

UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M COMPANY, MERCK & CO., INC. and )  
MERCK SHARP & DOHME CORP., ) Case No.  
 ) IPR2018-01054  
Petitioners, ) IPR2018-01055  
 ) Patent No.  
vs. ) 8,936,177  
 )  
APTAR FRANCE S.A.S., )  
 )  
Patent Owner. )

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DEPOSITION OF CHARLES E. CLEMENS  
San Diego, California  
Tuesday, July 16, 2019

Reported by:

Tricia Rosate, RDR, RMR, CRR, CCRR  
CSR No. 10891  
Job No. 163986

<div>Page 2</div> <div> <p>1 2 3 4 Tuesday, July 16, 2019 5 9:18 a.m. 6 7 8 9 DEPOSITION OF CHARLES E. CLEMENS, 10 taken at 501 West Broadway, Suite 800, San Diego, 11 California, commencing at 9:18 a.m. and concluding at 12 2:27 p.m., Tuesday, July 16, 2019, before 13 Tricia Rosate, RDR, RMR, CRR, CCRR, CSR 10891, a 14 Certified Shorthand Reporter. 15 16 17 18 19 20 21 22 23 24 25</p> </div>	<div>Page 3</div> <div> <p>1 A P P E A R A N C E S: 2 For the Petitioners: 3 4 HONIGMAN MILLER SCHWARTZ AND COHN 5 155 North Wacker Drive 6 Chicago, Illinois 60606 7 BY: RON SKLAR, ESQ. 8 GREGORY MORRIS, ESQ. (Via teleconference) 9 ANDREW CHIPOURAS, ESQ. 10 11 12 13 14 15 AKIN GUMP STRAUSS HAUER &amp; FELD 16 Two Commerce Square 17 2001 Market Street 18 Philadelphia, Pennsylvania 19103 19 BY: JASON WEIL, ESQ. 20 (Via teleconference) 21 22 For the Patent Owner: 23 McKOOL SMITH 24 300 Crescent Court 25 Dallas, Texas 75201 BY: BENJAMIN MURRAY, ESQ.</p> </div>
<div>Page 4</div> <div> <p>1 A P P E A R A N C E S (Continued): 2 For the Patent Owner: 3 McKOOL SMITH 4 300 Crescent Court 5 Dallas, Texas 75201 6 BY: RYAN HARGRAVE, ESQ. (Via teleconference) 7 8 Also Present: 9 CHLOE COLEMAN 10 McKool Smith 11 12 EMILY SAUTER, ESQ. 13 In-House Counsel, Merck 14 (Via teleconference) 15 16 17 18 19 20 21 22 23 24 25</p> </div>	<div>Page 5</div> <div> <p>1 I N D E X 2 WITNESS: Charles E. Clemens 3 EXAMINATION PAGE 4 By Mr. Sklar ..... 6, 93, 130 5 By Mr. Murray ..... 127 6 E X H I B I T S 7 EXHIBIT DESCRIPTION PAGE 8 Exhibit 1001 United States Patent No. 43 9 US 8,936,177 10 Exhibit 1001.2 United States Patent No. 98 11 US 9,370,631 12 Exhibit 1013 Guidance for Industry - 35 13 Integration of Dose-Counting 14 Mechanisms into MDI Drug 15 Products 16 Exhibit 1057 Deposition Transcript, Charles 25 17 E. Clemens, April 24, 2019 18 Exhibit 1075 Petitioners' Reply to Patent 22 19 Owner's Response 20 Exhibit 2018 Article, Plastic Part Design 20 21 For Injection Molding 22 Exhibit 2021.1 Declaration of Charles E. 8 23 Clemens In Support of Patent 24 Owner's Response to Petition 25 For Inter Partes Review of U.S. Patent No. 8,936,177 Exhibit 2023.1 Declaration of Charles E. 7 Clemens In Support of Patent Owner's Sur-Reply to Petition For Inter Partes Review of U.S. Patent No. 8,936,177</p> </div>

<p style="text-align: right;">Page 6</p> <p>1 SAN DIEGO, CALIFORNIA; TUESDAY, JULY 16, 2019</p> <p>2 9:18 A.M. - 2:27 P.M.</p> <p>3 - - - -</p> <p>4 MR. SKLAR: At the court reporter's request,</p> <p>5 if we could have the individuals joining by phone</p> <p>6 announce who is on, that would be appreciated.</p> <p>7 MS. SAUTER: I'll go ahead and start. This is</p> <p>8 Emily Sauter. I'm from Merck.</p> <p>9 MS. HARGRAVE: Ryan Hargrave with McKool Smith</p> <p>10 on behalf of Aptar.</p> <p>11 MR. WEIL: This is Jason Weil from Akin Gump.</p> <p>12 MR. MORRIS: It's Greg Morris from Honigman</p> <p>13 for petitioners.</p> <p>14 MR. SKLAR: And I'm Ron Sklar on behalf of</p> <p>15 petitioners, as well.</p> <p>16 CHARLES E. CLEMENS,</p> <p>17 having been first duly sworn, testified as follows:</p> <p>18 EXAMINATION</p> <p>19 BY MR. SKLAR:</p> <p>20 Q We've met one time before, Mr. Clemens.</p> <p>21 Good morning.</p> <p>22 A Good morning.</p> <p>23 Q I am going to start off, Mr. Clemens, by</p> <p>24 handing you a copy of an exhibit that I've labeled as</p> <p>25 Exhibit 2023.1.</p>	<p style="text-align: right;">Page 7</p> <p>1 (Exhibit 2023.1 was referenced.)</p> <p>2 BY MR. SKLAR:</p> <p>3 Do you recognize this exhibit, Mr. Clemens?</p> <p>4 A Yes, I do.</p> <p>5 Q And this is a copy of your declaration in</p> <p>6 support of Aptar's sur-reply in Case No. 2018-01054;</p> <p>7 correct?</p> <p>8 A Yes.</p> <p>9 (Recess due to technical difficulty.)</p> <p>10 BY MR. SKLAR:</p> <p>11 Q Okay. Mr. Clemens, before we took that brief</p> <p>12 break, I had handed you Exhibit 2032 -- sorry, excuse</p> <p>13 me -- 2023.1; correct?</p> <p>14 A That is correct.</p> <p>15 And we had agreed that this is a copy of your</p> <p>16 declaration in support of Aptar's sur-reply in</p> <p>17 Case No. 2018-01054; correct?</p> <p>18 A Correct.</p> <p>19 Q If I can ask you to turn to the last page of</p> <p>20 that exhibit, is that your signature at the bottom of</p> <p>21 the last page, Exhibit 2023.1?</p> <p>22 A It is.</p> <p>23 Q Before you signed this exhibit, did you</p> <p>24 carefully review this declaration?</p> <p>25 A I did.</p>
<p style="text-align: right;">Page 8</p> <p>1 Q Okay. So looking at that statement above your</p> <p>2 signature, am I correct that as of June 13, 2019, it is</p> <p>3 your belief that everything incorporated into this</p> <p>4 declaration is true and correct?</p> <p>5 A That is correct.</p> <p>6 Q Is that still your belief today?</p> <p>7 A It is.</p> <p>8 Q Did you review any materials, Mr. Clemens,</p> <p>9 prior to drafting this declaration?</p> <p>10 A Of course. Off the top of my head, I don't</p> <p>11 remember all the documents, but yes.</p> <p>12 Q Do you remember any of the documents that you</p> <p>13 reviewed prior to drafting the declaration that is</p> <p>14 Exhibit 2023.1?</p> <p>15 A Several of the patents, just reviewing all of</p> <p>16 the details of the patents, and pretty much the same</p> <p>17 reference material that has been identified in my other</p> <p>18 declarations.</p> <p>19 Q Okay. So let's pull those out. I just want</p> <p>20 to make sure I have a clear understanding of what you</p> <p>21 reviewed prior to drafting this. So if we could pull</p> <p>22 it out here for a moment --</p> <p>23 Okay. Mr. Clemens, I'm handing you a copy of</p> <p>24 a document that I've marked as Exhibit 2021.</p> <p>25 (Exhibit 2021.1 was referenced.)</p>	<p style="text-align: right;">Page 9</p> <p>1 BY MR. SKLAR:</p> <p>2 Q Do you see that?</p> <p>3 A Yes.</p> <p>4 Q Okay. And this document, which I've</p> <p>5 identified as Exhibit 2021.1 --</p> <p>6 Let me correct the record. I identified this</p> <p>7 as Exhibit 2021.1. Correct?</p> <p>8 A That's correct.</p> <p>9 Q And Exhibit 2021.1 is a copy of your</p> <p>10 declaration in support of Patent Owner's Response To</p> <p>11 Petition For Inter Partes Review in Case No.</p> <p>12 2018-010554; correct?</p> <p>13 A Yeah. That's what it says. Uh-huh.</p> <p>14 Q Okay. And I will turn your attention to</p> <p>15 paragraph 12 on page 5 of this declaration, 2021.1.</p> <p>16 Do you see that you have listed materials</p> <p>17 considered in that declaration there?</p> <p>18 A I'm looking at it again, but yes, I do see</p> <p>19 that.</p> <p>20 Q Are these the exhibits or the materials that</p> <p>21 you reviewed prior to drafting your declaration, which</p> <p>22 we've identified as 2023.1?</p> <p>23 A I believe that that is true. To be honest, I</p> <p>24 don't have a complete memory of everything I reviewed,</p> <p>25 but this looks pretty complete. So that -- that looks</p>

<p style="text-align: right;">Page 10</p> <p>1 pretty good.</p> <p>2 Q And just to be clear, so prior to drafting</p> <p>3 your declaration in support of Aptar's sur-reply in</p> <p>4 Case 2018-01054, did you review the Petition For</p> <p>5 Inter Partes Review that's listed in Item A on page 5</p> <p>6 of Exhibit 2021.1?</p> <p>7 A I believe I did look at --</p> <p>8 MR. MURRAY: Objection. Misstates the</p> <p>9 witness's previous testimony.</p> <p>10 THE WITNESS: I do believe that I -- I did</p> <p>11 look at sections of that document, but, again, I don't</p> <p>12 recall, you know, which -- all the documents that --</p> <p>13 that I read or what sections.</p> <p>14 BY MR. SKLAR:</p> <p>15 Q When you were drafting your declaration in</p> <p>16 support of Aptar's sur-reply, how did you identify</p> <p>17 which documents you felt you needed to look at prior to</p> <p>18 drafting this calculation?</p> <p>19 A I --</p> <p>20 MR. MURRAY: Objection to the extent that you</p> <p>21 would -- your answer would include anything that would</p> <p>22 be privileged conversations between you and your</p> <p>23 attorney.</p> <p>24 MR. SKLAR: Oh, okay. I'm sorry. That's</p> <p>25 fine.</p>	<p style="text-align: right;">Page 11</p> <p>1 MR. MURRAY: I would instruct you not to</p> <p>2 answer, but if it doesn't involve conversations with</p> <p>3 your attorneys, you can answer.</p> <p>4 THE WITNESS: I would just ask if you could</p> <p>5 maybe clarify your question a little bit more.</p> <p>6 BY MR. SKLAR:</p> <p>7 Q On your own, did you identify any documents</p> <p>8 that you felt you needed to review prior to drafting</p> <p>9 your declaration, which we've identified as</p> <p>10 Exhibit 2023.1?</p> <p>11 A Well, certainly I reviewed documents that are</p> <p>12 part of this list just to recall and refresh my memory</p> <p>13 of the topics that I've written about here. Of course</p> <p>14 much of the information on this declaration were</p> <p>15 already thoughts that I had developed earlier on, but</p> <p>16 because of the timing of things, I had to refresh my</p> <p>17 memory.</p> <p>18 Q And this declaration, which is Exhibit 2021.1,</p> <p>19 is that a document that you reviewed prior to drafting</p> <p>20 Exhibit 2023.1, which is your declaration in support of</p> <p>21 Aptar's sur-reply?</p> <p>22 MR. MURRAY: Objection. Asked and answered.</p> <p>23 THE WITNESS: Yes. I believe I did.</p> <p>24 BY MR. SKLAR:</p> <p>25 Q You understand that since you submitted the</p>
<p style="text-align: right;">Page 12</p> <p>1 declaration, which is Exhibit 2021.1, additional</p> <p>2 materials have been filed by the parties?</p> <p>3 Do you understand that?</p> <p>4 MR. MURRAY: Objection. Vague.</p> <p>5 THE WITNESS: What would those be?</p> <p>6 BY MR. SKLAR:</p> <p>7 Q Sure. Well, let me ask you this in a more</p> <p>8 straightforward manner.</p> <p>9 Did you review the petitioners' reply brief in</p> <p>10 this case prior to drafting your declaration in support</p> <p>11 of Aptar's sur-reply?</p> <p>12 MR. MURRAY: Objection. Asked and answered.</p> <p>13 THE WITNESS: I believe I did.</p> <p>14 BY MR. SKLAR:</p> <p>15 Q And did you review Mr. Piper's supplemental</p> <p>16 declaration, which was submitted in support of</p> <p>17 petitioners' reply brief prior to drafting your</p> <p>18 declaration in support of Aptar's sur-reply?</p> <p>19 MR. MURRAY: Objection. Asked and answered.</p> <p>20 THE WITNESS: Yes, I did.</p> <p>21 BY MR. SKLAR:</p> <p>22 Q Did you review any or examine any physical</p> <p>23 devices prior to drafting your declaration that is in</p> <p>24 support -- that you filed in support of Aptar's</p> <p>25 sur-reply in this case?</p>	<p style="text-align: right;">Page 13</p> <p>1 MR. MURRAY: Objection. Vague. Asked and</p> <p>2 answered.</p> <p>3 MR. SKLAR: And just a moment.</p> <p>4 The Patent Office rules are very clear in terms of what</p> <p>5 objections are permissible or not. In fact, the</p> <p>6 objection "vague" is expressly identified as an</p> <p>7 objection that isn't appropriate. We had an issue at</p> <p>8 our prior deposition with a number of objections that</p> <p>9 were made that were improper, and particularly due to</p> <p>10 the amount of time that we have in this case, I'm going</p> <p>11 to ask you to keep your objections to "form" and</p> <p>12 "foundation," which is what the Patent Office requires,</p> <p>13 and if necessary, we will contact the Board.</p> <p>14 Q Let me go back to that prior question.</p> <p>15 Did you review or examine any physical devices</p> <p>16 prior to drafting your declaration that is in</p> <p>17 support -- that you filed in support of Aptar's</p> <p>18 sur-reply in this case?</p> <p>19 MR. MURRAY: Objection. Form.</p> <p>20 THE WITNESS: Could you clarify what you mean</p> <p>21 by "device"? What --</p> <p>22 BY MR. SKLAR:</p> <p>23 Q Did you review anything that was not a</p> <p>24 publication?</p> <p>25 A I don't recall.</p>

Q You're not aware if you examined, for example, any inhalers prior to drafting the declaration that you submitted in support of Aptar's sur-reply?

MR. MURRAY: Objection to form.

THE WITNESS: I have a number of medical devices that -- on my well-organized desk. To be honest, I don't recall exactly what those devices are or if I picked one up and took a look at it, but it is possible.

BY MR. SKLAR:

Q Sitting here today, are you aware of any reason, as it relates to the drafting of your opinions expressed in Exhibit 2023.1, why you would have examined a physical device?

MR. MURRAY: Objection to form.

THE WITNESS: Could you repeat that?

BY MR. SKLAR:

Q I'll repeat it.

A All right.

Q Are you aware of any reason as it relates to the drafting of your opinions expressed in 2023.1 why you would have examined a physical device?

MR. MURRAY: Same objection.

THE WITNESS: One of the reasons I may have looked at a device -- which I don't recall if I did or

not at this point -- in the case would be to just try to help visualize how parts would interact or how they would come together.

BY MR. SKLAR:

Q And you don't know what device that was that you may have looked at?

A No, I do not.

Q Would it have been an MDI?

MR. MURRAY: Objection. Asked and answered.

THE WITNESS: Well, like I said, I have a number of medical devices on my desk, and there are one or two MDIs.

BY MR. SKLAR:

Q Outside of the devices that were already present on your desk, did you review any physical devices in drafting the opinions that are set forth in your declaration in support of Aptar's sur-reply?

MR. MURRAY: Objection. Form.

THE WITNESS: No.

BY MR. SKLAR:

Q Why didn't you include a list of materials considered in this declaration, 2023.1?

MR. MURRAY: Objection to form.

THE WITNESS: I was not instructed to.

///

BY MR. SKLAR:

Q You did include a list of materials considered in your declaration, which is Exhibit 2021.1; correct?

A That's correct.

Q Why did you include a list of materials considered in Exhibit 2021.1?

MR. MURRAY: Objection to form.

THE WITNESS: Sorry. Ask it again.

BY MR. SKLAR:

Q Why did you include a list of materials considered in Exhibit 2021.1?

A Well --

MR. MURRAY: Same objection.

THE WITNESS: Sorry.

In my collaboration with the attorneys and in putting together this declaration, that was one of the requests and requirements for working on the report.

BY MR. SKLAR:

Q So is it correct to say that it was not your decision whether or not to include a list of materials considered in your report?

MR. MURRAY: Objection. Form. Relevance.

THE WITNESS: Again, it was a collaborative effort on the 2021.1 report. It -- it was -- it became part of the information that we advanced in the

report.

BY MR. SKLAR:

Q And I'm just trying to understand if it was your decision to include a list of materials considered in Exhibit 2021.1.

MR. MURRAY: Counsel, I'm also going to object to the scope of this question as beyond the limited scope of this deposition. I'll let you continue for now, but if it continues, we may have to shut down this line of questioning.

BY MR. SKLAR:

Q You can answer the question.

A Typically when I'm working on these kinds of reports, that is something that is discussed collaboratively. That's very common, as I've worked on these in the past.

Q Sure. And that wasn't exactly my question, so let me just repeat it.

I'm just trying to understand if it was your decision to include a list of materials considered in Exhibit 2021.1.

MR. MURRAY: Objection. Asked and answered. Scope.

