

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M COMPANY, MERCK & CO., INC. and
MERCK SHARP & DOHME CORP.,
Petitioner,

v.

APTAR FRANCE S.A.S. and APTARGROUP, INC.,
Patent Owner.

Case IPR2018-01054 (Patent 8,936,177 B2)
Case IPR2018-01055 (Patent 9,370,631 B2)

Record of Oral Hearing
Held: August 12, 2019

Before HYUN J. JUNG, SCOTT A. DANIELS, and
RICHARD H. MARSCHALL, *Administrative Patent Judges*.

IPR2018-01054 (Patent 8,936,177 B2)

IPR2018-01055 (Patent 9,370,631 B2)

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The above-entitled matter came on for hearing on Monday, August 12, 2019, commencing at 1:06 p.m. at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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(Proceedings begin at 1:06 p.m.)

JUDGE JUNG: This is the hearing for Cases IPR2018-01054 and 01055. Petitioners 3M and Merck challenge certain claims of U.S. Patent numbers 8,936,177 and 9,370,631, owned by Aptar.

Starting with Petitioner's counsel, followed by Patent Owner's counsel, please state your name for the record.

MR. MASLOWSKI: Steven Maslowski from Akin Gump for Petitioners.

JUDGE JUNG: Thank you.

MR. SKLAR: Ron Sklar from Honigman, also for Petitioners.

JUDGE JUNG: Thank you, Counselor.

MS. MOORE: Ashley Moore from McKool Smith, on behalf of Patent Owner Aptar.

JUDGE JUNG: Okay.

MS. HARGRAVE: And Ryan Hargrave with McKool Smith on behalf of Patent Owner as well.

JUDGE JUNG: All right. Thank you, and welcome. As stated in the hearing order each party has 90 minutes of total time to present its arguments. Petitioner will proceed first, followed by Patent Owner. Each party may reserve time for rebuttal. Please refer to your demonstratives by slide number.

1 And please do not interrupt the presentations to make an objection.

2 And the Panel realizes there is an objection by Patent Owners to Petitioner's
3 Exhibit slide 16. With all that said, Petitioner, Mr. Maslowski, you may --

4 MR. MASLOWSKI: With your permission, Your Honor, Ron
5 Sklar from Honigman will handle the '177 patent first. And I will handle
6 the '631 patent. And we would also like to reserve 30 minutes of our 90
7 minutes for rebuttal.

8 JUDGE JUNG: Okay. All right, Mr. Sklar, you may proceed
9 when you're ready.

10 MR. SKLAR: Thank you, and good afternoon, Your Honors. I'm
11 Ron Sklar. And I will be presenting on the argument on the '177 patent
12 today, on behalf of Petitioners.

13 Turning to slide 3, the Board instituted this IPR on the '177 patent,
14 which is entitled Fluid Product Dispenser. According to the specification
15 of the '177 patent, the patent is generally directed to a fluid dispenser having
16 a dose counter that functions in a reliable manner.

17 There are two grounds of invalidity. Both cover the same five
18 claims. And on slide 4 we've reproduced independent claim 1. We've
19 highlighted three of the requirements of claim 1. One, a fluid dispenser,
20 two, a dose counter, and three, wherein that dose counter functions during
21 incomplete strokes.

22 All of these elements were known in the prior art. And as we will
23 be discussing here in a moment, on slide 5 we see that fluid dispensers
24 having dose counters were known in the prior art. Likewise, we will

1 discuss in more detail in a moment that rotating mechanisms that function
2 during incomplete strokes were also disclosed in the prior art.

3 Turning to slide 7, in 2003 the FDA issued guidance to the industry.
4 Prior to 2003 there were no commercialized MDIs on the market. And by
5 MDI I'm referring to an inhaler, a metered dose inhaler.

6 There were no MDIs on the market that had an integrated dose
7 counter. In its final guidance the FDA told manufacturers to implement
8 that. So they had to integrate a dose counting device into the development
9 of their MDIs. And they had to make sure that those MDIs avoided
10 undercounting.

11 Two months after the FDA issued that final guidance, Aptar filed its
12 priority application to the '177 patent. So the final guidance was March of
13 2003. Aptar filed its priority application in May of that same year.

14 So with that in mind, turning to slide 9. What we haven't seen here
15 is any argument from Aptar that fluid dispensers having dose counters were
16 not known in the prior art. That has not been in dispute. Rather, they've
17 focused on Rhoades's disclosure of an incomplete stroke. And so we will
18 focus on that here as well.

19 On slides 10 and 11 we simply summarize the prior art combinations
20 in this case. On slide 10, for example, we show that in the Ground 1
21 combination a POSA would have taken the teachings of Rhoades and
22 combined them with the teachings of Elliott.

23 Likewise, on slide 11 we show that a POSA would have taken the
24 teachings of Rhoades and combined them with Bason.

1 On slide 12 we show that Rhoades discloses an incomplete actuation
2 stroke. So let me describe for a moment. We have a four figure sequence
3 on this slide. And this is showing the Rhoades pen mechanism moving
4 from the retracted position to the depressed position.

5 There are, the first and last figures on this slide are Figures 8 and 9
6 from the Rhoades reference. And then the middle two figures are
7 annotations from Mr. Piper, Petitioner's expert, to illustrate how the
8 specification of Rhoades describes that process of moving from the retracted
9 to the extended position.

10 Let me just briefly describe the three components that we see on this
11 slide. The cream-colored plunger that you see, and we'll just -- we'll focus
12 on the first figure in this sequence, Figure 8 of the Rhoades patent.

13 The first figure shows that there are cream colored fingers. That's
14 the plunger that you depress when you're activating your mechanical pen.
15 It moves up and down axially. The orange cam body, likewise, as the
16 plunger depresses down, it will force the cam body downward as well. At
17 some point the cam body can also rotate, and we'll discuss that too.

18 And finally, we see blue colored stop members. A line has been
19 drawn across this slide in red to indicate that the stop members are stationary
20 throughout this process. They do not move. The only two components
21 that move are the white fingers, or cream colored fingers, and the orange
22 stop members. Excuse me, the orange cam body.

23 Okay. Starting with Figure 1 in the sequence, this is the pen of the
24 Rhoades mechanism at rest. This is fully retracted. It cannot write in this

1 position. As you move to Figure 2, you see that the plunger has now been
2 depressed a little bit further. And likewise, the cam body has moved down
3 accordingly.

4 However, the cam body cannot rotate at this point. Because the
5 blue stop members are sitting within these grooves of the orange cam body,
6 preventing rotation.

7 Now, in the third figure in the sequence, we get to the point where --
8 exactly where the blue stop members are no longer residing within the
9 orange cam body, within the groove of the cam body. At this point the cam
10 body is free to rotate.

11 Now, Rhoades discloses that there's still further depression beyond
12 this point. And we see that in Figure 9 of Rhoades. So even after the cam
13 body is capable of rotating, the plunger can be further depressed.

14 In Figure 3, when the cam body begins to rotate, it will rotate up and
15 to the right, and slide along the bottom surface of those blue stop members,
16 just like you can see it sliding along the bottom surface of the white fingers
17 right now. As it rotates, it would slide along the bottom of the blue stop
18 members.

19 But in Figure 9, the last figure in this sequence, on slide 12, we see
20 that there's a gap between the blue stop members and the top of the cam
21 body. Now, recall, as I explained before, that the stop members are
22 stationary. So that gap could not have been formed by the stop members
23 moving up. Rather, they can only be formed by the plunger being further
24 depressed.

1 Aptar has not addressed Figure 9. By Aptar I'm referring to the
2 Patent Owner in this case. Aptar has not addressed Figure 9 of Rhoades.
3 Instead, Aptar has relied on a video, an animation from a website on
4 thekidshouldseethis.com.

5 Now, this video we've objected to as hearsay. But it's also
6 irrelevant because it differs from the disclosure of Rhoades itself. You can
7 see on the left hand side of slide 13 we have a figure, a screenshot from this
8 animation on thekidshouldseethis.com. And on the right hand side we're
9 comparing that to Figure 9 of Rhoades.

10 On the left hand side you can actually see that what the animation
11 shows is the orange cam body rotating and sliding along the bottom surface
12 of those blue stop members. It doesn't show that gap.

13 Figure 9 of Rhoades, which is the reference, the prior art reference
14 that Petitioners rely on, does in fact show that gap. In fact, excuse me,
15 Aptar's expert admitted that these two disclosures were in fact different.

16 Turning to slide 14. I'm not going to spend much time on this
17 because this relates to the animation on thekidshouldseethis.com, not the
18 Rhoades reference that Petitioners have relied on. But just wanted to point
19 out that even this animation is not being consistent with the idea of an
20 incomplete actuation stroke. There's still potentially additional room that
21 the plunger can be depressed beyond the point that's shown in the video.

22 On slides 15 and 16 what we show is that this idea of an incomplete
23 stroke works in both directions. So up until this point we've been talking

1 about the incomplete stroke on the actuation stroke, on the depression of the
2 plunger.

3 However, it works on the return stroke as well. And to be clear,
4 this relates to claim 2. We were talking about claim 1 before when we
5 were talking about the actuation stroke. On the return stroke now we're
6 talking about claim 2.

7 So if we look at the figure in the top left hand corner of slide 15,
8 what we see here is the plunger. And in this figure it's in green. We see
9 the plunger right before it's about to be released. Okay. The yellow cam
10 body will be rotating up and to the right. And the plunger, the green
11 plunger is going to be released.

12 For the yellow cam body to reset, the green fingers need to clear the
13 next vertical surface of the yellow cam body. And we've identified those
14 two surfaces, those two points, in blue circles on the left hand figure of slide
15 15 at the top.

16 Once the green fingers clear those two surfaces in blue, further
17 depression of the plunger will cause the cam body to rotate again. It
18 doesn't matter that the plunger hasn't been released all the way back to its
19 rest point. It's now sitting on top of the next horizontal surface, if you will,
20 or oblique surface. And further depression of the plunger will cause it to --
21 will cause that cam body to rotate.

22 We turn to slide 17 now. And on slide 17, this is the FDA guidance
23 that we looked at earlier in the introduction to this presentation. We've
24 again, you know, seen this before. But again, the FDA told manufacturers

1 in its final guidance in 2003 that they need to integrate dose counting
2 devices into the development of their MDIs.

3 On slide 18 we see that given this directive from the FDA, POSAs or
4 skilled artisans would have looked to rely on known mechanisms in the field
5 that had a similar, that had such a mechanism, that converted linear to
6 rotational motion, right? With linear motion pushing down on the canister
7 of the plunger, and then the rotation of the cam body once you clear the stop
8 members. You don't need to reinvent the wheel. You can look to these
9 known mechanisms in the art.

10 Also because the FDA is now telling manufacturers that you need to
11 do this in virtually all of your MDIs going forward, a POSA's going to be
12 encouraged to look for those known mechanisms in an area where they show
13 also the ability to mass produce those types of mechanisms.

14 Not only would a POSA have looked to those known mechanisms, in
15 fact Mr. Piper did look to that known mechanism. And we show that here
16 on slide 19. You can see that Mr. Piper, around 1998 was actually asked to
17 design and build a dose counter for an inhaler. And he did in fact look to
18 the mechanism of a pen for that purpose.

19 On slide 20 we see that Mr. Clemens, again, Aptar's expert in this
20 case, gave testimony in another action that contradicts Aptar's position here.
21 So in this IPR, Aptar argues that a skilled artisan would not look to the
22 known mechanisms of a pen for converting linear to rotational motion.

23 But in a prior case, again involving another medical device, this was
24 an injection device, Mr. Clemens was asked, are there other ways for

1 converting linear to rotational motion? And again, this medical device he
2 was talking about in the other case also converted linear to rotational motion.

3 He was asked, are there other ways of doing this? And he
4 responded, yes, there are other ways of doing that. I'm going to flip
5 forward for a moment to slide 21. And you can see what those other ways
6 were. He said you can do that through gearing, through the use of cams,
7 through the use of springs -- the very same mechanisms that we find in
8 Rhoades.

9 Now, flipping back to slide 20, what Mr. Clemens said is that these
10 are basic mechanisms. And skilled artisans, engineers take these basic
11 mechanisms and they apply it to whatever product they're working on. It
12 doesn't matter if it's not optimum for the case. Skilled artisans know how
13 to optimize those things. They can apply those basic known mechanisms to
14 whatever product they are working on.

15 Okay. Flipping to slide 26 now, we'll discuss some stuff about
16 analogous art. As the Board noted in its Institution Decision, a reference is
17 analogous if it is reasonably pertinent to the particular problem with which
18 the inventor is involved.

19 We've summarized here the evidence in this case -- some of the
20 evidence in this case that demonstrates that in fact the mechanism of
21 Rhoades was in fact pertinent.

22 First of all, we just discussed Mr. Piper's prior testimony that he,
23 excuse me -- his testimony in this case that he had in fact looked to the
24 mechanism of a pen when designing a dose counter.

1 As for Mr. Clemens, we'll flip forward to slide 28. Here we have
2 another piece of prior testimony from another IPR proceeding, from Mr.
3 Clemens. And this also concerned a medical device. This was a safety
4 mechanism for protecting a needle. And in that case Mr. Clemens testified
5 that such mechanisms can be found in the age old mechanism of a
6 retractable ball point pen.

7 On slide 29 we also see that there's reference to this in the prior art,
8 to the use of mechanical pens, or when looking to design a medical device,
9 in particular even when designing MDIs. So on slide 29 we see a reference
10 on the right that's being discussed.

11 You can see there that it is in fact an MDI, an inhaler. And it has
12 an indexing mechanism. And at the bottom highlight you can see the
13 patent notes that the device for rotating the rod is an indexing mechanism
14 much like that of a ball point pen.

15 Turning back to slide 22 now, we see that here Aptar argued that a
16 skilled artisan would not look to Rhoades because it does not require strict
17 tolerances. And as the Board noted in its Institution Decision, the
18 challenged claims also do not require expressly close manufacturing
19 tolerances.

20 However, a POSA would have known how to coordinate those
21 tolerances if desired in a particular device. And Mr. Piper provided
22 significant testimony on that point.

23 Now, Aptar has also argued, and now I'm on, excuse me, slide 23.
24 Aptar has also argued that Rhoades teaches away from the use of the

1 mechanism, the rotating mechanism in Rhoades, because it does not require
2 close tolerances.

3 But excuse me, but it doesn't discourage or discredit the use of close
4 tolerances. It simply says that it's not required for purposes of the pen.

5 But that doesn't mean that a skilled artisan would be discouraged from
6 taking that device, from taking that component and utilizing it, and
7 coordinating the tolerances as appropriate for the MDI. And we've cited to
8 a Federal Circuit case that upholds that this is not a teaching away.

9 On slide 24 what we've noted here is that Aptar argues that a POSA
10 would not have looked to Rhoades, because it has a double click design.
11 So by that I mean, you know, when you're activating your pen, you click
12 down once to put it into the writing position. You click a second time to
13 release it back to the retracted position. So two clicks per one full cycle.

