

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3 3M Company, Merck & Co., Inc. and
4 Merck Sharp & Dohme Corp.,
5 Petitioners,
6

7 v.

8 AptarFrance S.A.S.,
9 Patent Owner.
10

11 Case IPR2018-01055
12 Patent No. 9,370,631 B2
13 &
14 Case IPR2018-01054
15 Patent No. 8,936,177 B2

16 ORAL DEPOSITION OF
17 CHARLES E. CLEMENS
18 APRIL 24, 2019
19
20
21
22
23

24 TSG JOB NUMBER: 158576

25 COURT REPORTER: Julie Brandt, CSR, RMR, CRR

<p style="text-align: right;">Page 2</p> <p>1 ORAL DEPOSITION OF CHARLES E. CLEMENS, produced as 2 a witness at the instance of 3M and Merck, and duly 3 sworn, was taken in the above-styled and numbered cause 4 on the 24th day of April, 2019, from 9:01 a.m. to 6:15 5 p.m., before Julie C. Brandt, RMR, CRR, and CSR in and 6 for the State of Texas, reported by machine shorthand, 7 at the offices of McKool Smith, 300 Crescent Court, 8 Suite 1500, Dallas, Texas. 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 3</p> <p style="text-align: center;">A P P E A R A N C E S</p> <p>1 2 3 FOR APTAR: 4 Ryan Hargrave, Esq. 5 McKOOL SMITH 6 300 Crescent Court 7 Dallas, Texas 75201 8 9 FOR 3M AND MERCK: 10 Jason Weil, Esq. 11 AKIN GUMP STRAUSS HAUER & FELD 12 Two Commerce Square 13 2001 Market Street 14 Philadelphia, Pennsylvania 19103 15 16 - AND - 17 18 Ron Sklar, Esq. 19 HONIGMAN MILLER SCHWARTZ & COHN 20 155 North Wacker Drive 21 Chicago, Illinois 60606 22 23 ALSO PRESENT: 24 Emily Sauter 25 MERCK IN-HOUSE ATTORNEY</p>
<p style="text-align: right;">Page 4</p> <p>1 INDEX 2 PAGE 3 Appearances..... 3 4 Proceedings..... 5 5 CHARLES E. CLEMENS 6 Examination by MR. WEIL..... 5 7 Examination by MS. HARGRAVE..... 249 8 Further Examination by MR. WEIL..... 252 9 10 Signature and Changes..... 254 11 Reporter's Certificate..... 256 12 13 DEPOSITION EXHIBITS IDENTIFIED 14 15 Exhibit 1052 Deposition Notice for Case 16 IPR2018-01054..... 7 17 Exhibit 1053 Deposition Notice for Case 18 IPR2018-01055..... 7 19 20 Exhibit 1054 Petition for Inter Partes Review 58 21 22 Exhibit 1055 Declaration of Charles E. 23 Clemens in West Pharma v. Sanofi 170 24 Exhibit 1056 Excerpts from the Deposition of 25 Charles E. Clemens in the Novo Nordisk v. Sanofi-Aventis, October 25, 2007..... 183</p>	<p style="text-align: right;">Page 5</p> <p>1 CHARLES E. CLEMENS 2 P R O C E E D I N G S 3 CHARLES E. CLEMENS, 4 having been first duly sworn, testified as follows: 5 EXAMINATION 6 BY MR. WEIL: 7 Q. Good morning, Mr. Clemens. 8 A. Good morning. 9 Q. Would you please state your name for the 10 record. 11 A. Charles E. Clemens. 12 Q. And Mr. Clemens, you've been deposed before? 13 A. I have. 14 Q. So you probably know how this goes, but I'll 15 run through some of the ground rules first. 16 A. Sure. 17 Q. How many times have you been deposed? Do you 18 know? 19 A. Maybe ten, 12 times. 20 Q. And you understand today you're under oath? 21 A. Yes, sir, I do. 22 Q. And you see there's a court reporter here who 23 will be typing down everything. So it's important we 24 don't speak over top of each other. So I will try to 25 let you finish answering before I ask a question and ask</p>

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<p style="text-align: right;">Page 6</p> <p>1 CHARLES E. CLEMENS</p> <p>2 that you let me finish my question before answering.</p> <p>3 Okay?</p> <p>4 A. I'll do my best.</p> <p>5 Q. We will try to take breaks every hour or so.</p> <p>6 If you need one earlier than that, just let me know.</p> <p>7 The only thing I ask is we don't take a break if there's</p> <p>8 a pending question, but if you need one, just let me</p> <p>9 know.</p> <p>10 A. Okay.</p> <p>11 Q. Throughout the day, your attorney may object</p> <p>12 to questions. You still have to answer the question</p> <p>13 unless she instructs you not to answer. Do you</p> <p>14 understand that?</p> <p>15 A. Yes, I do.</p> <p>16 Q. And you understand you can't discuss the</p> <p>17 substance of your testimony with anyone during the</p> <p>18 breaks today. Right?</p> <p>19 A. Yes, I understand that.</p> <p>20 Q. And if I ask you a question and you answer,</p> <p>21 I'll assume that you understood the question. But if</p> <p>22 you need clarification, you'll ask me for it, correct?</p> <p>23 A. Yes, I will.</p> <p>24 Q. And is there any reason you cannot provide</p> <p>25 full and accurate testimony today?</p>	<p style="text-align: right;">Page 7</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. No, there is not.</p> <p>3 Q. And you're providing opinions in two IPRs</p> <p>4 today. Correct?</p> <p>5 A. That is correct.</p> <p>6 Q. And I guess just for the record, we'll mark --</p> <p>7 I'll hand you the notice of deposition.</p> <p>8 (Exhibit 1052 marked.)</p> <p>9 Q. (BY MR. WEIL) So I handed Exhibit 1052 and</p> <p>10 that is the notice for deposition in IPR 2018-01054, and</p> <p>11 that relates to US Patent No. '177. Is that correct?</p> <p>12 A. Yes, that's what it appears to be.</p> <p>13 Q. And if I refer to the US Patent 8,936,177</p> <p>14 patent as the '177 Patent, you'll know what I mean?</p> <p>15 A. Yes.</p> <p>16 Q. And if I refer to this IPR as the '177 Patent</p> <p>17 IPR, you'll know what I mean?</p> <p>18 A. Yes, sure.</p> <p>19 (Exhibit 1053 marked.)</p> <p>20 Q. (BY MR. WEIL) And I'll hand you what's been</p> <p>21 marked Exhibit 1053, and that document is a notice of</p> <p>22 deposition in IPR2018-01055. Correct?</p> <p>23 A. Yes, that is correct.</p> <p>24 Q. And that IPR relates to Patent No. 9,370,631.</p> <p>25 Correct?</p>
<p style="text-align: right;">Page 8</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Yes.</p> <p>3 Q. And you'll understand if I refer to that</p> <p>4 patent as the '631 Patent. Right?</p> <p>5 A. Yes.</p> <p>6 Q. And we can refer to this IPR as the '631 IPR,</p> <p>7 patent IPR?</p> <p>8 A. Sure.</p> <p>9 Q. And you understand that those two patents are</p> <p>10 related to each other. Is that right?</p> <p>11 A. In -- yes, I suppose, sure.</p> <p>12 Q. I know parts of your two declarations are</p> <p>13 identical, background, analogous art, things like that.</p> <p>14 Is it okay if I just ask you those questions once and</p> <p>15 you'll understand that they apply equally to the</p> <p>16 testimony as the same in each IPR?</p> <p>17 A. Sure.</p> <p>18 Q. Before we go any farther, I am just going to</p> <p>19 hand you your declarations. So I hand you what's</p> <p>20 previously been marked Exhibit 2021 in IPR 2018-01054.</p> <p>21 And Mr. Clemens, let me know if you recognize</p> <p>22 that document.</p> <p>23 A. Yes. This appears to be my second</p> <p>24 declaration.</p> <p>25 Q. When you say "second declaration," is it the</p>	<p style="text-align: right;">Page 9</p> <p>1 CHARLES E. CLEMENS</p> <p>2 declaration related to US Patent No. '177?</p> <p>3 A. Yes, that's correct.</p> <p>4 Q. I am going to hand you what's been marked</p> <p>5 Exhibit 2021 in IPR2018-01055.</p> <p>6 (Reporter clarification.)</p> <p>7 Q. (BY MR. WEIL) And do you recognize that</p> <p>8 document, Mr. Clemens?</p> <p>9 A. Yes.</p> <p>10 Q. And is that your declaration relating to the</p> <p>11 '631 Patent?</p> <p>12 A. That is correct, it is the second declaration.</p> <p>13 Q. Right.</p> <p>14 A. Yes.</p> <p>15 Q. If you could turn to the last page, we will</p> <p>16 use the declaration from the '177 Patent. And is that</p> <p>17 your signature on the last page of the '177 Patent</p> <p>18 declaration?</p> <p>19 A. Yes, it is.</p> <p>20 Q. And you signed that on February 13, 2019?</p> <p>21 A. Correct.</p> <p>22 Q. Is February 13, 2019 the day you completed</p> <p>23 your declaration?</p> <p>24 A. That's when I finally signed it off, correct.</p> <p>25 Q. And did you draft the declarations yourself?</p>

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<p style="text-align: right;">Page 10</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. I would characterize it as a collaborative</p> <p>3 effect, you know, between the attorneys and myself. I</p> <p>4 generated the bulk of the inputs to it, and then it was</p> <p>5 formalized and then we, you know, hashed it out</p> <p>6 clarified it, but everything that's contained in these</p> <p>7 reports are 100 percent my opinions.</p> <p>8 Q. And do you recall when you first started</p> <p>9 working on these two IPRs?</p> <p>10 A. I do not recall the dates.</p> <p>11 Q. Do you recall roughly when you were contacted</p> <p>12 about working on the IPRs?</p> <p>13 A. Last year.</p> <p>14 Q. Do you recall who first contacted you about</p> <p>15 working on these IPRs?</p> <p>16 A. I believe it was a placement company, a</p> <p>17 company that -- you know, that hires experts for cases.</p> <p>18 Q. And you are being compensated for your work on</p> <p>19 this case. Correct?</p> <p>20 A. That is correct.</p> <p>21 Q. Have you ever done any work for Aptar before</p> <p>22 this?</p> <p>23 A. I have not.</p> <p>24 Q. And have you ever worked with the folks at</p> <p>25 McKool Smith before these cases?</p>	<p style="text-align: right;">Page 11</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. No, I do not believe I have.</p> <p>3 Q. I am going to hand you what has been marked as</p> <p>4 Exhibit 2006 in IPR201801054. And Mr. Clemens, do you</p> <p>5 recognize that document?</p> <p>6 A. This is a copy of my CV.</p> <p>7 Q. And to the best of your knowledge, is this an</p> <p>8 up-to-date copy of your CV?</p> <p>9 A. It appears to be one of the updated ones.</p> <p>10 Q. Okay. So let's look at page 1, and on page 1</p> <p>11 you identify Clemens Consulting Company.</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. What is Clemens Consulting Company?</p> <p>15 A. This was a company that I formed back in 1995</p> <p>16 after I left a company called IVAC Corporation. And I</p> <p>17 started my own consulting company, which I maintain and</p> <p>18 operate today, so --</p> <p>19 Q. Do you have any employees that work for you at</p> <p>20 Clemens Consulting Company?</p> <p>21 A. Not per se. I have associates that I use on</p> <p>22 different projects from time to time.</p> <p>23 Q. And you've been in charge of running Clemens</p> <p>24 Consulting Company from 1995 to present?</p> <p>25 A. That is correct.</p>
<p style="text-align: right;">Page 12</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And under professional on page 1 of your CV,</p> <p>3 there's three different items listed. Are those</p> <p>4 specific engagements you had through Clemens Consulting</p> <p>5 Company?</p> <p>6 A. Which ones in particular or any of them?</p> <p>7 Q. Sure. So let's take them one by one.</p> <p>8 So under professional, the first one says</p> <p>9 senior consultant project manager the IT group. What</p> <p>10 was the nature of that engagement?</p> <p>11 A. Sure. That was a client, BIT-Group is a</p> <p>12 client of mine and they specialize in in vitro</p> <p>13 diagnostic systems, and I ran a large program for them</p> <p>14 for a period of time.</p> <p>15 Q. So they approached you for work in your role</p> <p>16 at Clemens Consulting Company?</p> <p>17 A. Yes, that's correct. I do everything, you</p> <p>18 know, soup to nuts, either design or I'll manage</p> <p>19 projects. I've done, you know, pretty much the whole</p> <p>20 thing.</p> <p>21 Q. And you have experience getting those projects</p> <p>22 through FDA approval?</p> <p>23 A. I do.</p> <p>24 Q. And I guess next, the next item on that list,</p> <p>25 Invetech USA, is that another engagement you had in your</p>	<p style="text-align: right;">Page 13</p> <p>1 CHARLES E. CLEMENS</p> <p>2 time at Clemens Consulting Company?</p> <p>3 A. Correct. It's another client of mine who, you</p> <p>4 know, they're in San Diego, and they're also specialists</p> <p>5 in in vitro diagnostic systems. They also do medical</p> <p>6 devices.</p> <p>7 Q. And when you say "in vitro diagnostic</p> <p>8 systems," what do you mean? Can you give me an example</p> <p>9 of one?</p> <p>10 A. Sure.</p> <p>11 In vitro diagnostic systems can range from</p> <p>12 very simplistic or very complex. So very simple in</p> <p>13 vitro diagnostic would be a pregnancy test, and then a</p> <p>14 more sophisticated one is when you go into the doctor</p> <p>15 and you have a blood test and they need to look at</p> <p>16 whatever, 30 different blood markers. There are systems</p> <p>17 that take your blood and process it and test for all</p> <p>18 these various things. They're usually medium size,</p> <p>19 durable equipment, highly processed in terms of</p> <p>20 automation in what they do. Lots of different parts,</p> <p>21 lots of, you know, moving parts and what have you.</p> <p>22 Q. Okay. And the third entry also for Invetech</p> <p>23 is that the same nature, the same type of work, in vitro</p> <p>24 diagnostic systems?</p> <p>25 A. That is correct. I actually in that instance</p>

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took on employment with them for a period of time to run a large project. And so even though I was still doing a little bit of work in the consulting company, I was an employee with them.