THE WITNESS: Again, I do rely on a collaborative effort in putting these reports together,

<p style="text-align: right;">Page 18</p> <p>1 and that's one section that is usually discussed. It's  2 typically not something I would demand, but it is  3 something that comes about through a collaborative  4 process.  5 BY MR. SKLAR:  6 Q And would the same answer hold true as it  7 relates to Exhibit 2023.1?  8 MR. MURRAY: Objection. Form.  9 THE WITNESS: Yes.  10 BY MR. SKLAR:  11 Q Let's shift gears a little bit, and we're  12 going to talk about injection molding. Is that okay?  13 A Sure.  14 Q All right. You agree that an undercut can be  15 eliminated by adding a slot in the line of draw;  16 correct?  17 MR. MURRAY: Objection. Form.  18 THE WITNESS: My opinion in my reports is that  19 to mitigate an undercut condition with respect to the  20 devices that we're discussing here, one would have to  21 create openings in the device, which would affect the  22 flow path.  23 BY MR. SKLAR:  24 Q That wasn't my question again. Let me ask it  25 one more time.</p>	<p style="text-align: right;">Page 19</p> <p>1 You agree that an undercut can be eliminated  2 by adding a slot in the line of draw.  3 MR. MURRAY: Objection. Form.  4 THE WITNESS: Well, what I agree to in the  5 reports that I've written, which again I'm just giving  6 you my opinion, is that for the combinations that have  7 been described by petitioner to be affected in the  8 combination, one would have to create holes or --  9 you've stated slots. They're probably the same in  10 concept. But holes/slots would have to be created in  11 order to mitigate those undercut conditions.  12 BY MR. SKLAR:  13 Q Okay. Again, that didn't answer my question.  14 Just to be clear, you expressed your answer in  15 terms of what you agreed to in your report. I'm here  16 today to ask you about that report and understand what  17 your opinions were, and I can ask questions around  18 that, for that purpose. Okay? So with that said, let  19 me repeat my question, and I'd like you to answer my  20 question.  21 You agree that an undercut can be eliminated  22 by adding a slot in the line of draw?  23 MR. MURRAY: Objection. Form. Asked and  24 answered.  25 THE WITNESS: Perhaps you could ask it another</p>
<p style="text-align: right;">Page 20</p> <p>1 way, because to me, I've answered your question.  2 (Exhibit 2018 was referenced.)  3 BY MR. SKLAR:  4 Q All right. Mr. Clemens, I'm handing you a  5 document that I've marked as Exhibit 2018.  6 Do you see that?  7 A I do.  8 Q And this document appears to be an article or  9 book entitled "Plastic Part Design For Injection  10 Molding"; correct?  11 A Correct.  12 Q I'd like to turn your attention to page 99,  13 which is the last page of Exhibit 2018.  14 The last two sentences, I'm going to read them  15 for you, and then I'm going to ask you some questions.  16 "The side action, and added tooling costs,  17 could be eliminated if the part is designed with  18 consideration towards ejection. For example, the hole  19 could be replaced by a slot in the line of draw, and as  20 a result, no special side actions or core pulls are  21 required."  22 Do you see that?  23 A I do.  24 Q Do you agree with that statement?  25 A Well, may I read the paragraph in its entirety</p>	<p style="text-align: right;">Page 21</p> <p>1 so I can appreciate where it's -- how this is adding to  2 the idea here?  3 Q Yes, you may.  4 A Okay.  5 Q Okay. Let me repeat my question.  6 Do you agree that an undercut can be  7 eliminated by adding a slot in the line of draw?  8 MR. MURRAY: Objection. Asked and answered.  9 THE WITNESS: I would agree with what is  10 written in the document that you've shared with me, and  11 if that is something that can occur in a part, it could  12 do that.  13 BY MR. SKLAR:  14 Q We did confirm earlier that you reviewed the  15 petitioners' reply brief in this case; correct?  16 MR. MURRAY: Objection. Misstates the  17 witness's testimony.  18 THE WITNESS: I reviewed many documents. That  19 was one of them.  20 BY MR. SKLAR:  21 Q And you are familiar with the tool design that  22 petitioners proposed in this case; correct?  23 A That's correct.  24 Q And petitioners' tool design does add slots to  25 the housing; correct?</p>

<p style="text-align: right;">Page 22</p> <p>1 A Could we review the document which you're</p> <p>2 referring to, that section?</p> <p>3 Q Sure.</p> <p>4 A Thank you.</p> <p>5 (Exhibit 1075 was referenced.)</p> <p>6 BY MR. SKLAR:</p> <p>7 Q Okay. Mr. Clemens, I've handed you a copy of</p> <p>8 what I have marked down as Exhibit 1075. This is</p> <p>9 petitioners' reply brief in Case No. 2018-01054.</p> <p>10 Do you see that?</p> <p>11 A Yes.</p> <p>12 Q And I will direct you to the figure on page 6</p> <p>13 of petitioners' reply brief.</p> <p>14 Do you see that figure?</p> <p>15 A I do.</p> <p>16 Q And so my question was: You agree that</p> <p>17 petitioners' tool design does add slots to the housing</p> <p>18 of the inhaler body; correct?</p> <p>19 A So my interpretation of the drawing and the</p> <p>20 proposal of the tooling change here, I would</p> <p>21 characterize what would happen to the inhaler housing</p> <p>22 is that holes would be formed.</p> <p>23 Q So let me restate it, just using your</p> <p>24 terminology.</p> <p>25 You agree that petitioners' tool design adds</p>	<p style="text-align: right;">Page 23</p> <p>1 holes to the bottom of the housing; correct?</p> <p>2 A Holes would be formed in some part of the</p> <p>3 housing, which is proximal to the flow path, not really</p> <p>4 wanting to necessarily claim the bottom is --</p> <p>5 You know, what is bottom? So holes would be</p> <p>6 created proximal to the flow path.</p> <p>7 Q And those holes are in the line of draw;</p> <p>8 correct?</p> <p>9 MR. MURRAY: Objection. Form.</p> <p>10 THE WITNESS: They would be in the line of</p> <p>11 draw. Correct.</p> <p>12 BY MR. SKLAR:</p> <p>13 Q You can put that to the side. Thank you.</p> <p>14 A Okay.</p> <p>15 MR. SKLAR: You know what? Why don't we take</p> <p>16 just a real quick break, and then we'll circle back.</p> <p>17 (Recess taken 10:02 a.m. - 10:09 a.m.)</p> <p>18 BY MR. SKLAR:</p> <p>19 Q Welcome back, Mr. Clemens.</p> <p>20 A Thank you.</p> <p>21 Q Are you familiar with the FDA guidance that</p> <p>22 has been discussed in this case several times?</p> <p>23 A Yes. I have reviewed it a while ago, but yes.</p> <p>24 Q And are you aware that in 2003, the FDA issued</p> <p>25 final guidance stating that it recommended for</p>
<p style="text-align: right;">Page 24</p> <p>1 manufacturers with MDIs under development to integrate</p> <p>2 a dose-counting device into their MDI?</p> <p>3 A Yes, I do.</p> <p>4 Q And do you agree that at the time of the FDA's</p> <p>5 final guidance --</p> <p>6 Well, let me establish this. The FDA's final</p> <p>7 guidance was issued in March 2003; correct?</p> <p>8 A I believe that is correct.</p> <p>9 Q And at the time of the FDA's final guidance,</p> <p>10 MDIs generally did not include integrated dose</p> <p>11 counters; rights?</p> <p>12 A Dose counters were -- had existed in terms of</p> <p>13 concepts and patents. They had been worked on for</p> <p>14 several years, but at that time, I do not believe there</p> <p>15 was one that had been integrated into a device and was</p> <p>16 currently on the market.</p> <p>17 Q Now, the addition of a dose counter interferes</p> <p>18 with the inhalation flow path; correct?</p> <p>19 MR. MURRAY: Objection. Form.</p> <p>20 THE WITNESS: It does interact. Yes, it does.</p> <p>21 BY MR. SKLAR:</p> <p>22 Q I just want to make sure we understand,</p> <p>23 because you sort of changed the wording there a little</p> <p>24 bit. So let me reask my question.</p> <p>25 The addition of a dose counter interferes with</p>	<p style="text-align: right;">Page 25</p> <p>1 the inhalation flow path; correct?</p> <p>2 MR. MURRAY: Objection. Form. Asked and</p> <p>3 answered.</p> <p>4 THE WITNESS: I would say that "not</p> <p>5 necessarily" is probably, you know, a better answer.</p> <p>6 (Exhibit 1057 was referenced.)</p> <p>7 BY MR. SKLAR:</p> <p>8 Q Mr. Clemens, I'm going to hand you a copy of</p> <p>9 what I've marked as Exhibit 1057.</p> <p>10 This is a copy of your deposition transcript</p> <p>11 from your oral deposition on April 24, 2019; correct?</p> <p>12 A That's what it appears to be. Yes.</p> <p>13 Q I'm going to direct your attention to page 19.</p> <p>14 Sorry. Excuse me. 119.</p> <p>15 A Okay.</p> <p>16 Q Were you asked this question, and did you give</p> <p>17 this answer:</p> <p>18 "Question: And the inhalation flow path that</p> <p>19 you're referring to, that's from the stem</p> <p>20 block out the mouthpiece?</p> <p>21 "Answer: So it's created -- literally it's</p> <p>22 created by the canister being in the way,</p> <p>23 whatever else, you know, parts of the design,</p> <p>24 your counter. All that stuff interferes with</p> <p>25 the flow path that's coming in and out."</p>

<p style="text-align: right;">Page 26</p> <p>1 Do you see that?</p> <p>2 A I do.</p> <p>3 Q So let me ask you again. The addition of a</p> <p>4 dose counter interferes with the inhalation flow path.</p> <p>5 MR. MURRAY: Objection. Misstates previous</p> <p>6 testimony.</p> <p>7 MR. SKLAR: And, again, this speaking</p> <p>8 objection, that's the second time.</p> <p>9 Could you please mark that in the transcript?</p> <p>10 And if it happens a third time, we will</p> <p>11 contact the Patent Office so that we can proceed</p> <p>12 properly.</p> <p>13 Q I'll ask the question one more time. The</p> <p>14 addition of a dose counter interferes with the</p> <p>15 inhalation flow path; correct?</p> <p>16 A It is.</p> <p>17 Q Do you agree that skilled artisans knew in</p> <p>18 2003 how to re-optimize the inhalation flow path to</p> <p>19 account for changes in the MDI?</p> <p>20 MR. MURRAY: Objection to form.</p> <p>21 THE WITNESS: What I would agree to is that</p> <p>22 engineers in that time frame knew how to analyze fluid</p> <p>23 dynamics; that there were tools available that they</p> <p>24 could analyze that.</p> <p>25 ///</p>	<p style="text-align: right;">Page 27</p> <p>1 BY MR. SKLAR:</p> <p>2 Q And were skilled artisans at that time --</p> <p>3 meaning in 2003 -- able to use those tools in order to</p> <p>4 optimize the inhalation flow path?</p> <p>5 A They would have been able to use the tools to</p> <p>6 analyze and understand how the flow path was affected.</p> <p>7 And when you say "optimize," what do you mean?</p> <p>8 Q I'm using your words, actually, from your</p> <p>9 declaration. You used the word "optimize."</p> <p>10 A So in terms of what I was speaking to in my</p> <p>11 deposition, they could optimize for a particular</p> <p>12 reason. It wouldn't necessarily mean that --</p> <p>13 When I say "optimize," what I mean is that you</p> <p>14 could achieve the best result that your design could</p> <p>15 allow.</p> <p>16 Q And if, let's say, during the design process a</p> <p>17 part was changed or added such that it affected the</p> <p>18 inhalation flow path, would a skilled artisan in 2003</p> <p>19 have been able to use those tools to improve the</p> <p>20 inhalation flow path?</p> <p>21 MR. MURRAY: Objection to form.</p> <p>22 THE WITNESS: The tool could be used to</p> <p>23 analyze the flow path; however, in the topic that we're</p> <p>24 discussing here, and what I've been forming opinions</p> <p>25 about, is that the addition of these holes is a</p>
<p style="text-align: right;">Page 28</p> <p>1 complication, which even though you could optimize, it</p> <p>2 doesn't mean that it would perform correctly, and it</p> <p>3 would most definitely create complexities in the</p> <p>4 design. So there's no guarantee that you could -- yes,</p> <p>5 certainly you could optimize it, but it doesn't mean</p> <p>6 that it would optimize it to function.</p> <p>7 BY MR. SKLAR:</p> <p>8 Q Have you performed any tests on a device, such</p> <p>9 as one that the petitioners have proposed in this case,</p> <p>10 to determine whether or not the flow path of that</p> <p>11 device would be sufficient?</p> <p>12 A Would you repeat that?</p> <p>13 Q You in your last answer had said you're</p> <p>14 testifying about a certain topic, and I presume you're</p> <p>15 talking about the combinations that have been proposed</p> <p>16 in this case; correct?</p> <p>17 A That's correct.</p> <p>18 Q And you understand there are two proposed</p> <p>19 combinations as it relates to the '177 patent; correct?</p> <p>20 A Correct.</p> <p>21 Q And that's -- the combination of Elliott and</p> <p>22 Rhoades is Ground 1; right?</p> <p>23 A Correct.</p> <p>24 Q And Bason and Rhoades -- for your benefit,</p> <p>25 it's B-a-s-o-n -- is Ground 2; correct?</p>	<p style="text-align: right;">Page 29</p> <p>1 A Correct.</p> <p>2 Q Have you performed any tests on a device such</p> <p>3 as the ones that petitioners have proposed in Grounds 1</p> <p>4 and 2 of this case to determine whether or not the flow</p> <p>5 path of those devices would be sufficient?</p> <p>6 MR. MURRAY: Objection to form.</p> <p>7 THE WITNESS: What I have done is performed</p> <p>8 very large and complete computational fluid dynamics in</p> <p>9 devices that are similar, and I have had to adjust</p> <p>10 designs in order to achieve proper flow paths, which</p> <p>11 would make the device safe and effective. So I am</p> <p>12 aware --</p> <p>13 I have experience and certain intuition that</p> <p>14 helps me to understand the effects on, you know, the</p> <p>15 flow path of these kinds of drug-delivery devices. For</p> <p>16 some part of my opinion, that's what I base that on.</p> <p>17 BY MR. SKLAR:</p> <p>18 Q Okay. So once again, just to be clear, that</p> <p>19 wasn't my question. And I think you can see at this</p> <p>20 point, I'm going to be a stickler for making sure that</p> <p>21 I get the answer to my question, and it certainly will</p> <p>22 go faster for all of us here, but I'll keep repeating</p> <p>23 if necessary. I also know we're limited by time to a</p> <p>24 degree here, and certainly I don't want to have to</p> <p>25 involve the Board to request additional time because</p>



<p style="text-align: right;">Page 30</p> <p>1 the answers are nonresponsive. So if we can stick to  2 that question, I think we'll be able to move this  3 forward a little faster.</p> <p>4 My issue with your response is that you  5 mentioned that you had performed some analysis on  6 similar devices. That's not what I had asked you  7 about. Okay? So to be clear, I'll repeat my question.</p> <p>8 Have you performed any tests on the devices  9 that would result from the Bason/Rhoades combination to  10 determine whether or not the flow path of those devices  11 would be sufficient?</p> <p>12 MR. MURRAY: Objection. Form.</p> <p>13 THE WITNESS: That would be an impossible task  14 for me to perform.</p> <p>15 BY MR. SKLAR:</p> <p>16 Q So you have not done that?</p> <p>17 A The physical combinations have never been  18 created by anybody.</p> <p>19 Q Have you performed any tests on the devices  20 that would result from the Elliott/Rhoades combination  21 to determine whether or not the flow path of those  22 devices would be sufficient?</p> <p>23 A Since they've never been created, a test could  24 never be performed.</p> <p>25 Q When you said earlier that you had performed</p>	<p style="text-align: right;">Page 31</p> <p>1 tests or analysis on similar devices, did those similar  2 devices have through holes like the ones that we've  3 discussed in both the Ground 1 and Ground 2  4 combinations?</p> <p>5 A They had through holes, but because these  6 devices that we're discussing here in the combinations  7 are unique unto themselves, you know, they could never  8 be identical. But, yes, there were through holes in  9 the other devices.</p> <p>10 Q What were those other devices that you  11 analyzed?</p> <p>12 A I worked on an inhalation device for nicotine  13 delivery and also developed test equipment for the  14 analysis and optimization of the -- and confirmation of  15 the computational fluid dynamics model.</p> <p>16 Q For that same inhalation device, for nicotine  17 delivery?</p> <p>18 A Yes. Correct.</p> <p>19 Q Is that inhalation device for nicotine  20 delivery that you worked on an MDI?</p> <p>21 A How would you define an MDI?</p> <p>22 Q How would you define an MDI?</p> <p>23 A Well, you're asking the question. I would  24 like to understand what your question is getting to.</p> <p>25 Q Sure. You are being presented here as a</p>
<p style="text-align: right;">Page 32</p> <p>1 skilled artisan or an expert in this field. I would  2 like to understand what is your understanding of what  3 an MDI means in the context that we've been discussing  4 it.</p> <p>5 A Well, it can mean many things. An MDI in the  6 context of the combinations that we're discussing,  7 those are handheld devices that deliver a particular  8 quantity of drug; thus, metered-dose inhalation.</p> <p>9 The nicotine delivery system I was working on  10 also delivered a metered dose. So I would -- I would  11 consider it and classify it as a metered-dose inhaler,  12 disposable usually. They're reusable for a period of  13 time, but they're not durable. It's -- I think there  14 are a large number of devices which could be captured  15 under the umbrella of MDI.</p> <p>16 Q Where were the through holes on the inhalation  17 device for nicotine delivery that you worked on?</p> <p>18 MR. MURRAY: Objection to form.</p> <p>19 THE WITNESS: They were located proximal to  20 the -- well, they were proximal to the actual device  21 that was creating the droplets.</p> <p>22 BY MR. SKLAR:</p> <p>23 Q Can you explain that in more detail?</p> <p>24 A I would consider it upstream of the droplet  25 delivery device. One of the requirements for that</p>	<p style="text-align: right;">Page 33</p> <p>1 nicotine delivery device was that it be a rather small  2 form factor. And so, much like the metered-dose  3 inhalers in the combination, we have, you know, a  4 canister, things that are formed upstream. When you  5 shrink that form factor way down, you lose an entry  6 point for fresh air to be pulled past the device that's  7 generating the droplets. And so I was creating an  8 air stream with those holes.</p> <p>9 Q And what ultimately happened with that  10 project?</p> <p>11 A Ultimately what happened with that project was  12 Hewlett-Packard sued the company, the start-up. There  13 was -- so there was a disagreement, a business  14 disagreement between Hewlett-Packard, who was supplying  15 the delivery, the actual droplet-forming device, and  16 put them out of business.</p> <p>17 Q So that product did not move forward because  18 they were put out of business; correct?</p> <p>19 A That's correct.</p> <p>20 Q Are there any differences in terms of what you  21 analyzed as an engineer between the optimized  22 inhalation flow path for a nicotine delivery device and  23 the optimized inhalation flow path for a drug delivery  24 device?</p> <p>25 MR. MURRAY: Objection. Form.</p>

