrect. Allsop does not include any diagrams of a push-button cap. However, Allsop refers to an unenumerated “push-button cap” that may be “provided as part of the main housing 10 the cover the upper portion of the pressured dispensing container 15” in order to prevent “the ingress of dust, contaminants and moisture.” Ex. 1006 at 8:22-26. The push-button cap cannot be axially displaceable to the housing 10 if it is also “part of” the housing 10. Based on Allsop’s limited description of the push-button cap as a component that may be

included as “part of” the housing to “cover” the canister, a person of ordinary skill in the art would have understood that the push-button cap could be included as an optional protective cover, like that of Allsop’s mouthpiece cover, which does not move axially. *See* Ex. 1006 at 6:28-32 (“Optionally the mouthpiece 12 may be covered by a mouthpiece cover when the 30 apparatus is not being used, in order to protect the mouthpiece 12 from dust, dirt or other matter.”).

31. Petitioners’ expert, Mr. Piper, proposes that Allsop’s push-button cap could be axially depressible if designed as shown in the diagram below. This would render the device in Allsop inoperable.



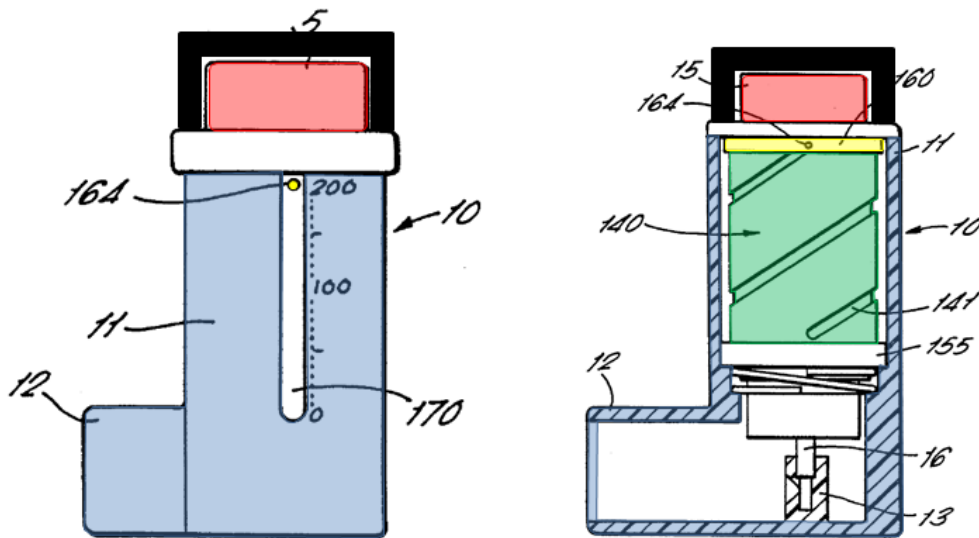
32. Piper’s depiction of the push-button cap (above) has sides that appear to recess into the device in between the housing 10 and the inner housing 140. This would not be possible because the push-button cap would encounter ring 160 with pins 161/162 and one of two things would occur: (1) the ring 160 with pins 161/162 would prevent the cap from being depressed, or (2) the depression of the cap would cause the pins 161/162 of ring 160 to be pushed downward, resulting in indicating an inaccurate number of doses remaining.

2. “a second member being engageable with said first member and said stationary body”

33. Claims 1 and 3 of the ‘613 Patent require a “second member being engageable with said first member and said stationary body.” Allsop does not meet this claim description for at least two reasons. First, Allsop’s push-button cap cannot be the “first member” for the reasons described above in Section VII.A.1. Second, Allsop does not meet this claim description because the push-button cap in Allsop is not “engageable with” Allsop’s inner housing 140 (which Petitioners argue satisfies the “second member” element limitation). As explained above, the push-button cap cannot be axially depressible because the sides of the push-button cap would interfere with the proper functioning of the inner housing 140 by pressing down on the ring 160 and pins 161 and 162, disabling the counting mechanism of Allsop, and rendering the device in Allsop unable to correctly indicate the doses remaining in the device.

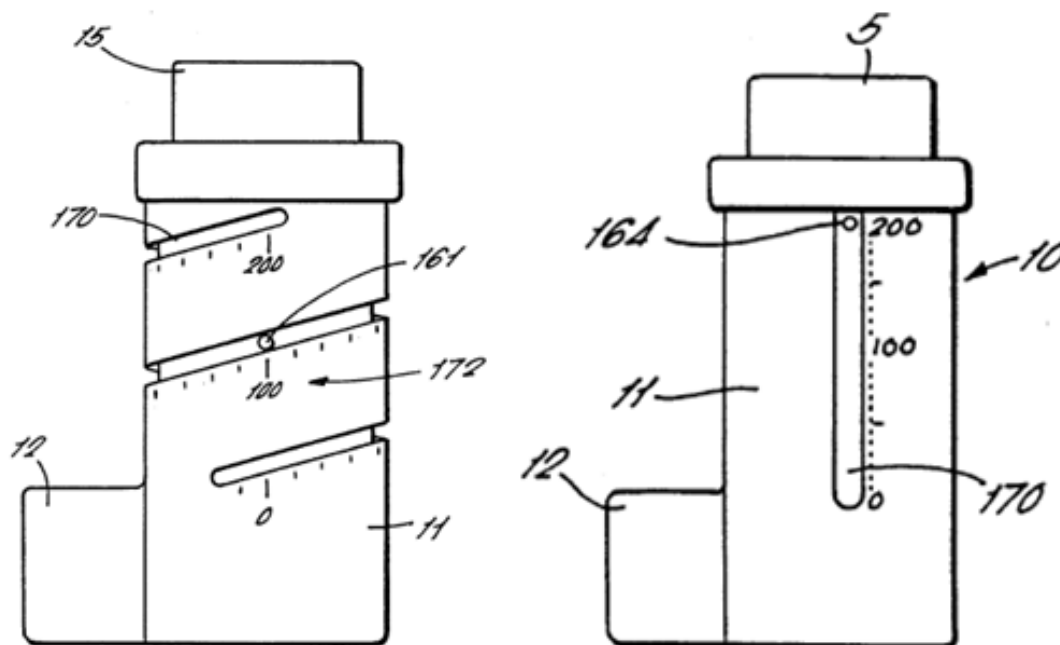
3. “when said first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”

34. Claims 1 and 3 of the ‘613 Patent require that “when said first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values.” Allsop does not meet the “first member” element of this claim limitation because Allsop’s push-button cap does not displace axially, as I explain above. If Allsop’s push-button cap could be axially displaceable, then depression of the cap (annotated below in black) would disrupt the proper functioning of the ring 160 with pins 161 and 162.



Ex. 1006 at Figs. 1, 3 (annotated).

35. Allsop also does not meet the requirement of changing “a displayed dose value from among the plurality of displayable dose values.” The claim language of the ‘631 Patent is specific to require changing a “**displayed**” value from “**displayable**” values. The requirement that there is one dose value that is visible to the user at any given time from among multiple possible dose values that could be displayed. In other words, only one dose value may be seen by a user at a time according to this claim limitation. In Allsop, all of the dose values are always shown on the exterior of the inhaler housing. Ex. 1006 at 8:27-29 (“Markings 172 are printed or embossed on an exterior surface of the housing 10 adjacent the slots 170.”). This is clear from Allsop’s Figures 1 and 13, below. It is my opinion that Allsop therefore does not disclose this element of claims 1 and 3 because it does not observe changing a single “**displayed**” dose value from among a plurality of “**displayable**” dose values since the plurality of Allsop’s dose values are always **displayed**.



Ex. 1006 at Figs. 1, 13.

36. For these reasons, Allsop does not teach or disclose that when a “first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values.”