Q. And are the in vitro diagnostics you described, is that the bulk of the work you've been doing between 2010 and 2017?

A. I would say maybe 50 to 60 percent of the time.

Q. And do you consider those in vitro diagnostic systems you described to be medical devices?

A. Yes, they are.

Q. And the other 40 to 50 percent of the time, how would you characterize the nature of your work?

A. Some of it was on medical device product development, various medical device projects that I work on, either through myself or another company called Fallbrook Engineering, which is also included in here, and also have been involved in product liability and patent expert work.

Q. And near the bottom of the page, there's a heading "Products and Areas of Expertise." What is that section conveying?

A. So this is just a section to kind of highlight

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the various areas that I've specialized in.

Q. I see on there you list liquid drug inhalers. Can you tell me a little bit specifically what you mean about liquid drug inhalers?

A. Sure.

So I kind of highlighted some of that in my report just so that it would be easy to pull out and for everybody to see. But so I've had various experiences working in respiratory care and, like I said, I highlighted some of them in here.

One of them was when I left IVAC Corporation, I took on a project, which was about a three-year project, for full and partial liquid ventilation. And that's where they fill your lungs up with a drug and you are respiration on top of that drug. Of course, you're unconscious when this is happening. You have all this drug. And as you breathe, you evaporate the drug. And I designed a system which captured the breath as it came out and pulled the drug out of the breath, reconstituted it and delivered it back into the patient. And at the same time, the patient would be breathing through a vaporizer, a custom vaporizer which I designed. And it was custom because it had quite interesting properties rather than what water would have. And so it had to all

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be custom -- custom designed. That is one example of a respiratory care product that I worked on. That went into clinical trials, and we actually saved a number of infants from death.

Another example would be around year 2000, I went to work for Aerogen to develop a highly optimized aerosol generator which was insert injection molded, and so I developed and qualified that system. There's plenty to talk about there if you want to talk about that.

And then, you know, just over time -- and I highlighted a few more in here. I worked with Dura for a short period of time, helping them out. K-O-S, "KOS," was developing a breath actuated inhaler that I worked on for them and -- I think it was General Pharma. It's a holding company, General Pharma something. It's in my report. And they wanted to develop a powdered drug inhaler. So I was -- my involvement in that project was setting up the requirements and the early documentation that you need to have for their investors.

Q. Okay. You also identified drug injector pens. What are those devices?

A. So injection pens, a very common one that everybody knows about is the EpiPen. So that's a single

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dose automatic injection pen. I also have looked at many and -- many insulin injectors. So they're just small mechanical devices which can either be a single dose, you know, one shot type of injector or multiple dose over periods of time with an actual drug vial that's inside and then you have disposable needles.

Q. And do you recall any of the specific drug injectors that you've looked at besides the EpiPen?

A. I would say the various companies that, you know, I've looked at of the actual pens, I would say Novo, Teva, Sanofi, Twinject. Twinject was a specific project I worked on which was a two-shot EpiPen. There are lots and lots more. I don't recall off the top of my head.

Q. Those ones that you mentioned, were you analyzing them within the context of your work with Clemens Consulting Company?

A. Yes. All this work is pretty much in the context of Clemens Consulting.

Q. You mentioned Novo. Do you remember what their product was called?

A. Well, they have a number of products. You know, I don't recall any particular names, brand names off the top of my head, but they have a number of

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2 products.

3 Q. These products we're talking about, these are
4 drug injector pens?

5 A. They're primarily insulin injection pens,
6 yeah.

7 Q. Okay. And you mentioned Sanofi. Do you
8 remember what their injector pen was?

9 A. SoloSTAR was one. Again, these companies have
10 a number of models. And EpiPen was another one.
11 Twinject was another pen I worked on. Also I just
12 recalled, I forgot to mention -- I think it's in here --
13 just skipping back real quick on inhalers, I worked on a
14 project. This is a very interesting project, where I
15 incorporated HP print head technology into an inhaler
16 and the print head was designed -- I worked with HP to
17 design the print head to create respirable sized drug
18 droplets. That was another project that I optimized the
19 air stream and the fluid dynamics.

20 Sorry. I diverted from the inject or pens.

21 Q. The print head that you just mentioned, what's
22 that mean? What's the print head in?

23 A. In your HP printer, you have a specific print
24 head, which is several hundred little tiny ejectors of
25 liquid, and they literally boil the liquid, the ink

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2 inside the chip. And so the print head is the -- is
3 where all this -- it's a chip. It's where all the ink
4 is fed to through a reservoir, and then it's digitally
5 fired. So you can literally create -- well, obviously
6 in printers you can create just about anything, you
7 know, any kind of a picture, but the company I worked
8 for recognized that it could be used to actually deliver
9 drugs.

10 Q. Okay. Gotcha.

11 I guess the last thing I want to ask about on
12 your CV, you see on the last page you list a number of
13 patents. Is that right?

14 A. That's correct.

15 Q. Patents and applications, I should say.

16 A. Uh-huh.

17 Q. And are any of these related specifically to
18 inhaler technology?

19 A. They are not.

20 Q. I know you mentioned some of this stuff is
21 discussed in more detail in your report. So why don't
22 we turn to in the '177 Patent declaration. We could
23 just start at paragraph 4. You mentioned you have over
24 38 years of experience as an engineer. Right?

25 A. Hard to admit, but it's actually more.

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2 Q. Okay.

3 A. Probably more like 40.

4 Q. Okay. So I was going to ask. Is that
5 38 years counted from the start of your work at IVAC, or
6 did you start it somewhere else?

7 A. I would say that's counted from after I
8 graduated.

9 Q. Okay.

10 A. Yeah.

11 Q. And you graduated in '79?

12 A. In '79. At the very end of '79. So '80 was
13 really the start, but I was doing, you know, work -- I
14 was developing a pyrolytic coating laboratory prior to
15 that.

16 Q. Okay. So is it safe to say 40 years about?

17 A. Yeah. That's close enough.

18 Q. Okay. Paragraph 6, I think you're talking
19 about the work you did at IVAC Corp. We've already
20 talked about some of this. Correct?

21 A. (Witness nods head.)

22 Q. And was any of the work you did at IVAC Corp
23 related to MDIs?

24 A. No. I hesitate a little there because they
25 did try to get into some other kind of products, but I

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2 don't believe I worked on any -- anything that had
3 anything to do with MDIs there.

4 Q. But you were working on things that were fluid
5 dispensers?

6 A. A lot of pumps and controllers. Liquid drug
7 delivery. Vital signs monitoring, blood pressure,
8 temperature. But, yeah, I mean, they're primarily a
9 fluid drug delivery system company.

10 Q. Okay. But in the context of that work, you
11 did work with -- I am looking maybe two-thirds of the
12 way down to paragraph 6, durable and disposable products
13 utilizing small mechanisms, plastic injection molded
14 parts, produced in quantities of millions. Right?

15 A. Yes, sir.

16 Q. And it's your position that your work,
17 including the work at IVAC that contributes to your
18 qualifications and experience to give the opinion in
19 these IPRs?

20 A. Absolutely.

21 MS. HARGRAVE: Let me just object to the
22 previous question, mischaracterizes the witness's
23 testimony.

24 Q. (BY MR. WEIL) Well, let me just ask. Is it
25 your position that your work at IVAC contributes to your

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qualifications to give expert testimony in these IPRs?

A. I believe all of my experience in its entirety is in some way related and contributes to the totality of my expertise in these matters.

Q. And one more question about paragraph 6. I think it's the last sentence. You talk about establishing and managing training for DFMA. Can you just tell me a little bit more about what you meant, what your role was and what you were describing in that sentence?

A. Certainly.

At the time I -- in the company at IVAC, I was leading pretty much all their mechanical engineering in the company. They had different groups like instruments and disposable type groups and what have you, but I was in charge of the all the mechanical engineering which encompassed all of that. There was a great deal of design work going on in these instruments which they all contain lots of parts. There were just countless plastic disposable administration sets. All these were made in the millions in quantities because they were all disposable. So you can imagine from a mechanical engineering standpoint, there was a lot of overhead and a lot of cost that was associated with all this. And

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back in those days in the '80s and early '90s, there wasn't a whole lot of thought being put into optimizing the design. It was more about getting the design together and getting it out to the field. And I recognized an opportunity because I started my career in sustaining engineering, which was cleaning up the mess that development created for me in production, and I recognized an opportunity for the company to get better at design, because that was kind of my -- that was my role there. And so I learned about Boothroyd Dewhurst, who invented the concept of design for manufacturability. They put out their own software and their own system. And it kind of was rejected at first by traditional engineering, and then it began to expand and become more popular. I adopted it right away, and I hired a company and took all the mechanical engineers in the company and had all them trained in this thought process of engineering, which is an up-front engineering process for not only achieving your results, your functional results and your requirements, but also it met requirements of lower part cost, cheaper processing, lower -- essentially lower overhead for your designs. And it took on -- it was a little hard at first to get everybody on board with it, but once I was able to do

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that, the company was very excited. I actually used one of the main products, new products to kind of show off the ability of the DFMA process, and it was so successful that they created a department that was dedicated to design for manufacturability. So --

Q. Okay.

A. -- that's what that's all about.

Q. Okay. And I guess you mentioned at first it was hard to get everyone on board, but the goal was to, you said, lower part cost, cheaper processing, essentially lower the overhead for these products you're manufacturing. Correct?

A. That is correct.

Q. So the DFMA design process taught the designers to design devices with as few components as possible to make the embodiment easier to manufacture once it was commercialized. Is that correct?

MS. HARGRAVE: Objection, mischaracterizes the witness's testimony.

A. It started off as -- it started off as a program, a software program that basically forced an engineer to ask questions about their design, and you would have to go through and answer these questions truthfully. And, again, it was a little hard to adopt

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because, you know, traditional engineers thought their designs were just fine the way they were, but it forced them to make decisions and change their design based on the answers to those decisions.

Q. (BY MR. WEIL) Okay.

A. So that's -- it's literally a process, a thought process of going through your design. Essentially, you establish a concept and then you start applying all these questions.

Q. Okay. So aside from the explanation you've given, would you agree with me that DFMA taught designers to design designs with as few components as possible to make the embodiment easier to manufacture once it was commercialized?

A. So the result of fewer parts was possibly one of the outcomes. There were other outcomes. For instance, you may want to, you know, not do a machine process but you would want to, rather, do a forming process. You know, so there were various things that DFMA could give you.

Q. So you do agree, though, that fewer parts was one of the possible outcomes of the DFMA process. Right?

MS. HARGRAVE: Objection,

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mischaracterizes the witness's testimony.

A. So, again, it wouldn't necessarily be one of the answers. It could have been one of the answers, but it's -- I would say that the process forces the engineer to consider many possibilities for reducing the overhead of the design.

Q. (BY MR. WEIL) So I think we might be saying the same thing, so let me just ask that exact question again.

So you do agree, though, that fewer parts was one of the possible outcomes of the DFMA process. Right?

MS. HARGRAVE: Again, objection, mischaracterizes the witness's testimony.

A. It wouldn't necessarily be that result. And through the processing, the processing method, you might be able to incorporate multiple features of a single part together and, you know, using another process. And sometimes one of the results would be, you know, you could reduce the parts. So that it was, you know, one of many possible outcomes.

Q. (BY MR. WEIL) So would you agree with the statement that DFMA taught designers to design designs with as few components as possible or not?

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A. That may have been an outcome of it, yes, I do agree with that.

Q. Okay. Let's jump ahead to paragraph 8. I think this is where you were discussing -- I think you've already told me about some of the specific projects you worked on at Clemens Consulting Company.

A. Yes.

Q. And before, you had mentioned a three-year project. Is that the one that starts out between 1995 and 1998?

A. Yes, sir.

Q. And then about halfway down you say "Between 1999 and 2000, I developed a patented low cost injection molded high performance aerosol generator for use in inhaler projects for Aerogen Incorporated." Right?

A. That is correct.

Q. Is that one of the patents listed on your CV?

A. No, unfortunately, it is not. The manager I was working for felt that he conceptualized it, even though I did all the work on it, and my name did not find its way on that patent.