<p style="text-align: right;">Page 34</p> <p>1 THE WITNESS: What I would say about that is  2 that every inhalation device is different from the  3 other, unless they're just replicates of the same. And  4 even when they're replicates, there's variation; right?  5 But each inhalation device would be unique unto itself.  6 Yeah.  7 BY MR. SKLAR:  8 Q When you work on the design of an MDI, is the  9 inhalation flow path always the correct inhalation flow  10 path from the beginning of the project through the end?  11 MR. MURRAY: Objection. Form.  12 THE WITNESS: So, you know, it depends on the  13 project that you are working on. If you are assigned  14 to a project where you're creating a MDI or, you know,  15 an inhalation device from scratch, you know, obviously  16 it evolves.  17 If you are sustaining a inhalation device, the  18 hope is that you don't disturb it, because -- you know,  19 unless the flow path was at fault, unless there's a  20 problem with the flow path. So in terms of, you know,  21 would the flow path be the same from beginning to end  22 of the project? Well, it would depend.  23 BY MR. SKLAR:  24 Q But you agree that in 2003, based on the FDA's  25 guidance, a change would have to be made to MDIs, which</p>	<p style="text-align: right;">Page 35</p> <p>1 could disturb the inhalation flow path; right?  2 MR. MURRAY: Objection. Form.  3 THE WITNESS: What I would say is that anytime  4 you would go into an MDI, an existing MDI, if you  5 wanted to add something to it, again, that would fall  6 under the umbrella that I would refer to as sustaining,  7 that would require a check of the flow path.  8 BY MR. SKLAR:  9 Q I'm going to hand you another document that  10 I'm marking as 1013.  11 (Exhibit 1013 was referenced.)  12 BY MR. SKLAR:  13 Q And this exhibit is the final guidance from  14 the FDA; correct?  15 A It appears to be that. Yes.  16 Q That's from March 2003?  17 A Yep. Yes.  18 Q And if you look at the Bates stamp in the  19 lower right-hand corner, it's page 6 of 7. Do you see  20 a header, "General Recommendations"?  21 A I see that, yes.  22 On paragraph 8?  23 Q Yes.  24 And so the general recommendation -- one of  25 the general recommendations from the FDA is that</p>
<p style="text-align: right;">Page 36</p> <p>1 manufacturers with metered-dose inhalers under  2 development for oral inhalation integrate a  3 dose-counting device into the development of their MDI  4 drug product; correct?  5 A Correct.  6 Q So am I correct that there could have been  7 certain manufacturers who were already in the process  8 of developing an MDI who would now have to make this  9 change that the FDA is requiring? Correct?  10 MR. MURRAY: Objection. Form.  11 THE WITNESS: Yes. I believe that's what this  12 is stating.  13 BY MR. SKLAR:  14 Q And that change could affect the inhalation  15 flow path; right? The addition of the counter could  16 affect the inhalation flow path.  17 I think we established that earlier; right?  18 A As I said, if you're working on an inhaler and  19 you get into a sustaining situation where you're adding  20 something to -- you know, if the flow path has already  21 been established and then you now want to do something  22 that you fear might interfere with it. But even if you  23 didn't fear that, you would be -- you would have to  24 check it, you know, as a -- you know, just to qualify  25 it. So --</p>	<p style="text-align: right;">Page 37</p> <p>1 Q So I think that's a good point. I'd like to  2 be clear about that.  3 Any change that you make to your design will  4 require reverification of the product; correct?  5 A In medical devices, if you have an established  6 device that's already on the market, you wouldn't  7 revalidate everything or re- -- you wouldn't retest  8 everything. You would test the specific areas that  9 might be affected. So that would be a retrospective  10 test, a verification test, as opposed to a validation,  11 but it would be a verification test. So not all things  12 get tested, but anything subsystem which it may have an  13 effect on.  14 Q So inhalation flow path would be something  15 that would be retested if, say, a change is made to the  16 design of the product.  17 A I believe that for MDIs, inhalation devices,  18 because the delivery of the drug and the quantity of  19 the drug is critical to the safety and efficacy, that  20 that would -- that would necessarily have to be  21 retested, probably regardless -- for any changes except  22 for maybe labeling.  23 Q And if the tools that engineers use to do that  24 retesting determine that the addition of some component  25 or -- let me -- scratch that. Strike that.</p>

<p style="text-align: right;">Page 38</p> <p>1 If the tools that engineers use to retest the  2 inhalation flow path determine that some change to the  3 design of the MDI has caused an unsatisfactory change  4 to the inhalation flow path, what tools or what would  5 an engineer do in order to try to correct that?  6 MR. MURRAY: Objection to form.  7 THE WITNESS: Again, we can say a change --  8 you know, which is something different about the design  9 that you're evolving it to -- it could be a simple  10 change, or it could turn out to be a complicated  11 change. So in all cases, they would have to -- what  12 would be common is that there would be tests that have  13 already been validated to show that there is a  14 correlation to how safe and effective the device is out  15 in the field. Those -- once established, they would  16 just continue to use those tools. The change, whatever  17 the change is, could be -- like I said, have minor or  18 major effects, and sometimes those changes need to be  19 actually pulled back, because you could create a device  20 that is no longer meeting its spec. So it really is  21 dependent on the change and the complexity that it  22 causes in the flow path.  23 BY MR. SKLAR:  24 Q How do through holes affect the inhalation  25 flow path?</p>	<p style="text-align: right;">Page 39</p> <p>1 A I guess the simplest way to answer that would  2 be just to say that the fluid dynamics of a vessel is  3 impacted by many aspects of that vessel, and when you  4 inject a feature -- it could be a bump or it could be a  5 hole or it could be a rib or it could be -- you know,  6 there's many different effects by whatever changes you  7 make in the flow path of the vessel. So obviously  8 adding holes, one of the things --  9 I'm not going to be able to, you know,  10 completely answer the question in terms of a particular  11 instance, because we don't, you know, have the tools in  12 front of us to run it and to actually define what those  13 are, but, for instance, one of the effects could be --  14 well, necessarily would be the addition of high  15 velocity fresh air being injected into an already  16 established flow path, and that would -- in MDIs, it's  17 not only just the simple flow path, but it's how the  18 drug is being carried in the flow path, in what -- in  19 what area or portion of the cross-section of the flow  20 path; the distance that the drug travels from point of  21 injection to the lung gets disturbed.  22 So there's a myriad of considerations that get  23 impacted when you especially throw in a feature such as  24 openings, which can create a lot of issues with the  25 flow path. So it's rather complicated. Yes, there are</p>
<p style="text-align: right;">Page 40</p> <p>1 tools that you would use to analyze it, but like I was  2 saying before, you know, there are simple changes, and  3 then there are very complicated changes.  4 Q Are there any ways for skilled artisans to  5 reduce the amount of fresh air being injected into a  6 flow path?  7 A Certainly. There could be ways to do that.  8 Q Does the '177 patent say anything about an  9 inhalation flow path?  10 A I don't recall.  11 I would add to that, however --  12 The patent is about metered-dose inhalers.  13 So, inherently, you know, it's a device for delivering  14 drugs. So that is an aspect that immediately comes to  15 your mind as you're reading the patent; that that is --  16 that's part of what that patent -- it's part of what  17 that patent is addressing.  18 Q But the '177 patent doesn't specifically  19 describe how to set a proper inhalation flow path;  20 right?  21 A I don't recall.  22 Q Let's assume for a moment that it doesn't.  23 Okay? If I'm going --  24 I'm going to represent to you that it does  25 not, okay, for purposes of this question. So given</p>	<p style="text-align: right;">Page 41</p> <p>1 that the '177 patent does not discuss an inhalation  2 flow path, is it your opinion that a skilled artisan  3 reading the '177 patent would be capable of making a  4 fluid dispenser that has a proper inhalation flow path?  5 MR. MURRAY: Objection. Form.  6 THE WITNESS: Okay. Let me just make sure I  7 got this right. So you're saying assuming the patent  8 says nothing about a flow path, would a skilled artisan  9 be able to -- I'm sorry -- adjust? Modify?  10 BY MR. SKLAR:  11 Q To make a fluid dispenser like the ones  12 claimed in the '177 patent that has a proper inhalation  13 flow path.  14 A Well, I guess I would have to say that the  15 presumption is that one would be able to make it work.  16 But given that the patent does incorporate in its  17 specification, you know, many of the functioning  18 features of an MDI, I would say yes, you know, you  19 would be successful. So --  20 Q So if I were to incorporate all of those  21 features that are claimed in the '177 patent, you would  22 have confidence that my device would have a proper  23 inhalation flow path? Because it has all the features.  24 A Well, the '177 patent isn't a -- it's not a  25 design file for a particular MDI. It's a specification</p>

<p style="text-align: right;">Page 42</p> <p>1 describing conceptually a unique approach to an MDI.  2 So, I mean, I would have to see something that's more  3 of a -- design-related information.  4 Q What do you mean you'd have to see something  5 that's more design-related information?  6 A Well, I believe you're asking, you know, you  7 would have a successful finished product, and what I  8 would say to that is that to analyze that, I would have  9 to see the design file, the -- what is it that you've  10 reduced a practice from this patent? The  11 presumption -- as I stated before, the presumption is,  12 in following the specification that you would  13 incorporate many, many aspects of functioning MDIs.  14 And I'm just saying that I would like -- I would  15 have -- to analyze that properly, I would have to see  16 what that's been reduced to practice.  17 Q So I guess I'm a little unclear about what  18 your testimony is. Is it your testimony that you're  19 not certain whether a skilled artisan would be able to  20 make a fluid dispenser pursuant to the claims of the  21 '177 patent that would have a proper inhalation flow  22 path?  23 MR. MURRAY: Objection. Form.  24 THE WITNESS: I guess what I'm saying is that  25 the question that you're proposing to me is abstract in</p>	<p style="text-align: right;">Page 43</p> <p>1 that I have never analyzed a device that has been a --  2 a device reduced to practice from the patent itself.  3 But the presumption is, yes, you would be able to do  4 that.  5 (Exhibit 1001 was referenced.)  6 BY MR. SKLAR:  7 Q Okay. I'm going to hand you a document that  8 I've marked as Exhibit 1001.  9 This is the U.S. Patent No. 8,936,177;  10 correct?  11 A Correct.  12 Q And that's what we've been referring to as the  13 '177 patent; right?  14 A That is correct.  15 Q I'll ask you to take a moment and take a look  16 at claim 1 of the '177 patent, which can be found in  17 column 9. Let me know when you've had a chance to read  18 claim 1.  19 A Okay.  20 Q You agree that claim 1 does not say anything  21 about the inhalation flow path; correct?  22 A I do not see those words in that claim.  23 Q Is there anything in that claim that provides  24 guidance to a skilled artisan as to how to set the  25 inhalation flow path?</p>
<p style="text-align: right;">Page 44</p> <p>1 A Well, I believe that the patent is directed to  2 fluid dispensers, and one of those would be an MDI.  3 And so inherently, you would -- you would associate  4 that as part of it. Otherwise, it wouldn't be, you  5 know, a successful fluid dispenser.  6 Q Well, I guess what I'm asking you is: Where  7 is that part of it coming from? Where is that  8 knowledge about how to set the inhalation flow path  9 coming from?  10 A I guess it comes from -- what? -- over 50  11 years of development of metered-dose fluid-dispensing  12 devices.  13 Q Okay. So would it be correct to say it's  14 based on the knowledge of the skilled artisan?  15 A I think it's based on the fact that it's a  16 patent directed to those devices. So it's inherent.  17 Q You have a number of patents to your name;  18 correct?  19 A I do.  20 Q Do you recall how many, off the top of your  21 head?  22 A It's about a dozen.  23 Q Do you see the first line of claim 1 says "a  24 fluid dispenser comprising" --  25 Do you see that?</p>	<p style="text-align: right;">Page 45</p> <p>1 A Yes.  2 Q So do you understand the significance of the  3 word "comprising"?  4 A I'm not sure what you're thinking, but if you  5 can describe it maybe --  6 Q Sure. So in patent law, we say "comprising"  7 is a transitional term, which means it's open-ended.  8 So, in other words, the claim or the alleged infringing  9 product to meet the claim must have all the limitations  10 that are listed in claim 1, but it could have others.  11 Do you understand that?  12 A Yes.  13 MR. MURRAY: I'm going to object to this line  14 of question as calling for a legal conclusion.  15 BY MR. SKLAR:  16 Q A -- an MDI having --  17 Do you agree that claim 1 could cover an MDI  18 that has through holes?  19 MR. MURRAY: Same objection.  20 THE WITNESS: I'm not an attorney, a patent  21 attorney, so I'm not sure about the -- whatever -- the  22 legal aspects of your question, but something that is  23 as general as a fluid dispenser, if that's all you're  24 going on, you could -- many possible things could be  25 happening in that fluid dispenser.</p>

<p style="text-align: right;">Page 46</p> <p>1 BY MR. SKLAR:</p> <p>2 Q And that could include -- that claim 1 could</p> <p>3 cover an MDI that has through holes; correct?</p> <p>4 MR. MURRAY: Same objection.</p> <p>5 THE WITNESS: It could include any features</p> <p>6 that would --</p> <p>7 I'm assuming you're referring to just meeting</p> <p>8 that claim. Assuming it didn't have any relevance to</p> <p>9 the elements of the claim, I mean, yes, there are</p> <p>10 many -- there could be many features that are included.</p> <p>11 BY MR. SKLAR:</p> <p>12 Q What would be the cost of a tool having the</p> <p>13 arms that have been proposed by petitioners? And</p> <p>14 that's for both the Ground 1 and Ground 2 combinations</p> <p>15 in the '177 IPR.</p> <p>16 MR. MURRAY: Objection. Form.</p> <p>17 THE WITNESS: I wouldn't be able to answer</p> <p>18 that as I'm sitting here today, because there are many</p> <p>19 variables associated with what that would be, and all</p> <p>20 those variables would have to be defined and reviewed.</p> <p>21 So it's not -- I'm not comfortable trying to speculate</p> <p>22 on that right now.</p> <p>23 BY MR. SKLAR:</p> <p>24 Q Did you determine -- strike that.</p> <p>25 Did you perform any specific calculation to</p>	<p style="text-align: right;">Page 47</p> <p>1 determine how much additional maintenance would be</p> <p>2 required for a tool having arms such as the ones</p> <p>3 proposed by petitioners in Ground 1 and Ground 2 of the</p> <p>4 '177 IPR?</p> <p>5 A What my opinion is --</p> <p>6 Petitioners are proposing that they make a</p> <p>7 simple and easy combination and that the motivation of</p> <p>8 doing this is that because it is simple and easy and</p> <p>9 essentially interchangeable. What I know is what</p> <p>10 they're attempting to combine is not interchangeable.</p> <p>11 It will cause complexities, and there will be a nonzero</p> <p>12 effect on cost and complexity to the tooling, and it</p> <p>13 will most likely be a large nonzero effect. So the</p> <p>14 simple and easy motivation is -- I think, is not</p> <p>15 accurate.</p> <p>16 Q Again, that wasn't my question. You've done a</p> <p>17 pretty good job at least, so I'll let you off the hook</p> <p>18 easy. But I do want to get back again, and try to</p> <p>19 answer my question. Okay?</p> <p>20 Did you perform any specific calculation to</p> <p>21 determine how much additional maintenance would be</p> <p>22 required for a tool having arms such as the ones</p> <p>23 disclosed by petitioners in Grounds 1 and 2 of the '177</p> <p>24 IPR?</p> <p>25 A Again, how I answered previously: There are</p>
<p style="text-align: right;">Page 48</p> <p>1 so many variables and dependencies that I would have to</p> <p>2 do an actual calculation. But, again, what I do know</p> <p>3 is it's a nonzero effect and most likely a large</p> <p>4 nonzero effect.</p> <p>5 Q Did you perform any specific calculation to</p> <p>6 determine how frequently the arms might break?</p> <p>7 A My -- so my past experience in working with</p> <p>8 plastic injection molding and tooling engineers, which</p> <p>9 has been in excess of 30 years, again, it tells me that</p> <p>10 there is a nonzero effect on complexity. And, in</p> <p>11 particular, when you're using these kinds of mold arms</p> <p>12 that are being proposed, there is a very large</p> <p>13 maintenance issue that is associated with them,</p> <p>14 particularly when you're using multicavity tools, which</p> <p>15 these devices produced by the millions dictate. And</p> <p>16 they're very large, complex tools that need to be done</p> <p>17 very, very carefully and very simply.</p> <p>18 So in terms of maintenance, yes, there will be</p> <p>19 a -- certainly a nonzero effect on that, and it will be</p> <p>20 a large nonzero effect.</p> <p>21 Q Is the effect the same for both Ground 1 and</p> <p>22 Ground 2?</p> <p>23 A They most likely would not be identical, but</p> <p>24 they will be similar.</p> <p>25 Q Do you agree that in 2003, skilled artisans</p>	<p style="text-align: right;">Page 49</p> <p>1 were familiar with the injection molding concept of</p> <p>2 adding arms to create through holes?</p> <p>3 A I believe that that was something that is</p> <p>4 very -- would have been known and understood. So I</p> <p>5 would have to say certainly.</p> <p>6 Q Did you perform any tests to determine how the</p> <p>7 cooling layout would be affected in the devices</p> <p>8 proposed by petitioners in Grounds 1 and 2 of the '177</p> <p>9 IPR?</p> <p>10 A Again, we're talking about adding a</p> <p>11 significant feature in a tool that would have been</p> <p>12 existing without them that will have, like I said, a</p> <p>13 large nonzero effect on the tooling costs. It will</p> <p>14 also interfere with the layout of multicavity, large,</p> <p>15 multimillion-dollar tools which will have an effect on</p> <p>16 the cooling layout. All these -- all these changes and</p> <p>17 things will interact with the tooling costs, and</p> <p>18 they're not simple; they're complicated and costly.</p> <p>19 Q Again, that wasn't my question. Let's try</p> <p>20 that again.</p> <p>21 Did you perform any tests to determine how the</p> <p>22 cooling layout would be affected in the devices</p> <p>23 proposed by petitioners in Grounds 1 and 2 of the '177</p> <p>24 IPR?</p> <p>25 A Due to the fact that these devices don't</p>