B. Claims 2 and 4 of the ‘631 Patent Are Not Anticipated By Allsop

37. I understand that a dependent claim is not anticipated if claim limitations within the independent claim are not anticipated. Therefore, because Allsop cannot anticipate independent claims 1 and 3, it is my opinion as a person of ordinary skill in the art that Allsop also cannot anticipate dependent claims 2 and 4 for these same reasons.

VIII. Ground 2: Claims 1-4 of the ‘631 Patent Are Not Anticipated by Marelli

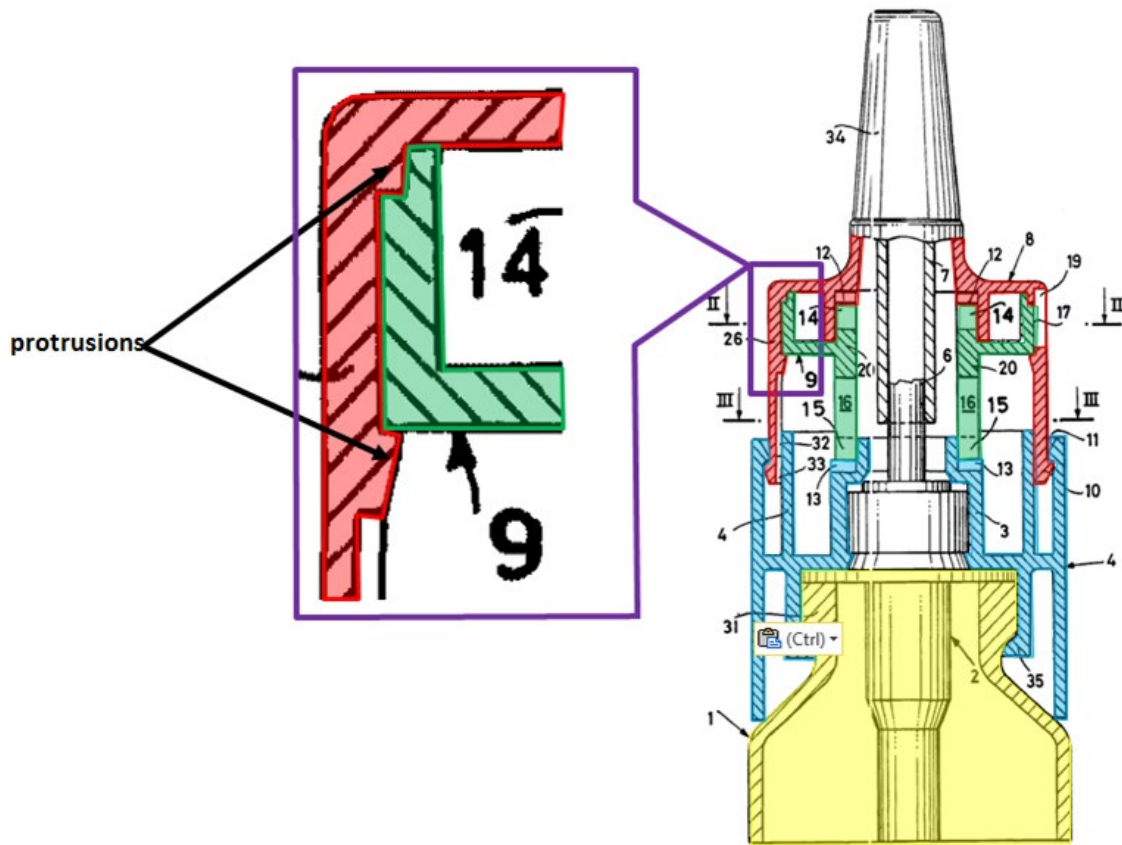
38. Petitioners assert that claims 1-4 of the '631 patent are anticipated by Marelli. It is my opinion as a person of ordinary skill in the art that claims 1-4 are not anticipated by Marelli.

A. Claims 1 and 3 of the '631 Patent Are Not Anticipated by Marelli

39. It is my opinion as a person of ordinary skill in the art that claims 1 and 3 of the '631 Patent are not anticipated by Marelli.

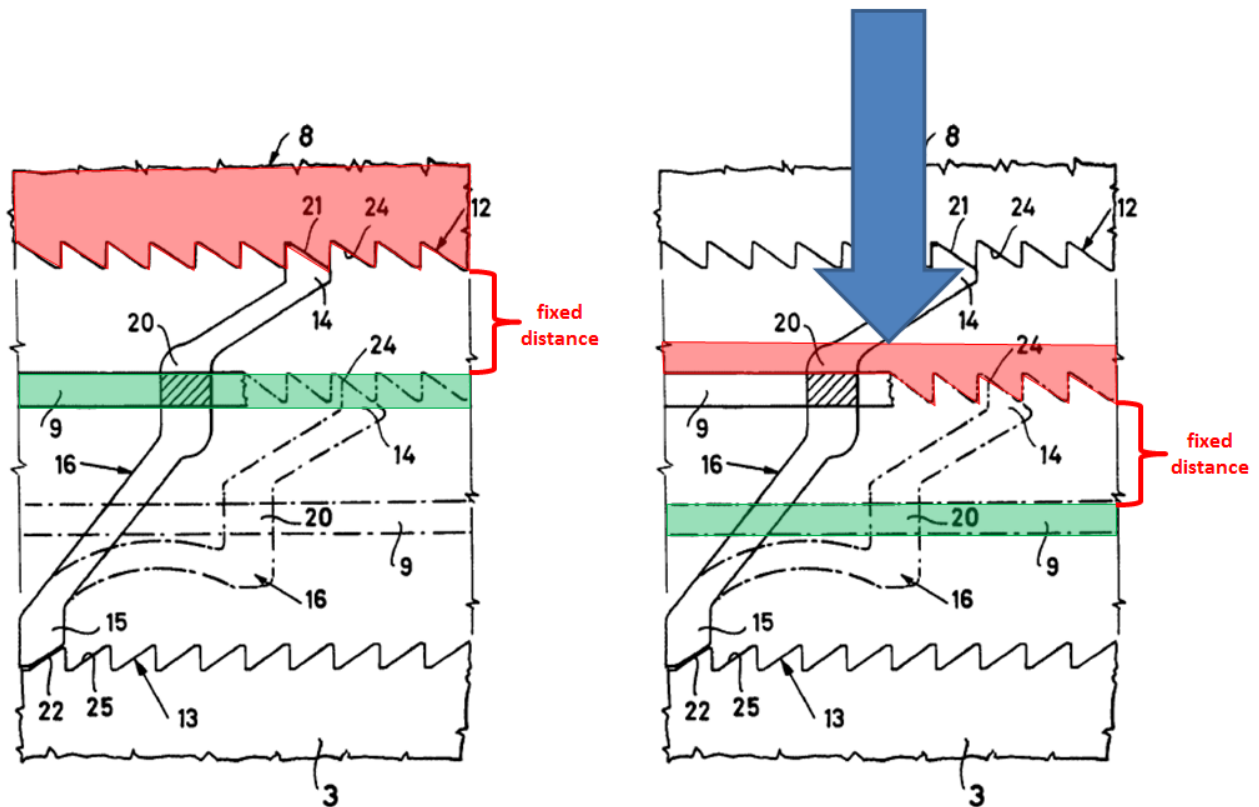
1. “a second member that is displaceable axially and in rotation relative to said stationary body”

40. Claims 1 and 3 of the '613 Patent require “a second member that is displaceable axially and in rotation relative to said stationary body.” Petitioners point to Marelli's rotating element 9 as the “second member” element and Marelli's nasal 8 as the “stationary body” element of this claim limitation. However, Marelli cannot anticipate this claim limitation because element 9 does not move axially relative to Marelli's nasal 8. Rotating element 9 sits in a channel within the nasal 8, affixed between two protrusions on nasal 8's interior. Ex. 1008 at 3:45-52, Fig. 1. Because the nasal 8 is stationary according to the Petitioners, Marelli teaches that element 9 must also be stationary due to the protrusions on the nasal 8 that hold it in position. Ex. 1008 at 3:45-52, Fig. 1.