14 In fact, as Mr. Piper explained, this double click inhaler would have
15 a number of advantages over current MDIs. And specifically that it would
16 avoid the loss of prime issue.

17 However, Mr. Piper also testified that if a single depressant release
18 inhaler were desired, a POSA would know how to do that. And he
19 described that. You see that on slide 25. He both described it in his
20 petition, and provided an illustration of what that could look like as well.

21 Okay. We're going to flip now to slide 30. And Aptar has raised a
22 number of operability arguments in this case. In doing so, it has ignored
23 *KSR*, and it has treated the skilled artisan as an automaton.

1 On slide 31 we see that not only has Aptar treated the skilled artisan
2 as an automaton in the context of these IPRs; however, it's applied a double
3 standard in the context of the Specification of the '177 patent, and its
4 prosecution history. Aptar applies a different standard to the skilled
5 artisan.

6 So you can see at the top of slide 31 we have a quote from the
7 prosecution history. The examiner had issued a rejection because certain
8 structures and connections between those structures had not been disclosed.
9 And Aptar told the Patent Office that those structures and connections do not
10 need to be disclosed. A skilled artisan would understand them.

11 Another example of this is at the bottom of slide 31. Here you can
12 see, now let me step back for a moment. To understand this, the FDA's
13 guidance, which required skilled artisans to put dose counters -- to integrate
14 dose counters into all of their MDIs going forward, Aptar's expert, Mr.
15 Clemens, admitted that such a modification to current devices would affect
16 the inhalation flow path of that device.

17 So as of the FDA's guidance, anyone who's going to follow that
18 guidance is going to affect whatever inhalation flow path already existed in
19 that device, and they would have to redesign a new inhalation flow path, or
20 at least reconfirm that it was accurate.

21 However, Aptar has criticized these IPRs for not describing how a
22 POSA would set the inhalation flow path, or has alleged that POSA would
23 be unable to set an inhalation flow path.

1 You can see at the bottom of slide 31, Mr. Clemens was testifying on
2 cross examination. He was being asked, well, in the context of the '177
3 patent, since this new modification that the FDA requires will in fact change
4 the inhalation flow path, how would a skilled artisan know how to do that?
5 Because the '177 patent's Specification does not describe that. And his
6 answer to that is, well, it would come from over 50 years of development of
7 metered dose fluid dispensing devices.

8 The Federal Circuit has told us that you cannot apply this type of
9 double standard. What's good for the goose is good for the gander. So if
10 you did not provide that type of detail in your Specification, you can't be
11 heard to complain that the prior art also does not provide that level of detail.

12 We're going to briefly discuss objective indicia of non-obviousness.
13 Aptar has raised two issues in this IPR. And this applies to both patents --
14 both the '177 patent and the '631 patent that are at issue in this hearing
15 today.

16 Now, on slide 42, here we are responding to Aptar's argument
17 regarding long felt need. And there was no long felt need. The FDA
18 guidance was published in 2001, was draft guidance. And 2003 was the
19 final guidance.

20 Aptar admitted that it was simply answering the FDA's call. That's
21 not a long felt need. That is a shortly felt regulatory requirement, and that
22 is explained in the *Ecolochem* case that's cited on the bottom of page 42.

23 Finally, the other secondary consideration raised by Aptar was
24 failure of others. And quite simply, Aptar has put forth no evidentiary

1 support to suggest that anyone else in the industry tried and failed to achieve
2 this.

3 If Your Honors have any questions, I would be more than happy to
4 answer them. Otherwise I would turn over the floor to my colleague, Mr.
5 Maslowski.

6 JUDGE JUNG: I have no questions, Mr. Sklar.

7 MR. SKLAR: Thank you, Your Honors.

8 MR. MASLOWSKI: Good afternoon, Your Honors. Again,
9 Steven Maslowski for Petitioners. I'm going to start with slide 44 and the
10 '631 patent.

11 Now, we have four grounds of institution for the '631 patent. Two
12 grounds of anticipation and two grounds of obviousness. And before I get
13 to the specifics of those, just a quick mention about the claims. On slide 45
14 here we have independent claim 1 and dependent claim 2. There are two
15 independent claims and two dependent claims at issue in this patent.

16 Now, claim 1, independent claim 1 defines various structural
17 elements. For example, it talks about a first member, a second member,
18 broad structural elements. It talks about a stationary body. It talks about
19 a fluid reservoir. And then it simply talks about the way those structural
20 elements move relative to each other. So there's no mention of incomplete
21 actuation or return strokes in the '631 patent. So in some respects it's a
22 little simpler.

23 On slide 46 we have claims 3 and 4. And independent claim 3 is
24 very similar to independent claim 1. Again, structural elements and simply

1 defining the way that these different members, for example, move relative to
2 each other in the reservoir and the other various components.

3 So starting with Ground 1. Ground 1 of the '631 patent is that
4 claims 1 to 4 are anticipated by Allsop. There are two primary disputes
5 with regard to Allsop, and we've bucketed them this way. One is the push
6 button cap, the so called first member that Petitioners are pointing to. And
7 the second is the displayable dose value limitation.

8 Now, first Aptar takes issue with whether the push button cap of
9 Allsop is enabled, and also whether and how it would operate. So let's look
10 at those issues. I'm going to jump ahead to --

11 JUDGE JUNG: Mr. Maslowski --

12 MR. MASLOWSKI: Yes.

13 JUDGE JUNG: Before you go on, do you agree with Patent
14 Owner's contention that the Board need not resolve any dispute about
15 ordinary level of skill in regard to -- for these two cases?

16 MR. MASLOWSKI: I do agree with that for one primary reason,
17 which is that regardless of the specific definition we want to give to that
18 person of skill in the art, I think we know from the '177 patent prosecution
19 history what that person knows.

20 JUDGE JUNG: Okay.

21 MR. MASLOWSKI: So Aptar's admissions in the '177 file history
22 sort of carried the day, in terms of what the person of skill in the art,
23 regardless of number of years of experience we want to give them, what they
24 know, and what they're able to do. So I think that's the important point.

1 JUDGE JUNG: Okay. Thank you, Mr. Maslowski. And second
2 question, do you also agree with Patent Owner's contention that no claim
3 terms have to be construed to reach the final written decision in these two
4 cases?

5 MR. MASLOWSKI: Yes, we do agree with that, Your Honor.
6 Based on the positions that they've taken, we do not believe that any claim
7 terms require construction.

8 JUDGE JUNG: Okay. Thank you, Mr. Maslowski.

9 MR. MASLOWSKI: So we're on slide 49. And I'd like to look at
10 the push button cap issue first. And Aptar says Allsop does not enable the
11 push button cap. So let's look first at what Allsop says about the push
12 button cap.

13 So Allsop says, a push button cap, not shown, may be provided as
14 part of the main housing 10 to cover the upper portion of the pressurized
15 dispensing container 15. Advantageously, this prevents the ingress of dust
16 contaminants and moisture into the apparatus.

17 So Allsop says what the push button cap is, where it is, and what it
18 does. And Petitioner's expert, Mr. Piper, illustrated the push button cap of
19 Allsop, in green, as shown in the picture in the bottom right hand corner.
20 And to be clear, he added the green portion. He illustrated the push button
21 cap. It's a cap with a push button. Pretty straightforward.

22 The push button cap is the claimed first member in the '631 patent
23 claims. Now, let's look next at Aptar's depiction of the push button cap.
24 We're on slide 50.

1 The bottom left hand depiction is Aptar's expert, Mr. Clemens, and
2 what he views the push button cap to be. As you can see, it's a cap, but
3 there's no push button. There's nothing to push, nothing moves.
4 According to Mr. Clemens, Allsop doesn't describe how the push button cap
5 operates or how it connects.

6 But the portion of the Specification from Allsop that we just looked
7 at describes exactly that. It operates by being pushed. It moves axially.
8 It's located on top of the housing to cover the container, to prevent the
9 ingress of contaminants.

10 The lack of enablement argument from Aptar fails. And it is
11 simply that. It's argument.

12 JUDGE JUNG: Mr. Maslowski, before you go on. You said that
13 Allsop discloses that the push button cap moves axially. Can you pinpoint
14 where it says that, or where one of ordinary skill in the art would understand
15 that's being disclosed?

16 MR. MASLOWSKI: With respect to, I'll go back to slide 49. In
17 terms of where it's defined, and the function that it carries out. So in the
18 text it says, it's part of the main housing 10 to cover the upper portion of the
19 pressurized dispensing container. And that's where our expert, Mr. Piper,
20 has positioned it. And the push button is, you know, to actuate the device.
21 So to actuate the device without the push button cap, you push down on top
22 of the dispensing container. With the push button cap in place, one of skill
23 in the art, as illustrated by Mr. Piper, has shown that you push the button,
24 which pushes the canister, which actuates the device.

1 JUDGE JUNG: And I think your position is that this phrase push
2 button cap cannot be interpreted to mean a cap for a push button? So the
3 cap itself cannot be the push button?

4 MR. MASLOWSKI: I understand that Aptar made that argument.
5 But the device is still lacking a push button. So if it really is a cap that
6 covers a push button, then what's the push button? There is no push button
7 even in Mr. Clemens's depiction. He has a cap again. There's no push
8 button present.

9 JUDGE JUNG: Yes. You may go on.

10 MR. MASLOWSKI: So going back to the enablement argument,
11 Allsop has presumed enabled. And Aptar has not provided any evidence in
12 support of its non-enablement argument, and has certainly failed to
13 undertake an analysis --

14 JUDGE DANIELS: I'm sorry. Before we -- can you guys hear
15 me okay?

16 MR. MASLOWSKI: Yes, Your Honor.

17 JUDGE JUNG: Yes.

18 JUDGE DANIELS: This is Judge Daniels. Sorry, Mr.
19 Maslowski. Before you go on, couldn't it -- if I'm understanding this push
20 button discussion that we just had, is it your position that a push button cap
21 as described in Allsop is intended to push down? There's a physical
22 connection between the dispenser inside and the push button cap, so that the
23 user actuates that push button cap, and it pushes down, and then hence
24 pushes the dispenser, which actuates? Is that your all's position?

1 MR. MASLOWSKI: That's exactly right.

2 JUDGE DANIELS: And then, and my -- they can answer this
3 question when it's their turn. But couldn't it be that the, what Patent
4 Owner's position here is that the cap is just pushed into place to cover the
5 device? I mean, I don't see anything that the push button in their
6 description that tells me that the push button is pushing down on the
7 dispenser.

8 MR. MASLOWSKI: That is, it's our position --

9 JUDGE DANIELS: Does it cover the upper part? Go ahead.
10 Sorry.

11 MR. MASLOWSKI: Sure. Our expert, as one of skill in the art,
12 understands this teaching to be that the push button cap is part of the
13 working device. So it's there to coexist during operation of the device.
14 And so it covers the upper portion of the container.

15 And again, I would understand Mr. Clemens's position to be right if
16 it was just a cap. So if there was a cap to enclose the device, to keep it
17 clean, or something like that. But it's a push button cap. So our expert
18 has interpreted the extra component of button.

19 There's a button. And under a normal interpretation, a button
20 means, you know, activating that button to actuate that device. So it's sort
21 of a combination of two things. It's a cap, a cap that has a push button -- a
22 push button that resides on top of the canister to allow actuation.

23 JUDGE DANIELS: Got you. Perfect. Thank you.

1 MR. MASLOWSKI: Okay. So we'll move on from the push
2 button cap as the first member limitation, and jump to slide 52. And
3 another dispute with regards to the push button cap is whether the push
4 button cap engages the second member, the inner housing in Allsop.

5 And again, along these same lines, Aptar contends that Allsop
6 doesn't teach that limitation, because the push button cap does not engage
7 the inner housing. And just to be clear, again, the push button cap is the
8 first member. The inner housing is the second member of the claims.

9 And as Mr. Piper explained in his opening declaration, Allsop
10 teaches engagement of the inner housing by the push button cap. The first
11 member, or push button cap as we've discussed, pushes down on the
12 canister, thereby engaging with the inner housing and causing it to move
13 axially downward.

14 That meets that limitation of the first member engaging the second
15 member. So unless there are further questions, I'll move on from the push
16 button cap and go to slide 53 for the second primary dispute with regards to
17 Allsop, which relates to the displayable dose value limitation.

18 To be honest, I think there's some confusion on this one, because
19 there have been attacks from Aptar in the briefing that Allsop doesn't teach
20 displayable dose values, whereby values are hidden and then only become
21 apparent through a slot or similar structure.

22 And Allsop discloses two separate ways to do the displayable dose
23 values. And it's our position that either one meets the claim limitation.

1 But let's go to the second one, which is directly on point with the arguments
2 from Aptar on this claim element.

3 And what Allsop says with respect to displayable dose values is that
4 the ring 160 may be replaced with a series of numbers or other markings.

5 And then it goes on to say, spaced such that only a single number or marking
6 is visible at any one time through the slots 170. That's the displayable dose
7 value limitation right there.

8 And one more note with regards to this disclosure is that Allsop does
9 say the rings 160 may be replaced with a series of numbers or other
10 markings. So Aptar has made various arguments with regards to the
11 operability of Allsop.

12 Contending, for example, that the push button cap would interfere
13 with the rings, and the whole device wouldn't work. Allsop also teaches,
14 you don't even need the ring. You can simply put the numbers on the inner
15 housing and make it work.

16 I'd like to move on to Ground 2. Ground 2 is that claims 1 to 4 are
17 anticipated by Marelli. There's one dispute with regards to Ground 2, and
18 that relates to the claim limitation, a second member that is displaceable
19 axially and in rotation relative to the stationary body.

20 And moving to slide 55, the dispute on Marelli relates to Aptar's
21 contention that it says, Petitioner has defined the second member as rotating
22 element 9, and nothing else. That's not true.

23 The Petition, which is in the top right hand box, we've quoted part of
24 it there, says Marelli teaches a rotating element 9, second member.

1 Rotating Element 9 is integral with small flexible legs 16. The Petition
2 goes on for almost an entire page of text after the quoted portion on slide 55,
3 to discuss the operation of the integral legs, and how they operate to move
4 axially and in rotation.

5 And if there was even a question about whether the Petitioners were
6 counting legs 16 as part of the second element, then the analysis of '631
7 patent claim 2 ends this dispute once and for all. Claim 2 of the '631 patent
8 requires that the second member comprise at least one multi toothed gear.

9 Petitioners and their expert pointed of course to the integral legs 16
10 as the multi toothed gear of the second element of claim 2. And that's on
11 page 49 of our Petition. This should resolve the sole dispute about whether
12 Marelli -- or whether Petitioners have contended that Marelli, and the second
13 element of Marelli, includes the flexible legs 16.

14 I'm going to move on to Ground 3. And I'm now on slide 57. And
15 slide 57 is a brief introduction to Ground 3, which is obviousness based on
16 the combination of Bason plus Rhoades. And as explained in Petitioner's
17 evidence, a person of ordinary skill in the art would have been motivated to
18 improve the teachings of Bason in view of a reference like Rhoades.