Q. Is it your opinion that you're the one that conceptualized that project?

A. I believe I was one of the patent inventors.

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Q. Okay. Then at the bottom of this paragraph, you talk about the inhaler product design projects that you worked on for several companies between 2004 --

A. Yes.

Q. -- and 2012. Right?

Starting first with the Dura Pharmaceuticals. 2004, is that when you began working on that project?

A. Did you want to ask a question about inject digital aerosols which happened prior to that? Just checking to see. That was the HP printer head and nicotine delivery system.

Q. Gotcha.

A. At first, it was not projected as a nicotine delivery system, and then HP found out about it and then they shut the project down.

Q. Gotcha. Okay. We've got enough about the --

A. Yeah.

Q. -- nicotine project. Let's talk about the inhalers. So Dura Pharmaceuticals, that project, is 2004 the year that you began that project?

A. That is correct. It was -- I would say maybe about a three to six-month task.

Q. And what was the task?

A. They were -- they were having difficulties in

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their clinical trials with their powdered insulin inhaler, and so I was helping to put together a verification testing to validate or verify the design changes that they were having.

Q. You said the inhaler was already in clinical trials?

A. Yes, sir.

Q. And did that inhaler have a dose counter on it?

A. It did, but it's a little bit different than what's involved in this case because they had cartridges with specific powdered containers. So it's a little bit different.

Q. So is that the type of device where you would look at the number of cartridges remaining to know how many doses were left?

A. Yes. And there were some mechanical means for detecting when a blister was used.

Q. Then you had a project with Kos Pharmaceuticals in 2006. Is that right?

A. That is correct.

Q. And what type of device did that project entail?

A. That entailed helping to optimize a design

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that was conceptualized, put into CAD, and the company did not have any of the design documentation related to it. So I helped to create a lot of the design documentation around it, held a couple of design reviews to force a brainstorming of changes to the design and, you know, we captured these design changes. This was kind of unique breath actuated inhaler, and so it had some new and unique aspects to the device.

Q. Did that inhaler have a dose counter on it?

A. I believe it did, but I believe it was electronic.

Q. And you said that project was -- it sounds like it was pretty early on in the project you were optimizing a design that was conceptualized?

A. The company had a design and they needed additional resources. They had too many projects going on, several other inhalers going on, and so they hired -- now this particular one, I was hired not specifically as Clemens Consulting but as an associate of Fallbrook Engineering. I still worked as Clemens Consulting, but I just get hired through them sometimes. So yeah.

Q. Do you know -- like I said, it sounds like it was pretty early in the project. Do you know when the

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company first conceptualized that design?

A. I do not. I cannot say. I don't have that information on the top of my head.

Q. But your work was in 2006?

A. Yes.

Q. And it was conceptualized, but you were optimizing the design?

A. Correct. We were trying to move it along, you know, to, you know, closer to a production stage.

Q. And then the last one you list is General Pharma Partners that you worked with in 2012. Is that right?

A. Yes.

Q. And what was that device?

A. That was a powdered -- powder inhaler, and I believe it was powder -- I am sorry, I can't remember the drug. I think it was a powdered albuterol. I don't know for sure. But anyway, it was a powdered inhaler, and that was another one that was very early in the project date. This is a holding company. They bring together funding partners, and then they -- what we were doing, I was involved in creating the early documentation, the requirements, and breaking those down into the various design requirements, and we started to

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do hazard analysis, faulting. So it's the early part of the design.

Q. And did that inhaler have a dose counter on it?

A. Yes, it did. Again, it was similar to the Dura example, because they had blister --

Q. Okay.

A. -- blister pack drug.

Q. And the Kos Pharmaceuticals project in 2006, I can't remember if you said, was that a powdered inhaler?

A. No.

Q. No.

A. That was liquid, and they used an electronic counter -- dose counter, EDC.

Q. And prior to -- had you worked on any inhaler projects prior to 2004 -- sorry. Inhaler projects may be a little broad.

Let me ask -- well, you referred to these three as various inhaler product design projects. Had you worked on any inhaler product design projects prior to 2004?

A. Well, the Aerogen project, so '99 to 2000. That was a -- you know, essentially a metered-dose inhaler. And then after that was the digital -- Injet

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digital aerosol, and that was a hand-held inhaler. So I would say maybe since '99.

Q. In those two examples, the Aerogen project, did that one have a dose counter? Did that inhaler have a dose counter on it?

A. They were contemplating -- they wanted one. They did not have one. They were contemplating an electronic dose counter.

Q. And for the Injet digital aerosols project in 2003, did that product have a dose counter?

A. It did not.

Q. Back to talking about some of your expert witness work that you mentioned earlier, you worked as an expert witness in IPRs before. Right?

A. Yes, I have.

Q. Do you know about how many IPRs you've been an expert in?

A. Not as many as the other kind. Maybe -- off the top of my head, I don't recall, but maybe two or three.

Q. Okay. Do you recall who any of the parties were in those IPRs?

A. One was related to hemodialysis, and that was -- I might have it on my resumé. Is it okay if I

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2 take a look at that --
3 Q. Sure.
4 A. -- to refresh my memory? It might be in here.
5 I'm sorry. I don't recall.
6 Q. Okay. Do you remember any others other than
7 that hemodialysis IPR?
8 A. Yeah, what was the other one? There was a
9 drug injector, an injector pen IPR. I'm drawing a
10 blank. I'm sorry.
11 Q. That's okay.
12 But you've never worked on an IPR related to
13 an MDI. Correct?
14 MS. HARGRAVE: Objection,
15 mischaracterizes the witness's testimony.
16 A. I don't recall.
17 Q. (BY MR. WEIL) When I asked you about IPRs,
18 you said not as many as the other one. Is the other
19 one, did you mean expert testimony in district court
20 cases?
21 A. Yes.
22 Q. And do you recall how many times you've been
23 an expert witness in a district court case?
24 A. Let's say maybe a dozen.
25 Q. And do you recall the subject matter of any of

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2 actually studied and optimized and redesigned.
3 MS. HARGRAVE: And I object to the form
4 of the previous question as vague.
5 Q. (BY MR. WEIL) All right. Let's turn to
6 paragraph 12 in your report where you list the materials
7 considered, and is that a full list of the materials you
8 considered to come to your opinions in the IPRs? Sorry,
9 in this IPR?
10 A. I believe it is.
11 Q. Have you ever spoken with Fabien Poulard?
12 A. I have not spoken to him.
13 Q. Do you know who that is?
14 A. Yes.
15 Q. Who is it?
16 A. It is the inventor.
17 Q. Do you know whether Fabien Poulard ever looked
18 to the mechanism of a mechanical pen when designing the
19 dose counter in the patents at issue?
20 A. If I understand your question correctly, I
21 don't really know what he ever thought.
22 Q. Let me just try to rephrase it. I think the
23 answer is the same.
24 Do you have any personal knowledge whether or
25 not he ever looked to a mechanical pen when designing

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2 those cases?
3 A. Several are patent related cases in injector
4 pens, both single dose and multi dose. One was a
5 connector. A mini med connector related patent case.
6 I've been involved in company protected information.
7 What do they call that when somebody is accused of
8 stealing trade secrets? I've done I think one or two of
9 those. Several in product liability in terms of pump
10 failures, insulin pump failures or IV fluid delivery
11 pump failures. There was one on disinfecting caps.
12 That was a patent case.
13 Q. So you mentioned some injector pens. Do you
14 recall who the parties inspector those cases?
15 A. Sanofi, Novo, Teva. Pretty much the names I
16 gave you before. Those are the ones that kind of come
17 to my mind.
18 Q. So those names you gave me before, had your
19 work with those products -- let me start that over.
20 Those names you gave me before, were you
21 familiar with those products based on your expert
22 witness work?
23 A. The ones that I mentioned, yes. In terms of
24 injector pens, specifically I've worked on the EpiPen,
25 Twinject. So I mean, there are other pens that I've

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2 the inventions in the challenged claims?
3 A. I do not know of anything that Fabien thought.
4 Q. Okay. If you turn to paragraphs 14 and 15,
5 this is where you're discussing a person of ordinary
6 skill in the art. Correct?
7 A. Yes.
8 Q. And in paragraph 14, you recite petitioner's
9 proposed definition of the person of ordinary skill in
10 the art. Correct?
11 A. That is correct.
12 Q. And do you agree with that definition?
13 A. Well, I don't have an opinion on it in my
14 report here.
15 Q. So you neither agree nor disagree?
16 A. Well, I understand that the parties dispute
17 what that is, and I just simply don't have an opinion on
18 it.
19 Q. But you do understand you're giving your
20 opinions in -- from the perspective of the person of
21 ordinary skill in the art. Correct?
22 A. That is correct.
23 Q. And you don't have an opinion on who that
24 person is?
25 A. Well, I --

10 (Pages 34 to 37)

<p style="text-align: right;">Page 38</p> <p>1 CHARLES E. CLEMENS 2 MS. HARGRAVE: Objection, vague. 3 THE WITNESS: Sorry. 4 MS. HARGRAVE: Sorry. I didn't mean to 5 interrupt you. 6 THE WITNESS: That's okay. 7 A. I certainly meet the definition of a person of 8 skill in the art in the eyes of the petitioners, and 9 judging by my background, I probably fit a lot of 10 definitions. 11 Q. (BY MR. WEIL) And your opinions are then 12 given from your perspective. Is that correct? 13 A. They're -- 14 MS. HARGRAVE: Objection, 15 mischaracterizes the witness's testimony. 16 A. My opinions are and analyses are based of a 17 person of skill in the art at the time of the 18 inventions. 19 Q. (BY MR. WEIL) And a person of skill in the 20 art has 38 or 40 years of engineering experience. Is 21 that right? 22 A. That is not an opinion that I've rendered 23 anywhere. 24 Q. So let me just make sure I understand this 25 testimony now. You have no opinion yourself on what the</p>	<p style="text-align: right;">Page 39</p> <p>1 CHARLES E. CLEMENS 2 level of ordinary skill of art is in these cases. 3 Correct? 4 A. I'm sorry. That mischaracterizes what I said. 5 Q. Okay. 6 A. I believe what I said was that in my report I 7 have not rendered an opinion. I certainly meet the 8 definition that has been laid out here by the 9 petitioners at least. I qualify at least for that, but 10 in my analyses and in my opinions, forming my opinions 11 in the report, I have done so through the perspective of 12 a person skilled in the art at the time of the 13 invention. 14 Q. And that person that you're referring to, the 15 person skilled in the art at the time of the invention, 16 is a person pursuant to petitioner's definition here in 17 paragraph 14. Isn't that correct? 18 MS. HARGRAVE: Objection, vague. 19 A. Again, I do understand the parties have not 20 agreed on what exactly that definition is. I personally 21 meet the -- at least the description that petitioners 22 have proposed. And, again, you know, my opinions are 23 based on -- you know, the opinions formed are based on 24 how a person of skill in the art at the time of the 25 invention would view these.</p>
<p style="text-align: right;">Page 40</p> <p>1 CHARLES E. CLEMENS 2 Q. (BY MR. WEIL) Okay. So in your previous 3 testimony, I am just going to read it so there's no 4 mischaracterization. But in my analyses and in my 5 opinions, to form my opinions in the report, I have done 6 so through the perspective of a person skilled in the 7 art at the time of the invention. That was your 8 testimony. Correct? 9 A. I haven't seen it, but it sounds pretty close. 10 Q. My question is this person of skill in the art 11 whose eyes you're looking through, what is the 12 definition of that person? Can you give me one? 13 A. I have not formed an opinion on that in my 14 report, and I do understand that the parties dispute it. 15 That will be determined, I imagine, at some point. 16 Q. So you have not formed an opinion in your 17 report and you understand the parties dispute it and it 18 will be determined at some point. So for your analysis, 19 how did you apply what the level of skill in the art 20 was? 21 A. Again, I didn't formally outline and specify a 22 particular definition of that in my report, but taking 23 the petitioner's position and knowing that I have more 24 than enough qualification for a person skilled in the 25 art, I can take that information and form opinions in</p>	<p style="text-align: right;">Page 41</p> <p>1 CHARLES E. CLEMENS 2 view of the references in the patents during that time, 3 and that's how I can consider myself at that -- you 4 know, in view of that information, taking that into 5 consideration in analyzing the information I would be 6 taking the position of a person of skill in the art. 7 Q. And just so we're crystal clear, you cannot 8 tell me in a sentence the qualifications of that person. 9 Correct? 10 MS. HARGRAVE: Objection, asked and 11 answered. 12 A. I have not formally defined what that is in my 13 reports. 14 Q. (BY MR. WEIL) Did you formally use anything 15 when you were coming up with your opinions in 16 obviousness? 17 A. I -- 18 MS. HARGRAVE: Objection, vague. 19 A. Yeah, I am not sure I have anything to add to 20 what I've said. 21 Q. (BY MR. WEIL) Okay. We'll just go through a 22 few more questions on the obviousness analysis and then 23 we can take a break. Okay? 24 A. Okay. I would point out in my report, you 25 know, in line 15 I do point out that in the eyes of the</p>

11 (Pages 38 to 41)