Ex. 1008 at Fig. 1 (annotated).

41. Marelli specifically teaches that the fixed distance element 9 and nasal 8 is always maintained, even during actuation of the device. As shown below in my annotation of Marelli's Figure 4, when the user depresses the nasal 8 to actuate the device, the nasal 8 (shaded in red) and the element 9 (shaded in green) move in conjunction with one another such that the axial spacing between these two components does not change.



Ex. 1008 at Fig. 4 (annotated).

42. For these reasons, as a person of skill in the art it is my opinion that Marelli does not meet the limitation of the '631 Patent requiring “a second member that is displaceable axially and in rotation relative to said stationary body.”

2. “when said first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”

43. This element is not present in Marelli because the rotating element 9 cannot “be displaced axially . . . relative to” the nasal 8 for the same reasons as I explain in Section VIII.A.1.

3. Claims 2 and 4 of the '631 Patent Are Not Anticipated By Marelli

44. I understand that a dependent claim is not anticipated if claim limitations within the independent claim are not anticipated. Therefore, because Marelli cannot anticipate independent claims 1 and 3 of the '631 Patent, it is my opinion as a person of ordinary skill in the art that Marelli also cannot anticipate dependent claims 2 and 4 for these same reasons.

IX. Ground 3: Claims 1-4 of the '631 Patent Are Not Obvious Under 35 U.S.C. § 103 over Bason in View of Rhoades

45. Petitioners assert that claims 1-4 are obvious over Bason in view of Rhoades. It is my opinion as a person of ordinary skill in the art that claims 1-4 are not obvious over Bason in view of Rhoades.

A. Modification of Bason in View of Rhoades

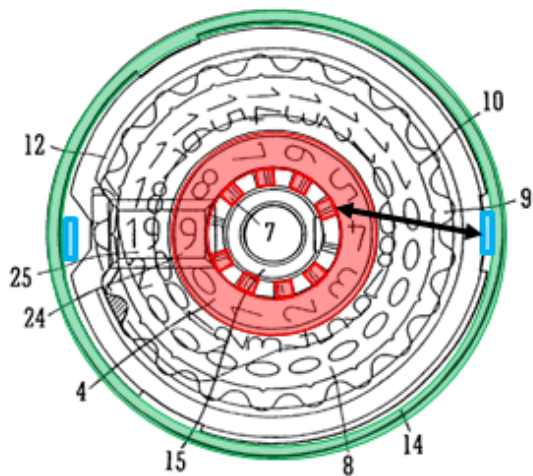
46. Petitioners assert that a person of ordinary skill in the art would have been motivated to modify Bason in view of Rhoades. However, Petitioners' description of the modification of Bason in view of Rhoades does not contain adequate description of the design concept that shows the interworkings of the device and how it would function, or that the combination practices the limitations of claims 1-4 of the '631 Patent.

47. Petitioners' description of the Bason and Rhoades combination is contained at pages 53 through 56 of the Petition. It states that the combination is a

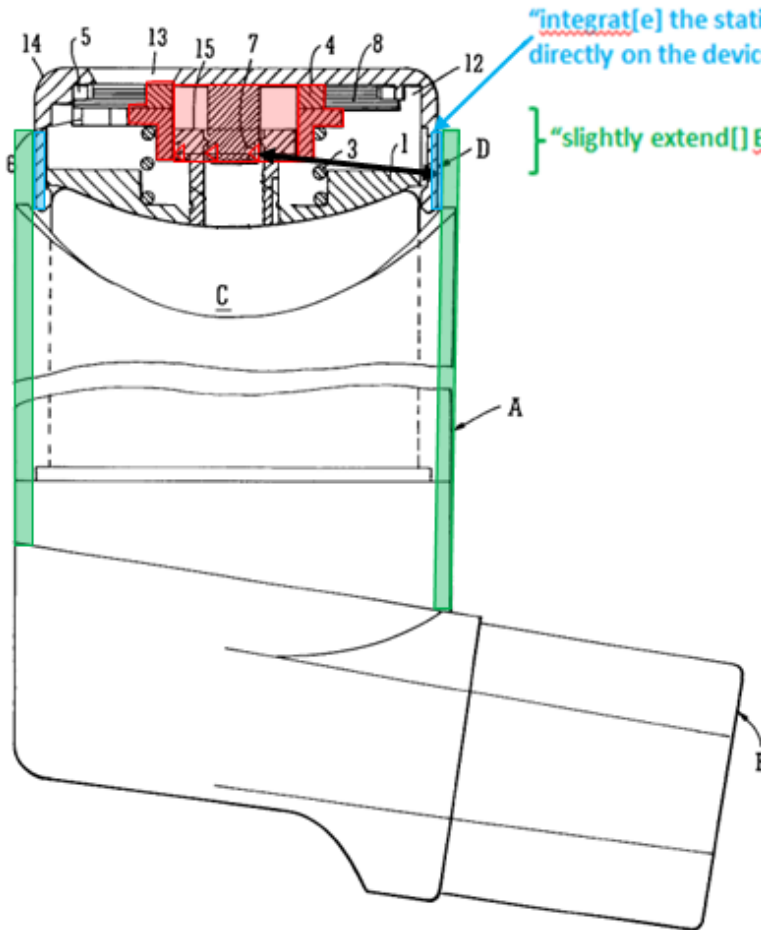
predictable modification where a person of ordinary skill in the art would have slightly extended Bason's inhaler body, integrating the stationary gear (tooth 2) of Bason into the inhaler body. Petitioners state that the rest of the components would be connected in the same way they are connected in Bason. Petitioners include no figures describing how the modification would have been constructed.

48. 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 Bason components in a way that ensures operability of the device and interoperability between the components. Petitioners do not indicate how the teeth 2, which are disclosed as a component of Bason's base 1, would be integrated into the inhaler body, where the teeth would be located in relation to the remaining components, or how such a modification might affect the efficacy of the dose counting functionality disclosed in Bason. Petitioners do not assert that any particular components of Rhoades would be incorporated into the modification.

49. Based on Petitioners' description, the proposed Bason and Rhoades combination would look like the diagram below, having an inhaler body that is slightly extended (shaded in green), teeth 2 (shaded in blue) that are directly integrated into the inhaler body, and the remaining components, such as ring 4 with teeth 7 (shaded in red), are connected in the same way as they are in Bason.



"the rest of the components could be connected in the same way they are in Bason" and "would retain their same functions"



"integrat[e] the stationary gear" now "formed directly on the device housing[/inhaler body]"

"slightly extend[] Bason's inhaler body"

Ex. 1007 at Figs. 1, 4 (annotated).

B. Claims 1 and 3 of the '631 Patent Are Not Rendered Obvious over Bason in view of Rhoades

50. It is my opinion as a person of ordinary skill in the art that claims 1 and 3 of the '631 Patent are not rendered obvious over Bason in view of Rhoades.