<p style="text-align: right;">Page 50</p> <p>1 exist, there is no tooling that exists. There's no  2 software for mold flow analysis that exists. There is  3 no way I could perform that kind of a test.  4 Q Do skilled artisans or engineers have any  5 resources available to them to mitigate any of the  6 potential effects that you've identified in your report  7 of adding mold arms to the designs of Ground 1 and  8 Ground 2 in the '177 petition?  9 A Tooling engineers and tooling companies would  10 definitely have tools to attempt to minimize the impact  11 of these kinds of changes. And certainly if they are a  12 good company and good engineers, they would try to  13 mitigate as much as they could. But I'm -- my opinion  14 is that -- and that's incorporated in my opinion, that  15 that --  16 My assumption is that would have happened, but  17 yet even after that, it would still be a large nonzero  18 effect on cost and maintenance, et cetera.  19 MR. SKLAR: All right. Why don't we take a  20 quick break and come back.  21 MR. MURRAY: Sounds good.  22 (Recess taken 11:03 a.m. - 11:15 a.m.)  23 BY MR. SKLAR:  24 Q Welcome back, Mr. Clemens.  25 A Thank you.</p>	<p style="text-align: right;">Page 51</p> <p>1 Q Okay. In your declaration --  2 I'm still talking about your declaration for  3 the '177 IPR. I believe we've identified it as 2023.1.  4 Correct?  5 A Correct.  6 Q In your declaration, you state that the hoop  7 stress or bending stress is undesirable because it can  8 exceed the plastic material yield point. Right?  9 A Yes. Correct.  10 Q Well, just so we can have consistent  11 terminology here, what is the units that that is  12 measured in, the plastic material yield point?  13 A It could be -- well, depending upon, I guess,  14 your units that you're using, but, you know, pounds per  15 square inch or, you know --  16 It would vary depending upon, you know,  17 whether you're using the metric system or not. It's  18 usually measured in force per unit area.  19 Q What is the plastic material yield point for  20 the devices resulting from the combinations proposed by  21 petitioners in Grounds 1 and 2 of the '177 patent?  22 MR. MURRAY: Objection to form.  23 THE WITNESS: That would depend on what the  24 materials are.  25 ///</p>
<p style="text-align: right;">Page 52</p> <p>1 BY MR. SKLAR:  2 Q Is there any sort of standard that you've come  3 across in the use of MDIs? What is the standard --  4 Well, let me ask this first: Is there a  5 standard plastic material yield point for MDIs?  6 A I think that all these devices are unique unto  7 themselves. The materials that are selected are  8 selected for many different reasons. So they're all  9 going to be unique unto themselves.  10 Q Did you perform any tests to determine whether  11 a snap-fit would exceed the plastic material yield  12 point in a respiratory device described by petitioners  13 in Grounds 1 and 2 of the '177 IPR?  14 A Well, I guess I'd have to answer that question  15 based on the opinion that I render in my declaration,  16 and that is that, again, it is a -- it is a complicated  17 nonzero effect on change to the design. So my opinion,  18 what I'm stating in here, is that this is a complexity.  19 It is not necessarily going to prove to be successful.  20 It is a complication, which is not a circumferential  21 assembly. It is not necessarily what I would consider  22 a simple, easy change to a design. And so therefore --  23 You know, that's -- that's what my opinion is  24 stating here, is that it's going to be problematic.  25 Q You agree it's at least possible, that it</p>	<p style="text-align: right;">Page 53</p> <p>1 could be successful? In other words, it's possible  2 that inserting Rhoades' cam body into the inhaler body  3 of either Ground 1 or Ground 2 could be accomplished  4 without exceeding the plastic material yield point of  5 the inhaler body?  6 MR. MURRAY: Objection. Form.  7 THE WITNESS: So I appreciate your question.  8 Not being able to actually see what these devices are  9 and do a proper analysis, an engineering analysis, I  10 can say that this will be a complication. To what  11 degree it's a complication or whether it's possible or  12 impossible would depend on what these devices actually  13 look like.  14 BY MR. SKLAR:  15 Q So, to be clear, you're not certain to what  16 degree this snap-fit that has been proposed by  17 inserting the cam body into the inhaler body would be  18 likely to exceed the plastic material yield point.  19 A What I'm -- what my opinion is and what I'm  20 certain about is that it is going to be a nonsimple,  21 complicated change to the design that will need to be  22 addressed. And so, thus, my opinion is that this is  23 going in -- it's going against the notion that there  24 would be motivation to combine these designs, because  25 they really aren't interchangeable. They're unique</p>

<p style="text-align: right;">Page 54</p> <p>1 devices.</p> <p>2 And this is truly a complicated change, which</p> <p>3 is going to have to be dealt with, so, you know,</p> <p>4 that's -- without any physical devices to analyze;</p> <p>5 without, you know, any- -- anything to really discuss</p> <p>6 among engineers.</p> <p>7 We do know for certain it will be a</p> <p>8 complexity. It's an addition- -- additional</p> <p>9 complexity, and it makes the combination nonsimple.</p> <p>10 Q Does it mean that the combination is likely to</p> <p>11 exceed the plastic material yield point?</p> <p>12 A It depends on the design.</p> <p>13 Q And you can't really say that without having</p> <p>14 the actual devices and doing a proper analysis or</p> <p>15 engineering analysis; correct?</p> <p>16 A What I can say is that it's a significant</p> <p>17 enough complexity to the design that this is a</p> <p>18 likelihood. An engineered skilled -- a skilled artisan</p> <p>19 at the time would be immediately concerned about this</p> <p>20 as a risk, and certainly not necessarily one that can</p> <p>21 be managed.</p> <p>22 Q I'm a little confused, because I've heard</p> <p>23 testimony saying it is likely, I've heard testimony</p> <p>24 saying it's not likely, and I'm not really sure where</p> <p>25 you've ended up. So I want to understand.</p>	<p style="text-align: right;">Page 55</p> <p>1 Can you tell me the degree of likelihood that</p> <p>2 inserting the Rhoades cam body into either of the</p> <p>3 Ground 1 or Ground 2 inhaler bodies would result in</p> <p>4 exceeding the plastic material yield point of those</p> <p>5 bodies?</p> <p>6 MR. MURRAY: Objection to form.</p> <p>7 THE WITNESS: I would have to say that it's</p> <p>8 really impossible to answer that question based on my</p> <p>9 previous responses.</p> <p>10 BY MR. SKLAR:</p> <p>11 Q Have you ever utilized snap-fits in any of the</p> <p>12 devices that you've worked on?</p> <p>13 A Sure.</p> <p>14 Q Can you identify those?</p> <p>15 A Off the top of my head, I can't -- I can't</p> <p>16 relate the specifics, but conceptually, it would have</p> <p>17 been additional parts, such as perhaps a cap that would</p> <p>18 want -- that you would snap it into something. There</p> <p>19 were some prototype designs I worked on, that they</p> <p>20 snapped together in terms of -- the housing halves were</p> <p>21 designed to snap together.</p> <p>22 So there have been various aspects of those</p> <p>23 designs and many other designs.</p> <p>24 Q These snap-fits that you've used in the past,</p> <p>25 were these on medical devices?</p>
<p style="text-align: right;">Page 56</p> <p>1 A Everything I've worked on in my career has</p> <p>2 pretty much been medical devices.</p> <p>3 Q Can you estimate in total how many snap-fits</p> <p>4 you have used on devices that you've worked on?</p> <p>5 A I cannot.</p> <p>6 Q More than 100?</p> <p>7 A I have no idea. I honestly can't --</p> <p>8 I'm not sure, but I've worked on many, many</p> <p>9 devices.</p> <p>10 Q More than 50?</p> <p>11 A It would certainly be -- it would be greater</p> <p>12 than, let's say, maybe -- you know, certainly more than</p> <p>13 ten.</p> <p>14 Q Were any of these devices respiratory medical</p> <p>15 devices that have snap-fits that you worked on?</p> <p>16 A I would refer to my previous answer that I</p> <p>17 gave just a few minutes ago, that some of those were</p> <p>18 related to inhaler devices.</p> <p>19 Q Thank you for clarifying. I missed that, so I</p> <p>20 apologize. Thank you.</p> <p>21 Okay. I have a couple products here. I'm</p> <p>22 going to hand the first one to you. This is identified</p> <p>23 as Exhibit 1071.</p> <p>24 (Exhibit 1071 was referenced.)</p> <p>25 ///</p>	<p style="text-align: right;">Page 57</p> <p>1 BY MR. SKLAR:</p> <p>2 Q And if you'll take a look at that --</p> <p>3 Are you familiar with that device that I've</p> <p>4 handed you?</p> <p>5 A It looks a little bit like a nebulizer.</p> <p>6 Q That's correct. It's the Monaghan Aeroeclipse</p> <p>7 nebulizer.</p> <p>8 Have you ever heard of that particular brand</p> <p>9 of nebulizer before?</p> <p>10 A No, I have not.</p> <p>11 Q But you're generally familiar with it as a</p> <p>12 nebulizer?</p> <p>13 A Yes. That's correct.</p> <p>14 Q And a nebulizer is a respiratory device?</p> <p>15 A That is correct.</p> <p>16 Q And I only have one of these, so I'm going to</p> <p>17 ask you to hand it back and forth with me as I sort of</p> <p>18 demonstrate some of its snap-fit functionality.</p> <p>19 A Oh, sure.</p> <p>20 Q So there's a flapper on top here.</p> <p>21 Do you see that flapper?</p> <p>22 A I'd assume that that green part is like a</p> <p>23 silicone --</p> <p>24 Q Yes.</p> <p>25 A -- piece?</p>

1 Q Okay.

2 A Okay.

3 Q Can we refer to that as a flapper?

4 A Flapper. I would agree.

5 Q Okay. And do you see that there's a hinged  
6 piece above the flapper?

7 A That is a living hinge. Correct.

8 Q And if I push that hinge down without moving  
9 the flapper, that hinge snaps into place; correct?

10 MR. MURRAY: Objection. Foundation.  
11 Relevance.

12 You can answer.

13 THE WITNESS: Just to be correct -- not  
14 critical -- but there is a male feature which fits into  
15 a female feature. So it's not the hinge that's  
16 snapping. It's the male and female features.

17 BY MR. SKLAR:

18 Q Okay. Let me -- and thank you for that  
19 clarification. I think that's correct.

20 So to be clear, there is a male feature that  
21 snaps into the female feature to hold the flapper in  
22 place.

23 A May I see that again?

24 Q Yes. You break it, you buy it.

25 A No. I get you.

1 So I don't have my loupe handy, but what I  
2 would -- just based on --

3 It's a small feature. So based on what I see  
4 here, it looks like it might be more of an interference  
5 fit. You know, I'm not really sure how you're --

6 You know, when we say "snap-fit," we're both  
7 envisioning something in our minds, but they're not  
8 necessarily the same.

9 But what these two features look like is an  
10 interference fit and may not necessarily be a  
11 snap-fit.

12 Q How do you differentiate between an  
13 interference fit and a snap-fit?

14 A Well, a snap-fit typically entails features  
15 that possess ramps to facilitate movement across each  
16 other, and then vertical walls relative to the ramps  
17 such that they -- once they climb over the feature  
18 itself, the two features come together rather quickly,  
19 making -- creating a sound, snap, and the vertical  
20 walls interact such that you can't pull them apart.

21 In this instance, it looks like the features  
22 are designed to have an interference, but, again,  
23 without a loupe, maybe they're --

24 I mean, I don't see a true snap feature there,  
25 but I would call that an interference fit.

1 Q Regardless of what you call it, is it correct  
2 that it appears for this male portion to be inserted  
3 into the female portion, it has to have some effect on  
4 the yield point of the body that it's fitting into?

5 MR. MURRAY: Objection. Form. Foundation.

6 THE WITNESS: The fact that it requires force  
7 to create the connection -- and, you know, I am using  
8 the term "interference" -- there's got to be stress  
9 applied in the parts.

10 BY MR. SKLAR:

11 Q And the same would hold true; that when you  
12 have an interference fit, you have to make sure that  
13 you don't exceed the plastic material yield point of  
14 the parts. Correct?

15 A If your parts did not previously have those  
16 features and you suddenly needed to put one of those  
17 features in, that is an additional change, complexity,  
18 to the design, and it would have to be analyzed.

19 Q And to be clear, when you say it would have to  
20 be analyzed, you would have to make sure that even in  
21 an interference fit, that you don't exceed the plastic  
22 material yield point of the parts.

23 A So depending upon the application and the  
24 criticality of, you know, the feature itself and what  
25 the demands are on it, you could have various -- you

1 could have various solutions to that. So, I mean, it  
2 could be a one-and-done, or it could be something that  
3 is intended to be durable. So there is a lot of  
4 answers, a lot of solutions to what that interference  
5 fit might be.

6 Q Regardless of whether it's one-and-done or  
7 not, though, even to get the items together in the  
8 first place, you need to ensure that placing those  
9 items together into that interference fit or snap-fit  
10 does not exceed the plastic material yield point of  
11 those parts; correct?

12 A So, you know, just to be clear,  
13 "one-and-done," means probably something different to  
14 everybody, too. But it is not uncommon to exceed the  
15 material yield point on something that is meant to  
16 connect once, and it is utilized and then thrown away.  
17 So it really depends on the design; it depends on the  
18 requirements, the demands of the feature, and the  
19 functionality of the feature.

20 Q Just so I understand the one-and-done example  
21 that you referenced, is it your testimony that in  
22 getting those parts together in the first instance, it  
23 does not matter whether the parts exceed the plastic  
24 material yield point of the components?

25 MR. MURRAY: Objection. Form.



<p style="text-align: right;">Page 62</p> <p>1 THE WITNESS: What my answer was is that it  2 depends, and it depends on all of the things that I  3 said previously. So, I mean, unless you want me to  4 repeat them, I'll save time.  5 BY MR. SKLAR:  6 Q The particular component that we're looking at  7 on this nebulizer, which I've identified as  8 Exhibit 1071, is not a one-and-done type of fit;  9 correct?  10 MR. MURRAY: Objection. Form and foundation.  11 THE WITNESS: So are you referring to the  12 little feature, snap-fit, that you're calling --  13 BY MR. SKLAR:  14 Q That's correct.  15 A To be honest, I'm not sure what that is being  16 used for. I don't know what the requirements are.  17 Q Okay.  18 A I mean, it could be a one-and-done to just get  19 the flapper on it.  20 Q Would you agree that on this device, the hinge  21 that we've been looking at, and specifically the male  22 part of the hinge and the female part -- the male part  23 of that fit --  24 A Yeah.  25 Q -- and the female part that it fits into, when</p>	<p style="text-align: right;">Page 63</p> <p>1 those parts fit together, the plastic material yield  2 point has not been exceeded?  3 MR. MURRAY: Objection. Foundation.  4 THE WITNESS: I do not know.  5 BY MR. SKLAR:  6 Q Would you be able to see some sort of crack in  7 the device if that plastic material yield point had  8 been exceeded?  9 A A yield failure could take different forms.  10 So a crack wouldn't necessarily have to be there.  11 Q Okay. What would you need in order to know  12 whether or not the plastic material yield point has  13 been exceeded on this device?  14 MR. MURRAY: Objection. Foundation.  15 THE WITNESS: To be accurate with your  16 analysis, you probably would have to strain gauge it  17 and perform your test, measure the strains, and do  18 calculations.  19 BY MR. SKLAR:  20 Q You're familiar with nebulizers of this  21 type -- correct? -- of Exhibit 1071?  22 A I'm familiar with nebulizers in general. I  23 haven't seen one like that, but I've worked on  24 nebulizers, yeah, in the past.  25 Q Would you have any concern if assembling this</p>
<p style="text-align: right;">Page 64</p> <p>1 device resulted in the plastic yield of the material  2 having been exceeded?  3 MR. MURRAY: Objection. Form.  4 THE WITNESS: Obviously that would depend on  5 what the feature was, the feature location, what its  6 function is, where -- you know, how the function  7 relates to the safety and efficacy of the functionality  8 of the device. Lots of things to answer there.  9 BY MR. SKLAR:  10 Q So with respect to that first part that we  11 have discussed, which is the male part that fits into  12 the female part, as it relates to that, would you have  13 any concern if assembling that part of the device  14 resulted in the plastic material yield point being  15 exceeded?  16 MR. MURRAY: Objection. Form.  17 THE WITNESS: Just to clarify, is your  18 question directed at that particular device that you're  19 holding and the hinged flap and the male and female  20 portion?  21 BY MR. SKLAR:  22 Q Let's limit it to this device for now, yes.  23 A That -- again, that appears to be an  24 interference fit. I don't --  25 You know, I haven't done any calculations. It</p>	<p style="text-align: right;">Page 65</p> <p>1 does appear to be in the proximity of the flow path to  2 the patient, so that would certainly require careful  3 consideration. If there was any risk -- and I can  4 assure you that in our risk analysis, that this would  5 be on it -- that it would have to be carefully analyzed  6 and shown that it's for the duration of the life of the  7 product and also -- well, just the life cycle is what  8 they call it, you know, from cradle to grave; that it  9 would not pose a risk to the patient in terms of a  10 failure of that type.  11 Q And to be clear, when you say "in terms of a  12 failure of that type," you mean in terms of ensuring  13 that the plastic material yield point was not conceded  14 by -- was not exceeded by snapping the male portion  15 into that female portion?  16 MR. MURRAY: Objection. Form. Foundation.  17 THE WITNESS: Or if it -- if it did, that it  18 would not result in a particular risk to the patient.  19 And, again, our conversation, if I might just add, is  20 directed towards the device that's in your hand, and  21 you know, specific to that particular instance.  22 BY MR. SKLAR:  23 Q Getting back to this device, I want to discuss  24 another component of that device, which is a cap.  25 Can we call this a cap?</p>