<p style="text-align: right;">Page 42</p> <p>1 CHARLES E. CLEMENS</p> <p>2 petitioners, I am a person of skill of the art.</p> <p>3 Q. Right, and that's why I was asking if this</p> <p>4 person whose eyes you've giving it through has 38 years</p> <p>5 of experience.</p> <p>6 A. Oh, yeah, no, that would be something else.</p> <p>7 That's my total experience.</p> <p>8 Q. Okay. So in your obviousness analysis, is it</p> <p>9 your understanding that petitioners were required to</p> <p>10 provide drawings of the combined references to show how</p> <p>11 the claims would have been obvious?</p> <p>12 A. It's my opinion that enough -- there needs to</p> <p>13 be more information, more detailed explanation of what a</p> <p>14 combined design or invention would be so that it can be</p> <p>15 understood and that others can believe that it's</p> <p>16 understood in the mind of the proposer. There was very,</p> <p>17 very little information provided for an analyses. I did</p> <p>18 the best I could, but it's quite limited.</p> <p>19 Q. You said there needs to be more detailed</p> <p>20 explanation so it could be understood and others can</p> <p>21 believe it's understood in the mind of the proposer.</p> <p>22 What did you mean by that?</p> <p>23 MS. HARGRAVE: Objection,</p> <p>24 mischaracterizes the witness's testimony.</p> <p>25 A. For somebody to be able to explain their</p>	<p style="text-align: right;">Page 43</p> <p>1 CHARLES E. CLEMENS</p> <p>2 design, they have to have a complete understanding of it</p> <p>3 in their own mind and to be able to describe it.</p> <p>4 Without adequate information to describe a design, it</p> <p>5 makes me question whether there is a design in the mind</p> <p>6 of the person who is proposing it.</p> <p>7 Q. (BY MR. WEIL) And that's your understanding</p> <p>8 of what's required by the obviousness analysis?</p> <p>9 MS. HARGRAVE: Objection, vague.</p> <p>10 A. My understanding is that -- my understanding</p> <p>11 is that the petitioners have the burden to describe</p> <p>12 their combinations in enough detail so that it can be</p> <p>13 understood.</p> <p>14 Q. (BY MR. WEIL) So it gets back to my first</p> <p>15 question. Does that require including pictures of the</p> <p>16 proposed combination?</p> <p>17 MS. HARGRAVE: Objection, asked and</p> <p>18 answered.</p> <p>19 A. That would be very helpful. That would be at</p> <p>20 least -- at least something more than was provided.</p> <p>21 Q. (BY MR. WEIL) But your position is it's not</p> <p>22 necessary to include such photos. Correct?</p> <p>23 MS. HARGRAVE: Objection,</p> <p>24 mischaracterizes the witness's testimony.</p> <p>25 A. I believe my position is well laid out in my</p>
<p style="text-align: right;">Page 44</p> <p>1 CHARLES E. CLEMENS</p> <p>2 report, and I would rely on what's in my report. And is</p> <p>3 there a specific area of the report that you would like</p> <p>4 to see clarified?</p> <p>5 Q. (BY MR. WEIL) Sure. Maybe I'm not being</p> <p>6 clear about my questions. My questions are about the</p> <p>7 analysis you performed. Is there a section in your</p> <p>8 report where you lay out the obviousness analysis?</p> <p>9 A. No, there is not.</p> <p>10 Q. So my questions are about the analysis you</p> <p>11 performed to determine these claims are obvious in your</p> <p>12 opinion.</p> <p>13 MS. HARGRAVE: Object to the form of the</p> <p>14 question. It doesn't look like a question.</p> <p>15 MR. WEIL: I'm still --</p> <p>16 Q. (BY MR. WEIL) So is it -- so you had</p> <p>17 mentioned -- and I'll try to get your testimony exactly</p> <p>18 correct. It is necessary for the proposer to have a</p> <p>19 complete understanding in their own mind of the combined</p> <p>20 device. Is that your understanding of what is required</p> <p>21 by the obviousness analysis?</p> <p>22 MS. HARGRAVE: Objection, vague.</p> <p>23 A. My opinion is or my comments in that regard</p> <p>24 are related to whether or not there's enough information</p> <p>25 that has been conveyed to understand what the</p>	<p style="text-align: right;">Page 45</p> <p>1 CHARLES E. CLEMENS</p> <p>2 combination, the new design is. There's such a lack of</p> <p>3 information that it isn't clear as to what exactly the</p> <p>4 design is.</p> <p>5 Q. (BY MR. WEIL) Was it your understanding that</p> <p>6 the petitioners need to describe routine modifications</p> <p>7 that a person of ordinary skill in the art would be able</p> <p>8 to make?</p> <p>9 A. Well, obviously it depends on what it is, what</p> <p>10 it is about the design and whether a person of skill in</p> <p>11 the art would have done so. So that's a particular</p> <p>12 analysis.</p> <p>13 Q. So if it is a routine modification that one</p> <p>14 skilled in the art could have done, there's no need for</p> <p>15 the petitioner to describe that. Is that right?</p> <p>16 A. Again, it would depend on what that is and in</p> <p>17 the context of the design and, you know, what the person</p> <p>18 of skill in the art.</p> <p>19 Q. And we'll get to specific, you know,</p> <p>20 paragraphs later, but you probably remember there are</p> <p>21 some opinions you have that one of skill in the art</p> <p>22 would not be able to put numerals on the cam body. Do</p> <p>23 you recall that opinion?</p> <p>24 A. Would you -- would you mind pointing it out</p> <p>25 specifically --</p>

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<p style="text-align: right;">Page 46</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. When we get to that part. We'll put that on</p> <p>3 ice for now. It will be easier to do it in order.</p> <p>4 I guess back to your understanding of what has</p> <p>5 to be shown in the combination, is it your understanding</p> <p>6 that the test for obviousness requires the features of</p> <p>7 one reference to be bodily incorporated into another</p> <p>8 reference?</p> <p>9 A. I'm not sure I understand your question.</p> <p>10 Q. Is it your understanding -- all these obvious</p> <p>11 combinations have two references. Right? Is it your</p> <p>12 understanding that the components of one reference have</p> <p>13 to be cut and pasted into the other references?</p> <p>14 A. Well, that -- you're describing a particular</p> <p>15 technique. That is helpful, but there are many ways</p> <p>16 that you can convey, you know, your concepts.</p> <p>17 Q. And one of ordinary skill in the art could</p> <p>18 modify those components as necessary to make them fit</p> <p>19 together in a combination. Right?</p> <p>20 A. Well, again, that depends. Depends on what</p> <p>21 the design is, what the -- you know, what particular</p> <p>22 aspect you're talking about. You know, it depends on</p> <p>23 the specific analysis that you're looking at.</p> <p>24 Q. And when you say "it depends," that means that</p> <p>25 that could be allowed. Right?</p>	<p style="text-align: right;">Page 47</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Well, not necessarily.</p> <p>3 Q. Sure. I understand --</p> <p>4 MS. HARGRAVE: You're okay.</p> <p>5 Q. (BY MR. WEIL) -- there may be some instances</p> <p>6 where that's not the case, but then there would be some</p> <p>7 instances where that is the case. Right?</p> <p>8 A. It's a hypothetical. I -- you know, it's</p> <p>9 difficult to answer, you know, the hypothetical because</p> <p>10 I think it depends on the particular situation, and you</p> <p>11 have to consider many aspects of, you know, what it is</p> <p>12 that you're talking about. It's an analysis process.</p> <p>13 So you've got to look at the details.</p> <p>14 Q. I guess what I'm getting at is you didn't come</p> <p>15 to the conclusion that petitioners failed to show these</p> <p>16 claims are obviousness because of any specific failing</p> <p>17 of not using pictures or --</p> <p>18 MS. HARGRAVE: Objection, vague.</p> <p>19 Objection, mischaracterizes the witness's testimony.</p> <p>20 A. Again, there are many ways of conveying the</p> <p>21 idea in, your ideas of a design, a definition of things.</p> <p>22 And that could take the shape of pictures. It could</p> <p>23 take the shape of, you know, sketches. It could take</p> <p>24 the shape of many things. Could be many things. How</p> <p>25 about a whole lot more description, you know, verbal</p>
<p style="text-align: right;">Page 48</p> <p>1 CHARLES E. CLEMENS</p> <p>2 description? You know, all of that contributes to</p> <p>3 conveying a complete understanding and a complete</p> <p>4 knowledge of a design that you're trying to present.</p> <p>5 MR. WEIL: All right, guys. Do you want</p> <p>6 to take a break?</p> <p>7 MS. HARGRAVE: Sure.</p> <p>8 (Break from 10:13 a.m. to 10:29 a.m.)</p> <p>9 Q. (BY MR. WEIL) So I am going to hand you what</p> <p>10 has been marked Exhibit 1001, and this is in the '177</p> <p>11 Patent IPR. And Mr. Clemens, do you recognize that</p> <p>12 document?</p> <p>13 A. Yes, I do.</p> <p>14 Q. What is that document?</p> <p>15 A. It's the -- what we're referring to as the</p> <p>16 '177 Patent.</p> <p>17 Q. And you understand the challenge claims in the</p> <p>18 IPR are claims 1, 2, 3, 9 and 21. Correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And those claims all cover a fluid dispenser.</p> <p>21 Right?</p> <p>22 A. Covers a fluid product dispenser.</p> <p>23 Q. So if we look at the claims, starting in</p> <p>24 column 9, claim 1, the first words are "fluid dispenser</p> <p>25 comprising." Right?</p>	<p style="text-align: right;">Page 49</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Yes, that's exactly right.</p> <p>3 Q. And I want to talk about some of the</p> <p>4 references that are asserted in this IPR. So I am going</p> <p>5 to hand you what has been marked as Exhibit 1006 from</p> <p>6 the '177 IPR. This is the Elliott reference.</p> <p>7 MS. HARGRAVE: Can you remind me which</p> <p>8 exhibit number this is?</p> <p>9 MR. WEIL: 1006.</p> <p>10 MS. HARGRAVE: Oh, there it is. I'm</p> <p>11 sorry.</p> <p>12 MR. WEIL: No problem.</p> <p>13 Q. (BY MR. WEIL) Mr. Clemens, do you recognize</p> <p>14 Exhibit 1006 from the '177 Patent IPR?</p> <p>15 A. Yes, I do.</p> <p>16 Q. And you understand that is the Elliott</p> <p>17 reference that is one of the references involved in the</p> <p>18 IPR?</p> <p>19 A. Yes, sir, I do.</p> <p>20 Q. And you discuss the Elliott references in</p> <p>21 paragraph 16 and 17 of your declaration. Correct?</p> <p>22 A. Yes.</p> <p>23 Q. And Elliott discloses a metered-dose inhaler.</p> <p>24 Right?</p> <p>25 A. Elliott is describing what they call a</p>

13 (Pages 46 to 49)