1. “a first member that is displaceable axially relative to said stationary body”

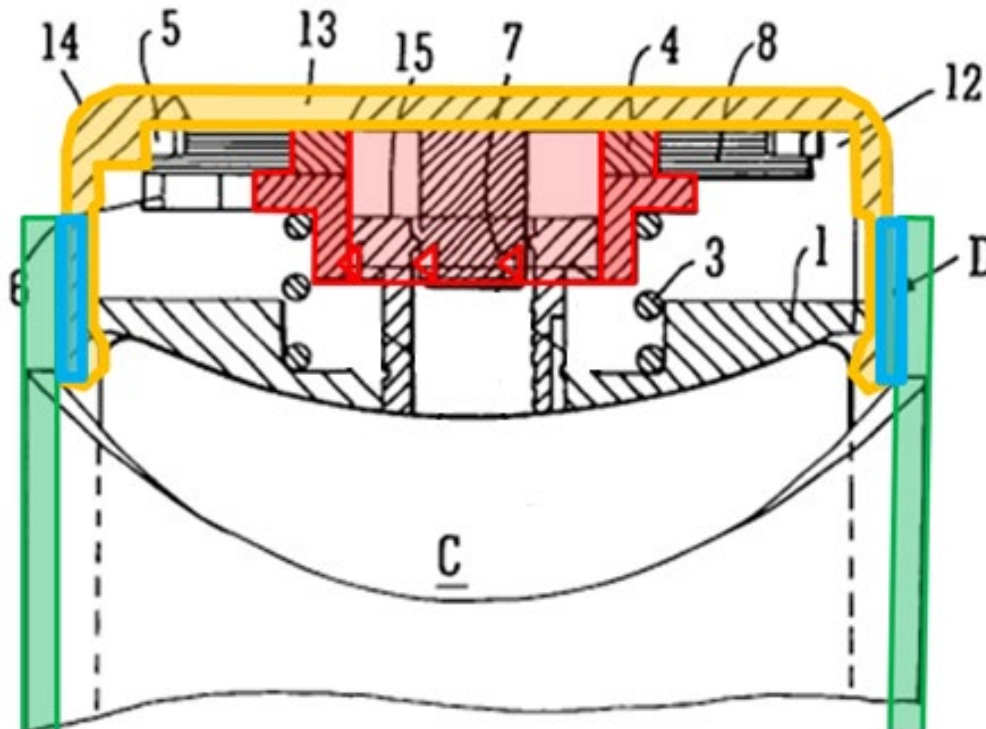
51. I understand that a patent is invalid as obvious under 35 U.S.C. § 103 if the differences between the subject matter sought to be patented and the prior art are such that the subject matter would have been obvious at the time the invention was made to a person having ordinary skill in the art. Whether 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.

52. Claims 1 and 3 of the '631 Patent require “a first member that is displaceable axially relative to said stationary body.” Petitioners’ proposed combination of Bason and Rhoades does not render this claim element obvious.

53. Petitioners propose that the “first member” limitation of claims 1 and 3 is either the Rhoades push button 35 or the Bason cap 14. This is incorrect.

54. First, the Rhoades push button 35 cannot meet the “first member” limitation of this claim because it is not included in Petitioners’ proposed combination of Bason and Rhoades.

55. Second, Bason’s cap 14 cannot be the “first member” because cap 14 cannot move axially since teeth 2 are molded onto the inhaler body in Petitioners’ proposed combination of Bason and Rhoades. In the annotated diagram of Petitioners’ proposed Bason/Rhoades combination below, Bason’s teeth 2 (shaded in blue) are molded directly onto the inhaler body (shaded in green). Because the teeth 2 occupy the same plane as cap 14 (in orange), the cap 14 cannot be axially depressed because teeth 2 create a physical barrier that prevents the cap 14 from recessing inside the inhaler body. This is a significant problem because Bason actuates the dose indicator device (and the medicinal canister) by depression and release of the cap 14. Petitioners’ proposed combination of Bason and Rhoades is therefore inoperable for its intended purpose because it is not possible for a user to depress cap 14 as required to actuate the device if teeth 2 are integrally molded onto the inhaler body.



Ex. 1007 at Fig. 1 (annotated).

56. For these reasons, Petitioners have not shown that the Bason/Rhoades combination discloses this claim element.

2. **“when said first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”**

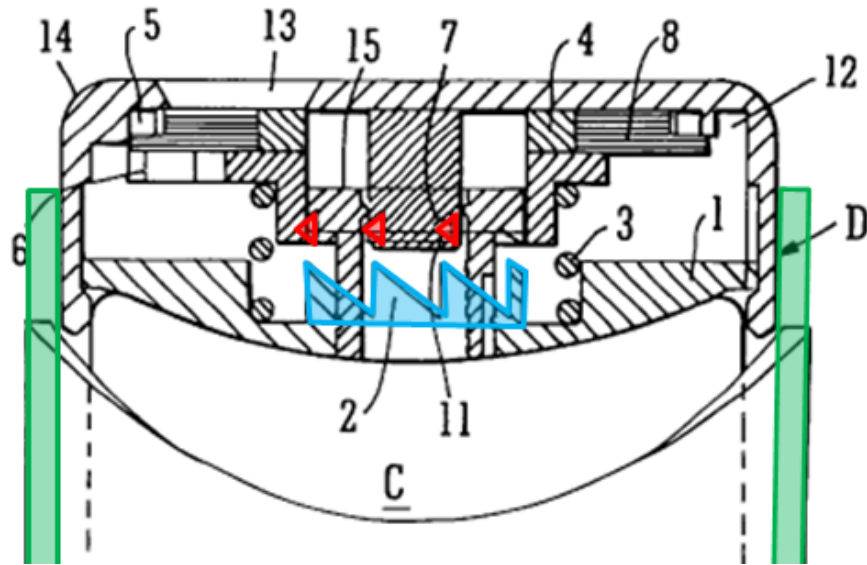
57. Claims 1 and 3 of the ‘631 Patent require that when “when said first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values.”

Petitioners proposed combination of Bason and Rhoades does not render this claim element obvious.

58. As I explain above, Petitioners' Bason and Rhoades combination does not disclose the "first member" element because the cap 14 does not move axially. In addition, Petitioners' Bason and Rhoades combination does not disclose the "second member" element of this claim. Petitioners and Mr. Piper propose that the "second member" could be the Rhoades cam body 20 or the Bason ring 4. This is incorrect.

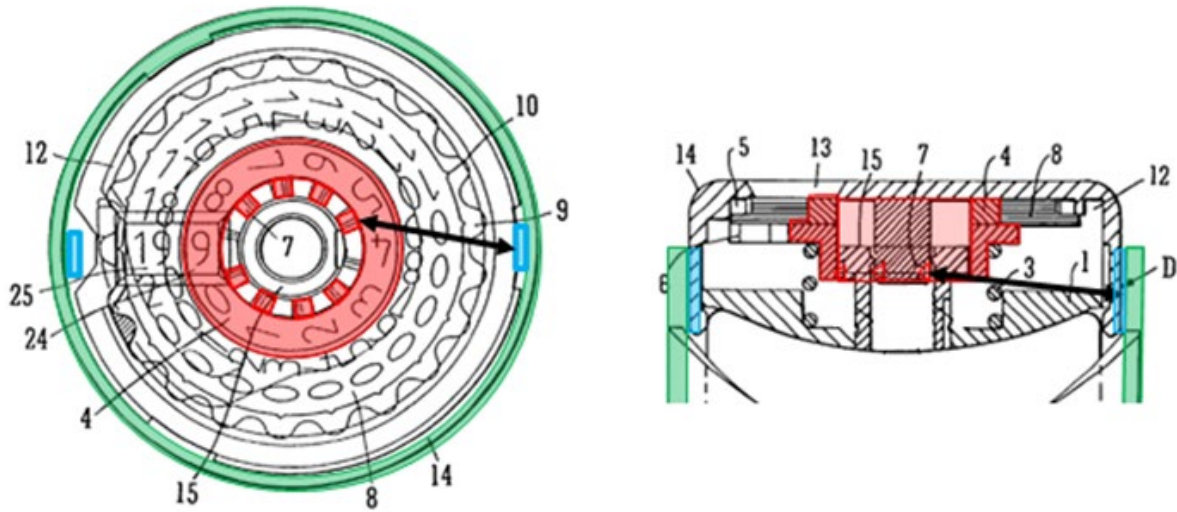
59. The Rhoades cam body is not included in Petitioners' proposed combination of Bason and Rhoades and so it cannot be the "second member" in this claim limitation.