19 That improvement would have included making the gear teeth of
20 Bason integral in the wall like the pen in Rhoades. And we've discussed
21 some combination, or discussed this exact combination with respect to the
22 '177. So I won't get into the technical details too much. But let me just
23 jump right to the -- what the disputes are with regards to the '631 patent.

24 So we've identified five issues in dispute here. There's a dispute

1 about motivation. And we'll get to that in a moment. The second and
2 third disputes on slide 58 refer to the Bason cap and the Bason gears. And
3 these are directed to Aptar's attacks, based on what I'll generally refer to as
4 the operability of the device.

5 In simple terms, Aptar suggests that if the gear teeth of ring 4 in
6 Bason are made integral in the wall of the device, the device won't work.
7 Petitioners -- or Aptar also contends Petitioners haven't provided detailed
8 drawings and the like to show that the combined device would physically
9 work. We haven't provided blueprints, engineering drawings to show that
10 the device would actually function as intended.

11 But that's the wrong standard. It's simply the wrong standard.
12 Under the proper analysis, according to *Graham* and *KSR*, if the record
13 shows that one, the references teach or suggest each limitation of the claim,
14 two, that a person of ordinary skill in the art would have had a reason to
15 combine the references, and three, that a person of ordinary skill in the art
16 would have had a reasonable expectation of success in combining them, then
17 the claims are unpatentable.

18 The Petition explains each of these three things. It walks through
19 the limitations and identifies where they're found in the prior art. It
20 explains why one would have been motivated to combine the references.
21 And it explains why a person of ordinary skill in the art would have been
22 able to do so, highlighting Aptar's admissions to that effect during
23 prosecution.

1 And with that, let's actually turn to some of Aptar's admissions
2 during prosecution. And before I get there actually, real quick, that there
3 was a rejection on Bason during prosecution, under 102. There was never a
4 rejection under 103.

5 Aptar made an amendment during prosecution to get over Bason by
6 adding a certain claim limitation. But there was never a rejection made
7 during prosecution under Section 103.

8 So turning to motivation. Again, the FDA guidance is the primary
9 motivation. It's been discussed in both Petitions in excruciating detail. It
10 was really sort of a watershed moment in the sense of, the FDA is the
11 regulatory body saying, now, industry, you must in all future MDIs integrate
12 dose counters. So it's really the first time manufacturers of drug products
13 are facing the prospect of having to incorporate dose counters into their
14 MDIs going forward.

15 And turning to slide 61, that the motivation evidence for improving
16 Bason to scale up mass production is there. Again, as proven by their -- or
17 as shown by the FDA push for manufacturers to go there, manufacturers are
18 looking for ways to mass produce these devices, do it efficiently, do it as
19 simply as possible.

20 And as Mr. Sklar has discussed, and I'll just briefly mention, a pen
21 type of device is exactly the type of device that a person of ordinary skill in
22 the art would have, and actually did look to when designing these types of
23 devices.

1 So let's look at slide 63, and be a little bit more specific about what a
2 POSA would have known and have been motivated to do in view of the
3 teachings of Bason and Rhoades.

4 So again, the FDA guidance is pushing for the mass production of
5 these, the requirement they need to be included. That requirement is
6 pushing a person of ordinary skill in the art, in view of a device like Bason,
7 to make it simpler. To take the stationary gear, to integrate it into the wall,
8 to make the device more economical, to make it easier to manufacture.

9 And in view of that, and in view of that motivation, the remaining
10 parts could be connected in the same way that they're connected in Bason.
11 Or as Mr. Piper expressly testified, they could be connected in other ways
12 well understood in the art.

13 Now, Aptar and its expert have ignored Mr. Piper's testimony on this
14 point. Instead, Aptar's response to the position is that -- in response to the
15 Petition is that if you move the gear to the wall, the cap won't move, and the
16 gears won't interact.

17 But a POSA knew exactly how to make that happen, just as Aptar
18 admitted during prosecution of the '177 patent. Now, let's look at what I'm
19 talking about. We can skip ahead to slide 65.

20 Aptar's position now in 2019 is that with the change that we just
21 talked about of moving the gear to the wall of Bason, that suddenly the
22 Bason cap does not meet the first member claim limitation, because the teeth
23 that would have been molded onto the inhaler body prevent the cap from
24 moving axially, as is required by the claim.

1 But in 2011 Aptar told the Patent Office that the details of known
2 structural elements for the connections between the reservoir, the body, the
3 actuator, and the counter element were intentionally omitted from their
4 patent.

5 Why were they intentionally omitted? Aptar explained, because
6 one of ordinary skill in the art would understand the structure and
7 connection of a body, reservoir, actuator, counter, and dispenser member.
8 Thus, specific structural connections need not be disclosed in the
9 specification.

10 Aptar's argument doesn't stop with just the cap. It makes a similar
11 argument with respect to the gears of the device. It says that -- Aptar says
12 that if Bason is modified as suggested by Petitioners, to move teeth 2 of base
13 1 to the inhaler body, then teeth 7 cannot engage teeth 2.

14 Again, what did Aptar say in 2011 specifically with respect to gears?
15 They said, one of skill in the art would have understood how to shape and
16 structure the gears, and their novel interaction with each other, in the
17 claimed invention. Again, one of skill in the art knew how to do this.
18 They knew how to make the connections, just as Mr. Piper testified to in this
19 case.

20 We'll jump ahead to slide 70. Although Mr. Sklar touched on it, I
21 think it's worth revisiting the *Epstein* case just briefly. Again, Aptar is seeking
22 to apply a double standard here. It's seeking to hold Petitioners to a standard
23 in their obviousness analysis that is nowhere close to the same standard that
24 Aptar claimed was necessary for its allowed patent.

1 Aptar was very clear that its patent need not describe how a person of --
2 need not describe how to connect components because a person of ordinary
3 skill in the art knew how to do it.

4 And in fact, its figures, which are shown in, two figures are shown on
5 the right hand side here of slide 70. Its figures are lacking in any sort of detail
6 as to how the components are connected.

7 Again, the two figures here, they don't get any better than this, quite
8 frankly, the two figures on the right. They're the only type of figures that
9 you'll find in the Aptar Specification. In Figure 1, for example, which is in the
10 top right hand corner, you see the canister, which is Number 2. It's floating in
11 the air. And in Figure 21, there isn't even a canister at all.

12 Yet Aptar argues that Petitioners invalidity case is inadequate, because
13 it claimed we didn't describe the obviousness combinations in sufficient detail,
14 or with drawings to show how the gears would interact. Aptar can't have it
15 both ways. *Epstein* makes it clear.

16 JUDGE JUNG: Mr. Maslowski, if we agree that *In re Epstein* applies
17 to the facts of this case, would you agree that we don't have to rely on the
18 arguments made in your reply?

19 MR. MASLOWSKI: Yes. If there are no other questions on
20 Ground 3, we'll move to Ground 4. I'll be quick with Ground 4. Ground
21 4 is that a POSA would have been motivated to improve the Bason device
22 by moving the counting mechanism, in view of the teachings of Allsop, to be

1 below the canister. That's what Allsop teaches. Allsop teaches rotation of
2 the inner housing by virtue of gears that we'll talk about in a second, that are
3 below the canister.

4 To highlight the disputes with regards to Ground 4, here it's much of
5 the same motivation to combine again the Bason cap and the Bason gears,
6 displayable dose values, which I will touch on just for a moment at the very
7 end. And again, secondary considerations, which my colleague, Mr. Sklar,
8 already covered.

9 I won't spend much time on the motivation. We've seen the
10 guidance multiple times. Maybe to jump ahead to slide 75. And on slide
11 75, just to reiterate the point of why. Why would one have -- one of skill in
12 the art have been motivated to do this? Motivated to move the counting
13 mechanism of Bason below the canister?

14 As shown in the bottom portion of slide 75, Allsop teaches integrally
15 molding the collar, which is the stationary gear in Allsop which drives the
16 rotation of the inner housing of the device. It talks about integrally
17 molding that piece, which again is below the canister.

18 And this is the same change we're talking about in Ground 4. The
19 same motivations, same teaching. Take the Bason counting mechanism
20 and move it below the canister. And moving the counter from the top of
21 the canister in Bason, and integrally molding the gears into the wall make it
22 more reliable, make it cheaper to manufacture. And that motivation was
23 certainly there from the FDA guidance.

1 And jumping to our last slide, slide 77. Aptar says again that a
2 POSA would not know how to configure their device to make it operable
3 once the dose counter is moved below the canister. Again, the prosecution
4 history tells a completely different story. And to be honest, or to be clear,
5 we haven't by far set out all of the examples of the statements in the
6 prosecution history on this issue.

7 We've made numerous mentions of many of them in our brief. But
8 I just want to make that point clear, that we're not sort of cherry picking
9 from small parts of the prosecution history. But in fact, this was a
10 consistent theme, and a consistent position from Aptar throughout
11 prosecution.

12 But on this point, in the Institution Decision at page 25 it points out
13 that, or it says, "We agree that Petitioner does not address expressly
14 modifying Bason further, so that the number of doses remaining would be
15 visible by also moving the window of Bason. At this stage, however, the
16 record indicates such a modification was known, and well within ordinary
17 skill."

18 So with regards to the displayable dose values, the Institution
19 Decision was clear. Yes, we did not expressly -- we did not address
20 expressly modifying Bason further so that the number of doses remaining
21 would be visible by also moving the window.

22 But at that stage the record showed that it was within the skill of the
23 ordinary -- a person of ordinary skill in the art. Nothing has changed. The
24 evidence hasn't changed. There's been no attack from Aptar that somehow our

1 definition of a person of ordinary skill in the art is somehow wrong, and that the
2 level of skill we've ascribed to that person is wrong. There hasn't been an
3 attack that somehow the prosecution history and all of the statements there are
4 somehow wrong, that a person of ordinary skill would know how to make these
5 types of changes. Nothing has changed.

6 So in the end, we respectfully request that the claims of the '631 patent
7 be held invalid on the four grounds that we've identified. And if there are no
8 further questions, I will take a seat.

9 JUDGE JUNG: I have no questions, Mr. Maslowski.

10 MR. MASLOWSKI: Okay. Thank you.

11 (Pause.)

12 MS. MOORE: Apologies for the delay. Thank you, Your Honors.
13 I will also reserve 30 minutes.

14 JUDGE JUNG: All right. Please proceed.

15 MS. MOORE: Thank you. I will also start with the '177 patent, and
16 will go in the same exact order that Petitioners have gone for their presentation.
17 So if we look here. Okay. So if we go to slide 2, we're looking at essentially
18 the Table of Contents.

19 We'll be discussing a combination of Elliott and Rhoades, which is
20 Ground 1. We'll be discussing Ground 2, which is a combination of Bason
21 and Rhoades. And then of course, we have four main disagreements for each
22 of these combinations that I'll walk through with you.

1 Ground 1 is Elliott and Rhoades. As you can see here, we have the
2 Elliott inhaler and we have the Rhoades pen. This combination essentially
3 requires all of the gearing on the left hand side of slide 3 to come out and be
4 replaced in its entirety with all of the gearing from Rhoades, which is on the
5 right hand side.

6 Here we have the details of the combination. Again, swapping out.
7 On slide 4, we show Rhoades swapping out the cam body for the counting
8 mechanism of Elliott. We're going to mold stop members onto the Elliott
9 inhaler body.

10 And then everything else should function essentially in the same
11 way. We've pointed out a number of deficiencies. And of course,
12 Petitioners in their reply added some additional details.

13 I'd like to start with the stationary body element. We are going to
14 look at three problems for this particular claim element. And if we're
15 looking at slide 7, I've shown here what is the Elliott and Rhoades
16 combination.

17 To our understanding, there are stop members which are shown in
18 purple on each side of the inhaler body. There's the cam body, which is in
19 this yellow-orange color. And then of course, we have the exterior inhaler
20 body in blue, and the reservoir in red.

21 Now, we take issue with the operability of this particular
22 combination for a few reasons. And the problem all stems from the stop
23 members being molded into the side of the inhaler body. We contend that
24 this is complicated and expensive.

1 It defeats the entire purpose of the motivation to combine, which is
2 to make it cheap, make it easy, have fewer parts. This is the exact opposite
3 of that. It's complicated. It's more expensive. And then of course two
4 additional reasons, which are, it interferes with the flow path of the inhaler.

5 And then of course, you can't get the cam body. You can't
6 assemble it. Because it must get past these stop members. And we don't
7 believe you can do that with this particular combination.

8 So we saw in Petitioner's reply, they suggest that these stop members
9 are going to be formed by having these mold arms, they're those orange
10 pieces on the side, essentially looking like toothpicks coming up through the
11 bottom of the inhaler. That's how the inhaler body is itself formed.

12 We believe that this is a complicated and expensive mechanism.
13 The tool itself obviously is complicated. You have to have these mold
14 arms inserted up in there. They are narrow. They're small. So they're
15 likely to bend. They're likely to break.

16 It's going to increase the maintenance of this machine substantially.
17 The cleaning aspects of the machine, which have to be done regularly, it will
18 have to be done much more precisely. And again, we have this issue of the
19 mold arms potentially bending or breaking. When you go to remove the
20 housing, you have to slide it up all the way above these mold arms. And
21 that's unlikely to happen without damaging them.

22 In response, we basically get one response to this argument, which is
23 the molding treatise that Mr. Clemens, our expert, cites to says, side action

1 tools can be avoided, in which case this would be a cheap, inexpensive
2 process.

3 That is truly irrelevant to what we're discussing here. We never
4 suggested that a side action tool is necessary for this molding process. In
5 fact, the reason it's expensive, the reason it's complicated is sheerly by
6 adding the mold arms themselves. And that is obviously part of this
7 combination. It's not eliminated. So it is an added expense. It's an
8 added complication.

9 And in fact, our expert, Mr. Clemens, says repeatedly in his
10 deposition that it's a large, non-zero effect on the cost of creating this
11 machine, maintaining this machine, cleaning this machine, and creating a
12 housing that actually will work for its intended purpose.

13 So second -- our second issue with this particular combination is that
14 once you have the resulting housing formed from these mold arms, you will
15 have two holes in the bottom of the inhaler housing. If we look at the
16 bottom right hand side of slide 9, for example, these holes could be one in
17 front of the valve block, one behind the valve block.

18 Well, what does that do? When an inhaler is dispensing
19 medication, and the user is inhaling, what will happen is that they will inhale
20 and pull fresh air from those holes into the inhaler. And it will disturb the
21 flow path. It disturbs the particle size. It disturbs the distribution of the
22 drug. And quite frankly, causes a lot of that drug to not even make it to the
23 user. And both parties agree that this is --

24 JUDGE DANIELS: Why wouldn't you plug those holes?

1 MS. MOORE: We didn't get that information from Petitioners.
2 They didn't make that suggestion, nor did they suggest any way that you
3 could do that after it's been assembled.