<p style="text-align: right;">Page 66</p> <p>1 MR. MURRAY: Objection. Form. Foundation.  2 THE WITNESS: I'll go along with that.  3 BY MR. SKLAR:  4 Q Okay. I have removed the cap from the device.  5 Do you agree with that?  6 A Yes.  7 Q And now I'm placing the cap back on the device  8 and snapping it into place; correct?  9 A Correct.  10 Q Okay. Is that a snap-fit on this nebulizer,  11 which is Exhibit 1071?  12 MR. MURRAY: Objection. Form. Foundation.  13 Relevance.  14 THE WITNESS: I'll take -- I'll look at the  15 parts here again.  16 So I do see features that are similar to what  17 I was describing earlier, which appear --  18 Again, I don't have a loupe to see  19 specifically, but they appear to have ramps and  20 vertical edges or surfaces which would fit within each  21 other, and as you demonstrated a moment ago, that when  22 it is assembled, it -- this particular device does emit  23 a snap sound.  24 BY MR. SKLAR:  25 Q And just to be clear, as it relates to --</p>	<p style="text-align: right;">Page 67</p> <p>1 Well, let me -- give me a moment. I just want  2 to read that last answer.  3 When you said that it appears to have ramps --  4 And I'm talking this case. When you said that  5 the cap appears to have ramps and vertical edges or  6 surfaces, are you suggesting that it's akin to an  7 interference fit?  8 A What I would -- what I would say to that is  9 that you could incorporate an interference fit into a  10 snap-fit. Again, there are thousands of snap-fit  11 designs, as you can well imagine. Whether this one has  12 an interference fit, I don't know. I would have to  13 look at the design and analyze it. So --  14 Q Is there any less concern with exceeding the  15 plastic material yield point if you are using an  16 interference fit as opposed to a snap-fit?  17 A When you're designing parts, I would say that  18 where you are with respect to the yield of your  19 materials is always a design consideration, and it's a  20 strategy -- you may be actually using it as part of  21 your design, but it's hardly ever, I would say -- never  22 say never, but it's hardly ever an instance where  23 you're not considering it.  24 Q So to be clear, you consider the plastic  25 material yield point regardless of whether you're using</p>
<p style="text-align: right;">Page 68</p> <p>1 an interference fit or a snap-fit.  2 A What I'm saying is that whenever you're doing  3 mechanical design and there is a -- you're trying to  4 put parts together -- obviously there's many ways of  5 putting parts together, but if you're counting on an  6 interference fit or a snap-fit of this type of design,  7 that's just one of the check boxes that you have to  8 consider as you complete the design.  9 Q And I'm just trying to understand, because you  10 sort of -- you distinguished a little bit between a  11 snap-fit or an interference fit, and so I'm just trying  12 to understand the significance --  13 A Of that?  14 Q Yeah.  15 And so are you suggesting that in some way,  16 perhaps an interference fit is less likely to exceed  17 the plastic material yield point?  18 MR. MURRAY: Objection. Form.  19 THE WITNESS: No. It just totally depends.  20 And as I said before, you could design a  21 snap-fit with or without interference, an interference  22 fit. And I would assign -- the only significance I  23 would assign to the yield relative to your design work  24 is if it -- you know, if it had an impact; you know,  25 whether or not it's a requirement or if there's a</p>	<p style="text-align: right;">Page 69</p> <p>1 specific requirement of where you are with respect to  2 the yield.  3 BY MR. SKLAR:  4 Q Okay. So for both interference fits and  5 snap-fits, engineers will have to account for the  6 plastic material yield point of the product.  7 A It's part of the design process.  8 Q Are you familiar with this part of the  9 nebulizer?  10 MR. MURRAY: Objection. Form.  11 THE WITNESS: I don't know the product.  12 BY MR. SKLAR:  13 Q Are you familiar with a part called a  14 secondary?  15 MR. MURRAY: Objection. Form. Foundation.  16 THE WITNESS: Off the top of my head, I'm not  17 sure what aspect of the nebulizer that we're talking  18 about.  19 BY MR. SKLAR:  20 Q Sure. Okay. So for purposes of today, I'm  21 just trying to establish some language we can use so  22 that it's easier for us to converse.  23 Can we call this the internal portion of the  24 nebulizer?  25 A Yes.</p>

<p style="text-align: right;">Page 70</p> <p>1 Q Thank you.</p> <p>2 Okay. On this internal portion, do you see</p> <p>3 that there is another living hinge? Is that correct?</p> <p>4 A Correct.</p> <p>5 Q Okay. And the living hinge can be folded</p> <p>6 down, and a male portion of the living hinge can be</p> <p>7 inserted into a female portion and snapped together;</p> <p>8 correct?</p> <p>9 A It does appear --</p> <p>10 Let's see. You know, without magnification, I</p> <p>11 can't see the features precisely, but judging just on</p> <p>12 the general look of it, it looks like it could be a</p> <p>13 small snap-fit, but it would be very small.</p> <p>14 Q The sound certainly sounds like a snap; right?</p> <p>15 A Yeah. Now, the sound -- I'll just say that on</p> <p>16 a true snap-fit, you're certainly going to hear that</p> <p>17 sound, because you're ramping over features which then</p> <p>18 slam together. In some of these hinged designs, you</p> <p>19 could be just simply getting past a large feature,</p> <p>20 which again goes more towards a press fit. But there</p> <p>21 is a bit of a difference. A true press fit wouldn't</p> <p>22 necessarily emit the sound, but because there are flat</p> <p>23 surfaces coming together, when you achieve that fit --</p> <p>24 you know, that friction and fit, you have to exceed a</p> <p>25 point of high force, which then suddenly reduces to a</p>	<p style="text-align: right;">Page 71</p> <p>1 lower force, and the flat parts come together making</p> <p>2 that snap sound.</p> <p>3 Q So on this particular respiratory device,</p> <p>4 Exhibit 1071, we've identified at least three snap-fits</p> <p>5 or interference fits; correct?</p> <p>6 MR. MURRAY: Objection. Form.</p> <p>7 THE WITNESS: That's correct.</p> <p>8 BY MR. SKLAR:</p> <p>9 Q Are these types of products approved by some</p> <p>10 regulatory body?</p> <p>11 MR. MURRAY: Objection. Foundation.</p> <p>12 THE WITNESS: The FDA, it does provide</p> <p>13 clearance, marketing clearance, for respiratory devices</p> <p>14 such as that.</p> <p>15 BY MR. SKLAR:</p> <p>16 Q And would effectiveness of the device play a</p> <p>17 role in that clearance?</p> <p>18 MR. MURRAY: Objection. Foundation.</p> <p>19 Relevance.</p> <p>20 THE WITNESS: That is usually the foundation</p> <p>21 of their approval, is to review the file and to see</p> <p>22 that the producer has achieved all the requirements for</p> <p>23 release to the market.</p> <p>24 BY MR. SKLAR:</p> <p>25 Q And if these snap-fits on 1071 in some way</p>
<p style="text-align: right;">Page 72</p> <p>1 make the product unsafe for use or ineffective, would</p> <p>2 you expect that the FDA would reject that device?</p> <p>3 MR. MURRAY: Objection. Form. Foundation.</p> <p>4 Relevance.</p> <p>5 THE WITNESS: What the FDA would look for is</p> <p>6 indications that the developer has followed the typical</p> <p>7 requirements for a medical device launch. So they</p> <p>8 wouldn't actually be approving, you know, what they</p> <p>9 did. They would just be looking for -- or the</p> <p>10 technical correctness. They would be looking to see,</p> <p>11 for instance, did they do a risk analysis where things</p> <p>12 such as you're describing would show up, and, you know,</p> <p>13 it would be produced; that, "Yes, we did look at these</p> <p>14 things." And then they would say, "Okay. They did a</p> <p>15 risk analysis." So that's kind of what the FDA would</p> <p>16 be doing.</p> <p>17 BY MR. SKLAR:</p> <p>18 Q I want to talk for a moment about the Bason</p> <p>19 and Rhoades combination in the '177 IPR. Okay?</p> <p>20 And your position is that significant force</p> <p>21 would be required to rotate a canister during an</p> <p>22 actuation stroke. Is that right?</p> <p>23 A That's correct.</p> <p>24 Q In reaching that conclusion, that significant</p> <p>25 force would be required to rotate a canister during an</p>	<p style="text-align: right;">Page 73</p> <p>1 actuation stroke, did you examine any MDIs having a</p> <p>2 canister that rotate relative to a valve stem?</p> <p>3 A My opinion is based on my previous experience</p> <p>4 working with these devices in that time frame. And I</p> <p>5 did -- so I didn't obtain in particular a canister from</p> <p>6 that time period and reanalyze it. I'm just familiar</p> <p>7 with it from experience.</p> <p>8 Q Okay. That was a little unclear, and I think</p> <p>9 in part you were talking about a couple different</p> <p>10 devices there. So let me reask my question.</p> <p>11 In reaching your conclusion that significant</p> <p>12 force would be required to rotate a canister during an</p> <p>13 actuation stroke, did you examine any MDIs that have</p> <p>14 canisters that rotate relative to the valve stem?</p> <p>15 A Again, my opinion is based on my experience</p> <p>16 with the valves and canisters from that time period. I</p> <p>17 think that plays directly into my opinion there.</p> <p>18 Q But, see, we have a little disconnect here,</p> <p>19 because you're talking about your experience with</p> <p>20 valves and canisters from that time period, and we're</p> <p>21 not being clear about the functionality of the valves</p> <p>22 and canisters that you were actually looking at. So</p> <p>23 let me reask my question. Okay? Listen carefully, and</p> <p>24 please answer my question.</p> <p>25 In reaching your conclusion that significant</p>

<p style="text-align: right;">Page 74</p> <p>1 force would be required to rotate a canister during an  2 actuation stroke, did you examine any MDIs that have  3 canisters that rotate relative to the valve stem?  4 A All of these valves will rotate if enough  5 force is applied to them relative to the canister.  6 Q I'd like you to take a look at Exhibit 1057.  7 And, again, that's your deposition transcript from  8 April 24, 2019; correct?  9 A Yes.  10 Q I'd like you to take a look at page 202, and  11 then we'll direct you to line 10.  12 Were you asked this question, and did you give  13 this answer:  14 "Can the canister rotate about the stem?  15 "Answer: In the valve design certainly that  16 I've seen and am familiar with, that isn't how  17 they're constructed."  18 Do you see that?  19 A Yes.  20 Q Okay. So let me repeat my question now.  21 In reaching your conclusion that significant  22 force would be required to rotate a canister during an  23 actuation stroke, did you examine any MDIs that have  24 canisters that rotate relative to the valve stem?  25 MR. MURRAY: Objection. Form.</p>	<p style="text-align: right;">Page 75</p> <p>1 THE WITNESS: Do you mind if I read the whole  2 page to get the context of this?  3 BY MR. SKLAR:  4 Q Please do. Yes.  5 Have you had a chance to read that page,  6 Mr. Clemens?  7 A I'm in the process of reading it. Thank you.  8 Okay. And the specific question that you're  9 asking is --  10 Q Let me repeat it.  11 A Sure.  12 Q In reaching your conclusion that significant  13 force would be required to rotate a canister during an  14 actuation stroke, did you examine any MDIs that have  15 canisters that rotate relative to the valve stem?  16 A So my answer to that is that the valve designs  17 are intended for axial movement, and they're not  18 intended for rotational movement. But applying enough  19 force, of course you could rotate the two relative to  20 each other. And for the purposes of the recent  21 analysis, no, I did not. I did not locate drug  22 canisters from that time period to do testing.  23 Q Did you perform any calculation to determine  24 how much force would be required to rotate the canister  25 during the actuation stroke?</p>
<p style="text-align: right;">Page 76</p> <p>1 A Again, not having these specific parts or the  2 design detail itself so that I could utilize legitimate  3 data from that time period, I was not capable of  4 performing a calculation. But my opinion is based on  5 design experience, knowledge, and the development of  6 devices which use these canisters that have the valves.  7 Q So is it your testimony that you have no way  8 of obtaining an MDI from the 2003 time period that is  9 capable of -- that has a canister capable of rotating  10 about the valve stem?  11 MR. MURRAY: Objection. Form.  12 THE WITNESS: Just to repeat, given enough  13 force, you can rotate them relative to each other, and  14 my opinion is that that force is significant.  15 BY MR. SKLAR:  16 Q That wasn't my question. Let me focus you  17 again.  18 You had just testified that not having these  19 specific parts, you couldn't perform a specific  20 calculation. I'm just asking. Did you in any way  21 attempt to obtain an MDI from 2003 that was capable --  22 that had a canister capable of rotating about the valve  23 stem?  24 MR. MURRAY: Objection. Form.  25 THE WITNESS: That would -- I would be unable</p>	<p style="text-align: right;">Page 77</p> <p>1 to obtain all of the information, because the design  2 information is confidential to companies. So that was  3 not an option for me.  4 BY MR. SKLAR:  5 Q You do have MDIs sitting on your desk;  6 correct?  7 MR. MURRAY: Objection. Form.  8 THE WITNESS: I do.  9 BY MR. SKLAR:  10 Q Are you capable of measuring the amount of  11 force required in the linear direction to overcome the  12 frictional fit between the valve stem and the seal?  13 A Certainly I could do some measurements, some  14 force measurements.  15 Q Did you do those force measurements in  16 reaching the conclusions that you expressed in  17 Exhibit 2023.1, which is your declaration in support of  18 Aptar's sur-reply?  19 MR. MURRAY: Object to form.  20 THE WITNESS: I'm sorry. What part are you  21 referring to?  22 BY MR. SKLAR:  23 Q Same part we've been talking about for this  24 past ten minutes, about your testimony that a  25 significant amount of force would be required to rotate</p>

<p style="text-align: right;">Page 78</p> <p>1 the canister about the valve stem.</p> <p>2 So let me repeat my question. Did you perform</p> <p>3 any force measurements on -- strike that.</p> <p>4 In reaching your conclusions in your</p> <p>5 declaration in support of Aptar's sur-reply in the</p> <p>6 '177 IPR, did you measure the force required in the</p> <p>7 linear direction to overcome the frictional fit between</p> <p>8 the valve stem and the seal?</p> <p>9 MR. MURRAY: Objection to form.</p> <p>10 THE WITNESS: When you say "linear," do you</p> <p>11 mean axial?</p> <p>12 BY MR. SKLAR:</p> <p>13 Q Yes. In the direction that the user would</p> <p>14 depress the canister.</p> <p>15 A I did not perform any specific force test and</p> <p>16 am relying on those kinds of tests and experiences that</p> <p>17 I've had in the past during the time of, you know, the</p> <p>18 patent. To perform an accurate force test on devices</p> <p>19 back in that time frame would not be possible.</p> <p>20 Q Why do you say it would not be possible?</p> <p>21 A We're talking about 2019, and the time frame</p> <p>22 between then and now has been so great that those</p> <p>23 designs are no longer performing to what they were</p> <p>24 originally designed to perform at.</p> <p>25 Q Has the amount of force required in the axial</p>	<p style="text-align: right;">Page 79</p> <p>1 direction changed significantly from 2003 to today?</p> <p>2 A I don't know.</p> <p>3 Q You would agree that in 2003, the amount of</p> <p>4 force required in the axial direction could not be more</p> <p>5 than at least the average user could exert; correct?</p> <p>6 A There is certainly, you know, a human factor</p> <p>7 aspect of this that was taken into consideration during</p> <p>8 those days, and even more so now. You know, what that</p> <p>9 number is today, I haven't done tests recently to know.</p> <p>10 Q Would you have expected it to change</p> <p>11 significantly from 2003 to today? And, again, I'm</p> <p>12 referring specifically to the amount of force required</p> <p>13 in the axial direction.</p> <p>14 MR. MURRAY: Objection. Form.</p> <p>15 THE WITNESS: It probably would not, you know,</p> <p>16 judging on, you know, the fact that it's a medical</p> <p>17 device and the canisters have been made for quite a</p> <p>18 long time.</p> <p>19 BY MR. SKLAR:</p> <p>20 Q I'm going back to physics class a little bit</p> <p>21 here, if you don't mind, but I presume that's okay with</p> <p>22 you.</p> <p>23 You would agree with me that the frictional</p> <p>24 force between the valve stem and the valve seal is the</p> <p>25 same regardless of whether the valve stem is moving</p>
<p style="text-align: right;">Page 80</p> <p>1 axially or rotationally?</p> <p>2 A So it would depend on the forces of each</p> <p>3 application.</p> <p>4 Q Could you elaborate on that?</p> <p>5 A Well, you asked about frictional force.</p> <p>6 Q I did.</p> <p>7 A And frictional force is dependent on -- well,</p> <p>8 it's dependent on the normal force and the coefficient</p> <p>9 of friction between the surfaces that are in contact.</p> <p>10 So depending upon the normal force, assuming that</p> <p>11 you -- I'm assuming that we're talking about the same</p> <p>12 materials in contact, that would give you a potentially</p> <p>13 different result.</p> <p>14 Q I want to clarify. In this case, regardless</p> <p>15 of whether you're moving in the axial direction or the</p> <p>16 rotational direction, the friction is between the valve</p> <p>17 stem and the seal; correct?</p> <p>18 MR. MURRAY: Objection. Form.</p> <p>19 THE WITNESS: Well, yes. That's definitely</p> <p>20 true. I am not familiar with all the designs of the</p> <p>21 valves, but you know, there are many aspects of the</p> <p>22 valve that could come into play as to how you might</p> <p>23 rotate the valve versus put them into an axial</p> <p>24 movement. And this is because the --</p> <p>25 One of the concerns about an MDI is the fact</p>	<p style="text-align: right;">Page 81</p> <p>1 that you can put a leverage on that valve, because</p> <p>2 you're applying a force on the top of the canister, and</p> <p>3 so you have a bit of a fulcrum. And any kind of</p> <p>4 angular change to the valve stem could cause a leak.</p> <p>5 And there's -- that's a concern that has always been --</p> <p>6 has always been a requirement in these canister and</p> <p>7 valve designs, you know, since the beginning. And so I</p> <p>8 believe -- it's my opinion that that's one of the</p> <p>9 reasons why they're not really intended to be rotated</p> <p>10 relative to one another; they're just intended to work</p> <p>11 axially.</p> <p>12 BY MR. SKLAR:</p> <p>13 Q I get it, but that's a totally different issue</p> <p>14 from what I'm asking you about. Okay? I didn't ask</p> <p>15 you anything about leaking. I'm simply asking you a</p> <p>16 question about physics, if you will. Okay? And all</p> <p>17 I'm asking you --</p> <p>18 Okay. I will repeat my question.</p> <p>19 In this case, regardless of whether you're</p> <p>20 moving in the axial direction or the rotational</p> <p>21 direction, the friction between the valve stem and the</p> <p>22 seal is the same.</p> <p>23 A If the -- my answer to that is hopefully the</p> <p>24 same as what I thought I said, and that is if the</p> <p>25 normal forces and the coefficient of frictions are the</p>