60. The Bason ring 4 cannot be the "second member" element of this claim limitation because even if it were possible for the cap 14 to be axially depressed despite the blockage created by the teeth 2 on the inhaler body, Petitioners' modifications to Bason prevent the ring 4 from being indexed in rotation. Bason discloses "upwardly directed" teeth 2 (shaded in blue below in the annotated diagram below) formed around the center of base 1, and "inwardly directed" teeth 7 (shaded in red below) formed around the inner surface of ring 4. Ex. 1007 at 2:28-38.



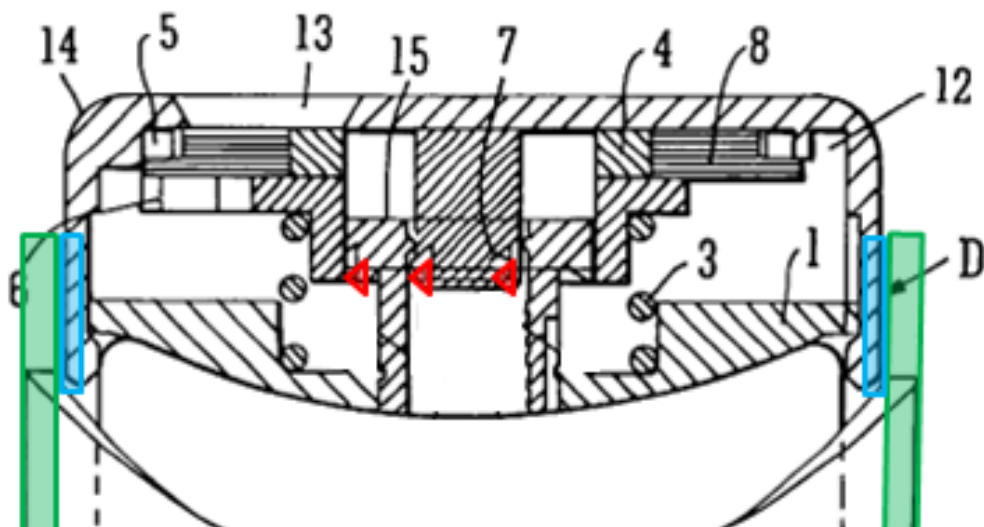
Ex. 1007 at Fig. 1 (annotated).

61. Bason teaches that teeth 7 are situated directly above teeth 2 such that teeth 7 “engage” with teeth 2 causing the ring 4 to rotate when the cap 14 is axially depressed. Ex. 1007 at 2:28-38, 3:15-4:4. A critical issue with the functionality of Petitioners’ Bason and Rhoades combination is that teeth 7 are not able to “engage” with teeth 2. If the teeth 2 are molded directly onto Bason’s inhaler body they no longer “engage” with teeth 7 because teeth 7 (shaded in red below) are located near the center of the cap inside of ring 4, and teeth 2 (shaded in blue below) are located around the interior circumference of the inhaler body.



Ex. 1007 at Figs. 1, 4 (annotated).

62. The teeth 7 thus cannot engage teeth 2 because teeth 7 are separated from teeth 2 by numerous interfering components of Bason, including the cavity 1a of the base 1, the radially outwardly directed flange of the ring 4, spring 3, and the sides of the cap 14: *See Ex. 1007 at 2:20-38, 43-58, 3:15-22.* As a result, when the cap is depressed, teeth 7 do not engage with tooth 2 in order to rotate the ring 4.



Ex. 1007 at Figs. 1 (annotated).

63. If teeth 7 and teeth 2 cannot engage, ring 4 cannot rotate in order to change the displayed dose value as required by this claim element. If the dose numbers cannot advance, the patient will not know how many doses of medication are in the inhaler. Without an indication of the number of doses remaining in the inhaler, Petitioners' Bason and Rhoades combination is rendered inoperable for Bason's stated purpose of "indicat[ing] the number of times the pressurized canister is depressed to dispense a dose of the drug." Ex. 1008 at 1:15-17.

C. Claims 2 and 4 of the '631 Patent Are Not Rendered Obvious over Bason in view of Rhoades

64. I understand that a dependent claim is not obvious if claim limitations within the independent claim are not obvious. Therefore, because claims 1 and 3 are not rendered obvious over the Bason/Rhoades combination, neither are dependent claims 2 and 4.

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

65. 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 Bason with Rhoades at the time of the invention of the '631 Patent.

66. 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.

67. The stated purpose of the '631 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 each time liquid is dispensed by the fluid dispenser."

68. The mechanism of Rhoades does not include any means for counting nor dispensing liquid out of the ball tip after it has been actuated and extended. Rather, Rhoades's stated purpose is to "provide a ball point writing instrument having an improved push button operated projecting and retracting mechanism." Ex. 1009 at 1:15-17.

69. The protracting 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 extremely unique for their purpose (requiring 60 people to create) and are not easily modified or interchanged for other purposes. *See* Ex. 2020. 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. Rhoades only 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 of dispensing ink out of the reservoir at all. In fact, the Rhoades purpose completely ignores the amount of liquid ink in the reservoir.

70. 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, it 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 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 jet, 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 carefully 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: the droplets may be too small and will be exhaled by the patient, or 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.

71. 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.

72. 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. In addition, 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."

73. 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 '631 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.

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

75. 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 why a person seeking to improve the accuracy of an MDI would look to non-precision components like those of an ink pen.

76. In addition, an MDI requires execution and coordination of repeatable multiple functions within a very small travel distance. For example, the travel distance of an MDI with a dose indicator device must 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.

77. 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 (has no potential health safety issues such as non-delivery of a life-saving drug) 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.” Ex. 1009 at 8:6-16.

78. 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. Whether or not Rhoades's cam mechanism is highly optimized for low cost to

manufacture, a person of ordinary skill in the art would understand that it simply was not designed for the accuracy and precision that is required for functionality in an MDI. 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 Bason 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, why they would have been motivated to do, or why they would have any reasonable chance of success of incorporating Rhoades' non-precision components into an MDI absent evidence that such a combination had ever even been attempted.

79. Third, a person of ordinary skill in the art would not have been motivated to modify Bason in view of Rhoades because the proposed modification would be inoperable for its intended purpose. Piper asserts that elimination of the base part 1 is an important motivation for moving teeth 2 to the inhaler inner wall. But this presents an undesirable assembly problem that would deter a person of ordinary skill in the art. Petitioners do not disclose how the components of Bason would be modified as Petitioners describe while maintaining operability of the device as described in Bason. Further, Petitioners provide no explanation as to how the teeth 2 would be integrated into the inhaler, where the teeth would be

located in relation to the remaining components, or how such a modification might affect the efficacy of the dose counting functionality disclosed in Bason.

80. However, if the “tooth 2” is integrated into the inhaler body, then it cannot engage with tooth 7. When the cap is depressed, the teeth 7 do not engage with tooth 2. This is because the teeth 7 are located near the center of the cap inside of ring 4 compared to tooth 2, which is located on the inhaler body near the outer circumference of the device. As a result, teeth 7 cannot engage with tooth 2 in order to rotate the ring 4. If the ring 4 cannot rotate, then the dose numbers will not advance, and the patient will not know how many doses of medication are in the inhaler. Without an indication of the number of doses remaining in the inhaler, Bason is rendered inoperable for its intended purpose of “indicat[ing] the number of times the pressurized canister is depressed to dispense a dose of the drug.”