4 If you think about it, the way that the inhaler is assembled is you
5 have the inhaler body. You have a valve block, and then you'll have the
6 cam body, and then you have the canister, all sitting there.

7 So in order to assemble that device, and then put holes somewhere in
8 that inhaler body -- first of all, it wasn't described by the Petition or Mr.
9 Piper, and I don't think it would make sense for you to be able to do that the
10 assembly of the device. So --

11 JUDGE DANIELS: So you have a couple of other problems too,
12 right? I mean any time you put -- any time you plug a hole in something
13 that a medical patient is going to inhale, you've got a problem of something
14 being inhaled, correct?

15 MS. MOORE: Yes. Exactly, Your Honor. And then of course
16 we don't know what that would do to the inhalation path as well. Does that
17 stick up into the inhalation path and then cause further disturbance to the
18 particle size, and the ability for that medication to get to the user? And of
19 course the choking hazard, as you mentioned.

20 JUDGE DANIELS: But they have -- but they say this is easy.
21 And yet your position is that you'd almost invariably -- you would have to
22 have these holes of some sort, to get these, for the arms, right?

23 MS. MOORE: Exactly, Your Honor. The way that these devices
24 are molded is that you have this orange piece on the exterior, with the mold

1 arms coming up through it. And then you have the mold core, which is the
2 bright yellow in the middle, that you vice down and basically create a
3 container.

4 And then inject -- plastic is injected into that mold, and fills every
5 crevice that is not already occupied by the mold cavity, the orange pieces, or
6 the mold arms, or the mold core. So it is -- by necessity you will have
7 these holes in the bottom of the device.

8 JUDGE DANIELS: Okay. Thank you.

9 MS. MOORE: Yes, Your Honor. And going back to the holes
10 there causing this problem, both parties agree that this is critical for the
11 medicine to get to the patient correctly, and to not disturb what is going on
12 with this inhaler, and as the medicine is coming out of the inhaler.

13 For example, our expert, Mr. Clemens, said at Paragraph 51 that this
14 was a critical component, and that's why this combination wouldn't work.
15 And Mr. Piper, in his deposition at page 139 said that, I would agree that the
16 particle size emitted by an MDI affects the deposition rate of the patient,
17 thus the efficacy of the medication.

18 And then again at page 140 he said, there are components of the
19 spray pattern that could be varied substantially enough that they would have
20 a bigger impact on the efficacy of the device as well.

21 So even Petitioner's own expert admits that this is a critical, critical
22 piece of how this device functions. And if it is disturbed in any way, it
23 renders the device inoperable for its intended purpose. And therefore it
24 cannot be an appropriate 103 combination.

1 Now, we heard from Petitioners, their first response to this is to then
2 point to the '177 patent file history and Specification, and suggest that
3 because we didn't preempt this argument there, that somehow we have
4 foreclosed our ability to argue this particular combination is inoperable.

5 And they cite the *Epstein* case, which Your Honor mentioned a
6 moment ago. The *Epstein* case is utterly irrelevant to our particular fact
7 pattern here. The *Epstein* case related to the enablement of a single piece
8 of prior art. And therefore, the same enablement standard was applied to
9 both the patent at issue and the piece of prior art.

10 The distinction here is that we're arguing about a 103 combination.
11 And then how do you combine these two things together? And then how
12 do you get over the significant problem that we identified? And that is
13 Petitioner's burden to do, regardless of what the contents of the file history
14 are.

15 Of course Aptar cannot anticipate ten years into the future we're
16 going to be involved in the litigation involving a certain number of patents,
17 and how they might be combined, and need to foreclose all of those
18 arguments by including them in either the specification or the file history.
19 That's just not what the *Epstein* case stands for. So that's the first reason
20 that that particular argument is incorrect.

21 And of course the underlying premise that the '177 patent or the '631
22 patent don't disclose the relevant details is also incorrect. The '177 patent
23 has 17 pages of typed text that's telling us what that invention is. It has 21
24 figures. We obviously got nothing close to this level from the Petitioners.

1 We got less than half a page, and not a single figure. That's certainly not
2 enough narrative explanation. And we had no way to discern what exactly
3 would be happening here. And of course, we still haven't heard today.

4 Petitioners have that burden. They have the burden to prove
5 obviousness. They have to provide more than conclusory testimony. Our
6 briefing is replete with that point and case law supporting that point. That's
7 all we got: conclusory testimony.

8 And despite having three opportunities to tell us how to fix this
9 problem in their Petition, their Reply, their Sur-Reply, we still don't know
10 what the answer to this question is.

11 And then finally, the last problem with this particular issue of
12 combining these two is the assembly of the device itself. We have the cam
13 body. I'm on slide 10. And the cam body in orange, and we have the stop
14 members in blue, molded to the sides of the inhaler.

15 If you push down on that cam body on a rigid plastic piece, and
16 you're trying to pass by these stop members, it's going to create hoop stress
17 and bending stress along that point, where you're trying to vice that cam
18 body past the stop members. That is going to damage the cam body,
19 damage the stop members, or damage the inhaler body.

20 All three of those things are just critical to the performance of the
21 device. If any one of them are damaged, it's not going to count the doses
22 correctly, or if the inhaler body is damaged, again, we're injecting fresh air
23 into this process, and that medicine isn't making it to the user.

1 For this reason, again, we have no explanation from Petitioners how
2 to fix this problem. So it's inoperable. And because it's inoperable, it
3 cannot form the basis for obviousness.

4 Here we have a couple of quotes that support that proposition on
5 claim -- on slide 12, the *General Electric*. It just says, rejections on
6 obviousness grounds cannot be sustained by mere conclusory statements.
7 Of course, that's what we believe we have here. With that I will move on
8 to --

9 JUDGE JUNG: Ms. Moore, before you move on, I'd like to talk
10 about the mere conclusory statements.

11 MS. MOORE: Yes.

12 JUDGE JUNG: What exactly are the mere conclusory statements?
13 Is it the reason to combine? The motivation? Is it how you actually put it
14 together? Is that what you think is conclusory?

15 MS. MOORE: So it's a combination of things. First of all, it's the
16 description of the combination itself and how all the pieces would work
17 together.

18 And then of course for the three issues that we identified in the prior
19 set of slides, it's how are those items dealt with, if at all.

20 And the seeming reaction from Petitioners is that, oh, a person of
21 skill in the art could figure it out. I don't have to tell you anymore a person
22 of ordinary skill in the art could figure it out. That is not the case law.

23 We have an *Albritton* case which says that when structural details
24 regarding the proposed combination, merely surmising that one would have

1 understood how to do it, it's too thin a reed to support a conclusion of
2 obviousness.

3 And I think that's the level that we've gotten here from the
4 Petitioners.

5 JUDGE JUNG: But just to -- just so I understand your position.
6 You're not really disputing that there is a lack of motivation to make a
7 combination, or that there's not a substitution of some kind. I think you're
8 disputing that it just can't be done by one of ordinary skill in the art.

9 MS. MOORE: It can't be done by one of ordinary skill in the art, or
10 at the very least Petitioners haven't explained to us how to do it.

11 JUDGE JUNG: Okay. And do you believe, for example, in the
12 previous slides, hoop stress, stress energy, all that kind of stuff, is that
13 beyond the asserted ordinary level of skill?

14 MS. MOORE: The identification of the problem is certainly not
15 beyond one of ordinary skill. But the problem that then is, okay, this isn't
16 going to work, how do I make it work? And we didn't get that information
17 from Petitioners. And the way that the device has to be assembled prevents
18 one from actually making it work.

19 So it's just a fact of these two particular references and trying to
20 combine them. Maybe it's the fact that Rhoades is a pen and wasn't
21 intended to be used this way. Maybe it's something else. But in any
22 event, the Petitioners haven't told us how to do it.

1 JUDGE JUNG: And so as the consequence of your arguments, you
2 would agree that it's beyond the ordinary level of skill to actually assemble
3 the components in the manner proposed by the Petitioners?

4 MS. MOORE: Correct.

5 JUDGE JUNG: Okay.

6 MS. MOORE: So with that, I'll move on to the next claim element
7 that we believe is not met by the combination of Elliott and Rhoades. It is
8 listed here in slide 11. It is a counter element that is displaceable axially
9 and in rotation relative to step body (phonetic).

10 The issue we have here with this one is that I think both parties are in
11 agreement. Bias force or a bias mechanism is necessary to hold all of these
12 components together so that when you press down on something, it forces
13 other things downward, and then the cam body can rotate. That's just a
14 requirement of these two combinations. You have to have that particular
15 bias force in order to make it work.

16 In Elliott, that particular bias mechanism was a bell crank. In
17 Rhoades, it's a series of two springs, one above the mechanism and one
18 below. And of course, as you'll see as the theme of our discussion
19 today, the Petition doesn't mention any of that at all. It doesn't talk about
20 the bias mechanism that would be needed. It doesn't say whether it's a bell
21 crank or a spring, or a series of springs. So we were forced to guess at
22 what that might be and respond accordingly.

23 And Petitioners today have said that this not a big deal because the
24 POSA isn't an automaton. They would have been able to figure it out.

1 And while it is true, a POSA is not an automaton, they're also not expected
2 to be a mind reader.

3 This comes back to the same point we were discussing a moment
4 ago, which is that if you're going to have an obviousness combination as I'm
5 showing here on slide 12, you have to have some articulated reasoning.
6 You have to have some rationale. You have to explain it in some amount
7 of detail.

8 Again, the *Albritton* case says if you're missing the structural details,
9 it's too thin a reed to support an obviousness combination. And this really
10 is the point we're making. We need more to understand what the
11 combination even is.

12 And of course, had you provided that detail in the first instance, you
13 would have understood these problems with your combination and told us
14 how to fix them if it were possible. And they didn't. So we believe that
15 this is not described in any detail, this counter element in the bias force in
16 the petition.

17 So in the Reply, we heard from Petitioners that obviously it would be
18 a spring. We would put a spring at the bottom of this inhaler device. This
19 also fails on the merits.

20 You see here in slide 13 on the right-hand side, we have one of two
21 options where the spring could be. The spring could be around this valve
22 block here. But even Petitioners concede that when it's placed around the
23 valve block, it's going to prevent the medicine from getting out of the valve
24 and into the patient.

1 And so the other option -- so Petitioners concede that that one is not
2 correct, the one on the right-hand side. So Petitioners suggest that the one
3 in the middle with the spring around the valve stem is going to be the option
4 that would be employed in the Elliott and Rhoades combination.

5 However, this particular item also fails, as shown here in the middle
6 of slide 13, because the spring is going to provide additional force outward
7 between the valve block and the top of the canister, and then the valve stem
8 sits in between it.

9 When you do this, when you provide this additional spring distance
10 here, that is going to pull the valve stem out of the valve block. That is a
11 very big problem.

12 When the valve stem is not tightly fitted into the valve block, the
13 medicine, when it is dispensed, is going to hit the top of the valve block and
14 then blow back. It's going to rebound and not make it to the patient at all.

15 Even Mr. Piper, Petitioner's expert, suggested that you have to have
16 a very tight press fit for this canister and the valve stem to work.

17 And by putting the spring in this location, it's going to pull the valve
18 stem out. The medicine will not get into the valve block and be dispensed
19 to the user.

20 Petitioner's response to this is that a person of ordinary skill of the art
21 could have figured it out. The '177 patent doesn't describe the spring in
22 any detail, and therefore I don't have to either. That is essentially the
23 argument.

1 That's wrong for a couple of reasons. First of all, the premise is
2 wrong. The '177 patent does describe the spring. It describes it in several
3 locations. It's in each of Figures 9 to 21 of that patent. There are 12
4 figures that show where that spring is, show how it interacts with the other
5 components, show how it is used to accomplish the invention.

6 It's claimed in claim 10, and it's described in Columns 6, 8, and 9 of
7 the Specification. So we have a lot of detail about what that spring looks
8 like, where it goes, and how it works in the '177 patent. So to suggest that
9 because the '177 patent doesn't talk about it, so I don't have to either, is
10 wrong.

11 In addition, of course, Mr. Clemens's testimony is about Figure 5,
12 which happens to be one of the figures that doesn't have the spring. But
13 when you look at the totality of the patent, obviously we'd be able to figure it
14 out.

15 And then finally what's disclosed in the '177 patent has nothing to do
16 with the standard of obviousness and what's necessary for a combination,
17 and why this combination wouldn't work for its intended purpose. That's
18 not what the *Epstein* case stands for, as I mentioned previously.

19 For that reason, and because we still don't know even today how this
20 would be accounted for, how the spring would not operate to pull that valve
21 stem out of the valve block, we believe this combination is inoperable.

22 It wouldn't deliver the medicine to the user as intended, and it cannot
23 form a basis of obviousness as discussed here at these cases on slide 14. A

1 modification that renders the invention inoperable for its intended purpose is
2 not obvious.

3 With that, I will move on to the next claim element unless there are
4 questions. Okay, the last one --

5 JUDGE DANIELS: Well, this goes along with -- it seems to go
6 along with your theme that while it may be possible, and a person of
7 ordinary skill in the art could do this, there's not enough detail in their
8 petition and perhaps in their reply -- depending on the amount of evidence
9 they have responding to yours -- that really explains that someone would
10 have done this. That seems to me to be what your theme is -- is that clear?

11 MS. MOORE: Yes. No one would have made this combination.
12 Because the moment you put these things together and you start recognizing
13 all of these problems, you wouldn't be led to this combination in the first
14 place.

15 And I think another component of that is that one problem then
16 cascades to another, to another, to another, until at some point you hit a
17 roadblock. And that's what has happened here.

18 JUDGE DANIELS: Thanks. Thanks.

19 MS. MOORE: So the last element I would like to discuss for this
20 combination is the incomplete actuation stroke. And I know it's been
21 boiled down to just those three words. It's obviously a little bit more
22 complicated than that. There are some interrelated portions of this claim
23 element that I'd like to discuss.

1 The '177 and '631 patents, they were designed to overcome
2 undercounting. What that means is when a user depresses on their inhaler,
3 not all the way, just a little bit, some medicine comes out, and then they
4 release it, the dose counter doesn't count it.

5 And they maybe do that three or four times, dispense a little bit of
6 medicine, pressing halfway but not all the way, and then releasing that
7 inhaler, and none of those doses were counted, at which point you get to the
8 end of the life of that inhaler.

9 It has no more medicine in it, but your dose counter still shows three,
10 four, or five doses left, which obviously can lead to a big problem for
11 someone suffering from a life-threatening illness.

12 Now, the '177 and '631 patents intended to address that. And this
13 claim element is how they addressed it. What they do is that there's an
14 incomplete actuation stroke, some medicine comes out. Even if you don't
15 press all the way and get that full stroke, the complete actuation stroke, you
16 will still actuate the dose indicator device. You will still turn that dial so
17 that you count the dose.

18 That is the critical piece or one of the critical pieces of this patent, is
19 that you're going to count the incomplete dose, so that at the end of the life
20 of the device, you may have a little bit of medicine left in there. But to be
21 safe, we're going to show it as zero.