<p style="text-align: right;">Page 50</p> <p>1 CHARLES E. CLEMENS</p> <p>2 mechanical impulse counter.</p> <p>3 Q. And is it your understanding that that counter</p> <p>4 can be used in a metered-dose inhaler?</p> <p>5 A. Yes, that is correct.</p> <p>6 Q. And maybe if we just look at the picture you</p> <p>7 have in your declaration at the top of page 8, in that</p> <p>8 picture the -- I'll wait until you're there. In that</p> <p>9 picture, the canister sits on top of the counter.</p> <p>10 Correct?</p> <p>11 A. The canister is -- it's completely, I guess,</p> <p>12 inside the actuator there.</p> <p>13 Q. Right.</p> <p>14 A. In the picture there.</p> <p>15 Q. Yeah.</p> <p>16 And what you've shown in the red box that you</p> <p>17 have drawn there, that's the counting mechanism.</p> <p>18 Correct?</p> <p>19 A. That is correct.</p> <p>20 Q. And that counting mechanism is near the bottom</p> <p>21 of the actuator. Right?</p> <p>22 A. It's near the bottom of the actuator, correct,</p> <p>23 near the mouthpiece there, yeah.</p> <p>24 Q. And the canister sits on top of that counting</p> <p>25 mechanism. Correct?</p>	<p style="text-align: right;">Page 51</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Well, the canister is mounted in the valve</p> <p>3 block, which is down at the bottom there. And then the</p> <p>4 counter and the canister interact.</p> <p>5 Q. And when assembled, that counting mechanism</p> <p>6 that you show in the red box has an opening through the</p> <p>7 center. Correct?</p> <p>8 A. Yes, it has an opening in the center, right.</p> <p>9 Uh-huh.</p> <p>10 Q. And in this Elliott device, the stem of the</p> <p>11 canister passes through that opening into the stem --</p> <p>12 the valve block. Correct?</p> <p>13 A. It moves -- yes, it is mounted -- the canister</p> <p>14 literally sits on the, let's see, item 17 there, and the</p> <p>15 valve portion of the canister fits firmly into the valve</p> <p>16 block, which is mounted below at the bottom of the</p> <p>17 actuator.</p> <p>18 Q. And the stem passes through the center of the</p> <p>19 counting mechanism to do that. Correct?</p> <p>20 A. The stem passes through the center, that is</p> <p>21 correct.</p> <p>22 Q. I am going to hand you now what has been</p> <p>23 marked Exhibit 1007 in the '177 IPR. And Mr. Clemens,</p> <p>24 do you recognize that exhibit?</p> <p>25 A. Yes, I do.</p>
<p style="text-align: right;">Page 52</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. What is that exhibit?</p> <p>3 A. This is the Rhoades patent.</p> <p>4 Q. And you discuss the Rhoades patent in</p> <p>5 paragraphs 18 and 19 of your declaration. Is that</p> <p>6 correct?</p> <p>7 A. Yes, that is correct.</p> <p>8 Q. Near the bottom of page 9, you state that, The</p> <p>9 plunger 34 and push button 35 interact with the cam body</p> <p>10 20 and are biased upward by a return spring 38. Right?</p> <p>11 (Reporter clarification.)</p> <p>12 MR. WEIL: Let me just say it again.</p> <p>13 Q. (BY MR. WEIL) The plunger 34 and push button</p> <p>14 35 interact with the cam body 20 and are biased upward</p> <p>15 by return spring 38.</p> <p>16 Do you see that?</p> <p>17 A. In my report --</p> <p>18 Q. Yeah.</p> <p>19 A. -- I do see that, yes.</p> <p>20 Q. Does component 34 directly interact with cam</p> <p>21 body 20?</p> <p>22 MS. HARGRAVE: Objection, vague.</p> <p>23 A. Okay. 34. And can you give me a little more</p> <p>24 detail what you mean by interact directly?</p> <p>25 Q. (BY MR. WEIL) Does a piece of plunger 34</p>	<p style="text-align: right;">Page 53</p> <p>1 CHARLES E. CLEMENS</p> <p>2 touch cam body 20?</p> <p>3 A. Yes, it does. 34 -- just trying to be a</p> <p>4 little precise here, because everything is numbered and</p> <p>5 all these different features, but do you mean that the</p> <p>6 fingers 44 and 45 that extend from the part that is</p> <p>7 pointed to as 34 as being the same part? Or how is your</p> <p>8 question formed so I can understand?</p> <p>9 Q. I guess I'm really asking what you meant in</p> <p>10 this sentence. It says the plunger 34 and push button</p> <p>11 35 interact with the cam body 20. And -- let me just</p> <p>12 make the question more clear.</p> <p>13 Is it your understanding that fingers 43 and</p> <p>14 44 are integral with plunger 34?</p> <p>15 MS. HARGRAVE: Objection, vague.</p> <p>16 A. I believe in the patent referred to the</p> <p>17 plunger as sort of the part that's below where the</p> <p>18 spring is mounted so that --</p> <p>19 Q. (BY MR. WEIL) I guess you can look above the</p> <p>20 figures. You have just above that paragraph figure 2,</p> <p>21 you can see component 34 and that's the plunger.</p> <p>22 Correct?</p> <p>23 A. Yes, that is the plunger, right.</p> <p>24 Q. And coming off of that, you can see finger 44.</p> <p>25 Correct?</p>

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A. Correct.

Q. And the fingers are directly connected, the same piece as plunger 34. Correct?

A. Yes, that's what it looks like.

Q. Okay. So now let's look at figures 8 through 11 of Rhoades, in the Rhoades patent. I am also going to hand you the petition from the '177 Patent IPR, and in the petition, you'll see that those same figures are included on pages 25, 27 but with certain components colored. So in case it's easier to use the colored ones, we have the petition there as well. Okay?

A. Okay.

Q. So I just want to be sure that we're on the same page in the mechanism of Rhoades. If you look at figure 8 of Rhoades, and it's on page 25 of the petition, that figure depicts the pen in its retracted state with stop members 45 and 46 at the bottom of the deep grooves. Right?

A. I believe that's correct.

Q. I guess just to go through the colors in the petition. The stop members are -- you understand are the ones colored in red. Correct?

A. Yes, that's correct.

Q. And the yellow is the cam body 20. Correct?

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A. Agreed, yes.

Q. And the plunger at 34 with teeth 43 and 44 is colored in green. Right?

A. Yes, that's green.

Q. Then as the push button 35 and plunger 34 are depressed, fingers 43 and 44 push the cam body downwards until the stop members come out of those deep grooves. Right?

A. That's correct.

Q. And once the stop members come out of those grooves, the cam body is free to begin rotating. Right?

A. That is correct.

Q. And that's what's pictured in figure 9, the cam body has started to rotate. Is that right?

A. Yes, that's correct. I believe Rhoades states that as soon as the stop members pass over the tip of that cam feature there, when it's fully depressed, that steps that cam -- the tips of those two cams pass each other and then it rotates.

Q. So it's your understanding that Rhoades says that happens when it's fully depressed?

A. That's exactly what Rhoades says.

Q. Well, look at figure 9. You just said that it starts to rotate as soon as the tip of the stop member

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leaves that groove. Correct?

A. That's correct.

Q. You can see in figure 9 that the cam body is pushed down farther than the stop member having just left the groove. Right?

A. No, it is not.

Q. It's not?

A. No, sir.

Q. So if we look in figure 9, finger 43 and stop member 45, are those two pieces colinear with each other?

MS. HARGRAVE: Objection, vague.

Q. (BY MR. WEIL) Let me ask. Do you understand what I mean by colinear?

A. I'm not sure.

Q. So colinear, along the same straight line.

A. Which line are you referring to?

Q. If we look at the bottom sloped face of finger 43 and the bottom sloped face of stop member 45, those are not along the same line. Correct?

A. Can we use one of your pictures to see --

Q. Sure.

A. -- what you're pointing at?

Q. Okay. Look at figure 9. And before we do

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that to better explain what I mean by colinear, if you look at figure 11 --

A. Okay.

Q. -- do you see the bottom sloped face at the stop member and the bottom sloped face of finger 43, they're along the same line. Correct?

A. Okay. I see that.

Q. If you look at figure 9, they are not along the same line. Correct?

MS. HARGRAVE: Objection, vague.

A. They are -- you're referring to fingers 43 and stop members 45.

Q. (BY MR. WEIL) Correct.

A. They are colinear but their cam surfaces are offset.

Q. What do you mean by cam surfaces are offset?

A. The cam surfaces, the surfaces that are making contact with the cam, cam surfaces. However, that is not -- that really has nothing to do with what a fully depressed -- the conversation that we're having.

As soon as the tip of that stop member 45 and 46, the tip of that cam passes over the tip of surface 50 and surface -- well, it's not -- yeah, 52, the cam moves. That's -- if I had a pen, I could show you maybe

<p style="text-align: right;">Page 58</p> <p>1 CHARLES E. CLEMENS</p> <p>2 in a little more --</p> <p>3 Q. Sure. Why don't you go ahead.</p> <p>4 A. Is it okay?</p> <p>5 Q. Sure. And I'll tell you what, we'll mark this</p> <p>6 as an exhibit number.</p> <p>7 MS. HARGRAVE: Okay.</p> <p>8 Q. (BY MR. WEIL) Let me mark the '177 petition</p> <p>9 that Mr. Clemens is going to annotate as Exhibit No.</p> <p>10 1054.</p> <p>11 (Exhibit 1054 marked.)</p> <p>12 A. This right here, when the stop member cam</p> <p>13 surface, the tip of that cam surface, passes the tip of</p> <p>14 this opening in the cam -- do you see the tip of this</p> <p>15 cam and the cam feature and the tip of that cam? As</p> <p>16 soon as it passes that, it rotates. That is a full</p> <p>17 depression.</p> <p>18 Q. (BY MR. WEIL) Okay. So you've drawn a blue</p> <p>19 line, and that's the point at which --</p> <p>20 MS. HARGRAVE: Did you draw anything on</p> <p>21 there?</p> <p>22 THE WITNESS: Yeah.</p> <p>23 A. I'm sorry. This line -- you can see that the</p> <p>24 cam is rotating and the stop member has just reached the</p> <p>25 tip of that and goes no further. It just rotates.</p>	<p style="text-align: right;">Page 59</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) The blue line that you draw --</p> <p>3 that you drew, is it at the very top of the deep groove.</p> <p>4 Right?</p> <p>5 A. Right.</p> <p>6 Q. And if I'm understanding you correctly, as</p> <p>7 soon as the red stop member has passed that point --</p> <p>8 A. That tip.</p> <p>9 Q. That tip, it starts to rotate?</p> <p>10 A. Correct.</p> <p>11 Q. So it starts to rotate when that tip of the</p> <p>12 red stop member is touching the yellow. Correct?</p> <p>13 A. No.</p> <p>14 MS. HARGRAVE: Objection.</p> <p>15 Q. (BY MR. WEIL) It doesn't rotate then?</p> <p>16 A. It's still touching.</p> <p>17 Q. Right. Okay. So it has just cleared and it</p> <p>18 starts to rotate?</p> <p>19 A. That's correct.</p> <p>20 Q. You do see a gap between the yellow cam body</p> <p>21 and the red stop member. Correct?</p> <p>22 A. In the motion of the cam follower and the cam,</p> <p>23 the stop member, there is no distance between the two of</p> <p>24 them, none. It's just as soon as it comes out of the</p> <p>25 cavity, the opening, the cam body rotates and Rhoades</p>
<p style="text-align: right;">Page 60</p> <p>1 CHARLES E. CLEMENS</p> <p>2 characterizes that as a full depression.</p> <p>3 Q. Can you point to me in Rhoades where he says</p> <p>4 that?</p> <p>5 MS. HARGRAVE: You can sit. And you can</p> <p>6 take as much time as you need to review it.</p> <p>7 A. This is when computers are really helpful.</p> <p>8 Q. (BY MR. WEIL) Yeah. And I don't know if it</p> <p>9 helps, but did you explain that anywhere in your</p> <p>10 declaration that might point you to some place in</p> <p>11 Rhoades?</p> <p>12 MS. HARGRAVE: If you want to answer that</p> <p>13 question, you can feel free to review the entirety of</p> <p>14 your declaration.</p> <p>15 Q. (BY MR. WEIL) Feel free to review.</p> <p>16 MS. HARGRAVE: But, Counsel, please keep</p> <p>17 your objections to form pursuant to the PTAB Rules.</p> <p>18 A. I was just going to say, I would have to</p> <p>19 review that just to, you know, refresh my memory, but I</p> <p>20 want -- I have to go through this here.</p> <p>21 Q. (BY MR. WEIL) And Mr. Clemens, to the extent</p> <p>22 it helps, on page 22 of your declaration you have a</p> <p>23 couple of citations to Rhoades. Sorry. Strike that.</p> <p>24 A. I am just going to use a pen to underline some</p> <p>25 words --</p>	<p style="text-align: right;">Page 61</p> <p>1 CHARLES E. CLEMENS</p> <p>2 MS. HARGRAVE: You can just read it.</p> <p>3 THE WITNESS: Is that okay?</p> <p>4 MS. HARGRAVE: I would just read it into</p> <p>5 the record so it's clear.</p> <p>6 THE WITNESS: All right.</p> <p>7 A. So there's at least three places where this is</p> <p>8 described that I can remember, and I am going to see if</p> <p>9 I can find them. But one place is near the bottom of</p> <p>10 column 5. It's line 72. As push button 35 is fully</p> <p>11 depressed, the fingers 43 and 44 are displaced further</p> <p>12 forwardly and will carry them -- with them the cam body</p> <p>13 20 until the stop surface is blah, blah, blah.</p> <p>14 You have to read this in context and look at</p> <p>15 the figure to see what I'm talking about, but that --</p> <p>16 they use the term "fully depressed" there.</p> <p>17 In column 1, line -- it's the third object.</p> <p>18 Maybe it's the second object. Maybe line 18 there.</p> <p>19 Another object of the invention is to provide a</p> <p>20 ballpoint writing pen instrument, having an improved</p> <p>21 push button operating projecting and retracting</p> <p>22 mechanism which operates upon successive full</p> <p>23 depressions of the push button to propel the writing</p> <p>24 point into an exposed and projected from the barrel. So</p> <p>25 it actuates on a full depression.</p>