81. Alternatively, if base 1, itself, is made integrally with inhaler body A, Petitioners do not explain how cap 14 can be depressed sufficiently to actuate the inhaler. Nor do Petitioners describe how the canister C could be placed inside the body A if the base 1 is integral to body A. In other words, if the base and inhaler body are formed as one integral piece, there is no longer any access to the interior of the inhaler so that the canister of medicine can be placed inside. Moreover, if base 1 is eliminated and teeth 2 moved to the inhaler wall, there is no longer anywhere to mount Central Bush part 15 (and other parts that interface to it) which

has teeth 14a that are necessary for the second half of counting functionality. Thus, Petitioners' alternative modification also renders Bason inoperable for its intended purpose.

82. In summary, 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.

X. Ground 4: Claims 1-4 of the '631 Patent Are Not Obvious Under 35 U.S.C. § 103 over Bason in View of Allsop

83. Petitioners assert that claims 1-4 are obvious over Bason in view of Allsop. It is my opinion as a person of ordinary skill in the art that claims 1-4 are not obvious over Bason in view of Allsop.

A. Modification of Bason in View of Allsop

84. Petitioners assert that a person of ordinary skill in the art would have been motivated to modify Bason in view of Allsop. However, Petitioners' description of the modification of Bason in view of Allsop does not contain adequate description of the design concept that shows the interworking's of the device and how it would function, or that the combination practices the limitations of claims 1-4 of the '631 Patent.

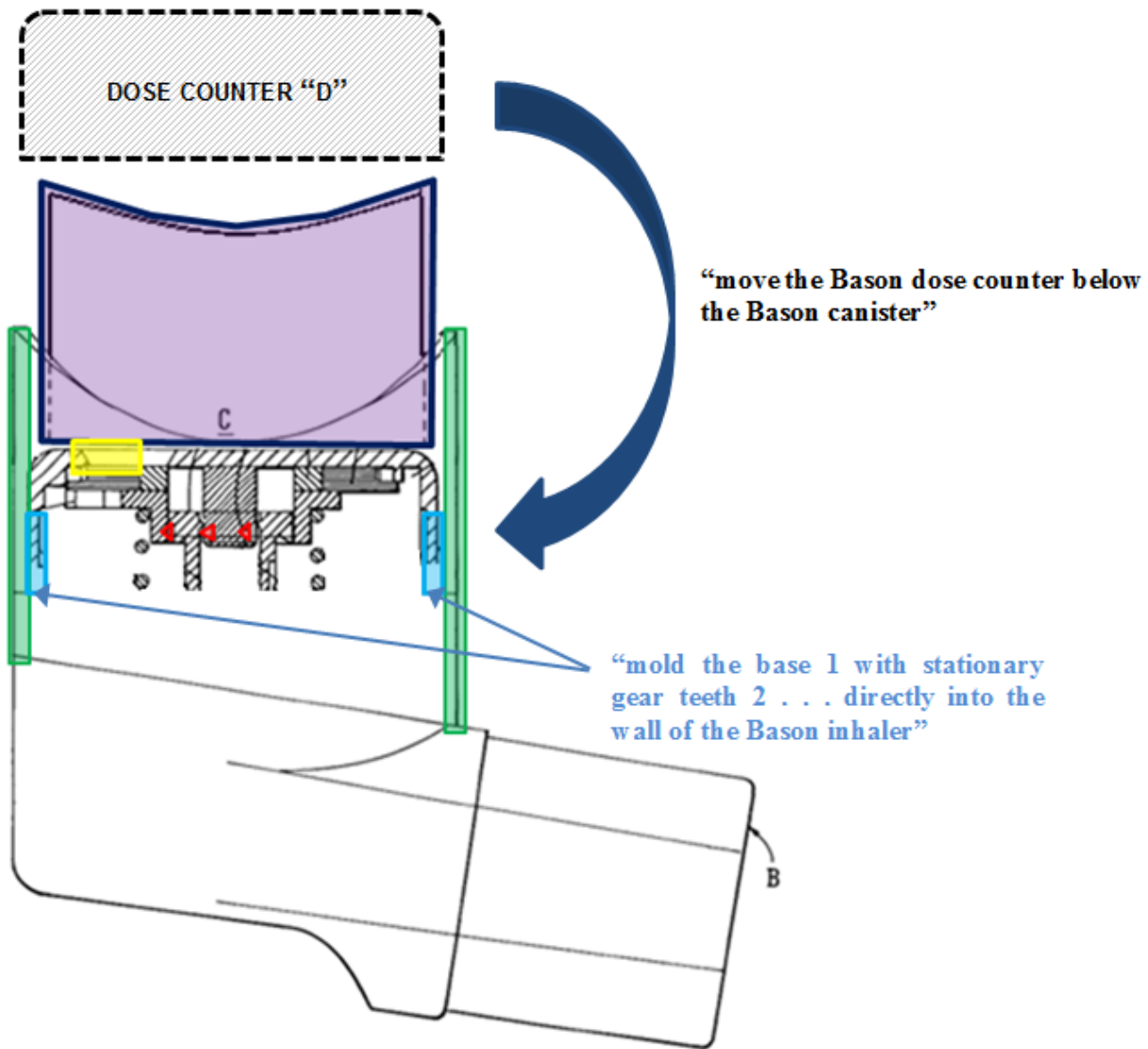
85. Petitioners' description of the Bason and Allsop combination is contained at pages 66 through 68 of the Petition. It states a person of ordinary skill

in the art would have modified Bason by moving the Bason dose counter below the Bason canister, where the rotational mechanism is located in Allsop, and integrally molded the teeth 2 into the inhaler housing. Petitioners include no figures describing how the modification would have been constructed.

86. The problem with this conclusory description is that Petitioners again fail to describe how a person of ordinary skill in the art would have substituted the Allsop components for the Bason components in a way that ensures operability of the device and interoperability between the components. Petitioners do not disclose how the components of Bason would be modified as Petitioners describe while maintaining operability of the device as described in Bason. For example, Petitioners have not explained how the dose counting components of Bason can be disengaged from the base 1 (now eliminated after incorporating teeth 2 onto the inhaler's inside diameter wall), moved below the canister, engaged with some stationary component so as to allow the canister to be axially displaceable to such component, and still function in the way described in Bason. Petitioners also do not describe how the valve extending from the canister through the counting mechanism would clear the components of the counting mechanism and still allow the canister to be axially displaceable relative to a stationary component (which must also engage with the counter element) as required by the claims of the '631 Patent. Petitioners also fail to explain how teeth (2) can be integrally formed in the

housing if the dose counter is moved to the bottom of the device. Petitioners do not assert that any particular components of Allsop would be incorporated into the modification.

87. Based on Petitioners' description, the proposed Bason and Allsop combination would look like the diagram below, Bason's dose counter being moved to immediately below the canister (shaded in purple), base 1 with teeth 2 (shaded in blue) is directly integrated into the inhaler body (shaded in green), and the remaining components, such as ring 4 with teeth 7 (shaded in red), are connected in the same way as they are in Bason.



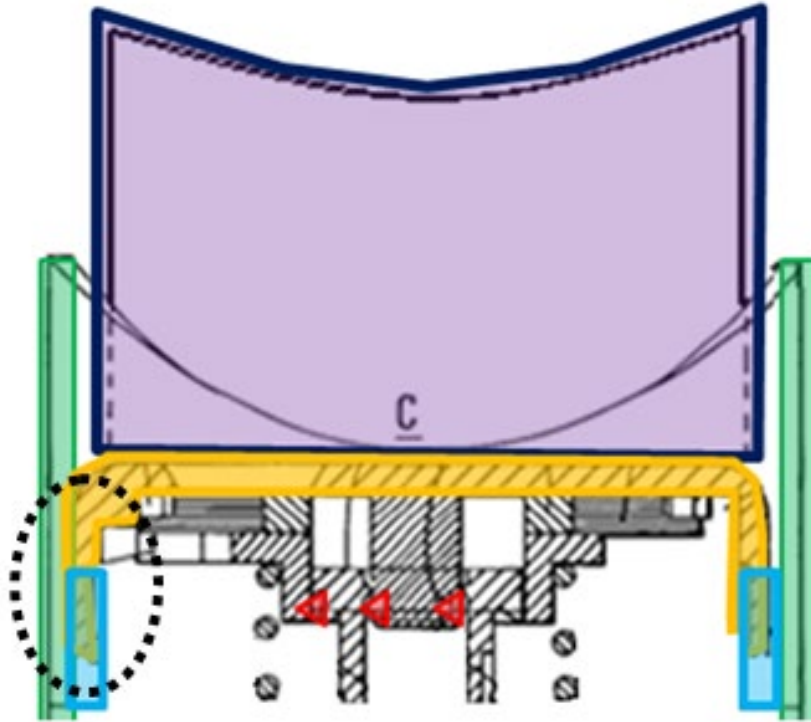
Ex. 1007 at Fig. 1 (annotated).