22 Now, I'd like to start by saying this is very, very different from
23 Rhoades -- very different from Rhoades. We're on slide 17 now. And
24 Rhoades, first of all, is a pen. So you click that pen once, you can write

1 until that pen goes dry. It doesn't matter. So it has absolutely nothing to
2 do with doses or counting, or even caring how much information -- or how
3 much liquid is in the ink reservoir. So we're just not led to think about that
4 as a problem. And second of all, Rhoades doesn't prevent undercounting,
5 and it doesn't have an incomplete actuation stroke that results in counting
6 that dose. And let me explain why.

7 If we look at the left-hand side of slide 17, it's Figure 8 from the
8 Rhoades patent, we see the fingers, 43 and 44, they're identified in green.
9 You press down on the fingers that are green, and that in turn presses down
10 on the cam body, identified in yellow. And at that point, medicine will
11 come out.

12 Let's say you press halfway down to number 46 here. Press
13 halfway down, some medicine comes out, and then you release the plunger.
14 What happens? The cam body does not rotate. It hasn't gone far enough
15 to clear phase 58. It does not rotate. That dose was not counted.

16 There's another example. You press about 85 percent of the way
17 down, press to where it says cam body 20, that arrow in red, and then you
18 release. Medicine has come out, the dose was not counted, the cam body
19 did not turn. A user could do that until the container runs out of medicine
20 and not have turned the cam body once. It does not -- Rhoades does not --

21 JUDGE DANIELS: Ms. Moore, couldn't you make the -- well, I
22 actually have some questions for both you and Mr. Sklar about this
23 mechanism. But the one drawback to your argument here, and actually I'm
24 buying some of what you're saying, but the drawback here, right, is that the

1 actuator could be made -- the actuator that actually dispenses could be made
2 so that it doesn't dispense until later on in the axial movement, correct?

3 MS. MOORE: So if you're suggesting that you press that plunger
4 down, the cam body starts to rotate, and then the medicine is dispensed, is
5 that what you're suggesting?

6 JUDGE DANIELS: No, no. But you may press down on the cam
7 body, but the actuator it dispenses may not in fact be actuated until later on
8 in the stroke.

9 MS. MOORE: So if I understand the question correctly, that you
10 would create some kind of -- something in the valve stem that would make
11 that happen, I guess I would say, first of all, that's not described in the
12 petition nor in any of the Petitioner's papers where we could have responded
13 to that argument and asked my expert what his response to that argument
14 would be.

15 But I will suggest that if you're going to press down on these fingers
16 and actuate something, the way that Rhoades discloses it is that a full
17 depression causes actuation -- a full depression causes the pen to be in the
18 protracted state versus a retracted state.

19 So there isn't this concept of an incomplete stroke or a partial stroke,
20 because you either press it all the way, or you press it not at all, in which
21 case the pen doesn't come out. Does that answer your question?

22 JUDGE DANIELS: Right. And that goes to your point here
23 where it's the green fingers, and they're sliding down. And there's only
24 axial movement here, no sort of rotational movement. Then what you're

1 saying is there has to be some sort of dispensing of the product. And if
2 someone were to let up on those fingers, then there is no rotation of the cam
3 body which would not advance the counter.

4 MS. MOORE: Yes, Your Honor. That's it precisely.

5 JUDGE MARSCHALL: Could you address the --

6 JUDGE DANIELS: Okay, sorry.

7 JUDGE MARSCHALL: I'm sorry. Could you address
8 Petitioner's argument based on Figure 9 --

9 MS. MOORE: Yes.

10 JUDGE MARSCHALL: -- showing the gap between the bottom of
11 this stop and the top of the cam?

12 MS. MOORE: Yes. So let me address that in a couple of ways.
13 First of all, we've heard a lot about the gap in Figure 9. And what is it?
14 What it is is a full depression. The only description that we have, and it's
15 here at the bottom of slide 17, it describes a full depression which I'll explain
16 in a moment.

17 So there's nothing that discusses in Rhoades the ability to press
18 further once the cam body has started to rotate. There's no description of
19 that whatsoever. Rhoades does not suggest you press further.

20 And then second of all, what Figure 9 actually shows, if you were to
21 draw a horizontal line across Figure 9, and see the tip 58, where it aligns,
22 and where the bottom tip of the stop member aligns, you will see that they
23 are exactly at the same vertical distance.

1 So no vertical distance has changed in Figure 9. It's just showing
2 that the cam body has rotated a slight portion to the right.

3 JUDGE MARSCHALL: But as it rotates, it moves upward in the
4 figure, correct?

5 MS. MOORE: It moves upward in the figure, yes. Yes, Your
6 Honor.

7 JUDGE MARSCHALL: And so we're in a sense missing a figure
8 between Figure 8 and Figure 9, where the vertical edge of the cam is aligned
9 with the vertical edge of the finger, correct?

10 MS. MOORE: Correct. Yes, there are a series of steps that are
11 missing from Rhoades.

12 JUDGE MARSCHALL: Now, when those vertical edges are
13 aligned, wouldn't their contact point be below the bottom edge of the stop
14 member?

15 MS. MOORE: When the vertical edges of the finger -- or are you
16 talking about the stop member?

17 JUDGE MARSCHALL: The vertical edge of the finger and the
18 cam 58. When those edges are aligned, their contact point would be below
19 the bottom of the stop member 46, correct?

20 MS. MOORE: If you're referring to the color coded version from
21 their slide, that is the way that they have drawn it, yes. Is that the way that
22 it operates? No.

1 So the way that it operates -- and I think this is what was intended by
2 the figure -- is it just wanted to show the instant that the cam body starts to
3 rotate.

4 For example, if you were to look at the video or just look at these
5 figures here, you have a spring that's on the top, a spring that's on the
6 bottom. The moment that the stop member clears phase 58, the cam body
7 is forced to rotate. It is forced to rotate; it's instantaneous. You cannot
8 press further at that point because it's in the process of turning.

9 And that is not going to allow any downward movement or axial
10 movement. If you think about when you click a pen, you can't immediately
11 click it again and get additional force to be applied. Those springs absorb it
12 all, so there is no additional movement there.

13 And then also if you look at Figure 5 of Rhoades, it shows the pen in
14 the fully depressed state. The spring at the top is completely compressed.
15 Each of its coils is touching the coil below. There is no ability for that pen
16 to depress further. The coil is 100 percent compressed.

17 So any movement that's happening there, it's simply in Figure 9
18 showing the rotation. And we don't have any description of that in
19 Rhoades. We just simply do not have anything that tells us there's further
20 depression, that there's a gap, why there would be a gap, what that gap
21 represents. None of that's present in Rhoades.

22 It's all backfilled by Mr. Piper. And the reality is that's not how this
23 device would work when you take into account the springs. It just is not
24 going to allow that to happen.

1 I'd like to talk a little bit about why this is a full depression on slide
2 17. We have here a portion of the Specification on the right-hand side that
3 says we're going to talk about the axial distance between cam surfaces 52,
4 and bottom surfaces 53. So 53 is at the bottom; 52 is towards the top of the
5 cam body. The axial distance between those two that's identified by phase
6 58, that's defined here as a full depression, not a partial depression, not an
7 incomplete depression. It is a full depression.

8 And it defines it again later on in that same sentence by saying that
9 this full depression is what causes alternate pairs of cam surfaces and bottom
10 surfaces -- that's 53 and 52 -- to be engaged by the stationary stop members.

11 So it's simply defining that as the full depression. There's no need
12 to go further at that point. There's no need to press further. There's no
13 description of pressing further. That's the complete stroke. There is no
14 further stroke in addition to that one.

15 Do Your Honors have any other questions on incomplete actuation
16 stroke?

17 JUDGE JUNG: No, I have no questions.

18 MS. MOORE: Okay. The last point I'd like to make with Elliott
19 and Rhoades is that there's no reason to combine these. We've talked it a
20 little bit, but there's counting in Rhoades. There's no doses in Rhoades.
21 There's a protracted state, a retracted state, which Petitioner's would call the
22 double click inhaler.

23 We've not had either expert in this case say they've ever seen or
24 operated a double click inhaler. In fact Mr. Clemens suggests this is

1 contrary to the typical usage pattern, and a patient would not understand that
2 that is how to use an inhaler and wouldn't have used it that way.

3 And then of course we had some citations to Mr. Clemens's
4 testimony from a different case. That different case related to an EpiPen,
5 so it makes sense you'd look at a pen for an EpiPen.

6 An EpiPen is a retracted state to protect that needle and then you
7 protract it to deliver medication and then of course you retract it again so
8 that the needle is not exposed.

9 Makes sense that you would think of a pen with an EpiPen. Does
10 not mean that every other medical device should be considered a pen. An
11 inhaler, a scalpel, an MRI machine, a stent, there's no reason you would look
12 to a pen for any of those things.

13 With that, I will go to the next combination that's Bason and
14 Rhoades.

15 I'd like to note for the panel that we have a Bason and Rhoades
16 combination here for the '177 patent. We also have one for the '631
17 patent. They are drastically different.

18 In this particular one we are swapping out, we're bonding the cam
19 body to the canister and changing a lot of the gearing.

20 The way it works in the '631 patent is you essentially keep
21 everything the same, but just add stop members on the outside of the inhaler
22 body.

1 This means that it's not a predictable result. It's not a predictable
2 combination. You don't simply substitute one for another and have a
3 predictable result.

4 Clearly the same person looked at the same two references and came
5 to two different combinations. It's not a predictable result. There's no
6 reason to combine these in this way.

7 Again we have here on slide 21, the details for the combination and
8 of course we're going to bond the cam body into the base of the canister of
9 Bason. We will add guide members and stop members and then in the
10 Reply a series of additional changes are made.

11 Briefly, we have the same argument for the stationary gear. The
12 device inoperable for the same reasons. The mold arms, the ability to
13 assemble it. I won't go through that again in detail here.

14 We also have the counter element, and I will talk about that for a
15 little bit. So, the counter element is required to be bonded in this particular
16 example.

17 In which case not only the cam body has to turn, but the canister has
18 to turn and that's not the way that this is going to work in real life as you
19 may expect.

20 The MDI treatise that our experts cited, none of those canisters
21 rotated. They didn't suggested that they rotate and in fact, they wouldn't
22 rotate because it's critical, as shown here on slide 25, that you minimize
23 leakage. And that you maintain the force required to actuate the dose in
24 acceptable level.

1 Adding an additional layer of complication by trying to turn the
2 canister while keeping the valve stem stationary is going to introduce all
3 kinds of problems that will then cause leakage. They will cause these seals
4 not to work properly. Wear them out prematurely.

5 Petitioner's main response is that his expert could force a 20 year old
6 inhaler to turn inside the inhaler body. But that in no way proves that the
7 canister was designed to do that or that it wouldn't leak or that it wouldn't
8 cause a whole host of other issues.

9 Or that it in any way resembles either Bason or Rhoades, such that
10 it's a representation of the prior art or how that combination would work.

11 For that reason we believe that this particular element is not met.
12 The combination again is inoperable for its intended purpose.

13 The last claim element I'd like to talk about for this particular
14 combination is the cooperation claim element and also the incomplete
15 actuation stroke. The first portion of this claim element of slide 27 says the
16 counter element cooperates firstly with the stationary gear and secondly with
17 the reservoir.

18 I'm going to stop there and talk about this. Cooperation. Again,
19 in this particular combination the counter element or the cam body is
20 bonded, permanently glued to the canister so that it functions as one unitary
21 piece.

22 That's not cooperation. If you look in the patent Specification and
23 look you at the claims, you will see that the first gear cooperates with the
24 stationary gear.

1 Then the first gear will move and it no longer cooperates with the
2 stationary gear and then at Column 7, Lines 1 through 4 of the patent, the
3 first gear of counter element comes to cooperate once again with the
4 stationary gear.

5 It's cooperating, it ceases to cooperate, it cooperates once again.
6 That is not a description of two pieces that are permanently glued together
7 and function as one.

8 This particular claim element, the cooperation element, is not met by
9 the Bason and Rhoades combination.

10 And of course we have the incomplete actuation stroke argument
11 again, I won't go through it again in detail, but just to remind the panel.

12 The incomplete stroke shown here at 29 in the middle diagram, press
13 down on the plunger, dispense a portion of medicine, because the cam body,
14 or because the stop member in blue has not cleared the cam body, identified
15 with the green circle, the dose isn't counted.

16 It is not actuating the dose indicator device upon an incomplete
17 actuation stroke. It's a complete actuation stroke. Everything in Rhoades
18 describes it as a full depression.

19 I'd like to turn to the '631. Unless Your Honors have any questions
20 on the 177?

21 JUDGE JUNG: No. I have no questions.

22 MS. MOORE: Okay. We're at the '631 patent. It's a different
23 set of slides, so my slide numbering starts over, I apologize.

1 The slide 2 is our Table of Contents here. We're going to go again
2 in the same order that Petitioner's in all of the briefing.

3 We'll start with Allsop, go on to Marelli, and then go back to Bason
4 and Rhoades and Bason and Allsop.

5 Slide 3 we're showing the Allsop reference here. This particular
6 reference, it was considered during prosecution.

7 We see nothing new in what Petitioners raise that would suggest we
8 need to revisit the U.S.P.T.O.'s original decision that the '631 patent is valid
9 over this particular reference.

10 We'll start with the first member. Displaceable axially relative to
11 said stationary body. We believe this claim element is not met because the
12 cap is not enabled and even if it were shown, it would actually interfere with
13 the inner workings of this device and therefore not anticipate this particular
14 claim element.

15 So, if we look here at slide 6, this is the entire description that we
16 have for the cap. This is it. A push button cap not shown may be
17 provided as part of the main housing to cover the upper portion of the
18 pressurized dispensing container 15.

19 As Your Honors noted, it says cover. There's nothing about
20 pressing. There's nothing about pushing it. There's nothing telling you
21 how a cap, a push button cap would operate if it's supposed to operate
22 according to Petitioners.

1 The only thing it says further is that this prevents the ingress of dust,
2 contaminants and moisture into the apparatus. This is very similar to
3 another description in the Allsop patent.

4 It's for a mouthpiece cap. A mouthpiece cover. It says almost
5 identically the same thing and there's suggesting that a mouthpiece cap
6 would be any different from this cap here.

7 There's nothing suggesting it would actually be a press button or how
8 that would work if it were a press button.

9 All we have, again, are the vague intimations of an expert and his
10 testimony without any support in the actual reference itself. We believe
11 that this inappropriate. This is improper.

12 The case law prevents you from inferring any more than what's
13 actually described here, which is not enough.

14 If we actually look at what a cap might look like, we can see it here
15 in slide 7. If the cap were to be depressible, what you would see is that the
16 sides of it would that then try to fit between the outer housing in blue, the
17 inner housing in green.

18 It would try to recess in between those two things. It can't do that.
19 The pins and the ring, which are identified in yellow, are in the way.