<p style="text-align: right;">Page 82</p> <p>1 same, then you would have the same frictional force.</p> <p>2 Q That's all I'm asking.</p> <p>3 A But I'm just saying that these valves are</p> <p>4 different, and there are other aspects of them which</p> <p>5 could cause higher forces.</p> <p>6 Q And, again, you haven't analyzed an MDI that</p> <p>7 has a canister that is capable of rotating around the</p> <p>8 valve stem; right?</p> <p>9 A My -- that's a mischaracterization of what I</p> <p>10 said and what my opinion is. What I've said is you can</p> <p>11 rotate all of them given the proper force.</p> <p>12 Q So in valve stems that you have seen, they are</p> <p>13 constructed such that they can -- such that the</p> <p>14 canister can rotate about the valve stem.</p> <p>15 MR. MURRAY: Objection. Form.</p> <p>16 THE WITNESS: The canisters that I've worked</p> <p>17 with in the past have -- all of them have required</p> <p>18 significant force to rotate the canister relative to</p> <p>19 the stem, the valve stem.</p> <p>20 BY MR. SKLAR:</p> <p>21 Q So the valve stems that you have -- excuse me.</p> <p>22 Sorry.</p> <p>23 The MDIs that you have on your desk, in your</p> <p>24 office, have canisters that are capable of rotating</p> <p>25 about the valve stem.</p>	<p style="text-align: right;">Page 83</p> <p>1 MR. MURRAY: Objection. Form.</p> <p>2 THE WITNESS: Just to repeat what I said</p> <p>3 before, all of these valve stems and canisters can</p> <p>4 rotate relative to each other given a high enough</p> <p>5 force.</p> <p>6 BY MR. SKLAR:</p> <p>7 Q So I just want to make sure I'm clear.</p> <p>8 You have canisters on your desk right now that</p> <p>9 are capable of rotating about the valve stem; correct?</p> <p>10 A They all will rotate relative to each other</p> <p>11 given enough force.</p> <p>12 Q Let's make clear we're answering my question.</p> <p>13 On your desk right now, in your office, you</p> <p>14 have canisters that are capable of rotating about the</p> <p>15 valve stem.</p> <p>16 MR. MURRAY: Objection to form.</p> <p>17 THE WITNESS: All of the canisters and valves</p> <p>18 that are out there in the world that are used for MDIs</p> <p>19 will rotate relative to each other given enough force.</p> <p>20 BY MR. SKLAR:</p> <p>21 Q Including the ones sitting on your desk right</p> <p>22 now.</p> <p>23 A All of them do.</p> <p>24 MR. MURRAY: Objection to form.</p> <p>25 ///</p>
<p style="text-align: right;">Page 84</p> <p>1 BY MR. SKLAR:</p> <p>2 Q And that includes the ones that are sitting on</p> <p>3 your desk right now.</p> <p>4 A When I say "all," I'm including all of them.</p> <p>5 Q And those are the same canisters that were</p> <p>6 sitting on your desk before you submitted your</p> <p>7 declaration in support of Aptar's sur-reply in the</p> <p>8 '177 IPR?</p> <p>9 MR. MURRAY: Objection to form.</p> <p>10 THE WITNESS: Again, "all" would include</p> <p>11 canisters on your desk and my desk and everybody else's</p> <p>12 desk.</p> <p>13 BY MR. SKLAR:</p> <p>14 Q I don't have any on my desk, but I just want</p> <p>15 to be clear. Those MDIs that are capable of</p> <p>16 rotating -- that have canisters capable of rotating</p> <p>17 about the valve stem were on your desk in your office</p> <p>18 during the period of time that you were working on your</p> <p>19 declaration in support of Aptar's sur-reply to the '177</p> <p>20 patent?</p> <p>21 MR. MURRAY: Objection to form.</p> <p>22 THE WITNESS: Those valve stems and canisters</p> <p>23 would have required a significant force to rotate,</p> <p>24 and --</p> <p>25 ///</p>	<p style="text-align: right;">Page 85</p> <p>1 BY MR. SKLAR:</p> <p>2 Q I didn't ask what -- excuse me.</p> <p>3 Let's focus, because we have --</p> <p>4 A I'm just trying to answer your question.</p> <p>5 Q But you're not answering my question. My</p> <p>6 question is very clear. I'm not asking you how much</p> <p>7 force would be required to rotate those. All I'm</p> <p>8 asking you, okay, is whether or not those canisters</p> <p>9 that were capable of rotating about the valve stem were</p> <p>10 available to you while you were working on forming your</p> <p>11 opinions that are expressed in the declaration that you</p> <p>12 submitted in support of Aptar's sur-reply to the '177</p> <p>13 patent.</p> <p>14 MR. MURRAY: Objection to form.</p> <p>15 Mr. Sklar, I'd ask that you please try to</p> <p>16 refrain from interrupting the witness when he's</p> <p>17 answering your question.</p> <p>18 MR. SKLAR: When he's answering the question,</p> <p>19 there will be no interruptions.</p> <p>20 Q Can you please answer the question?</p> <p>21 A Again, the canisters that were on my desk, as</p> <p>22 with all canisters, are capable of rotating with</p> <p>23 respect to each other, given enough force, which is</p> <p>24 significant. And, yes, those canisters were on my</p> <p>25 desk, and I would have had to have -- if I wanted to do</p>

<p style="text-align: right;">Page 86</p> <p>1 a test to understand what the relative forces are, it 2 would have been significant and is the basis for my 3 opinion. 4 Q But you didn't do that test to determine what 5 the actual force would be to rotate the canister about 6 the valve stem during an actuation stroke. 7 A Again, I have answered this question before. 8 I didn't do the test. It wouldn't be an accurate test. 9 But I have done tests in the past, which I draw upon 10 from my experience. So I have that knowledge. 11 Q Those tests in the past, were they testing the 12 amount of force that would be required to rotate a 13 canister about a valve stem? 14 A Yes. 15 Q Okay. When were those tests conducted? 16 A Back when I was working on MDIs in the past. 17 Q Can you be more specific? 18 A Well, as any good engineer would do, and being 19 familiar with the design that you're working with and 20 familiarizing yourself with the different elements of 21 inhalers, of course reviewing and analyzing the valves 22 and the canisters and how they're made is all part and 23 parcel of understanding the design. So doing tests 24 such as being -- you know, being aware of forces to 25 actuate a valve or to disturb a valve, those are all</p>	<p style="text-align: right;">Page 87</p> <p>1 kinds of things that engineers typically do. 2 Q Did you specifically test how much force would 3 be required to rotate a canister about a valve stem? 4 MR. MURRAY: Objection to form. 5 THE WITNESS: I did perform that test. 6 BY MR. SKLAR: 7 Q What were the results? Do you have that data? 8 A I do not have that information on the top of 9 my head. 10 Q Okay. 11 A It was significant, though. 12 Q When did you perform that test? 13 A Probably at least a few times between 2000 and 14 2005. 15 Q So before your April 24, 2019 testimony; 16 correct? 17 A Correct. 18 Q And yet during that testimony, you testified 19 that the valve stems cannot rotate or the canister -- 20 excuse me. Strike that. 21 During that testimony on April 24, 2019, you 22 testified that the canister cannot rotate about the 23 valve stem. 24 MR. MURRAY: Objection. Form. 25 ///</p>
<p style="text-align: right;">Page 88</p> <p>1 BY MR. SKLAR: 2 Q Correct? 3 A Can you show me what we're talking about in 4 my -- 5 Q It's the same transcript that we read before. 6 Were you asked this question and did you give this 7 answer? It's page 202. 8 "Question: Can the canister rotate 9 about the stem? 10 "Answer: In the valve designs certainly 11 that I've seen and am familiar with, that 12 isn't how they're constructed." 13 A That -- yeah. They're not intended to -- 14 they're not intended to rotate. That's not how they're 15 constructed. They're not constructed and intended to 16 rotate that way. 17 Q You do not say anything about intent here, do 18 you? 19 Let me ask the question again. Tell me, were 20 you asked this question and did you give this answer: 21 "Can the canister rotate about the stem? 22 "Answer: In the valve designs certainly that 23 I've seen and am familiar with, that isn't 24 how they're constructed." 25 MR. MURRAY: Objection. Form.</p>	<p style="text-align: right;">Page 89</p> <p>1 THE WITNESS: You read the words. So I'm not 2 disputing that that's what I said. But I know what I 3 said, and I know what the meaning of that is, and I'm 4 trying to express that to you. 5 BY MR. SKLAR: 6 Q So it is your testimony now that you have in 7 the past measured how much force is required to rotate 8 a canister about a valve stem. 9 A In the past, I have done tests for information 10 purposes, for design purposes, and that -- those forces 11 are significant. 12 Q But you did not do a specific calculation for 13 this case to determine what the actual force would 14 be -- what actual force would be required to rotate a 15 canister about a valve stem? 16 MR. MURRAY: Objection. Form. 17 THE WITNESS: Again, my answer to that was I 18 don't have access to confidential design information, 19 which I could utilize to perform a calculation. 20 BY MR. SKLAR: 21 Q And you did not attempt to do that on any of 22 the devices for this case that you had accessible to 23 you, for example, in your office; correct? 24 MR. MURRAY: Objection to form. 25 THE WITNESS: I have devices. They represent</p>

<p style="text-align: right;">Page 90</p> <p>1 an instance in design; they don't represent the  2 complete design. To do that, I would need the proper  3 design documentation to perform that kind of analysis  4 and calculation.  5 BY MR. SKLAR:  6 Q You agree with me that these devices have been  7 around for decades; correct?  8 A Yes.  9 Q We talked earlier that the amount of force  10 required to move the device in the axial direction  11 probably would not have changed significantly between  12 2003 and now; correct?  13 MR. MURRAY: Objection. Form.  14 THE WITNESS: That being an ergonomic,  15 patient-related, functional aspect, most likely has  16 been pretty consistent; may have gotten a little less  17 over time. But I'm not -- again, I'm not familiar with  18 what the trends have been since that time frame.  19 BY MR. SKLAR:  20 Q You could have approximated for purposes of  21 this case using another MDI; correct?  22 MR. MURRAY: Objection. Form.  23 THE WITNESS: I already know that it's a  24 significant force. I'm not sure how that would have  25 added to my experience and knowledge.</p>	<p style="text-align: right;">Page 91</p> <p>1 BY MR. SKLAR:  2 Q What is the calculation that you would use if  3 you had the data to determine how much force would be  4 required to actuate an MDI if the canister was capable  5 of rotating about the valve stem during that actuation?  6 A I would probably utilize a torque watch of  7 some kind and at least -- I would at least do that.  8 That would give a good indication.  9 Q Is there an equation that you could use if you  10 knew, for example, the force of friction between the  11 valve stem and the seal? Is there an equation that you  12 could use to calculate the amount of force required to  13 activate an MDI if the canister was capable of rotating  14 about the valve stem?  15 A If I utilized the torque watch and did those  16 tests, I could utilize that information and try to  17 estimate what -- and studying the design of the valve,  18 which would require the detailed drawings, I could  19 estimate the force that is being created by whatever  20 the design is. And, you know, I wouldn't be able to  21 assign where each component of the force is being  22 assigned to relative to the valve design, but at least  23 from an external standpoint, we would at least have  24 that information.  25 MR. SKLAR: Okay. Let's take a quick break.</p>
<p style="text-align: right;">Page 92</p> <p>1 MR. MURRAY: Before we go off the record, I  2 just want to object on the record to the introduction  3 of Exhibit 1071 as not being authenticated, lack of  4 foundation, and relevance.  5 MR. SKLAR: All right. Off the record.  6 (Lunch recess taken 12:32 p.m. - 1:16 p.m.)  7  8  9  10  11  12  13  14  15  16  17  18  19  20  21  22  23  24  25</p>	<p style="text-align: right;">Page 93</p> <p>1 SAN DIEGO, CALIFORNIA; TUESDAY, JULY 16, 2019  2 1:16 P.M. - 2:27 P.M.  3 - - - -  4 EXAMINATION (Continued)  5 BY MR. SKLAR:  6 Q Welcome back, Mr. Clemens.  7 A Thank you. Good to be back.  8 Q We agreed earlier that in 2003, MDIs generally  9 were not designed to require a patient to use maximum  10 force to actuate the device; correct?  11 MR. MURRAY: Objection. Form.  12 THE WITNESS: What I would say is back then,  13 as it is true today, there was most likely an  14 established ergonomic force that was established and  15 determined by whatever company was developing the MDI,  16 and then that would establish the force range that they  17 were setting as a requirement for actuating.  18 BY MR. SKLAR:  19 Q You would agree they wouldn't set that  20 requirement at the maximum amount of force that a user  21 is generally capable of exerting; correct?  22 A A maximum force as --  23 What would that be? I'm not sure I  24 understand.  25 Q Well, you explained that there's an ergonomic</p>



<p style="text-align: right;">Page 94</p> <p>1 factor. I presume that it wouldn't be good design to  2 set the maximum actuation force at the --  3 Sorry. Excuse me.  4 It would not be a good design to set the  5 actuation force at the maximum amount of force that a  6 patient is generally capable of exerting; correct?  7 A That would be a good assumption.  8 Q And so I think based on that, we agreed  9 earlier that, in 2003, MDIs generally were not designed  10 to require a patient to use maximum force to actuate  11 the device; correct?  12 MR. MURRAY: Objection. Form.  13 THE WITNESS: The maximum force, yes, that  14 you're describing, which is the largest force  15 capable -- you know, a patient's capable of utilizing.  16 Yeah. It would not have been designed that way.  17 BY MR. SKLAR:  18 Q So some additional force could be required  19 without exceeding the maximum force that a patient is  20 capable of exerting; correct?  21 A Some -- say that again. Some --  22 Q If you start with sort of the standard MDIs in  23 2003, some additional actuation force could be required  24 without still exceeding the maximum force that a  25 patient is capable of exerting.</p>	<p style="text-align: right;">Page 95</p> <p>1 A So if I'm understanding you correctly,  2 whatever the theoretical ergonomic force was back in  3 those days was certainly lower, if not much lower, than  4 the maximum that a patient could exert, and -- so,  5 yeah, there would be a difference.  6 Q Correct.  7 And so you could add some additional force  8 requirement without exceeding the maximum force that a  9 patient was capable of exerting.  10 A You could add force -- you could add force  11 somewhere in between there. Correct.  12 Q In your declaration -- again, Exhibit 2023.1,  13 which is your declaration in the '177 IPR -- you state  14 that "a rotation mechanism such as that in Rhoades  15 cannot impart the significant force necessary to rotate  16 the canister." Correct?  17 A Well, let's read what I said here.  18 Q And that's in paragraph 9, and it's on page 5.  19 A Sure. Yeah. So we're talking about a pen  20 mechanism, which is designed with very, very low forces  21 that would not be intended and capable.  22 Q So in making that statement in paragraph 9,  23 are you referring to the Rhoades cam body exactly as it  24 appears in Rhoades, such that you would just take it  25 out of Rhoades and plop it into an MDI body?</p>
<p style="text-align: right;">Page 96</p> <p>1 MR. MURRAY: Objection to form.  2 THE WITNESS: I am -- my opinion is based on  3 the notion that you would utilize that kind of design,  4 and -- but very closely. It wouldn't be exactly that  5 design. It's quite small. But it would have to be,  6 you know, resized.  7 But as I understand what petitioners are  8 suggesting, is that we just make a combination of these  9 things, essentially a substitution. And, you know,  10 that kind of mechanism just probably would not be able  11 to do that.  12 BY MR. SKLAR:  13 Q How much force can the rotation mechanism of  14 Rhoades impart?  15 MR. MURRAY: Objection to form.  16 THE WITNESS: Without actually having physical  17 parts and a particular design to analyze, it would be  18 pure speculation for me to attempt to do that, to  19 make -- to give that a number. So, you know, I  20 wouldn't be comfortable trying to do that.  21 BY MR. SKLAR:  22 Q Do all MDIs use the same type of seal?  23 And when I'm referring to a seal, I'm  24 referring to the same seal that we've been discussing  25 between the valve stem and the canister. So with that</p>	<p style="text-align: right;">Page 97</p> <p>1 in mind, let me repeat the question.  2 Do all MDIs use the same type of seal between  3 the valve stem and the canister?  4 A I would say no, they do not, because there are  5 different manufacturers of valves, and they're  6 constantly trying to improve on them. But I don't  7 know -- I don't know about them all. So -- but I would  8 just say that there isn't just one particular standard  9 that's always used.  10 Q Do you agree that the different seals that are  11 used may impart a different amount of frictional force  12 between that seal and the valve stem?  13 A I do not believe that there is a standard that  14 they're necessarily following, which would necessitate  15 them to all achieve the same kind of design or force.  16 I do not believe there is a standard.  17 Q I appreciate it. I think you tried to answer  18 the question, but I want to make sure I'm clear. I'll  19 reask it. I think what you're saying is "yes."  20 Do you agree that the different seals that are  21 used may impart a different amount of frictional force  22 between that seal and the valve stem?  23 A There will always be a variance in the forces,  24 and so not only would you necessarily see a variance  25 between manufacturers and valve designs, but also in a</p>

<p style="text-align: right;">Page 98</p> <p>1 given valve design, you will also see a variance of  2 force. Just -- that's the nature of designing. Again,  3 the design.  4 (Exhibit 1001.2 was referenced.)  5 BY MR. SKLAR:  6 Q Okay. Mr. Clemens, I'm going to hand you  7 what's been marked as Exhibit 1001.2. This is a copy  8 of U.S. Patent No. 9,370,631; correct?  9 A That is correct.  10 Q And if I refer to this as the '631 patent,  11 you'll understand what I'm talking; right?  12 A Yes, sir.  13 Q And you understand that this patent is the  14 subject of the other IPR in this case, which is  15 2018-01055; right?  16 A I will take your words. I'll take it as  17 gospel.  18 Q And do you agree that the drawings that are  19 presented in this '631 patent are highly simplified  20 diagrams which do not show the fluid dispenser in  21 detail?  22 And I'll refer you back to column 5, line 3.  23 I'm actually using the inventor's own words. Let me  24 point you to that section.  25 A Sure.</p>	<p style="text-align: right;">Page 99</p> <p>1 Q I'll read that for you. "The drawings to  2 which the present description refers are therefore  3 highly simplified diagrams which do not show the fluid  4 dispenser in detail, but only in very diagrammatic  5 manner relating to the various portions that can be  6 moved relative to one another."  7 Do you see that?  8 A I do.  9 Q Do you agree with that statement?  10 A Yes, I do.  11 MR. MURRAY: Objection to form.  12 BY MR. SKLAR:  13 Q And you agree that the '631 patent does not  14 explain how all of the components, all of the claimed  15 components of the patent, connect?  16 MR. MURRAY: Objection to form.  17 THE WITNESS: The claims do not specifically  18 detail the -- whatever geometric connections, if I  19 understand what you're saying. It does not go into  20 that kind of fine detail.  21 BY MR. SKLAR:  22 Q And, likewise, the figures don't go into all  23 of that fine detail, showing the connections between  24 all of the claimed components in the '631 patent;  25 correct?</p>
<p style="text-align: right;">Page 100</p> <p>1 MR. MURRAY: Objection to form.  2 THE WITNESS: The patent and the schematics  3 do -- they do show --  4 Although it is schematically -- that is  5 true -- but it does show conceptually some geometries  6 and interactions to support the claims that they're  7 making.  8 BY MR. SKLAR:  9 Q But it doesn't actually show all of the  10 connections between all of the components of the fluid  11 dispenser described in the '631 patent; correct?  12 MR. MURRAY: Objection to form.  13 THE WITNESS: The patent doesn't show, let's  14 say, the connections that you might have to do in order  15 to reduce it to practice. You know, an actual device,  16 it doesn't show that.  17 BY MR. SKLAR:  18 Q The first embodiment of this patent is  19 disclosed in Figures 1 through 8. Why don't you just  20 take a moment to look at those figures.  21 You would agree with me that this --  22 Sorry. Have you had an opportunity to look at  23 those figures?  24 A Yes. I've scanned them. Thanks.  25 Q You would agree with me that for this fluid</p>	<p style="text-align: right;">Page 101</p> <p>1 dispenser disclosed in Figures 1 through 8 of the '631  2 patent to operate, there would need to be some sort of  3 biasing force; correct?  4 MR. MURRAY: Objection to form.  5 I'd also add that I think this is  6 potentially -- this line of questioning may exceed the  7 scope of this deposition, to the extent it's limited to  8 Mr. Clemens' declaration submitted in support of  9 Aptar's sur-reply.  10 THE WITNESS: Well, we know that there is  11 certainly a bias force that exists in the valves of the  12 canister. And it's been a while since I've reviewed  13 this in detail. I don't know if -- in the body of the  14 document, off the top of my head, if there are two,  15 three, or four other biasing forces, but I think  16 certainly by the nature of the biasing force in the  17 valve, that I would say yes. Of course there's biasing  18 force in this idea, this invention.  19 BY MR. SKLAR:  20 Q My question is slightly different. Let me  21 turn you to column 7, line 17. It's the line that  22 starts "With reference to FIG 5."  23 Do you see that?  24 A I do.  25 Q Okay. And I will read that for you.</p>

1 "With reference to FIG 5, it should be  
2 observed that when the user releases the pressure on  
3 the actuator member 30, the return spring (not shown)  
4 of the dispenser returns the reservoir 2 to its  
5 rest" -- and that's the number 2 -- "to its rest  
6 position by displacing the reservoir 2 axially relative  
7 to the body 1," so on and so forth.