B. Claims 1 and 3 of the '631 Patent Are Not Rendered Obvious Over Bason in view of Allsop

88. It is my opinion as a person of ordinary skill in the art that claims 1 and 3 of the '631 Patent are not rendered obvious over Bason in view of Allsop.

1. "a first member that is displaceable axially relative to said stationary body"

89. Petitioners propose that their Bason and Allsop combination discloses the “first member” limitation of claims 1 and 3 as either the Allsop push button cap or the Bason cap 14. This is incorrect because Allsop’s push-button cap is not included in the Bason and Allsop combination. Therefore it cannot be the “first member.” Bason’s cap 14 also cannot be the “first member.” As shown in the annotated diagram of Petitioners’ Bason/Allsop combination below, if base 1 with tooth 2 (shaded in blue) is molded onto Bason’s inhaler body (shaded in green), the cap 14 (shaded in orange) will not be able to move axially relative to the inhaler body because the teeth 2 block the cap from recessing further into the housing. Petitioners do not acknowledge this problem created by moving base 1 with teeth 2 to the inhaler body and do not suggest that the cap 14 should be modified to accommodate the presence of teeth 2. As a result, Petitioners’ combination would be inoperable for its intended purpose because depression of the canister would not result in depression of the cap 14 as needed to dispense medication from the canister and actuate the dose counter.



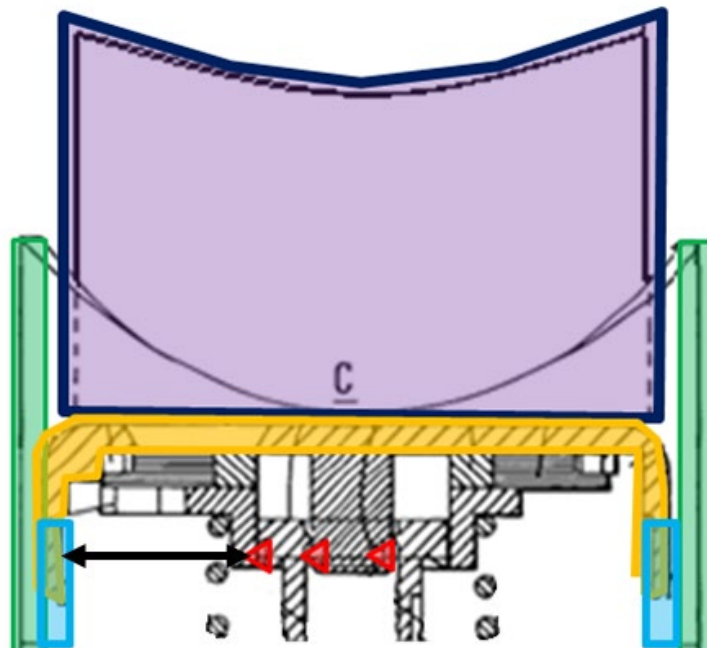
Ex. 1007 at Fig. 1 (annotated).

2. “when said first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”

90. Petitioners proposed combination of Bason and Allsop does not render this claim element obvious. As I explain above, the Bason/Allsop combination does not disclose the “first member” requirement because Allsop’s push-button cap is not included in the proposed combination and because Bason’s cap 14 cannot move axially relative to the inhaler body.

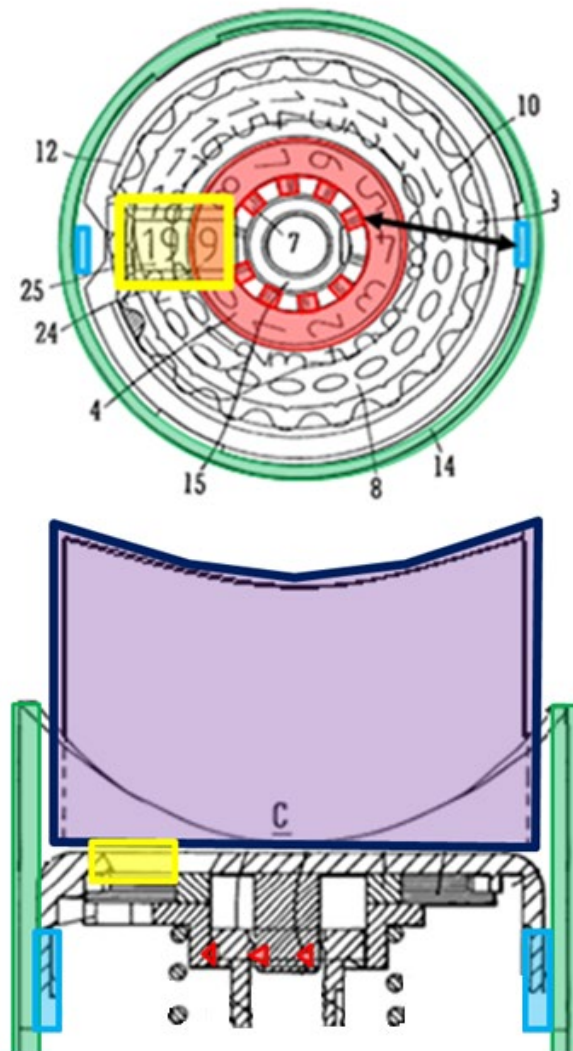
91. Petitioners identify either Allsop’s inner housing 140 or the Bason ring 4 as the “second member” of this claim limitation. Based on Petitioners’

description of the Bason/Allsop combination, it is not possible for either of these components to comply with the requirements of the above claim limitation. Allsop's inner housing 140 cannot be the "second member" because it is not included in the proposed Bason and Allsop combination. Bason's ring 4 also cannot be the "second member" because it cannot rotate in Petitioners' proposed combination as described. As shown in the annotated diagram below, base 1 with teeth 2 (shaded in blue) formed onto the inhaler body (shaded in green) will not "engage" teeth 7 (shaded in red) as required for ring 4 to rotate because teeth 2 are separated from teeth 7 by the radially outwardly directed flange of the ring 4, spring 3, and the sides of the cap 14. *See* Ex. 1007 at 2:20-38, 43-58, 3:15-22.



Ex. 1007 at Fig. 1 (annotated).