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<p style="text-align: right;">Page 62</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Column 5, line 22, successive full depressions</p> <p>3 of the push button 35 will, through corresponding</p> <p>4 movements of actuating fingers 43 and 44, successfully</p> <p>5 depress and rotate the cam body 20 so as to cause</p> <p>6 alternate pairs of cam surfaces 50, 52 and bottom</p> <p>7 surfaces 51, 53 to be engaged by the stationery stop</p> <p>8 members 45 and 46. This, in turn, will cause the point</p> <p>9 in cartridge unit 7 to assume alternatively an extended</p> <p>10 writing position and a retracted nonwriting position.</p> <p>11 This manner in which this is accomplished is then</p> <p>12 described. There's at least three places in this</p> <p>13 patent. There may be more.</p> <p>14 Q. (BY MR. WEIL) And so the record is clear, the</p> <p>15 three places that you pointed to are column 1, lines 18</p> <p>16 through 25; column 5, lines 22 through 32; column 5,</p> <p>17 lines 72 through 75. Is that right?</p> <p>18 A. Well, again, it's describing a process. So,</p> <p>19 you know, there may be more lines in order to capture --</p> <p>20 you know, before and after to capture the notion.</p> <p>21 Q. Okay. So those passages indicate when the</p> <p>22 plunger is fully depressed, this motion will happen.</p> <p>23 Correct?</p> <p>24 MS. HARGRAVE: Objection, vague.</p> <p>25 A. What --</p>	<p style="text-align: right;">Page 63</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) Let me rephrase it.</p> <p>3 A. Sure.</p> <p>4 Q. Those passages indicate that upon full</p> <p>5 depressions rotate the cam body. Correct?</p> <p>6 MS. HARGRAVE: Objection, vague.</p> <p>7 A. So my read of what these passages in the</p> <p>8 patent say from a person of skill in the art at the time</p> <p>9 of the invention, what they're describing is a full</p> <p>10 depression or an actuation of the pen causes the</p> <p>11 movement to occur. And the way that the cam and the cam</p> <p>12 fingers are set up -- as we can see in figure 9, as soon</p> <p>13 as the stop member is just outside of the relief in the</p> <p>14 cam, the cam body rotates, and that is what Rhoades</p> <p>15 refers to as a full depression.</p> <p>16 Q. (BY MR. WEIL) Back to the passages about the</p> <p>17 full depression. I don't think there's any question</p> <p>18 that once the device has been fully pressed down, the</p> <p>19 cam body has rotated. Right?</p> <p>20 A. The cam body rotates upon a full depression</p> <p>21 when the stop members are brought out of the cam feature</p> <p>22 which prevents it from rotating, but as soon as it</p> <p>23 leaves, the cam body rotates, and that's a full</p> <p>24 depression.</p> <p>25 Q. To get back to the specific passages you</p>
<p style="text-align: right;">Page 64</p> <p>1 CHARLES E. CLEMENS</p> <p>2 pointed to, they don't say anything whether it could</p> <p>3 start rotating before the full depression has been</p> <p>4 completed. Correct?</p> <p>5 MS. HARGRAVE: Objection, vague.</p> <p>6 A. I don't -- just sitting here right now -- I</p> <p>7 would have to read this patent and see what you're</p> <p>8 talking about, but --</p> <p>9 Q. (BY MR. WEIL) I am just saying that -- sorry.</p> <p>10 A. I was just going to say that Rhoades uses the</p> <p>11 term "fully depressed" and that's when the cam moves. I</p> <p>12 mean, the description is very clear in here how it's</p> <p>13 described.</p> <p>14 Q. So maybe a simpler question.</p> <p>15 Is it your understanding that the plunger can</p> <p>16 be depressed farther in the device after the cam body</p> <p>17 begins to rotate?</p> <p>18 A. That is not what Rhoades describes here.</p> <p>19 Q. And if we look at figure 9, you understand</p> <p>20 that the stop members 45 and 46 don't move. Correct?</p> <p>21 A. That's correct.</p> <p>22 Q. The fingers push the cam body downwards.</p> <p>23 Right?</p> <p>24 A. Correct.</p> <p>25 Q. In figure 9, you can see that the fingers have</p>	<p style="text-align: right;">Page 65</p> <p>1 CHARLES E. CLEMENS</p> <p>2 pushed the cam body down below the stop member.</p> <p>3 Correct?</p> <p>4 A. What you see is you are looking at a full</p> <p>5 depression and it's the point at which the cam body has</p> <p>6 been pushed far enough to allow the stop members to</p> <p>7 leave the opening, the cam opening there in the cam</p> <p>8 body. So here is the stop member. And as soon as --</p> <p>9 well, that's not even going to show it. It's just that</p> <p>10 as soon as the stop member -- because the cam body is</p> <p>11 preventing it from -- the cam body will not rotate</p> <p>12 because the -- it's pressing against the stop member.</p> <p>13 So as the stop member comes out of the opening, the cam</p> <p>14 opening, it rotates and Rhoades describes that as a full</p> <p>15 depression.</p> <p>16 Q. I understand your understanding, but looking</p> <p>17 at figure 9, you do agree with me that there is space</p> <p>18 between the bottom of stop member 45 and cam body 20.</p> <p>19 Correct?</p> <p>20 MS. HARGRAVE: Objection,</p> <p>21 mischaracterizes the witness's testimony.</p> <p>22 A. That does not relate actually, you know, to</p> <p>23 what I believe you're asking and that is, you know, when</p> <p>24 the cam body -- the moment the cam body moves under this</p> <p>25 spring force. And a full depression is when the cam</p>

17 (Pages 62 to 65)

<p style="text-align: right;">Page 66</p> <p>1 CHARLES E. CLEMENS</p> <p>2 body has been pushed past the stop member. So -- and</p> <p>3 you can see it can only go to the tip. It can't go any</p> <p>4 further because that's a full depression, and the cam</p> <p>5 body moves.</p> <p>6 Q. (BY MR. WEIL) So my question was a lot</p> <p>7 simpler.</p> <p>8 Do you or do you not see space in between the</p> <p>9 bottom angled surface of 45 and the cam body 20?</p> <p>10 MS. HARGRAVE: Objection, asked and</p> <p>11 answered.</p> <p>12 A. I think you're confusing the -- you're</p> <p>13 confusing how the mechanism works, because at this point</p> <p>14 where the fingers have pushed the cam, as soon as the</p> <p>15 tips of those cam surfaces pass each other, it rotates.</p> <p>16 It doesn't depress any further. So this space I think</p> <p>17 that you're referring to is not related to the distance</p> <p>18 that it's being pressed, because as soon as the stop</p> <p>19 members leave the opening, it rotates, and that's</p> <p>20 visually what's described here. If you were depressing</p> <p>21 it even further, you would see cam -- you would see stop</p> <p>22 members 45, 46 even higher.</p> <p>23 Q. (BY MR. WEIL) So you said, So this space I</p> <p>24 think that you're referring to. That was a quote of</p> <p>25 what you just testified. You do see a space there</p>	<p style="text-align: right;">Page 67</p> <p>1 CHARLES E. CLEMENS</p> <p>2 between the bottom of stop member 45 and cam body 20?</p> <p>3 MS. HARGRAVE: Objection, asked and</p> <p>4 answered.</p> <p>5 A. The question --</p> <p>6 Q. (BY MR. WEIL) The question is yes or no.</p> <p>7 A. Well, what I would say is to try to describe</p> <p>8 to you that the full depression could be defined as the</p> <p>9 space between the tips of those two cam surfaces.</p> <p>10 Essentially the line that I drew, you notice that it is</p> <p>11 essentially a line. There is no gap.</p> <p>12 Q. So the line that you drew on what we marked as</p> <p>13 1054, it's your position that is the full depression?</p> <p>14 A. That's the full depression, and that would</p> <p>15 be -- that's how Rhoades has described it. You would</p> <p>16 see an immediate movement of the cam which is described</p> <p>17 as a full depression.</p> <p>18 Q. Have you ever used a mechanical pen before,</p> <p>19 Mr. Clemens?</p> <p>20 A. Lots and lots, yes, I have.</p> <p>21 Q. And is it your understanding when you depress</p> <p>22 the plunger and hear the click, you can push the plunger</p> <p>23 a little farther?</p> <p>24 A. Well, you're describing pens -- many, many</p> <p>25 pens, mechanical or otherwise in your question, which</p>
<p style="text-align: right;">Page 68</p> <p>1 CHARLES E. CLEMENS</p> <p>2 is -- obviously, it doesn't relate to what the Rhoades</p> <p>3 is describing and that that's relevant to our</p> <p>4 conversation, but I'll give you that there are many</p> <p>5 kinds of designs out there that are not Rhoades.</p> <p>6 Q. Okay. And let me ask it more gently.</p> <p>7 Have you ever used a pen that you could</p> <p>8 depress and after you heard the click depress the</p> <p>9 plunger further?</p> <p>10 A. I don't think I've ever really you thought</p> <p>11 about it, but, you know, with the millions of pens out</p> <p>12 there, I'm sure there's all kinds.</p> <p>13 Q. So you don't know if you've ever used one like</p> <p>14 that?</p> <p>15 A. I don't think I have ever really thought about</p> <p>16 it --</p> <p>17 Q. Okay.</p> <p>18 A. -- until I started studying this patent. So,</p> <p>19 but yeah, the -- you know, the Rhoades is very specific</p> <p>20 with their design.</p> <p>21 Q. So Mr. Clemens, when that stop member passes</p> <p>22 that line that you drew in Exhibit 1054, the cam</p> <p>23 surfaces of the fingers and the stop members are not</p> <p>24 offset. Correct?</p> <p>25 A. That's not depicted here. Obviously 11, I</p>	<p style="text-align: right;">Page 69</p> <p>1 CHARLES E. CLEMENS</p> <p>2 guess, would show them being colinear, I think you</p> <p>3 referred to it as. But so what you're visually seeing</p> <p>4 here in figure 9 is the point of which the stop member</p> <p>5 comes out of that relief or that opening, and, you know,</p> <p>6 when they were -- when they were at the point -- well,</p> <p>7 ask your question again, because I want to make sure</p> <p>8 that I'm understanding exactly what you're --</p> <p>9 Q. I think you were about to get it. When they</p> <p>10 were at the point when it started to rotate --</p> <p>11 A. No, no. I was --</p> <p>12 MS. HARGRAVE: Could you read him the</p> <p>13 question again?</p> <p>14 MR. WEIL: Sure.</p> <p>15 A. Just ask the question again to make sure</p> <p>16 I'm --</p> <p>17 Q. (BY MR. WEIL) When the stop member passes the</p> <p>18 line you drew on Exhibit 1054 --</p> <p>19 A. Stop member, yeah.</p> <p>20 Q. And that's, I understand, when the cam body</p> <p>21 will start to rotate. Correct?</p> <p>22 A. Okay. So it's actually this picture.</p> <p>23 Q. Well, this picture in figure 9 it has already</p> <p>24 started to rotate. Right?</p> <p>25 A. Yes, but it doesn't matter because it's spring</p>

18 (Pages 66 to 69)

<p style="text-align: right;">Page 70</p> <p>1 CHARLES E. CLEMENS</p> <p>2 loaded. As soon as it passes, it rotates.</p> <p>3 Q. Right.</p> <p>4 A. So -- so ask the question.</p> <p>5 Q. Sure.</p> <p>6 A. Let's get to it.</p> <p>7 Q. So when the stop member passes that line that</p> <p>8 you drew in Exhibit 1054, the cam -- the bottom cam</p> <p>9 surface of the fingers and the bottom cam surface of the</p> <p>10 stop members are not offset, correct, at that exact</p> <p>11 point?</p> <p>12 A. That is not correct. It's what you're seeing</p> <p>13 here in picture 9 is when it -- is when it's rotating.</p> <p>14 That's a full depression.</p> <p>15 Q. So it's your understanding --</p> <p>16 A. It can't rotate until it's passed -- you know,</p> <p>17 until the stop members get out of that -- that space.</p> <p>18 Q. But we just talked about picture 9. That</p> <p>19 already shows rotation happening. Correct?</p> <p>20 A. Again, a full depression is described in this</p> <p>21 patent as when the stop members are brought out of the</p> <p>22 relief, the opening in the cam follower -- and I mean</p> <p>23 you can see that when the stop members are still in this</p> <p>24 relief and the edges are contacting and it can't move,</p> <p>25 the fingers are going to be -- well, so it can't --</p>	<p style="text-align: right;">Page 71</p> <p>1 CHARLES E. CLEMENS</p> <p>2 you're going to see an offset at that position. So</p> <p>3 this -- what you're seeing in figure 9 is the figure</p> <p>4 that you're looking for.</p> <p>5 Q. So Mr. Clemens, can you please turn to page 22</p> <p>6 of your report?</p> <p>7 MS. HARGRAVE: Which report?</p> <p>8 MR. WEIL: '177.</p> <p>9 A. Okay. I'm sorry. What page?</p> <p>10 Q. (BY MR. WEIL) Page 22. And you show a figure</p> <p>11 at the top of that page. Right?</p> <p>12 A. That is correct, yeah.</p> <p>13 Q. And you added in green into that figure the</p> <p>14 words "complete stroke." Right?</p> <p>15 A. That is correct.</p> <p>16 Q. And you labeled that figure pen at full</p> <p>17 depression, full press. Right?</p> <p>18 A. Correct.</p> <p>19 Q. And is the bottom face of the blue stop member</p> <p>20 and the bottom face of the white finger in your picture,</p> <p>21 are they offset?</p> <p>22 A. Well, you know, this is pretty, you know, kind</p> <p>23 of fuzzy and vague, but what is important to note here</p> <p>24 is the tip of the stop member. The blue part is right</p> <p>25 at the tip of the cam body. So that's the point at</p>
<p style="text-align: right;">Page 72</p> <p>1 CHARLES E. CLEMENS</p> <p>2 which it's going to rotate. So that's a complete</p> <p>3 stroke.</p> <p>4 Q. And at that point the bottom cam surface of</p> <p>5 the fingers and the bottom cam surface of the stop</p> <p>6 member are colinear. Right?</p> <p>7 MS. HARGRAVE: Objection, vague.</p> <p>8 A. This -- I am going to say that it could</p> <p>9 possibly be, you know, but it's -- but, again, what</p> <p>10 is -- this picture here is not a direct -- is not taken</p> <p>11 directly from Rhoades. So, you know, Rhoades could have</p> <p>12 many different embodiments, but what Rhoades is</p> <p>13 describing here and what's happening here is that as</p> <p>14 soon as the stop member passes the relief, then cam body</p> <p>15 will rotate.</p> <p>16 Q. (BY MR. WEIL) So you said that this picture</p> <p>17 is not actually describing what is described in Rhoades?</p> <p>18 MS. HARGRAVE: Objection,</p> <p>19 mischaracterizes the witness's testimony.</p> <p>20 A. It is an embodiment of Rhoades, according to</p> <p>21 the video, but I don't think there's anything that</p> <p>22 states that these two depictions, these two approaches</p> <p>23 are the same, are one and the same, but conceptually</p> <p>24 they are because in both instances, as soon as the stop</p> <p>25 members leave their respective positions, there is a</p>	<p style="text-align: right;">Page 73</p> <p>1 CHARLES E. CLEMENS</p> <p>2 rotation. So --</p> <p>3 Q. (BY MR. WEIL) And when you said these two</p> <p>4 depictions, these two approaches, you were pointing at</p> <p>5 figures 8 through 11 of Rhoades?</p> <p>6 A. Rhoades and the picture in my report, yes.</p> <p>7 Q. And in the picture in your report, do you see</p> <p>8 at the very top of the blue stop member there's</p> <p>9 additional space in that groove? Do you see space</p> <p>10 there?</p> <p>11 A. Yeah, I see a relief.</p> <p>12 Q. Do you think that the plunger could be pushed</p> <p>13 down further forcing the stop member into that space?</p> <p>14 A. I don't know because I haven't physically seen</p> <p>15 this particular pen which, you know, appears to be a CAD</p> <p>16 model. So --</p> <p>17 Q. So does it necessarily describe the Rhoades</p> <p>18 reference?</p> <p>19 MS. HARGRAVE: Objection,</p> <p>20 mischaracterizes the witness testimony.</p> <p>21 A. That's what it is presented as in the video.</p> <p>22 Q. (BY MR. WEIL) And you don't know whether the</p> <p>23 plunger can be pushed further forcing the blue stop</p> <p>24 member higher into the plunger group?</p> <p>25 A. I haven't done an analysis. I don't have a</p>