20 So, if you pressed down on this press button or push button cap that
21 again, is not described in Allsop, it would either not allow you to press down
22 because the pins and the ring are in the way.

23 Or if you press down with enough force it would simply drive down
24 that ring and then inaccurately tell us how many doses are in the container.

1 As a result, we believe that this element is inoperable. It's not
2 enabled. It's not described and does not anticipate this claim element.

3 The second claim element that's not met by Allsop is the portion
4 here, the second member, and I'm going to focus on what's identified here in
5 bold and underlining.

6 The second member being engageable with the first member and the
7 stationary body. Again, on slide 11 we have a picture of Allsop.

8 The first member is this alleged push button cap. The second
9 member is the inner housing identified in green.

10 Petitioners haven't explained how that engagement occurs, what that
11 engagement is or how the two operate together or in competition with one
12 another.

13 We believe that the cap again, it would interfere with the inner
14 housing if it did anything at all. It would simply cause the inner housing to
15 rotate and inaccurately display the number of doses. In which case, the
16 second member is also not anticipated by Allsop.

17 The last element I'd like to talk about here is the displaying of dose
18 value. I'm on slide 11. So the claim line, which in particular is changing
19 a displayed dose value from among the plurality of displayable dose values.

20 The plain meaning of these words is that displayed and displayable
21 mean two different things. In Allsop's description all of the displayed
22 values are all displayed at the same time.

1 So we're not alternating from one. We have them all available to
2 us. So we're not changing a displayed value from among the displayable
3 values. As you can see here, all of them are available.

4 Petitioners' response that they raised is that, there is another
5 embodiment that says you could put the numbers or some markings on the
6 inner housing and have a slot and it would work.

7 First of all, again there's no description of that in Allsop. We have
8 no diagrams to show how that would work. But, it does tell you a couple
9 of things.

10 It says that you would have a helical dose pattern, which looks like
11 the left hand figure of slide 12 and it says you would have a slot 170, which
12 looks like the slot in the middle diagram of slide 12.

13 If you combine those two things together you're still seeing multiple
14 dose values at one time. If you move that slot 170 over on top of the left
15 most figure, you will see the number 200, the number 100 and the number 0.
16 All at the same time.

17 You click that dose counter it will show 199 and 99. Then it will
18 198 and 98. So, we don't believe it would work first of all, but even if you
19 were to make the substitution here, it still wouldn't meet the claim element.

20 Because you're not just displaying one value at a time. You're still
21 displaying all of the plurality of values. Not just one.

22 Unless there are any questions on that I'll move on to Marelli.

23 Okay. Marelli is an inhaler. It's a nasal spray and the USPTO considered
24 Marelli also during prosecution.

1 And just like with Allsop, Petitioners haven't offered anything that is
2 out of the ordinary in Marelli or something that would be different with
3 Marelli this time around, such that we should reconsider what the USPTO
4 found in terms of validity over the Marelli reference.

5 I'm going to focus on this particular claim element on slide 14. A
6 second member that is displaceable axially and in rotation relative to said
7 stationary body. We believe this element is not met by Marelli.

8 If we take a look here at slide 15, what we can see is that nasal 8,
9 which is in red, that is the stationary body, according to Petitioners and we
10 have a ring nut that's in blue.

11 That is the first member identified by Petitioners and then we have
12 green rotating element 9, which is the second member.

13 What's critical to point out here is that if nasal 8 is stationary as
14 Petitioners contend, than so is rotating element 9. It will not move axially
15 as required by the claims.

16 The reason being that these protrusions here on either side of rotating
17 element 9 essentially vice it into place so that rotating element 9 only moves
18 if nasal 8 moves.

19 And since they're supposed to be stationary, both elements will in
20 fact, be stationary according to Petitioners.

21 Even Mr. Piper, the expert on behalf of Petitioners, agreed with us.
22 He said that the protrusions, he called them shoulders in his deposition at
23 Page 125, encapsulate rotating element 9 so that it is roughly held in place.

1 And perhaps as a result of this admission, in the Reply, we get a
2 different combination. We get a combination that adds integral legs
3 according to Petitioners.

4 But let's look. Let's see what's in the actual Petition. They
5 suggest this isn't a new argument. It's a very new argument.

6 First of all, on slide 17 we see what they identify as the second
7 element, the second member that both rotates and moves axially.

8 They say rotating element 9. They don't say integral flexible legs
9 16. Also, these two diagrams on slide 17 are from their Petition.
10 Identified in yellow is rotating element 9. Rotating element 9.

11 And then underneath it says counter element. It would have been
12 very easy and either one or both of these diagrams, to simply highlight the
13 flexible legs. They're there. They could have done it. They didn't.

14 They didn't intend for the flexible legs to be part of this element.
15 This should not be considered. It is late. It is inappropriate to be
16 changing your theory in a Reply and we should not be looking at that here.

17 JUDGE MARSCHALL: Do you contest the fact that the flexible
18 legs move axially?

19 MS. MOORE: So, what I would say is that axial displacement, as
20 defined in the Specification, and as you can see in Figures 1 through 4 of the
21 patent, is the counter element, it displaces the whole thing.

22 It displaces axially. It's one rigid piece that displaces up and down.
23 That is different than what we have here with flexible legs.

1 Rotating element 9 never moves. Yes, the integral leg moves up
2 and down according to the ring nuts being pressed but that's still not axial
3 displacement.

4 That at best is flexing or squeezing or compressing a small portion of
5 a much larger piece. The overall piece does not move.

6 JUDGE MARSCHALL: But the movement of the flexible legs 16
7 is axial, even --

8 MS. MOORE: It is in part, yes it is axial and it also moves in
9 rotation. So, our main argument with this one is we don't get to have new
10 arguments in a Reply.

11 This isn't simply the same argument recast. It's a new argument.
12 It shouldn't be considered in Reply and then even if we want to consider it,
13 the rotating element 9 does not move axially and if you want to add the
14 flexible legs to it, rotating element 9 still does not move axially as a whole.

15 JUDGE MARSCHALL: Well, they do refer to the small flexible
16 legs 16 on Page 46 of their Petition and describe its movements.

17 Is it your argument that that is insufficiently detailed or that they
18 should have shaded it in a figure?

19 MS MOORE: It is insufficient. All they were doing is describe
20 how this entire process works to cooperate and create a rotation.

21 But when they were actually identifying what meets the counter
22 element, you can see here in figure 4, it says counter element is rotating
23 element 9.

1 We have the paragraph here that leads with rotating element 9,
2 second element and then the very last sentence that caps off that particular
3 paragraph you're referring to, and it's the last sentence before this figure,
4 says this axial motion causes axial movement of element 9.

5 It says nothing about the flexible legs. It would have been very
6 easy for them to put that in their petition. They didn't do it.

7 And I think it's because they didn't intend to do that until their expert
8 admitted that this rotating element does not move axially.

9 And this is precisely the reason that we have to have all of this laid
10 out in the Petition and not have the rotating or moving target that we have to
11 hit.

12 That slide 19, Petitioner cannot submit new evidence or argument in
13 Reply that could have been presented earlier. It's inappropriate. It's
14 against the statute. It's against the case law. We shouldn't be considering
15 it here.

16 With that I'll move on to ground three. It is another Bason and
17 Rhoades combination. Again, this one is different than the '177 patent and
18 for that reason we don't believe that it was a predictable result.

19 It wasn't known. There's no expectation of success when you
20 combine these two things. If you can end up with multiple different ways
21 of combining them.

22 On slide 21 we have the actual list of how we're going to combine
23 these things. We're going to extend the inhaler body, integrate a stationary

1 gear tooth 2 into the inhaler body and then the rest of the components would
2 act the same way.

3 We have a number of additions in the Reply that of course we
4 believe are inappropriate but they still don't remedy the basic problems that
5 we have with this reference.

6 So, I'll go to slide 23 now, which will preview the inoperability
7 argument for this particular reference.

8 Bason and Rhoades when you combine them, at least as we
9 understood it in our original Response, the teeth would be formed on the
10 inhaler body.

11 So, the teeth are identified in blue and the teeth 7 that have to
12 cooperate with teeth 2 in order to make the ring rotate, those are shown in
13 red.

14 So if you look, there's a significant distance between those two.
15 They cannot cooperate, they cannot touch one another.

16 So it doesn't matter if you press that cap or not, it is not going to
17 rotate and count the dose because the teeth do not touch one another.

18 And I'll explain this in a little bit more detail in terms of the
19 inoperability as we get to the second element because that's really where the
20 rubber meets the road on understanding why this is a problem.

21 The first member, I'd also to talk about that for a moment, it is not
22 met by the Bason and Rhoades combination.

1 What we have here is a cap which is alleged to be the first element
2 that moves axially, but in the original petition, all that was described is that
3 you're going to have the stationary gears, blue, attached to the inhaler body.

4 So when you press down on the cap it interferes with the ability to
5 press the cap down, it wouldn't work. Of course in Reply, the Petitioners
6 changed their argument.

7 They suggest a number of modifications to the cap. But at the end
8 of day, these additional modifications kind of create a cascade of problems
9 that ultimately cannot be resolved, such that this combination is workable.

10 It really comes into focus with the second member element. I'm on
11 slide 26. So that's the one I'm going to focus on here. Second member is
12 caused to be displaced axially and permitted to rotate.

13 We don't believe either of these things are accomplished because the
14 combination itself doesn't work.

15 Again, the original combination we have teeth 2 in blue being moved
16 to the inhaler body. Teeth 7 stayed where they were, which is on the
17 inside.

18 They can't touch. The dose counter can't rotate. They can't count
19 the doses. This combination is inoperable.

20 You can see it again here from a top view. These two things don't
21 touch. They can't rotate. Doses can't be counted. Device is inoperable.

22 In return, in their Reply they suggest, okay well you would just
23 move everything else out, we'd move the cap out of the way. We would

1 move the teeth out, we would expand ring nut, or ring 4, so that it would
2 meet up with these teeth.

3 That creates a whole other problem. If we look at how Bason is
4 designed, the teeth 2, which are identified in blue on slide 31, and teeth 7
5 then also have to cooperate with teeth 14a, that are identified in purple. So
6 basically, teeth 7 in red are sandwiched between lower teeth 2 and upper
7 teeth 14a.

8 And in order to rotate when the cap is pressed down, teeth 7 touch
9 teeth 2 and rotate partially, and then when the cap is released teeth 7 come in
10 contact with teeth 14a to rotate the rest of the way.

11 And if we move teeth 2 out to the side of the device, then obviously
12 teeth 7, we've already established, won't meet up and we can't have a
13 rotation.

14 The suggestion there is to move the ring out so that these teeth would
15 cooperate on the edge. Well, that then means that teeth 14a don't work
16 because they're not moved either. So we have teeth 7 and teeth 2 but the
17 inability to rotate the rest of the way because teeth 14a are not in contact
18 with teeth 7.

19 In addition to this, this combination wouldn't work because if you
20 expand ring 4, if you see the arm here 6 and pawl 5, those are necessary to
21 rotate the 10's and 100's counter ring 8, which isn't shown here but that
22 particular pawl, is what it's called in the reference, will make that other ring
23 rotate so that we count accurately.

1 If we're going to expand ring 4 then there's no space for that arm,
2 there's no space for that pawl. There's no ability to rotate the 10's and the
3 100's.

4 So, we're still left with an inoperable device and then on top of that,
5 if you wanted to try and move 14a, those teeth out to the side, they have to
6 be on top of teeth 7.

7 So, we now have teeth 7, which has the dose values on it and then
8 we'd have to expand bush 15 with teeth 14a. It would have to lay on top of
9 ring 4. So, it would cover up the dose values that are on ring 4.

10 So yet again, we have stumbled onto another problem that can't be
11 solved, which is no matter -- you want to move these teeth, they will not end
12 up contacting one another and still allow you to count doses. For this
13 reason that claim element isn't met either.

14 Ground four, Bason and Allsop, I'll touch on it very briefly. What
15 we have here in this combination on slide 36 is moving the dose counter
16 underneath the canister.

17 Of course we have a number of problems with this particular
18 modification as well. We have the same teeth not touching. If you move
19 teeth 2 then teeth 7 can't cooperate. If you move teeth 7 then teeth 14a
20 can't cooperate. If you try to move teeth 14a, which isn't something
21 suggested by Petitioners, then you cover up all the dose values and you can't
22 see them.

23 So, this particular claim element isn't met because the whole device
24 is inoperable. The first member is inoperable, as I've just explained.

1 The second member is inoperable for the same reason and then the
2 last element that I'd like to get to here is the displaying the dose value.

3 So when you move the device, or when you have the original device,
4 we have it viewable on slide 45, the dose numbers are viewable from the
5 top.

6 If you move that cap to the bottom, dose numbers are no longer
7 viewable in slide 46. They suggest again that this would be a simple matter
8 for a person of ordinary skill in the art to figure out.

9 You would simply move that window to the side, but that doesn't
10 solve the problem because what we've done is we now have put a cap on the
11 side. We now have ribs on the side. We now have a slot on the side.
12 We've expanded ring 4 to touch the side. We've expanded ring 8.

13 We now don't know where bush 15 is going to be and all of those
14 numbers are located on the top surface not the side surface. We have a
15 pawl and an arm that would be on the side.

16 We have so many components there. It is impossible for you to
17 create a surface by which you could put dose numerals and see them through
18 the side of the device.

19 As a result, this particular claim element isn't met as well and we
20 haven't heard anything from them to the contrary that actually explains how
21 this would work.

22 They could've explained it in the Petition, in their Sur-Reply, in their
23 Sur-sur-Reply. We didn't hear at all how this would actually work if you
24 sit down and put your pen to paper and do it.

1 And of course, for the same reasons there's no motivation to combine
2 Bason and Allsop. We've essentially taken Bason and completely changed
3 everything about it.

4 The cap isn't on the top, it's on the bottom. All the rings are
5 different. All of them function differently. The window's not on the top,
6 it's on the side.

7 And if you take a combination and you change the basic principles
8 under which the prior art was designed to operate, it fails to support
9 obviousness.

10 That's the *Adidas* case cited in our briefing and we believe that's
11 exactly what has happened here with the Bason and Allsop reference. With
12 that, I'll cede the floor.

13 JUDGE JUNG: Thank you.

14 MR. SKLAR: Thank you, Your Honors. Again, I will be starting
15 off with rebuttal arguments with respect to the '177 patent.

16 This is again a relatively straight forward obviousness case. Two
17 grounds. Both of the grounds rely on just two references.

18 Want to start off, we heard some arguments from the Patent Owner
19 regarding Rhoades's disclosure of an incomplete actuation stroke.

20 First, Aptar has pointed to the Specification or portions of the
21 Specification that discuss that Rhoades operates upon complete depressions.

22 We agree. Just like the '177 patent describes that the dose counter
23 will function in a reliable manner, so too will the rotating mechanism in
24 Rhoades function in a reliable manner.