8 Do you see that?

9 A Yes, I do see that.

10 Q Okay. So you agree that the return spring is  
11 not shown in the figures; correct?

12 A Correct.

13 Q Despite the fact that the return spring is not  
14 shown, is it your position that a skilled artisan would  
15 be able to figure out where to place that return spring  
16 in order to operate the fluid dispenser?

17 MR. MURRAY: Objection to the form.

18 THE WITNESS: I'm sorry. Are you asking --

19 Could you repeat it again just to make sure  
20 I've got the right direction of your question?

21 BY MR. SKLAR:

22 Q Yes, I can.

23 Do you agree that -- oh, excuse me. Strike  
24 that.

25 Despite the fact that the return spring is not

1 shown, is it your position that a skilled artisan would  
2 be able to figure out where to place that return spring  
3 in order to operate the fluid dispenser disclosed in  
4 embodiment 1 of the '631 patent?

5 MR. MURRAY: Objection to the form.

6 THE WITNESS: So given that the invention here  
7 is shown schematically, although the interactions are  
8 described and helpful features are shown to do that, it  
9 gives a skilled artisan the broad -- a broad approach  
10 to how this could be achieved. So there could be many  
11 solutions. So given that, it isn't being too specific  
12 on the reduction of art. I would say that, you know,  
13 there would be many, many options that could possibly  
14 work, and the skilled artisan would be able to latch  
15 onto one of those.

16 BY MR. SKLAR:

17 Q Okay. You understand that in some of the  
18 combinations in this case and some of the prior art  
19 references, gears had been molded onto the inhaler  
20 body; correct?

21 MR. MURRAY: Objection. Outside --

22 I'll just say again I think that these  
23 questions, to the extent that you're asking Mr. Clemens  
24 to opine on what the '631 -- what a skilled artisan  
25 would or would not do with respect to the '631 patent

1 are outside the scope of Mr. Clemens' reply  
2 declaration.

3 BY MR. SKLAR:

4 Q You can answer the question.

5 A It seems like you have something that you're  
6 aware of that I can't think of off the top of my head.

7 Is there something you could point to that  
8 could help me remember?

9 Q Sure.

10 Do you recall, for example, in the Bason and  
11 Rhoades combination that teeth were molded onto the  
12 inhaler body in the ground that was presented for -- on  
13 patentability?

14 A Okay. So petitioners suggested this; right?  
15 Is that what you're --

16 Q Let me be clear. There's prior art that shows  
17 this as well. For example, you understand that Rhoades  
18 shows stop members molded onto the body of the pen;  
19 correct? The housing of the pen?

20 A I believe Rhoades does not show that. Rhoades  
21 is a stamped part.

22 Q Okay. Not in --

23 Okay. I understand. Okay. Let's refer,  
24 then, to petitioners' Ground 1 and 2 combinations.

25 You understand that teeth are being molded

1 onto the inhaler body; correct?

2 A Yeah. In reviewing their suggested  
3 combination, they propose that. Correct.

4 Q You agree that if gears are molded to the  
5 inhaler body, those gears are stationary relative to  
6 the inhaler body.

7 MR. MURRAY: Objection to the form. Calls for  
8 a legal conclusion.

9 THE WITNESS: Well, if you have a part, you  
10 know, that you had molded and you call it a stationary  
11 part or you call it whatever you want, but there's a  
12 part, and you mold features to it, they would be, you  
13 know, features that are -- they're permanently formed  
14 relative to other features on the part. So I would  
15 agree -- I would agree to that.

16 BY MR. SKLAR:

17 Q Okay. What was your process for determining  
18 what issues you addressed in your report? And by,  
19 "your report," I'm referring to your declarations that  
20 you submitted in support of Aptar's sur-replies in both  
21 IPRs, the '177 IPR and the '631 IPR.

22 MR. MURRAY: I'm going to object on the basis  
23 of privilege, to the extent that your answer would  
24 invade your discussions with attorneys, you should not  
25 answer, but to the extent it does not, you can answer.

<p style="text-align: right;">Page 106</p> <p>1 THE WITNESS: And, again, what was my process?</p> <p>2 Is that what you said?</p> <p>3 BY MR. SKLAR:</p> <p>4 Q Uh-huh.</p> <p>5 A Well, just briefly, as an engineer that has</p> <p>6 been through a number of designs, you know, after a</p> <p>7 while, you know, you develop an ability to kind of</p> <p>8 visualize designs. And, you know, my basic process was</p> <p>9 to take the reports that petitioners advanced and read</p> <p>10 them carefully and analyze them on what they were</p> <p>11 saying and showing, if there was something to see, and,</p> <p>12 you know, analyze the design based on the input that</p> <p>13 I'm given. Very broadly, that's what I would do, and</p> <p>14 envision what their -- what they were advancing and how</p> <p>15 that would -- that might work.</p> <p>16 Q So was it your approach if you identified an</p> <p>17 issue that you disagreed with, an issue that</p> <p>18 petitioners were advancing that you disagreed with,</p> <p>19 would you have addressed that in your declaration,</p> <p>20 Exhibits 2023 in both IPRs?</p> <p>21 A If I found an issue of a problem in terms of</p> <p>22 the combination of the parts -- or the -- of the</p> <p>23 prior arts, you know, which were intended to be</p> <p>24 simplistic and easy to combine, if I found a problem</p> <p>25 associated with that, yes, I'd try to identify that and</p>	<p style="text-align: right;">Page 107</p> <p>1 describe it.</p> <p>2 Q I'm trying to understand your --</p> <p>3 It seems like there's a qualification there.</p> <p>4 So let me ask my question.</p> <p>5 Was it your approach if you identified an</p> <p>6 issue that you disagreed with that petitioners were</p> <p>7 advancing in their reply briefs and in their</p> <p>8 declarations in support of those reply briefs, would</p> <p>9 you have addressed those issues in your declarations,</p> <p>10 which are Exhibits 2023 in both IPRs?</p> <p>11 MR. MURRAY: Objection to the form.</p> <p>12 THE WITNESS: I analyzed the -- you know, the</p> <p>13 descriptions, both by petitioners and by petitioners'</p> <p>14 expert, to visualize how the combinations were being</p> <p>15 described to work, and applying them to the claims.</p> <p>16 And, you know, I would -- in fact, I did identify those</p> <p>17 areas, those issues which I came across in trying to</p> <p>18 understand the combinations as they were advanced.</p> <p>19 BY MR. SKLAR:</p> <p>20 Q I'll ask you a different question.</p> <p>21 Are you aware that you are permitted to submit</p> <p>22 a seven-page declaration?</p> <p>23 MR. MURRAY: Objection to the form.</p> <p>24 THE WITNESS: Ask it again.</p> <p>25 ///</p>
<p style="text-align: right;">Page 108</p> <p>1 BY MR. SKLAR:</p> <p>2 Q Are you aware that you are permitted to submit</p> <p>3 a seven-page declaration?</p> <p>4 A I don't --</p> <p>5 I didn't even think about it.</p> <p>6 Q But are you aware that you are permitted to</p> <p>7 submit a seven-page declaration?</p> <p>8 MR. MURRAY: Objection to form.</p> <p>9 THE WITNESS: Since I was collaborating with</p> <p>10 the attorneys, if there was a --</p> <p>11 Again, I'm not a lawyer. If there was a legal</p> <p>12 reason why that would not be permitted or otherwise</p> <p>13 qualified in any way, I would have relied on them to</p> <p>14 advise me.</p> <p>15 BY MR. SKLAR:</p> <p>16 Q Okay. So let me just ask it again.</p> <p>17 Were you aware that you were permitted to</p> <p>18 submit a declaration up to and including seven total</p> <p>19 pages in each IPR?</p> <p>20 MR. MURRAY: Objection. Object to form.</p> <p>21 THE WITNESS: I honestly didn't think about</p> <p>22 it.</p> <p>23 BY MR. SKLAR:</p> <p>24 Q That wasn't my question. I didn't ask you if</p> <p>25 you thought about it.</p>	<p style="text-align: right;">Page 109</p> <p>1 Were you aware that you were permitted to</p> <p>2 submit a declaration of seven pages in each of these</p> <p>3 IPRs?</p> <p>4 MR. MURRAY: Same objection.</p> <p>5 THE WITNESS: Well, perhaps another answer I</p> <p>6 could offer you is that I'm aware that a declaration of</p> <p>7 zero pages could -- could, you know, have been offered.</p> <p>8 So, you know, again, I didn't -- I haven't even thought</p> <p>9 about it. But you could either respond or not, and the</p> <p>10 response could be whatever pages that you would care</p> <p>11 for it to be, unless there was some sort of legal</p> <p>12 restriction.</p> <p>13 BY MR. SKLAR:</p> <p>14 Q And so what I'm asking you is: Were you aware</p> <p>15 that there was a seven-page limit for each of the IPRs</p> <p>16 that you submitted -- sorry, excuse me -- for each of</p> <p>17 the declarations that you submitted in the two IPRs</p> <p>18 that we're discussing today?</p> <p>19 A Again, if there --</p> <p>20 MR. MURRAY: Objection. Form.</p> <p>21 THE WITNESS: If there was a legal restriction</p> <p>22 on the declarations, I was -- I didn't ask that</p> <p>23 question and was not aware of it.</p> <p>24 BY MR. SKLAR:</p> <p>25 Q So as far as you were concerned, you could</p>

1 submit a declaration of any length; is that correct?

2 MR. MURRAY: Objection. Form.

3 THE WITNESS: Again, I'll say that in  
4 collaborating with the attorneys that I was working  
5 with, that's what it was.

6 BY MR. SKLAR:

7 Q It's really not a difficult question. Okay?  
8 It's a "yes" or "no" question.

9 Were you aware of a seven-page limit with  
10 respect to the declarations that you submitted in these  
11 two IPRs that we've discussed today?

12 MR. MURRAY: I'm going to object to form,  
13 relevance, and scope. I don't see what this has to do  
14 with the content of his declarations.

15 THE WITNESS: Again, I will refer you to a  
16 previous answer that I gave, and that is if there was a  
17 legal limit that was assigned, I was not aware of that,  
18 but I was working in collaboration with them to create  
19 a response.

20 BY MR. SKLAR:

21 Q Did I reference legal limit in my question?

22 MR. MURRAY: Objection to form.

23 THE WITNESS: I am just trying to communicate  
24 to you that I didn't even think about it.

25 ///

1 BY MR. SKLAR:

2 Q I didn't ask if you thought about it, and I  
3 didn't ask if there was a legal limit. All I'm asking  
4 is if you were aware that there was a seven-page limit  
5 on the declarations that you submitted in this case.

6 MR. MURRAY: Same objection. Form.  
7 Relevance. Scope.

8 THE WITNESS: I'm sorry. I just -- I simply  
9 didn't even think about it.

10 BY MR. SKLAR:

11 Q So you don't know if you were ever aware of a  
12 page limit in this -- for your declarations in this  
13 case?

14 MR. MURRAY: Same objection.

15 THE WITNESS: I didn't --

16 I never thought about it.

17 BY MR. SKLAR:

18 Q Again, not my question. It's not a difficult  
19 question, and I'm not sure why we're beating around the  
20 bush here, which makes me a little more suspect. I  
21 thought this was a relatively benign question.

22 Were you aware that there was a seven-page  
23 limit for each of the declarations that you submitted  
24 in this -- in the IPRs that we have discussed here  
25 today?

1 MR. MURRAY: Same objection.

2 THE WITNESS: I was not aware that there was  
3 instructions, legal instructions, outside of the scope  
4 of my -- of my knowledge that may have existed to limit  
5 the report to seven pages.

6 BY MR. SKLAR:

7 Q Again, there's a qualifier there, and I didn't  
8 say anything about legal instructions. So I want to  
9 make sure we're very clear. Okay?

10 Were you aware that there was a seven-page  
11 limit for the declarations that you submitted in the  
12 IPRs that we have been discussing here today?

13 MR. MURRAY: Same objection.

14 THE WITNESS: I think my last answer should  
15 have answered every- -- everything that you were  
16 asking.

17 BY MR. SKLAR:

18 Q It did not, because you were talking about  
19 legal instructions, and I have not asked you anything  
20 about legal instructions. It's a very simple question.  
21 Okay?

22 "Yes" or "no." Were you aware that there was  
23 a seven-page limit for the declarations that you  
24 submitted in the IPRs that we have discussed here  
25 today?

1 MR. MURRAY: Same objection.

2 THE WITNESS: Was there a limit of  
3 instruction? Was there an instruction given to the  
4 parties that was limited to seven pages? Is that true?  
5 BY MR. SKLAR:

6 Q I'm asking the questions, and it's not -- it's  
7 not relevant to the issue. Okay? The point is, I'm  
8 simply asking if you were aware that there was a  
9 seven-page limit for the declarations that you  
10 submitted that we've been discussing for the IPRs  
11 today.

12 MR. MURRAY: Same objection.

13 THE WITNESS: Again, I was not aware of any  
14 instructions that may have been given to the parties to  
15 limit their reports by page number.

16 BY MR. SKLAR:

17 Q Let me ask it a different way.

18 Was it your understanding that you could draft  
19 a declaration that was seven-pages in length?

20 MR. MURRAY: Same objection.

21 THE WITNESS: The report was created on --  
22 based on a collaborative effort with the attorneys, and  
23 that is how it arrived at that point.

24 BY MR. SKLAR:

25 Q To be clear, I'm not asking about what you did

1 with your attorneys; I'm not asking about legal  
2 instructions. Okay? All I want to know is your  
3 knowledge. Okay? It's a "yes" or "no." Either you  
4 knew or you didn't know.

5 Did you know --

6 Let me repeat the question.

7 Did you know that the declarations that you  
8 were submitting in the two IPRs that we were discussing  
9 today were to be limited to seven pages?

10 MR. MURRAY: Same objection.

11 THE WITNESS: I was not aware, and I did not  
12 know that there was an instruction for limitation until  
13 working in collaboration with the attorneys, and we  
14 were able to take all the information that we had been  
15 discussing, and the opinions I had been offering were  
16 put into form.

17 BY MR. SKLAR:

18 Q Again, I'm not asking about an instruction.

19 Was it your understanding that your  
20 declarations were not to exceed seven pages in length?

21 MR. MURRAY: Same objection.

22 THE WITNESS: I did not have any foreknowledge  
23 that there was going to be a restriction of seven  
24 pages.

25 ///

1 declaration.

2 Q Well, I was clear about my time frame. I'm  
3 asking you prior to the filing of these declarations on  
4 June 13, 2019, were you aware that there was a  
5 seven-page limitation for your declarations?

6 MR. MURRAY: Same objection.

7 THE WITNESS: I honestly had no awareness of a  
8 restriction on page limitation until it took its final  
9 form.

10 BY MR. SKLAR:

11 Q Did it take its final form prior to the filing  
12 of the declaration on June 13, 2019?

13 A Well, I was reviewing and editing very close  
14 to that time frame, but, again, I have to tell you I  
15 never even had a thought about the number of pages.

16 Q Not what I asked. Okay?

17 You said you had no awareness of a page  
18 limitation until the declaration took its final form;  
19 correct?

20 A (Witness nods head up and down.)

21 Q Okay. This declaration took its final form  
22 before it was filed; correct?

23 A Of course.

24 Q Okay. So before this declaration was filed,  
25 were you aware that the declaration was to be limited

1 BY MR. SKLAR:

2 Q What do you mean by you did not have any  
3 foreknowledge?

4 A Well, I'm just answering you honestly. I  
5 worked in collaboration with the attorneys. We talked  
6 about many topics, and the more we talked about them  
7 and the more we were able to refine our -- the report  
8 topics and I was able to fine-tune my opinions, and  
9 then it ended up in this form. I did not have  
10 foreknowledge prior to that process that there was a  
11 limitation of seven pages.

12 Q Prior to the filing of these declarations,  
13 which took place on June 13, 2019, at any point prior  
14 to that filing, were you aware that your declaration --  
15 your declarations were to be limited to seven pages in  
16 length?

17 MR. MURRAY: Same objection. Form, relevance,  
18 scope.

19 THE WITNESS: I had no awareness, no knowledge  
20 beforehand that there was going to be a limitation on  
21 any of the declarations.

22 BY MR. SKLAR:

23 Q And when you say "beforehand," what do you  
24 mean by "beforehand"?

25 A During the process of creating the

1 to seven pages?

2 MR. MURRAY: Same objection.

3 THE WITNESS: Again, I was -- I had no  
4 knowledge or awareness of any limitation that was  
5 placed on the number of pages for the declaration.

6 BY MR. SKLAR:

7 Q Is there a reason why you can't give me a  
8 "yes" or "no" answer to whether or not you knew that  
9 your declaration was to be limited to seven pages?