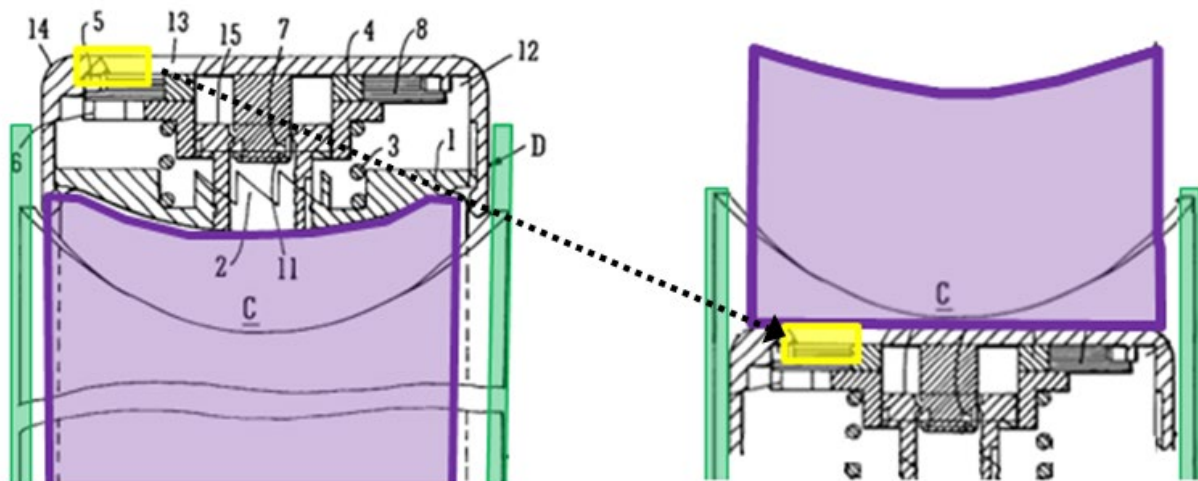
92. Petitioners further state that the limitation to “change a displayed dose value from among the plurality of displayable dose values” is present in their Bason and Allsop combination as either Allsop’s ring 160 and dosage markings 172 or as Bason’s dosage values on the upper faces of Bason’s ring 4 and ring 8. This is not possible based on Petitioners’ description of their Bason/Allsop combination. Allsop’s ring 160 and dosage markings 172 are not included in Petitioners’ described Bason/Allsop combination. And as I explain above, Bason’s ring 4 cannot rotate, so Petitioners’ Bason/Allsop combination cannot “change a displayed dose value from among the plurality of displayable dose values.” Bason’s ring 4 (shown below in red) and corresponding ring 8 (shown below in green) “each carry[] on its upper surface indicia visible through a window (13) in the cap.” Ex. 1007 at Abstract. If base 1 with tooth 2 is molded directly onto Bason’s inhaler body, when the cap 14 is depressed in Petitioners’ combination of Bason and Allsop, teeth 7 do not engage with tooth 2, ring 4 does not rotate, and each actuation of the inhaler does not cause a new dose value to be rotated into window 13 (shown below in yellow).



Ex. 1007 at Figs. 1, 4 (annotated).

93. In addition, Bason's dosage values on the upper faces of Bason's ring 4 and ring 8 cannot render the "displayed dose" element obvious because Bason's dose values are not "displayed" or "displayable" if the Bason dose counter is placed below the canister. Bason's display window 13 for viewing the number of doses remaining is on the top of the dose counter. Ex. 1007 at 2:56-3:6. In Petitioners' Bason and Allsop combination, Bason's dose counter is moved below

to a position “immediately below” the canister. Moving Bason’s dose counter D below the canister causes window 13 (shaded below in yellow) causes it to be covered by the bottom surface of the canister C (shaded below in purple). It is not possible to view the dose values through window 13 below the canister, and Bason is rendered inoperable for its stated purpose because it cannot “indicate the number of times the pressurized canister is depressed to dispense a dose of the drug.” Ex. 1007 at 1:15-17.



See Ex. 1007 at Fig. 1 (annotated).

94. For all these reasons, Petitioners’ proposed Bason and Allsop combination cannot render this claim element obvious.

C. Claims 2 and 4 of the ‘631 Patent Are Not Rendered Obvious over Bason in view of Allsop

95. I understand that a dependent claim is not obvious if claim limitations within the independent claim are not obvious. Therefore, because claims 1 and 3

are not rendered obvious over the Bason/Allsop combination, neither are dependent claims 2 and 4.

D. A POSA Would Not Have Been Motivated to Combine Bason with Allsop

96. Petitioners assert that a person of ordinary skill in the art would have been motivated to modify Bason in view of Allsop. I do not believe that a person of ordinary skill in the art such as myself would have been motivated or encouraged to combine Bason with Allsop at the time of the invention of the '631 Patent.

97. Petitioners have failed to explain why a person of ordinary skill in the art would have been motivated to make the asserted modification to Bason and reasonably expect success in doing so. For example, Petitioners argue that “the prior art explained that the fewer components and tolerances that needed to be modulated, the more accurate and reliable a device would be.” But Bason teaches away from the concept of fewer components, expressly teaching that “[p]referably, the entire device with the possible exception of spring 3 is made from individual pieces.” Ex. 1007 at 3:58-60.

98. Petitioners do not provide enough description of their proposed combination of Bason and Allsop to enable a person of ordinary skill in the art to understand the design concept, the interworkings of the device, or how the combination would successfully operate. Petitioners state that a person of ordinary

would have been motivated to “move the Bason dose counter below the Bason canister” and/or “integrally mold[] the teeth 2 into the inhaler housing.” Petitioners also state that all of the components of Bason would “retain[] their same functions” in the proposed combination. However, Petitioners’ suggested modifications would require that numerous components of Bason’s dose counter be completely redesigned, especially given the differences in how Bason and Allsop are respectively organized around the medicinal canister. Whereas Allsop teaches a device organized concentrically around and beneath the canister, Bason teaches a device that is confined within a cap attached to the base of the canister at the top of an inhaler. Petitioners furthermore do not explain how or why a person of ordinary skill in the art would have been motivated to combine Bason with Allsop considering the potential numerous issues affecting the operability of Petitioners’ proposed combination, including: (1) how to modify the cap and other dose counter components to account for the valve stem needing to travel through the middle of the dose counter; (2) how to redesign the window 13 now that the dose counter is located below the canister; (3) how to redesign rings 4 and 8 to contain dose values viewable through a window in the side of the inhaler; (4) how to make teeth 2 engage with teeth 7 and teeth 14a now that they are no longer able to touch and now that rings 4 and 8 are no longer able to assemble due to the

central bush 15 having no point of attachment; (5) and how to modify the cap to be depressible when new teeth 2 are on the interior surface of the inhaler body.

99. In addition, Petitioners' proposed modification to Bason would render it inoperable for its intended purpose. For example, Bason's display window for viewing the number of doses remaining is on the top of the dose counter. *See* Ex. 1007 at Abstract ("Within the cap (14) is a pair of independently rotatable rings, each carrying on its upper surface indicia visible through a window (13) in the cap."). If a person of ordinary skill in the art were to remove the counter from the top of the canister and place it below the canister, the display window would no longer be a portal for viewing the number of remaining doses. It would instead show the top of the canister, and there would be no way to view the remaining doses from the side of the inhaler body. It would not be possible for a user to view Bason's dose values through window 13 without redesigning the structure of the rings 4 and 8, central bush 15, Curved Arm 6, Pawl 5, downwardly directed wall 12, and radially inwardly directed kink 26. The counting mechanism would be completely useless for its intended purpose, as the patient could not see the number of doses remaining in the inhaler. Ex. 1007 at 1:15-20.

100. In view of the above problems, I do not believe that a person of ordinary skill in the art would not have had any motivation to make the proposed

modifications to Bason in consideration of Allsop and reasonably expect any success in doing so.

IV. Secondary Considerations of Non-Obviousness

101. For nearly fifty years before the invention of the dose indicator device as claimed in the '631 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 '631 Patent were aware of this problem, and yet were unable to create a satisfactory solution.

102. 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 '631 Patent. And MDIs had been available for nearly fifty years before the final Guidance was issued. The '631 Patent therefore clearly addressed the long-felt need in the industry for an accurate dose counter that avoided undercounting.

103. In my opinion, a person of ordinary skill in the art would not have combined Bason with Rhoades or Bason with Allsop. And if a person of skill in the art were lead to these combinations, it is only through the benefit of the '631 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 '631 Patent. No one successfully combined these features until the invention of the '631 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, 2018

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

Charles E. Clemens