1 It was designed to operate at the point before the complete
2 depression. In fact, it operates upon partial depressions and therefore it
3 necessarily operates upon full depressions as well. The Specification
4 doesn't say that it only operates upon full depressions.

5 One more point about that specific cite to the Specification that they
6 put up. They had cited a portion of the Specification which discusses the
7 engagement between certain surfaces of the bottom of the stop members and
8 the lowest portion of the cam body's groove and the upper portion of the cam
9 body's angled surface.

10 I believe the portions on the cam body were defined as 51 and 53 on
11 the lower surface and then 50 and 52 on the upper surface.

12 Again, they have stated that Rhoades operates upon successive full
13 depressions will cause the lower portion of the stop members to engage
14 those specific portions of the cam body.

15 Again, we agree. Successive full depressions means going through
16 a complete cycle within the pen. That includes the release of the pen as
17 well.

18 And if you look at Rhoades, Figures 8 through 11 describe the full
19 cycle of going from rest to extension to rest and what you will see is the two
20 Figures 8 and 10, excuse me, the two Figures that show a depression are
21 Figures 9 and 11.

22 During those depressions the surfaces identified by the Patent Owner
23 are not in engagement. They go into engagement during the release.

1 Again, Figure 9 shows the gap between those two surfaces and
2 therefore there is no engagement during that portion of the depression.

3 The Patent Owner also stated that Petitioners did not explain how a
4 skilled artisan would ensure that a dose was dispensed after the counter was
5 rotated.

6 So that it didn't dispense during only the axial portion where the cam
7 body can only be depressed axially and you know what, I'm sorry, why don't
8 we put up our slides.

9 Just to continue with this point, so they've said that, you know, the,
10 Petitioner has not explained how the dose can be expressed, only how we
11 can ensure that it's expressed only once the cam body has rotated.

12 That was specifically described by Mr. Piper. It's in Paragraphs 19
13 through 22 of his report. Mr. Piper explains that one of skill in the art
14 would have known to coordinate the tolerances between the various
15 components of the device to ensure that rotation occurred before the dose
16 was dispensed.

17 He also supported that position by citing two several prior art
18 references. For example, he cited to the Eckert reference, which is Exhibit
19 1011, which teaches that the switching mechanism is formed such that the
20 first counting ring is actuated and rotated farther even when a dispensing
21 stroke has been performed only incompletely.

22 It's using almost the identical language that Aptar has used in its
23 claim 1. Incomplete actuation stroke, Eckert has already disclosed in the

1 prior art that you would perform that rotation when the dispensing stroke has
2 been performed only incompletely.

3 Again, that's in Mr. Piper's declaration, Exhibit 1002 at Paragraph
4 19.

5 Now, we also heard from the Patent Owner that Figure 9 of Rhoades
6 was intended to show the instant that the cam body can start to rotate.

7 And that's simply not so. What you can see in Figure 9, which I've
8 put up on slide 12, and again it's the fourth figure in the sequence on slide
9 12.

10 What you can see in Figure 9 is that this is not the instant that the
11 cam body can rotate. The cam body has already rotated. It's already
12 rotated roughly halfway, maybe a quarter I would say, it's roughly a quarter.

13 I believe it was Judge Marschall who pointed out as well that when
14 the stop members clear the -- it's at the point where the stop members clear
15 the cam body, the cam body would be just below those stop members.

16 Patent Owner has pointed out that at this point in Figure 9 where you
17 already have rotation and you already have elevation, right, because the cam
18 body has moved up, that you can draw a straight line across these two from
19 the bottom of the stop members to the top of the cam body.

20 Again, you could only do this if there has been a comparable further
21 depression of the plunger. Otherwise the cam body, the top surface of the
22 cam body would be raised further above the bottom of the stop members.
23 It rotates up and to the right.

1 JUDGE DANIELS: Mr. Sklar, so looking at your, looking at your
2 slide 12, where does rotation -- is it fair to say that rotation starts -- of the
3 cam body -- essentially immediately after, the third, what's the third one
4 from the right, from the left?

5 MR. SKLAR: Correct.

6 JUDGE DANIELS: The one right before Figure --

7 MR. SKLAR: Not even right after, right there. That's the point
8 where the rotation of the cam body would start because the stop members
9 are no longer preventing rotation.

10 JUDGE DANIELS: And that's where, and that's where a
11 depression, that's where we'd have this dispensing of the, that's where
12 dispensing would start?

13 MR. SKLAR: Not necessarily, Your Honor. As Mr. Piper
14 explained, what a skilled artisan would do, is he would coordinate the
15 tolerances, taking into account where the cam body begins to rotate and how
16 much additional length you have to complete that full depression.

17 So for example, it might start after slightly further depression, for
18 example, two one thousands of an inch after the point that we see in Figure
19 3, as long as the tolerances of the valve and canister were set such that that
20 would ensure that the dose would come out after the depression, sorry, after
21 rotation began. That's what Mr. Piper explains in Paragraph 19.

22 JUDGE DANIELS: Right. So that was my question. That was I
23 think my question to Ms. Moore and she said that you all didn't say anything

1 about it and what you're saying is that Mr. Piper talks about this, this
2 relationship between the tolerances in Paragraph 19 through 22?

3 MR. SKLAR: He does, Your Honor. He explains specifically
4 and uses specific numbers actually to explain how if you knew that the total
5 travel distance was x and the total, you know, distance required for rotation
6 was, let's say y, right, you would have to ensure that the dose came out
7 somewhere between x and y, right.

8 And you would have to take into account the tolerances when you
9 did that.

10 JUDGE DANIELS: Okay.

11 MR. SKLAR: All right.

12 JUDGE DANIELS: Thank you.

13 MR. SKLAR: Yep. If there's no further questions I'll move on.
14 The Patent Owner has also presented some remarks that Petitioners included
15 new arguments regarding how a skilled artisan would combine the
16 references of grounds one and two.

17 In the Patent Owner's Response it raised for the first time arguments
18 that a POSA would not have known how to combine the prior art.

19 That they would not know how to account for a spring or injection
20 molding and again, to be clear, as it relates to the identified operability
21 issues, these are not claim requirements.

22 These are not something that's missing from the identified claim
23 requirements that the prior art does not show.

1 That's different from the cases that the Patent Owner has relied on in
2 this case for these operability issues.

3 Again, that's *Henry Gordon and Adidas v. Nike*, where there were
4 claim limitations that were not disclosed and the Petitioner added new
5 arguments, sometimes even new references to disclose those specific
6 limitations.

7 We simply pointed out in our Reply that here's our response to those
8 issues and they're not operability issues at all.

9 Okay, one of those operability issues that we heard from the Patent
10 Owner is that in both combinations snap fitting the cam body past the stop
11 members would damage the inhaler body.

12 On cross examination, Mr. Clemens, the Patent Owner's expert, was
13 asked what's the likelihood that snap fitting with these components past each
14 other would result in damage to the device.

15 And Mr. Clemens conceded, I would have to say that it's really
16 impossible to answer that question. That was in Exhibit 1077 at 55, lines 1
17 through 9.

18 And as we show in slide 33, Patent Owner also ignores that snap fits
19 are regularly used to connect the components of medical devices.

20 In fact, Petitioner's -- excuse me, Patent Owner's expert has utilized
21 them himself and he has even utilized them for purposes of connecting the
22 components of inhalers.

1 Aptar makes two argument regarding injection molding. First they
2 have argued that there is no practical tool for molding the device resulting
3 from the ground 1 and 2 combinations.

4 On slides 34 and 36 we show that the molding tools suggested by
5 Mr. Piper uses actually the same design as is taught by the treatise on
6 injection molding that Aptar has filed in this particular case.

7 Furthermore, Aptar's arguments regarding the inhalation flow path is
8 another example of this double standard that Aptar has been applying.

9 One thing I want to go back and point out, I believe Patent Owner
10 stated that *In re Epstein*, which is the case that we've relied on, was an
11 enablement case.

12 It was not -- and *In re Epstein* the Federal Circuit affirmed this
13 Board's rejection of a patent application on one of three grounds. So, it was
14 not an enablement case so, it's very similar to the facts that we have here.

15 On slide 38 we show that again, and I think this has been discussed,
16 the '177 specification says nothing about how to set the inhalation flow path.

17 And let me just remind Your Honors that the very nature of the
18 change required by the FDA which would be to insert a dose counter into an
19 MDI.

20 Patent Owner's expert agreed that this would affect the inhalation
21 flow path. So some modification to the inhalation flow path may have to
22 be made.

1 Still the '177 specification does not describe what that modification
2 would be. Again, *in re Epstein* says what's good for the goose is good for
3 the gander in this case.

4 I'd like to address an issue that Judge Daniels brought up and, Judge
5 Daniels, you had asked about whether someone could just simply plug the
6 holes.

7 There could be any number of ways that a skilled artisan would
8 know to account for holes in the flow path. Just like there could be any
9 number of ways that a skilled artisan may know how to account for the
10 addition of a dose counter in the flow path, which would alter the flow path
11 as had previously been known.

12 Mr. Clemens was asked about this on cross examination and he
13 explained that the addition of through holes injects high velocity fresh air.

14 It creates the addition of high velocity fresh air to the flow path of
15 the device. So, he was asked, are there ways that a skilled artisan could
16 reduce that amount of fresh air?

17 Certainly there could be ways to do that, he said. So absolutely
18 there could ways and, Judge Daniels, you had asked about plugging those
19 holes. There can be many other ways.

20 You could, for example the top of the MDI, the top of the inhaler
21 introduces a lot of fresh air into the device. You could, for example, shrink
22 the circumference of the top of the inhaler, that it's closer fitting to the
23 canister itself and therefore less fresh air is getting in.

1 But again, there could be many ways to do this. Mr. Clemens,
2 Petitioner -- excuse me, Patent Owner's expert admitted that certainly a
3 skilled artisan would have ways to do that.

4 JUDGE DANIELS: But that standard is really, would they have,
5 right? I mean, I'm not entirely immune to Patent Owner's argument here
6 that there's not a whole heck of a lot of description in your original Petition
7 about how this would actually be done.

8 I mean, there's enough to get us to institution but I guess the question
9 is, is there enough -- there's some reasoning that says, it leads me to believe
10 that it could have been done.

11 But would have is a whole other step and all these different things, I
12 mean I'm not immune to it.

13 There's a lot of, these are pretty simple devices at the end of the day
14 and the more manufacturing you have the bigger problems, right? The
15 more expense.

16 MR. SKLAR: So to address that, what we have here is actually less
17 manufacturing and less assembly.

18 In the original, if you want to say, one of the references, take it as
19 Elliot or as Bason, you have numerous components, maybe four components
20 for each dose counter.

21 So numerous rings, you have to have a base, you have to have
22 different things. What happens here is, right, once you know that you need
23 to mass produce these, because you need to implement them in all of your
24 devices, okay, you can now injection mold a device.

1 Now, there may be some additional capital cost, okay, but that's an
2 up-front cost, right. But there's savings then throughout the process.

3 Assembly costs, materials, so on and so forth, okay. So yes, there
4 would have been the motivation to do it because the FDA told you that you
5 need to incorporate these devices into all of your MDIs going forward.

6 So, that would have been the motivations and then Mr. Piper
7 explained that yes, there would have been a reasonable expectation for
8 success here.

9 And Mr. Clemens testimony supports that because even though
10 there's this introduction of high velocity fresh air, a skilled artisan would
11 know how to account for that and he would have ways to account for that.

12 So what you ultimately end up with is a more economical device that
13 can more easily be mass produced that would have fewer assembly costs and
14 so yes, a skilled artisan would have done that as well.

15 Okay, the Patent Owner also presented two arguments about springs.
16 The first I believe is that Patent Owner suggested that the Petitioners did not
17 disclose the inclusion of springs in the Petition.

18 Again, that's not the case. I would point Your Honors to the
19 Petition at page 25, which states that the Rhoades cam body fingers and stop
20 members cooperate, resulting in axial and rotational movement of cam body
21 20 under the force of spring 16. That's in the Petition at page 25.

22 The Petition further explains on page 32 that the components used to
23 rotate the cam body would be substituted in for the related components of

1 Elliot. The spring obviously being one of those components that is used to
2 rotate the cam body. So that is included.

3 On slide 39 again, we show that the Patent Owner's applying one
4 standard in the Specification of the '177 patent and one as it relates to the
5 prior art combinations asserted here.

6 Again, Mr. Clemens was asked about the fact that in the first
7 embodiment, and to be clear the Patent Owner, you know, suggested that
8 well, the '177 patent does disclose springs at other places, and it does. But
9 it doesn't disclose it for the first embodiment shown in Figures 1 through 8
10 of that Specification.

11 And Mr. Clemens understood that and he was asked about it and he
12 conceded that the '177 patent does not disclose where one would place those
13 springs.

14 But he still reached the result that a skilled artisan would have
15 known how to. In fact, there would be many, many options for doing that
16 according to Mr. Clemens and I'm pointing to his testimony on slide 39.

17 And the skilled artisan would latch onto one of those many, many
18 options for doing this.

19 Okay, Aptar also presented some arguments regarding the rotation of
20 the canister in the Bason-Rhoades combination, in its Patent Owner
21 Response, Aptar originally argued that the canister simply cannot rotate.

22 Mr. Piper explained that that was wrong and we see that on slides 41
23 and 42. Indeed the canister can rotate. It is connected or bonded to the
24 cam body itself.

1 And as the cam body rotates, the canister will rotate and it will rotate
2 about the valve stem which is press fit into the valve block.

3 In the Patent Owner's Sur-Reply, Aptar argued that even if the
4 canister can rotate above the valve stem, it would require additional force to
5 make that happen.

6 Mr. Clemens on cross examination testified that the amount of force
7 required to actuate a device, an MDI, it does not require a user to use their
8 maximum effort, right.

9 And obviously it wouldn't be designed that way. So, he conceded
10 that you could add an additional force requirement. You wouldn't have to
11 just loosen the seal.

12 Instead you could add an additional force requirement and that
13 would permit the cam body and the canister to rotate together and still allow
14 the user to actuate the device.

15 Finally, the Patent Owner presented some arguments regarding the
16 Bason and Rhoades combination. Aptar argued that the counter and
17 reservoir do not cooperate because they are connected.

18 Aptar did not offer a construction for connected under the BRI
19 standard which applies in this case. Certainly those components are
20 cooperating.

21 If you push down on the cam body you necessarily move the canister
22 and likewise if a force pushes up on the canister it necessarily has a resulting
23 effect on the cam body and so those are in fact cooperating.

1 If Your Honors have any further questions, I would be happy to
2 address those.

3 JUDGE JUNG: I have no questions.

4 MR. SKLAR: I will turn it over to my colleague again, Mr.
5 Maslowski. Thank you.

6 MR. MASLOWSKI: Thank you. I'll take the four grounds for the
7 '631 patent in order.

8 Again, with regards to Allsop, I'm on slide 49, there was a statement
9 that there's nothing in the Allsop reference about pushing. To the contrary,
10 there is.