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pen. I don't have any drawings, any descriptions of it. So to me it's, yes, there's a relief there; but what we see here is that, the same as Rhoades, as soon as the stop member passes that cam feature, the tips there, is when it rotates.

Q. But you would agree with me that if you push the plunger further and force the stop member into that relief, if that's possible, the fingers and cam body would be pushed down further and the bottom surfaces of the fingers would be offset from the surface of the stop member. Right?

MS. HARGRAVE: Objection, calls for speculation.

A. Yeah, I mean, it's a complete hypothetical. I can't say because I haven't seen this pen. I don't -- you know, it's -- you know, sitting here right now, I won't be able to have a fully considered opinion of something that I can't actually see, touch, you know, analyze, do something with, but --

Q. (BY MR. WEIL) Were you able to see, touch, analyze and fully do something with the pen when you came up with your opinion?

MS. HARGRAVE: Objection, vague.

A. Which opinion?

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Q. (BY MR. WEIL) The one -- the opinions that you have included in your declaration that we're looking at.

A. Well, I've been able to analyze the invention, the patent, which fully describes through the eyes of a person of skill in the art. So there's quite a bit of information given to me here.

Q. All right. I think just to wrap this up a little bit, you as an engineer with 38 plus years of experience, sitting here today you can't tell me whether pushing that plunger down a little bit further forcing the blue stop member higher into the relief would cause the bottom surface of the fingers and the stop members to be offset?

MS. HARGRAVE: Objection, asked and answered and calls for speculation.

A. No, I cannot. There is not enough information there for me.

Q. (BY MR. WEIL) And looking at figure 9 from the actual Rhoades reference, it's your position that there is not a gap between the bottom of the stop member and cam body 20. Is that right?

A. There is a gap. I thought we agreed on that a little earlier.

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Q. Okay.

A. But this is the -- this is the -- there has been no change in the relative position between the finger 43 and 44 and stop member 45 and 46 since the point of release of full depression that allows a cam to move. That is the position at which rotation can occur and full depression has occurred.

Q. So are you saying that rotation only begins when these two surfaces, bottom of finger 43 and bottom of cam 45 -- sorry -- stop member 45, are offset?

A. That's correct. When -- what you're seeing right here in figure 9 is what the relative positions of these two -- of the stop members 45 and 46 and fingers 43 and 44 have started rotation.

Q. And could the cam body start rotating when stop members and the bottom of the stop members and the bottom of the fingers were colinear?

A. They would not move.

Q. Why not?

A. Because you have not moved the stop members out of the relief in the cam.

Q. When the bottom of the -- so it's your position that when the bottom of the finger and the bottom of the stop member is colinear, you have not yet

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moved the stop member out of the relief?

A. You're still --

MS. HARGRAVE: Objection. Objection, mischaracterizes the witness's testimony.

A. The best way that I can describe this is the figure that you're looking at in figure 9 is the point -- is the relative positions between stop members and cam followers -- fingers when rotation occurs, and you can see that because the tips of the stop members, they're colinear. They're exactly at the same point. That's the only time when you can get the cam follower to move.

MR. WEIL: Ryan, do you know if lunch is here yet? We may stop for a bit?

MS. HARGRAVE: Let me go check, yes.

MR. WEIL: It is. All right. Do you want to take a lunch break?

MS. HARGRAVE: Yeah.

(Break from 11:29 a.m. to 12:19 p.m.)

Q. (BY MR. WEIL) Welcome back, Mr. Clemens.

A. Thanks.

Q. I do want to do a little more about Rhoades. First, I would like to show you the video Exhibit 2020 that you submitted with your declaration, and I am going

<p style="text-align: right;">Page 78</p> <p>1 CHARLES E. CLEMENS</p> <p>2 to start it at what I think is the relevant part. If</p> <p>3 you want to see the whole thing you can.</p> <p>4 A. Sure.</p> <p>5 Q. So I'll start the video at minute 1:52.</p> <p>6 (Video played.)</p> <p>7 Q. (BY MR. WEIL) Okay. Let me just rewind it a</p> <p>8 little bit. There at 1 minute 59 seconds, is that the</p> <p>9 line that you were drawing on Exhibit -- is that</p> <p>10 horizontal line in the video the line you were drawing</p> <p>11 on Exhibit 1054 we were talking about earlier?</p> <p>12 A. With the proviso that these are two different,</p> <p>13 you know, designs being shown here, but it does appear</p> <p>14 to be the point where those cam tips are meeting.</p> <p>15 Q. And your understanding is that point at minute</p> <p>16 1:59 in the video is when the cam body can begin to</p> <p>17 rotate. Correct?</p> <p>18 MS. HARGRAVE: Objection,</p> <p>19 mischaracterizes the witness's testimony.</p> <p>20 A. Yeah, as soon as the stop member clears the --</p> <p>21 well, actually, let me look at this here. Yeah, if it</p> <p>22 reaches that point, it will rotate exactly. If we</p> <p>23 advance it a little bit more, we should see it rotate.</p> <p>24 Q. (BY MR. WEIL) Right. And that was at -- that</p> <p>25 picture we were looking at was at 1:59 of the video, and</p>	<p style="text-align: right;">Page 79</p> <p>1 CHARLES E. CLEMENS</p> <p>2 I'll play it a little bit further.</p> <p>3 (Video being played.)</p> <p>4 Q. (BY MR. WEIL) So when the -- when we passed</p> <p>5 that point we were just talking about when it can begin</p> <p>6 to rotate the rotation, the cam body rotates but it's</p> <p>7 also forced upwards. Correct?</p> <p>8 MS. HARGRAVE: Objection, vague.</p> <p>9 A. Well, the cam body is going to be -- is going</p> <p>10 to be -- it's spring loaded, obviously, so it's going to</p> <p>11 be -- it's going to maintain contact, you know, with</p> <p>12 the -- depends on what situation you're in, but the</p> <p>13 fingers obviously are making contact with the cam, and</p> <p>14 so, you know, they would have to maintain that contact.</p> <p>15 Q. (BY MR. WEIL) And as that contact is</p> <p>16 maintained and it's rotated, the cam body physically</p> <p>17 moves upwards. Correct?</p> <p>18 A. Well, in the figure 9, it's actually moving</p> <p>19 down. The cam body is moving down.</p> <p>20 Q. So you understand there's a spring biasing the</p> <p>21 cam body upwards. Correct?</p> <p>22 A. There is -- the cam body is literally spring</p> <p>23 loaded both directions.</p> <p>24 Q. So your understanding of figure 9 is that once</p> <p>25 the stop member clears the tip of the cam body that</p>
<p style="text-align: right;">Page 80</p> <p>1 CHARLES E. CLEMENS</p> <p>2 we're talking about, the cam body is forced downwards?</p> <p>3 Is that what you're saying?</p> <p>4 A. No. I'm saying that the -- in this picture,</p> <p>5 the cam body is just -- is turning, is rotating, but it</p> <p>6 has -- obviously to get to that position, it was being</p> <p>7 pressed down by the fingers, yes.</p> <p>8 Q. And in figure 9 that we're looking at, we may</p> <p>9 have already talked about this, but the cam body has</p> <p>10 begun to rotate already. Correct?</p> <p>11 MS. HARGRAVE: Objection, asked and</p> <p>12 answered.</p> <p>13 A. Yeah, it's kind of a, you know, instantaneous</p> <p>14 thing. And, you know, it happens fairly quickly.</p> <p>15 Q. (BY MR. WEIL) But the figure shows the tooth</p> <p>16 in the middle of the sloped face 50. Right?</p> <p>17 A. Sort of at the beginning, but yeah, it's</p> <p>18 passed that. You know, it has moved past that point.</p> <p>19 Q. So it has started --</p> <p>20 A. Where the tips -- where the tips passed.</p> <p>21 Q. It has started at least some amount of</p> <p>22 rotation?</p> <p>23 A. Rotation.</p> <p>24 Q. And as it rotated to the right -- let me be</p> <p>25 more precise. As the cam body was rotated to the right,</p>	<p style="text-align: right;">Page 81</p> <p>1 CHARLES E. CLEMENS</p> <p>2 it was also forced upwards. Correct?</p> <p>3 MS. HARGRAVE: Can I just object to</p> <p>4 vague. You're pointing to the video, and it's --</p> <p>5 MR. WEIL: We can close the video.</p> <p>6 MS. HARGRAVE: Okay.</p> <p>7 A. Counselor, were you referring to the figure?</p> <p>8 Q. (BY MR. WEIL) Yeah. Figure 9 of Rhoades.</p> <p>9 A. Yes.</p> <p>10 So the cam body just maintains, you know,</p> <p>11 contact with that cam surface of the finger itself.</p> <p>12 Q. And --</p> <p>13 A. So, again, it's literally rotating. The cam</p> <p>14 surfaces are rubbing, but it's rotating.</p> <p>15 Q. Well, just to be crystal clear on the</p> <p>16 mechanism of what's happening, in figure 9 as the cam</p> <p>17 body 20 is rotating, is it your understanding that the</p> <p>18 cam body also moves actually in either direction?</p> <p>19 A. Well, my understanding and my read of Rhoades,</p> <p>20 that's the -- literally, it's the point where it's fully</p> <p>21 depressed. So at this point, it's just -- you know,</p> <p>22 it's just rotating. It's rotated past that point where</p> <p>23 it's been released, and then it will -- then the button</p> <p>24 will be released and it pops up to this other position</p> <p>25 55 in figure 10.</p>

21 (Pages 78 to 81)