10 A Well, I'm just trying to answer your question  
11 honestly.

12 Q I don't think you are. I think the question  
13 can be answered very easily with a "yes" or a "no."

14 Let me try it again.

15 Prior to the filing of your declaration, were  
16 you aware that your declaration was to be limited to  
17 seven pages?

18 MR. MURRAY: Objection. Form. Relevance.  
19 Scope.

20 THE WITNESS: So help me understand what you  
21 mean by "awareness."

22 BY MR. SKLAR:

23 Q You don't understand what "awareness" means?

24 A I don't understand perhaps what you are -- the  
25 meaning that you're ascribing to the word "awareness."

<p style="text-align: right;">Page 118</p> <p>1 Q Did you think prior to the filing of this 2 paper that you could submit a 20-page -- 3 Sorry. You know what? Let's -- strike that. 4 At anytime prior to the filing of the 5 declarations that we have discussed here today, 6 Exhibits 2023 in both cases, were you informed that 7 your declarations were to be limited to seven pages? 8 MR. MURRAY: Objection. Privileged. 9 To the extent it implicates conversations with 10 your attorneys -- 11 BY MR. SKLAR: 12 Q And I'm not asking you to tell me -- 13 I don't need to know if this person told you 14 something or that person told you something. I don't 15 need to know what the conversation was. To be very 16 clear, I'm respectful of that, and I'm not asking. 17 I just want know what was your knowledge. 18 Okay? 19 A I'm going to just honestly say that I'm a 20 little confused by the whole questioning of this, but I 21 will say that I did not receive specific instructions 22 to limit my thoughts to an amount that would fit on 23 seven pages. I was not instructed to do that. 24 Q Wasn't my question. Okay? We'll try it 25 again.</p>	<p style="text-align: right;">Page 119</p> <p>1 At any point in time prior to filing the 2 declarations -- Exhibits 2023 in both of the IPRs that 3 we've been discussing today -- was it your 4 understanding that your declarations could not exceed 5 seven pages? 6 MR. MURRAY: Objection. Form. Relevance, 7 scope. 8 THE WITNESS: I believe my last answer 9 answered it. 10 BY MR. SKLAR: 11 Q It didn't. So can you answer my question 12 "yes" or "no"? Okay. You haven't once answered that 13 question "yes" or "no." I'm going to try it again. 14 At any point in time prior to filing the 15 declarations, Exhibits 2023 in both of the IPRs that 16 we've been discussing here today, was it your 17 understanding that your declarations could not exceed 18 seven pages? 19 MR. MURRAY: Objection. Form, relevance, 20 scope. 21 THE WITNESS: Well, I could not be aware or 22 have knowledge of a limitation on the number of pages 23 if I was not told that, and I've already answered 24 numerous times that I was not told that there was a 25 limitation. So therefore I could not have knowledge or</p>
<p style="text-align: right;">Page 120</p> <p>1 awareness of that limitation. 2 BY MR. SKLAR: 3 Q So is your answer "no"? 4 A I was not given -- given any instructions that 5 there was a limitation. 6 Q Okay. If you had identified other errors -- 7 Let me step back. 8 Do the positions that you've represented in 9 Exhibits 2023 in both of the IPRs represent all of the 10 disagreements that you have with petitioners' positions 11 as represented in their reply brief and Mr. Piper's 12 expert declaration in support of that reply? 13 MR. MURRAY: Objection. Relevance. 14 THE WITNESS: My response to that is these 15 combinations do have numerous aspects to them and 16 interactions. And, yes, of course, I could probably 17 identify other errors where there are some conflicts. 18 It's rare that -- especially, you know, in engineering 19 and during the process of analysis, you don't find 20 much. You usually find a lot. So -- 21 BY MR. SKLAR: 22 Q So is it still your position that the Rhoades' 23 plunger must be fully depressed before the Rhoades 24 cam body will rotate? 25 MR. MURRAY: Objection. This is outside the</p>	<p style="text-align: right;">Page 121</p> <p>1 scope of this deposition. 2 I'm going to instruct you not to answer. 3 MR. SKLAR: It's very much within the scope of 4 this deposition, and I will explain to you for a moment 5 why that is, and then you can determine if you want to 6 proceed with that instruction. 7 First of all, we have been discussing today at 8 length numerous combinations that relate to Rhoades, 9 that have Rhoades in the combination. You have 10 specifically addressed issues with respect to Rhoades' 11 cam body. You stated -- 12 For example, we discussed whether or not 13 Rhoades' cam body can be depressed -- or can be 14 inserted past the stop members, which implicates a 15 certain relationship between the stop members and 16 Rhoades' cam body. 17 Obviously the actuation stroke and the 18 movement of the cam body within Rhoades also implicates 19 the interactions between Rhoades' cam body and the stop 20 members. 21 Q I'm also going to ask you for a moment -- I'm 22 going to switch the line of questioning for a moment -- 23 and we'll get back to this -- to turn to Exhibit 2023 24 of the '177 patent -- 25 MR. MURRAY: '177.</p>

<p style="text-align: right;">Page 122</p> <p>1 THE WITNESS: Oh.</p> <p>2 BY MR. SKLAR:</p> <p>3 Q My apologies. Yeah. So we're going to look</p> <p>4 at 2023.1.</p> <p>5 And, again, this is your declaration in</p> <p>6 support of the sur-reply in the '177 IPR; correct?</p> <p>7 A Correct.</p> <p>8 Q And I'm going to ask you for a moment, in</p> <p>9 paragraph 2, what does it mean that you make this</p> <p>10 declaration as a supplement to the other declarations</p> <p>11 that you have submitted in this matter?</p> <p>12 A What does that mean?</p> <p>13 Q Uh-huh.</p> <p>14 A It just means that this is in addition to.</p> <p>15 Q Okay. And then paragraph 3, you list out your</p> <p>16 prior declarations in this case; correct?</p> <p>17 You list out, for example, your August 15,</p> <p>18 2018, declaration, which is Exhibit 2005; correct?</p> <p>19 A Uh-huh.</p> <p>20 Q And you list your February 13, 2019,</p> <p>21 declaration, which is Exhibit 2021; correct?</p> <p>22 A Yep. I see that.</p> <p>23 Q And you list your March 7, 2019, supplemental</p> <p>24 declaration; correct?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 123</p> <p>1 Q And then you say that the entirety of those</p> <p>2 declarations are incorporated herein by reference;</p> <p>3 correct?</p> <p>4 A That is what it says. Correct.</p> <p>5 Q And earlier today I asked you -- we took a</p> <p>6 look at your signature page.</p> <p>7 Do you remember that?</p> <p>8 A Yes.</p> <p>9 Q And I asked you is it your testimony that</p> <p>10 everything incorporated into your declaration, meaning</p> <p>11 Exhibit 2023, is true and correct; right?</p> <p>12 MR. MURRAY: Objection. Form.</p> <p>13 THE WITNESS: I believe that's true.</p> <p>14 BY MR. SKLAR:</p> <p>15 Q And you said that it was; right?</p> <p>16 A That's correct.</p> <p>17 MR. MURRAY: Object to the form.</p> <p>18 BY MR. SKLAR:</p> <p>19 Q And Exhibit 2021, for example, is incorporated</p> <p>20 by reference into this declaration, Exhibit 2023;</p> <p>21 correct?</p> <p>22 MR. MURRAY: Objection. Form.</p> <p>23 THE WITNESS: Ask the question again. It's</p> <p>24 incorporated by reference? Is that what you said?</p> <p>25 ///</p>
<p style="text-align: right;">Page 124</p> <p>1 BY MR. SKLAR:</p> <p>2 Q I'm using your words. Yeah. The entirety of</p> <p>3 those declarations is incorporated herein; correct?</p> <p>4 A That's what the words say.</p> <p>5 Q So I'm going to ask you again.</p> <p>6 Is it still your position that Rhoades'</p> <p>7 plunger must be fully depressed before the Rhoades</p> <p>8 cam body can rotate?</p> <p>9 MR. MURRAY: And I'm going to object again and</p> <p>10 maintain my objection.</p> <p>11 You should not answer that question on the</p> <p>12 basis of scope.</p> <p>13 The Board is clear that this is limited to the</p> <p>14 scope of his reply of his declaration given in support</p> <p>15 of Aptar's sur-reply. That content is not discussed</p> <p>16 whatsoever in that sur-reply, so that is the basis of</p> <p>17 my objection.</p> <p>18 MR. SKLAR: It's very clearly incorporated</p> <p>19 into this declaration.</p> <p>20 MR. MURRAY: If you want to take it up with</p> <p>21 the Board, you're welcome.</p> <p>22 BY MR. SKLAR:</p> <p>23 Q Do you intend to follow the instruction of</p> <p>24 your attorney?</p> <p>25 A I do.</p>	<p style="text-align: right;">Page 125</p> <p>1 MR. SKLAR: Let's take a break.</p> <p>2 (Recess taken 2:06 p.m. - 2:16 p.m.)</p> <p>3 BY MR. SKLAR:</p> <p>4 Q All right. Welcome back, Mr. Clemens.</p> <p>5 A Thank you.</p> <p>6 Q We established that the entirety of your prior</p> <p>7 declarations is incorporated into Exhibit 2023.1;</p> <p>8 correct?</p> <p>9 A Okay.</p> <p>10 MR. MURRAY: Form.</p> <p>11 THE WITNESS: Yeah. You're referring to</p> <p>12 paragraph 3? Yeah. We went through all the -- my</p> <p>13 previous declarations, and that -- the last sentence</p> <p>14 says the entirety of these declarations is</p> <p>15 incorporated.</p> <p>16 BY MR. SKLAR:</p> <p>17 Q And I'd like to turn your attention again to</p> <p>18 your signature page, if you could turn there. And</p> <p>19 through your signature, you declare the following: "I</p> <p>20 declare under penalty of perjury, under the laws of the</p> <p>21 United States of America and the State of California,</p> <p>22 that the foregoing is true and correct"; right?</p> <p>23 A That's correct, what it says. That's</p> <p>24 absolutely correct.</p> <p>25 Q And we established that your statement there</p>



1 also refers to everything that you've incorporated into  
2 this declaration; correct?

3 MR. MURRAY: Objection to form.

4 THE WITNESS: Yes.

5 BY MR. SKLAR:

6 Q Let me ask you. Given that statement, is  
7 there anything -- any position that you have taken in  
8 Exhibit 2021 that you do not believe to still be true  
9 and correct which you would like to correct now on the  
10 record?

11 A For Exhibit 2021?

12 Q Yes.

13 MR. MURRAY: Objection to form. I would  
14 object again on scope. This is outside the scope --

15 MR. SKLAR: I'm just asking about this  
16 declaration.

17 MR. MURRAY: Oh. You're asking about the --  
18 I'm sorry. The --

19 THE WITNESS: Well, this is 2021. Is that the  
20 one you're referring to?

21 BY MR. SKLAR:

22 Q But I'm asking you with respect to this  
23 statement in 2023. Is there anything in 2021 that you  
24 do not believe to be true and correct that you would  
25 like to clarify on the record now?

1 good engineers, they would try to mitigate as much as  
2 they could, but my opinion is that -- and that's  
3 incorporated in my opinion that my assumption is that  
4 that would have happened, but yet, even after that, it  
5 would still be a large nonzero effect on cost and  
6 maintenance, et cetera."

7 Do you remember that?

8 A I do.

9 Q Specifically with respect to petitioners'  
10 proposed combinations in the '177 petition -- strike  
11 that.

12 Specifically with respect to petitioners'  
13 proposed combinations in petitioners' reply with  
14 respect to the '177 petition, would a skilled artisan  
15 have been motivated to create a design that resulted in  
16 holes being introduced into the flow path?

17 MR. SKLAR: Objection. Form.

18 THE WITNESS: That would have been an  
19 undesirable change to a design to even occur.

20 BY MR. MURRAY:

21 Q And why do you say that?

22 A Because I'm probably -- I am probably not  
23 inaccurate by saying that billions of MDIs have been  
24 produced prior to this time, and none of them have  
25 holes in them for the specific reason that these MDI

1 MR. MURRAY: I'm still going to object as this  
2 being outside the scope, and on that basis instruct you  
3 not to answer.

4 BY MR. SKLAR:

5 Q And let me ask you. Is there anything you  
6 want to clarify, or do you intend to follow that  
7 instruction? And, again, this is your signature on  
8 Exhibit 2023?

9 A I believe I'll follow the instructions.

10 MR. SKLAR: We will leave it at that.

11 All right.

12 MR. MURRAY: Okay. I only have a brief  
13 redirect.

#### 14 EXAMINATION

15 BY MR. MURRAY:

16 Q Mr. Clemens, earlier you testified or rather  
17 earlier Mr. Sklar asked you "Do skilled artisans or  
18 engineers have any resources available to them to  
19 mitigate any of the reported -- of adding mold arms to  
20 the designs of Ground 1 and Ground 2 in the '177  
21 petition?"

22 And you responded "Tooling engineers and  
23 tooling companies would definitely have tools to  
24 attempt to minimize the impact of these kinds of  
25 changes, and certainly if they are a good company and

1 devices are highly optimized devices that have had  
2 their designs modified and refined over many, many  
3 years, decades, and to just assume that a skilled  
4 artisan would, through the -- through the thinking of  
5 simply and easily substituting a combination which  
6 created holes suddenly in the flow path that's already  
7 been optimized over decades is -- it's just not  
8 thinkable and would not be attempted.

9 MR. MURRAY: Okay. And could you pass me  
10 Exhibit 1071, the Monaghan Aeroeclipse nebulizer?

11 MR. SKLAR: There you go.

12 MR. MURRAY: Thank you.

13 Q Now, Mr. Clemens, prior to your deposition  
14 today, have you ever seen this specific device before?

15 A No, I have not.

16 Q So have you ever done any formal analysis on  
17 the device marked as Exhibit 1071 before?

18 A I've never seen the device before, I have  
19 never seen the design documents --

20 MR. SKLAR: Objection to form. Go ahead.

21 THE WITNESS: Oh. Sorry.

22 BY MR. MURRAY:

23 Q You can continue.

24 A And I really know nothing about it except for  
25 the few minutes I've had to give it a quick visual

<p style="text-align: right;">Page 130</p> <p>1 inspection, and for -- the features that I've been  2 asked about are substantially -- their size is  3 substantially small enough where I can't honestly make  4 a proper inspection.  5 Q And do you know whether this specific device  6 would have been available to a skilled artisan at the  7 time of the invention?  8 MR. SKLAR: Objection. Form.  9 THE WITNESS: I have no idea. I've never seen  10 it before. I don't know anything about it.  11 MR. MURRAY: Okay. No further questions.  12 That's all I have.  13 MR. SKLAR: Just a couple quick redirect.  14 FURTHER EXAMINATION  15 BY MR. SKLAR:  16 Q Nebulizers were certainly available prior to  17 2003; correct?  18 A Nebulizers also have been around for decades.  19 Q Do you expect that nebulizers prior to 2003  20 used snap-fits?  21 MR. MURRAY: Objection. Form.  22 THE WITNESS: I don't know.  23 BY MR. SKLAR:  24 Q Would you have expected them to use snap-fit?  25 Would you have expected nebulizers to have used</p>	<p style="text-align: right;">Page 131</p> <p>1 snap-fits prior to 2003?  2 MR. MURRAY: Objection to form.  3 THE WITNESS: I suspect that they could have.  4 BY MR. SKLAR:  5 Q I won't hold you to this number, but you  6 referenced perhaps billions of MDIs that have existed  7 throughout history. Let's just say a lot of MDIs have  8 existed throughout history; correct?  9 A Maybe not as many as McDonald's hamburgers,  10 but yes.  11 Q Did you speak with all of the designers of  12 those MDIs to determine why they did or did not  13 incorporate certain design features?  14 A Well, I've worked in conjunction with other  15 engineers that have -- that, you know, were working on  16 MDIs similar to what I was doing, and in groups, my  17 groups. So, yes, certainly there would have been  18 interaction for, you know, those kinds of discussions.  19 Q Okay. But you did not speak with all of the  20 designers of all of the prior MDIs to determine why  21 they did or did not incorporate certain design  22 features; correct?  23 A I have not spoken to all of them. That is  24 correct.  25 Q And you agree that prior to 2003, MDIs on the</p>
<p style="text-align: right;">Page 132</p> <p>1 market did not include integrated dose counters.  2 Correct?  3 MR. MURRAY: Objection to form.  4 THE WITNESS: I believe that that's true.  5 MR. SKLAR: No further questions.  6 MR. MURRAY: All right.  7 None for me.  8 (Proceedings concluded at 2:27 p.m.)  9  10  11  12  13  14  15  16  17  18  19  20  21  22  23  24  25</p> <hr style="width: 30%; margin-left: 0;"/> <p style="text-align: center;">Charles E. Clemens</p>	<p style="text-align: right;">Page 133</p> <p>1 I, Tricia A. Rosate, Certified Shorthand  2 Reporter licensed in the State of California,  3 License No. 10891, hereby certify that the deponent  4 was by me first duly sworn, and the foregoing testimony  5 was reported by me and was thereafter transcribed with  6 computer-aided transcription; that the foregoing is a  7 full, complete, and true record of said proceedings.  8 I further certify that I am not of counsel or  9 attorney for any of the parties in the foregoing  10 proceeding and caption named or in any way interested  11 in the outcome of the cause in said caption.  12 The dismantling, unsealing, or unbinding of  13 the original transcript will render the reporter's  14 certificates null and void.  15 In witness whereof, I have hereunto set my  16 hand this day: July 18, 2019.  17  18  19  20  21  22  23  24  25</p> <hr style="width: 30%; margin-left: 0;"/> <p style="text-align: center;">Tricia Rosate, RDR, RMR, CRR, CCRR  CSR No. 10891</p>


## ERRATA SHEET

Case Name:

Deposition Date:

Deponent:

Pg.	No.	Now Reads	Should Read	Reason
37	12	"but anything subsystem"	"But any subsystem"	miss-heard, or miss-spoke
42	9	"what is it that"	"what it is that"	Miss-heard or miss-spoke
43	1	"that has been"	"that hasn't been"	Miss-heard and miss-quoted"
48	1	"that I would have to..."	"that I would have to know to do"	Miss-heard and miss-quoted
49	12	"that would have been..."	"that wouldn't have been..."	Miss-heard and miss-quoted
52	20	"which is not a circumferential"	"which is a circumferential"	Miss-heard and miss-quoted


  
 Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

THIS \_\_\_\_ DAY OF \_\_\_\_\_, 2019.

(Notary Public) MY COMMISSION EXPIRES: \_\_\_\_\_

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