11 It's called a push button cap. It would sound a little silly if you said
12 a push button cap which could be pushed. Everybody understands. And
13 one of skill in the art certainly understands what a push button cap does.
14 You push the button.

15 Also, with regards to the ring and the -- go to slide 48. The ring,
16 which can rotate around inner housing 140 in the bottom left hand corner.

17 There were statements about inoperability because of interference
18 between the push button cap, for example, and the ring that has to rotate
19 around inner housing.

20 That argument fails to account for one fact, which is that Allsop
21 actually teaches that the ring isn't even necessary.

22 The ring 160 may be replaced with a series of numbers as described
23 in Allsop and as quoted on slide 48.

1 And along those same lines, with regards to displayable dose values,
2 to be honest there was a lot of attorney argument on this point.

3 There was a statement about, or a slide about how this second
4 embodiment here on slide 53 allegedly doesn't work.

5 That's not in the record. It's not in Mr. Clemens's testimony in any
6 way. That was attorney argument and Allsop is clear.

7 It's clear that it says the ring can be replaced and numbers can be put
8 on the inner housing such that only numbers can be seen, only the dose
9 values left can be seen through the slot.

10 It's presumed enabled. It's presumed to work.

11 JUDGE MARSCHALL: Is it your position that Allsop expressly
12 discloses all the limitations or is there some inherency argument lurking?

13 MR. MASLOWSKI: It's our testimony that they're all expressly
14 described. Expressly described. Okay, if there's nothing else on Allsop, I
15 will turn to Marelli.

16 And on Marelli there's a slide, it's slide 17 in Aptar's slide deck
17 where Aptar simply cited the first sentence from the Petition, which says
18 Marelli teaches a rotating element 9.

19 And then they said well, Petitioners didn't, never accounted for the
20 flexible legs. Of course that quote just fails to go to the second sentence,
21 which says rotating element 9 is integral with small flexible leg 16.

22 And as I talked about in my opening argument, Petitioners from day
23 one have considered flexible leg 16 to be part of the second element.

1 Because if you look at dependent claim 2 of the '631, jump back to
2 slide 45, claim 2, dependent claim 2, says wherein the second member
3 comprises at least one multi-tooth gear.

4 So, we're talking only about the second member in dependent claim
5 2. If you look at the Petition, if you look at Mr. Piper's declaration, he's
6 talking about element 9 with its integral leg 16.

7 It's the integral leg 16 which are the multi-tooth gears defined in
8 dependent claim 2. So we've been consistent from day one.

9 With that, I will move to ground three, four and obviousness and talk
10 about obviousness, really both of the combinations together and quite
11 frankly all of the obviousness combinations here.

12 Aptar's response on obviousness basically criticizes the Petition for
13 not providing a blueprint detailing how a person of skill in the art would
14 make a combined device.

15 We haven't provided engineering drawings and specifications and
16 the like. The law doesn't require that.

17 As the Board explained and in *Arctic Cat v. Polaris*, which is cited in
18 our brief, Petitioner is not required to account for every technical challenge
19 in order to show obviousness.

20 In fact, the Board rejected an argument similar to the one Aptar is
21 making in *Johnson Controls v. Wildcat Licensing*, IPR2014-304, Paper
22 4429.

23 Citing to a long line of Federal Circuit cases that explain quote, the
24 criterion for obviousness is not whether the references can be combined

1 physically, but whether the claimed invention is rendered obvious by the
2 teachings of the prior art as a whole. End quote.

3 And that's what we've shown here. We've shown that the
4 references teach and suggest each limitation of the claims.

5 Second, that a person of ordinary skill in the art would have had a
6 reason to combine those references.

7 And three, that a person of ordinary skill in the art would have had a
8 reasonable expectation of success in doing so.

9 That's what the law requires. The law does not require engineering
10 drawings. It does not require Petitioners to come forward with a physical
11 device and to show you exactly how every piece would work together and
12 what every dimension would be and how every gear would interact.

13 Aptar's made no attempt to show that the necessary modifications are
14 not routine or its inabilities -- abilities of one in ordinary skill in the art.

15 And if we go to slide 67 for example, this is why they haven't and
16 they really can't. They've said the opposite. They've said, on the record
17 during prosecution what one of ordinary skill in the art could do.

18 What could one of ordinary skill in the art do? Shape and structure
19 gears to interact. That's an exact argument that they're making now that
20 they say Petitioners did not do, that we did not show how gears would
21 interact in some of our combinations.

22 They said that's not necessary. One of skill in the art knows how to
23 do that. And in fact, if you go to slide 68, this is Mr. Clemens's testimony.

1 Mr. Clemens's position really is a simple technical analysis.
2 Technically he says, well if I jammed a gear on the side of Bason and kept
3 everything else identical it wouldn't work.

4 That was his ultimate analysis. It wouldn't work. So when he was
5 asked at his deposition, I'm going to hand you the petition from the '631
6 patent IPR. If you could turn to Page 55.

7 Looking at the fourth line from the bottom, the Petition says quote,
8 the rest of the components could be connected in the same way they are
9 connected in Bason or other ways well understood in the art.

10 Do you see that? Answer, I do. Question, your opinion does not
11 include that last clause, does it? Answer, it does not. And that's the issue
12 for obviousness here.

13 Is that Aptar's analysis simply forces a physical combination and
14 then they point to operability and say, when they forced those two references
15 together they don't work.

16 But that is not what the law requires. And the business about a new
17 argument and that we've changed our argument in Reply. We haven't
18 changed anything.

19 Your Honor, you asked a question about whether or not we needed
20 our Reply quite frankly to meet our burden. We don't. We've met our
21 burden with our opening Petition.

22 And in that Petition we've met the legal standard, which I've already
23 described.

1 So, in the end, Your Honors, our obviousness case is built on a
2 proper legal standard which shows that one of skill in the art was motivated
3 to combine the references that we've cited and to arrive at the claimed
4 invention and for that reason, grounds three and four of the '631 patent, the
5 claims 1 to 4 should be invalidated for obviousness.

6 And if there are no further questions --

7 JUDGE JUNG: No. No questions.

8 MR. MASLOWSKI: -- I will sit down with 11 minutes to go.

9 MS. MOORE: Your Honors, I would like to start by pointing out
10 that all of the unanswered questions that I talked about in our briefing and
11 that I talked about earlier today, still remain unanswered.

12 We have heard about, quote, lots of ways a person of ordinary skill
13 in the art could do it. It would be easy.

14 But when it comes time to actually tell us how, tell us why, tell us
15 where it is in the references, tell us what you're modifying, tell us what's
16 going to happen and how these pieces interconnect. We have zero detail.

17 For example, the mold arms, creating the holes in the bottom of the
18 device. We heard about lots of ways you could fix that. None of that's in
19 the Petition. None of it's in the Reply. None of it's in the Sur-Reply.
20 None of that was disclosed by Mr. Piper.

21 We have some attorney argument from today about what that might
22 be, but nothing that's an actual solution to the problem of the flow path being
23 disturbed that I discussed with the '177 patent.

1 Nothing about the holes and how it is you would fix that problem.
2 Nothing about the spring interfering with the valve block and having the
3 blowback of medicine.

4 We didn't hear a solution to that today. We didn't hear a solution in
5 any of the papers. We didn't hear a solution from Mr. Piper.

6 That problem still exists. Mr. Clemens's testimony remains
7 unchallenged on that point. That it would render the device inoperable
8 because the dosing of medication would not come out the end of the device.

9 We have Mr. Clemens's testimony speaking generally about a flow
10 path, we heard about that a moment ago. That obviously it would be easy
11 to figure out how to do that.

12 He said that a person of ordinary skill in the art could figure it out.
13 He was speaking generally about when you go to create an inhaler, yes you
14 could consider flow path and figure out how to make it work.

15 He wasn't talking about this combination in particular. He wasn't
16 talking about the fact that there are holes created by the mold arms and how
17 you would fix that.

18 He was speaking generally as a practical matter. Yes, you want to
19 consider the flow path. He was not suggesting it would be an easy matter
20 or known to one of skill in the art how to fix this particular problem
21 identified in this combination.

22 He also talked about snap fit testimony. We heard about that a
23 moment ago and that it would be easy to snap fit these pieces. It would not
24 require a large amount of skill.

1 And again, citations to Mr. Clemens's testimony. He was speaking
2 about medical devices generally. Yes, you can snap fit certain medical
3 devices together.

4 You can snap fit a cap over a mouthpiece. That does not mean that
5 the snap fit would work in this particular situation with this particular
6 combination with this particular set of issues.

7 We can't take general statements about medical devices in general
8 and then suggest that that somehow provides a reason and a basis for
9 combining these references for the '177 patent.

10 If it were so easy I feel sure we would have heard an answer to any
11 of our questions at some point in the briefing or today.

12 And finally, I know we've talked some about the *Epstein* case. I
13 would encourage the Board to read that case. You can actually see for
14 yourself, it is talking about enablement of a particular piece of prior art.

15 It's not talking about the standard for 103 obviousness proof. And
16 nothing in *Epstein* requires the patented technology, the '177 patent, and the
17 '631 patent to foresee into the future the combinations that might be asserted
18 against them in the prior art that might be concerted against them.

19 And then put all of those arguments and details into their
20 Specification. That's not the purpose of a Specification. That cannot be
21 and is not what *Epstein* stands for.

22 We heard some more about the incomplete actuation stroke for
23 Rhoades. Again, Rhoades does not tell us anything about a further
24 depression.

1 Every mention of rotating that cam body is on a full depression.

2 That is the only disclosure in Rhoades is that it's a full depression.

3 Everything talking about further depression, going past the cam body
4 and pressing again, none of that is from the actual Rhoades patent.

5 You didn't see any of that in the slides. All of it was back filled by
6 Mr. Piper. That's inappropriate. It is not the basis on which an
7 obviousness combination can rely. It must be in the references themselves.
8 It can't have missing elements filled in by the expert.

9 Coordinating tolerances. We heard a little bit about that a moment
10 ago. None of that was explained. We don't know how the tolerances are
11 coordinated. It's just an umbrella term. It covers all manner of things and
12 a person of ordinary skill in the art could figure it out. We don't know how.

13 How are they going to coordinate tolerances? Between which
14 pieces? Why? What are you going to do? Which piece is going to
15 coordinate with another?

16 How are you going to have a tolerance be effected? Is it the valve
17 stem? Is it the first member? Is it the second member? Is it the cam
18 body? Is it the stop member? Is it the fingers? Is it the spring? We
19 still don't know.

20 And *KSR* does not stand for that proposition. You have to have a
21 predictable combination. It has to be a known substitution. It has to yield
22 a predictable result.

1 And you have to have some kind of motivation to make those
2 changes. We didn't hear anything about why you would be motivated to
3 coordinated tolerances in a pen.

4 In a pen that you use to write. No one cares what the tolerances are
5 because you don't have doses. You don't have a finite amount of liquid that
6 you're trying to dispense to a user. It's a pen used to write. There's no
7 reason to coordinate tolerances there.

8 *Active Video* also says you have to articulate the reasoning behind
9 your obviousness combination. Again, we don't know how. We don't
10 know why. We don't know which pieces are being coordinated.

11 We don't know what the tolerances are or how they're being
12 coordinated. There's no motivation to do it in the first place because
13 Rhoades relates to a pen.

14 There would be no reason to combine these references and for all the
15 reasons in my first presentation, it wouldn't yield an incomplete actuation
16 stroke anyway, because it's a full depression that results in pressing, rotating
17 the cam body.

18 An incomplete actuation stroke, where you're just going up and
19 down in that channel, the bottom of which is 53, where the stop member
20 rests. When you go up and down in that channel and release medicine, the
21 cam body doesn't rotate.

22 And then finally for the '631 patent, we talked about the cap.
23 Apparently the disclosure that tells you how that push button cap works is by
24 the disclosure of the word push button.

1 That doesn't tell you how that cap works. It could simply be a cap
2 that covers a push button. We have no description in Allsop that it's
3 anything other than that.

4 Similar to the mouthpiece cap that's also described, which I don't
5 think anyone would contend is a push button. Allsop simply doesn't tell us
6 what it is. It doesn't provide the information. It's not enabled and that
7 claim element is not anticipated.

8 For Marelli we heard that by virtue of the fact that they disclosed the
9 flexible legs for dependent claim 2, that means that they always meant to
10 include it for claim 1.

11 I would argue the exact opposite is true. If you included the
12 flexible leg argument for dependent claim 2, all that shows me is that you
13 knew how to do it.

14 And if you wanted to talk about the flexible legs for claim 1, you
15 could have and should have done it. You didn't. There's a difference
16 between claim 1 and claim 2 and there's a difference between the arguments
17 for a reason.

18 It's because they didn't intend to include that argument in claim 1.
19 They waited until their expert admitted that that piece didn't rotate and then
20 they changed their story.

21 And then finally with respect to the combinations grounds three and
22 grounds four for the '631 patent. Essentially what we heard is that the
23 patent in the file history for the '631 patent repeatedly disclaims any
24 requirement of the Petitioners to explain their obviousness combinations.

1 That's not the law. Combinations must be made and explained in
2 more than conclusory statements. You must describe the structural details.
3 That's the *Albritton* case that I've mentioned a couple of times.

4 If you leave out the structural details, too thin a reed to support an
5 obviousness conclusion. We aren't asking for a blueprint. We're not
6 asking for a schematic.

7 All we're asking for is more than the two or three sentences that we
8 got. If you're going to make all of these modifications, which we saw quite
9 a number of them in the Reply.

10 You're going to take Bason, you're going to expand the cap to go on
11 the outside rather than the inside. You're going to add ribs. You're going
12 to add a window. You're going to make this ring bigger. You're going to
13 make this other ring bigger. You're going to move these teeth from the
14 inside to the outside.

15 All of that should have been in the Petition. We didn't get the
16 description that we needed and we were then foreclosed from talking about
17 it in our Response and limited to the very limited pages of a Sur-Reply.

18 And again, what we didn't hear today was any response to the teeth
19 not cooperating. If teeth 2 are moved to the outside of the inhaler body and
20 teeth 7 are moved to the outside of the inhaler body, then teeth 14a should
21 have been moved. They weren't and you can't actually do it because it
22 results in the dose values being covered up from ring 4.

23 That means bush 15 was going to sit on top of ring 4. The dose
24 values aren't going to be viewable, in which case the product doesn't work.

1 It doesn't rotate as intended and if it were so easy they certainly
2 could have told us. They could have told us in the Petition, the Reply, the
3 Sur-sur-Reply.

4 They didn't tell us and it's because it's impossible. Thank you, Your
5 Honor.

6 JUDGE JUNG: Thank you. Well, Mr. Sklar and Mr. Maslowski
7 and Ms. Moore, thank you for your presentations. They were very helpful
8 and very well argued. Your cases are submitted, and we are adjourned.

9 (Concluded at 3:41 p.m.)

IPR2018-01054 (Patent 8,936,177 B2)

IPR2018-01055 (Patent 9,370,631 B2)

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