<p style="text-align: right;">Page 82</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. Okay. Can you look in the Rhoades patent</p> <p>3 itself, column 5, starting at line 51? And I am looking</p> <p>4 at the part that says when the cam body 20 has been</p> <p>5 depressed to an extent sufficient to permit the rearward</p> <p>6 edges of stop surfaces 56 and 58 to clear the forward</p> <p>7 edges of stop members 45 and 46, figure 9, the cam body</p> <p>8 20 is free to rotate in the direction indicated by the</p> <p>9 arrow under the influence of the return spring 16,</p> <p>10 figure 1, which applies a constant rearward force to the</p> <p>11 cam body.</p> <p>12 So is your understanding of rearward force to</p> <p>13 be forcing the cam body back towards the plunger in the</p> <p>14 pen?</p> <p>15 A. Just to be accurate, I want to read this</p> <p>16 again --</p> <p>17 Q. Sure.</p> <p>18 A. -- just to make sure. Of course, I have an</p> <p>19 instantaneous answer, but let me just --</p> <p>20 Q. Feel free to read.</p> <p>21 A. Okay. I have oriented myself. So yes, so</p> <p>22 Rhoades is describing that there's a spring force which</p> <p>23 is maintaining the contact between the cam body and the</p> <p>24 finger 43s and 44. So it's rotating. It's rotating.</p> <p>25 And yes, there is a bias of the cam body, but it's just</p>	<p style="text-align: right;">Page 83</p> <p>1 CHARLES E. CLEMENS</p> <p>2 biasing it against that cam surface, of which it is now</p> <p>3 sliding, and it literally slams into the wall 59 and 57.</p> <p>4 So it snaps like that. So --</p> <p>5 Q. And to slide against the cam surface of the</p> <p>6 fingers and the stop members as it's rotating, it has to</p> <p>7 be moving upwards or else it would separate from them as</p> <p>8 it rotates. Right? "It" being the cam body.</p> <p>9 A. Well, I think since it's a click</p> <p>10 instantaneous, so what happens is that the fingers slam</p> <p>11 up against the wall, and then -- I've got to remember</p> <p>12 where I am, orient myself again.</p> <p>13 Yeah, so you fully depress and you achieve</p> <p>14 figure 9. And then, of course, you know, the natural</p> <p>15 thing is to release your finger. So what happens is you</p> <p>16 end up in figure 10. So your finger comes off the</p> <p>17 button, and the bias spring does, in fact, move the cam</p> <p>18 up into the stop members 45 and 46. And, you know, of</p> <p>19 course, stop members 45 and 46 get -- get, you know,</p> <p>20 positioned in how you view figure 10. That's the</p> <p>21 writing position.</p> <p>22 Q. Got it. Okay.</p> <p>23 THE WITNESS: Can I get some water?</p> <p>24 MS. HARGRAVE: Do you need a break?</p> <p>25 THE WITNESS: Just water is good.</p>
<p style="text-align: right;">Page 84</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) So if we go back to -- are you</p> <p>3 ready?</p> <p>4 A. Yes, sir.</p> <p>5 Q. Page 22 of your declaration in the "177</p> <p>6 Patent IPR. We were talking earlier -- I was asking</p> <p>7 about whether the bottom surface of the fingers and the</p> <p>8 stop member are colinear. Do you remember that?</p> <p>9 A. Yes, you asked that earlier.</p> <p>10 Q. Uh-huh. And is it your understanding that</p> <p>11 this point in this picture at the top of page 22 is when</p> <p>12 the cam body can begin to rotate?</p> <p>13 MS. HARGRAVE: Objection, asked and</p> <p>14 answered.</p> <p>15 A. I believe that that is true. I mean, you</p> <p>16 know, as I pointed out before, these appear to be two</p> <p>17 different approaches or the -- you know, to the same</p> <p>18 concept of Rhoades. This cam body is not configured the</p> <p>19 same as this cam -- Rhoades's cam body. So I mean, you</p> <p>20 know, I don't have, you know, the same kind of</p> <p>21 information that I have for Rhoades. But that point</p> <p>22 there, it does appear, since that is a stop member,</p> <p>23 since the cam body is past -- just past it and those</p> <p>24 little surfaces are no longer -- well, I would say that</p> <p>25 the stop member can no longer stop it, it will turn.</p>	<p style="text-align: right;">Page 85</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) Okay. So it will begin to</p> <p>3 turn. And would you agree with me that in this picture</p> <p>4 at this point, the bottom surface of the fingers and the</p> <p>5 bottom surface of the stop member are colinear?</p> <p>6 MS. HARGRAVE: Objection, asked and</p> <p>7 answered.</p> <p>8 A. Like I said, the picture is a little fuzzy,</p> <p>9 but it appears that they could be colinear.</p> <p>10 Q. (BY MR. WEIL) If we go back to figure 9 in</p> <p>11 Rhoades. Ready?</p> <p>12 A. Yes, sir.</p> <p>13 Q. Figure 9 in Rhoades. We talked before about</p> <p>14 the small gap that's visible below stop member 45 and</p> <p>15 above cam body 20. Do you remember me asking you</p> <p>16 questions about that?</p> <p>17 A. Yes.</p> <p>18 Q. And please correct me if I'm wrong, but you</p> <p>19 said that is the point at which it begins to rotate. Is</p> <p>20 that right?</p> <p>21 A. I believe my answer is -- to that is that the</p> <p>22 view, the picture that we're seeing in figure 9, is</p> <p>23 the -- is the same. I mean, the relative positioning of</p> <p>24 things is the same as soon as that point of rotation</p> <p>25 occurs. So the stop members are preventing rotation</p>

<p style="text-align: right;">Page 86</p> <p>1 CHARLES E. CLEMENS</p> <p>2 until the tips just pass each other, and then, bang, it</p> <p>3 can move. And so --</p> <p>4 Q. And -- and I think you said the reason why</p> <p>5 that is the point you've been describing is because the</p> <p>6 bottom tip, the tip part of stop member 45 and the top</p> <p>7 tip part of cam body right next to the number 54, to the</p> <p>8 left of 54, those are in the same line?</p> <p>9 A. They would be in the same line or same -- they</p> <p>10 would be coplanar.</p> <p>11 Q. Gotcha.</p> <p>12 MS. HARGRAVE: Let me object to the form</p> <p>13 of the previous question in that it mischaracterizes</p> <p>14 witness's testimony.</p> <p>15 Q. (BY MR. WEIL) But we already talked about in</p> <p>16 figure 9 the cam body has started to rotate at least</p> <p>17 some amount. Right?</p> <p>18 MS. HARGRAVE: Again, objection,</p> <p>19 mischaracterizes the witness's testimony.</p> <p>20 A. Yeah, so my response to that is as soon as the</p> <p>21 stop member stops preventing the cam from moving, it</p> <p>22 will move. And so this is -- you know, obviously it</p> <p>23 happens instantaneously but the cam body maintains its</p> <p>24 position relative to the finger and just rotates until</p> <p>25 it slams into that corner, and that's the click. That's</p>	<p style="text-align: right;">Page 87</p> <p>1 CHARLES E. CLEMENS</p> <p>2 one of the clicks you hear.</p> <p>3 MS. HARGRAVE: I'm going to also add an</p> <p>4 objection to the form of the previous question in that</p> <p>5 it was previously asked and answered.</p> <p>6 MR. WEIL: Counsel, could you please keep</p> <p>7 your objections to just form? The PTAB Rules are very</p> <p>8 clear on this.</p> <p>9 Q. (BY MR. WEIL) And in this Rhoades mechanism</p> <p>10 that we're looking at here in figures 8 through 11, as</p> <p>11 soon as the bottom surface of the finger 43 and the</p> <p>12 bottom surface of stop member 45 are colinear, it will</p> <p>13 begin to rotate, correct, cam body will begin to rotate?</p> <p>14 A. No.</p> <p>15 Q. No?</p> <p>16 A. No, sir.</p> <p>17 Q. Why not?</p> <p>18 A. So figure 9, all these relative parts we'll</p> <p>19 call them, you know, the stop members, 45, 46, fingers</p> <p>20 43, 44, and the cam body, the view you see right now is</p> <p>21 the same view when the stop members release the cam body</p> <p>22 to rotate. So what you're seeing here is sort of a</p> <p>23 midstream snap, if you will. And, you know, you can see</p> <p>24 as this thing continues to rotate, it clicks right into</p> <p>25 those fingers.</p>
<p style="text-align: right;">Page 88</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And that midstream snap, the cam body has</p> <p>3 moved upwards to some extent, right, to maintain contact</p> <p>4 with the bottom of finger 43?</p> <p>5 A. Well, I don't think that's necessarily</p> <p>6 described anywhere. If I could point to that -- is that</p> <p>7 in Rhoades?</p> <p>8 Q. Well, my question is more just from an</p> <p>9 engineering perspective. You're looking at a sloped</p> <p>10 face of the cam body.</p> <p>11 A. Yes.</p> <p>12 Q. You're looking at the sloped face of the</p> <p>13 finger. The cam body is being biased upwards by a</p> <p>14 spring. As soon as the stop member prevents it from</p> <p>15 rotating, the upward force causes it to rotate to the</p> <p>16 right because of these sloped faces. Correct?</p> <p>17 A. Yeah. I mean, you know, in view -- or figure</p> <p>18 9 as the spring force, the bias force is pressing the</p> <p>19 cam up against these fingers, yes, it would necessarily</p> <p>20 maintain its contact and start sliding down.</p> <p>21 Q. When you say "sliding down," what is sliding</p> <p>22 down?</p> <p>23 A. The slope of 50 and 52.</p> <p>24 Q. To be clear, the cam body -- for that to</p> <p>25 occur, the cam body is moving upwards. Is that your</p>	<p style="text-align: right;">Page 89</p> <p>1 CHARLES E. CLEMENS</p> <p>2 understanding of what's happening in Rhoades?</p> <p>3 A. So, again, let's kind of go through it because</p> <p>4 it might make more sense.</p> <p>5 Q. Sure.</p> <p>6 A. So in figure 8, you're retracted, right.</p> <p>7 Q. Yeah.</p> <p>8 A. We press on the button and the fingers 43 and</p> <p>9 44 push the cam body against spring bias. Right? And</p> <p>10 as soon as the -- we reach this point that we've</p> <p>11 discussed many times where the tips just pass, then you</p> <p>12 release your finger. So when you release your finger,</p> <p>13 you end up into position 10. So during that process of</p> <p>14 releasing your finger, then now you're floating again.</p> <p>15 And, indeed, the cam body will move away from the</p> <p>16 writing tip and then stabilize into figure 10 where you</p> <p>17 can write.</p> <p>18 Q. And as the cam body moves away from the</p> <p>19 writing tip, the little -- the tip of the cam body that</p> <p>20 we've been discussing -- it's immediately to the left of</p> <p>21 54 in figure 9 -- that will be higher than it was at the</p> <p>22 start of figure 8. Correct?</p> <p>23 A. No. Actually, it's lower.</p> <p>24 Q. If the cam body moves --</p> <p>25 A. Well, so this could be very confusing. We</p>

23 (Pages 86 to 89)

<p style="text-align: right;">Page 90</p> <p>1 CHARLES E. CLEMENS</p> <p>2 didn't make reference to what. So the stop members will</p> <p>3 be the same. We agree on that.</p> <p>4 Q. Correct.</p> <p>5 A. So -- but the cam will move away from the</p> <p>6 writing tip in such a way that you'll reach that figure</p> <p>7 10. So the tip of the stop members obviously stay the</p> <p>8 same.</p> <p>9 Q. Right. The tip of the stop members stays in</p> <p>10 the same place and the tip of the cam body has moved</p> <p>11 upwards. Correct?</p> <p>12 A. To reach figure 10, that is -- that is</p> <p>13 correct.</p> <p>14 Q. So back to figure 9, figure 9 shows the two</p> <p>15 tips we just talked about, the tip of the stop member,</p> <p>16 the tip of the cam body coplanar. Right?</p> <p>17 A. Yes.</p> <p>18 Q. And we agree that some amount of rotation has</p> <p>19 already begun to occur because we can see figure 43 has</p> <p>20 started to slide down face 50. Right?</p> <p>21 A. Like I said, it's -- you know, I think this</p> <p>22 view is attempting to show, you know, kind of an interim</p> <p>23 position, but what happens, according to Rhoades, is,</p> <p>24 you know, you fully depress, it releases and then goes</p> <p>25 into this position. So, you know, I would say that this</p>	<p style="text-align: right;">Page 91</p> <p>1 CHARLES E. CLEMENS</p> <p>2 is some sort of, you know, interim view.</p> <p>3 Q. And in this interim view where rotation has</p> <p>4 begun, wouldn't you expect the tip of the cam body next</p> <p>5 to number 54 in figure 9 to have moved upwards as we</p> <p>6 were just discussing?</p> <p>7 MS. HARGRAVE: Objection, asked and</p> <p>8 answered.</p> <p>9 A. No. Again, I have to disagree with your</p> <p>10 description. The view that we're seeing in figure 9 is</p> <p>11 the view that exists when rotation is actuated. That's</p> <p>12 just the way Rhoades is designed.</p> <p>13 Q. (BY MR. WEIL) All right. Mr. Clemens, figure</p> <p>14 9 of Rhoades, I think you just described to me this is</p> <p>15 the point at which the cam body begins to rotate?</p> <p>16 MS. HARGRAVE: Objection,</p> <p>17 mischaracterization of testimony.</p> <p>18 Q. (BY MR. WEIL) Let me ask that differently.</p> <p>19 A. Sure.</p> <p>20 Q. Is it your opinion that figure 9 shows the</p> <p>21 orientation of the cam surfaces of the fingers and the</p> <p>22 stop members at the point when Rhoades begins to rotate?</p> <p>23 A. Yes. I believe that this is a very rapid</p> <p>24 event and you'll hear a click, and then the second click</p> <p>25 you hear is the -- is figure 10.</p>
<p style="text-align: right;">Page 92</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. In looking at figure 9, you do agree there is</p> <p>3 some gap between bottom of stop member 45 and the top of</p> <p>4 cam body 20. Right?</p> <p>5 MS. HARGRAVE: Objection, asked and</p> <p>6 answered, mischaracterization of testimony.</p> <p>7 A. So there is no gap between the tip of the stop</p> <p>8 member and the tip of face 56 and 58 when this rotation</p> <p>9 occurs, but I see there is a gap below the stop member</p> <p>10 and the surface 50 and surface 52.</p> <p>11 Q. (BY MR. WEIL) All right. So for the purposes</p> <p>12 of our discussion, let's say that gap is X millimeters.</p> <p>13 Okay?</p> <p>14 At the point when that gap is .5X millimeters,</p> <p>15 will the cam body have begun to rotate?</p> <p>16 MS. HARGRAVE: Objection, calls for</p> <p>17 speculation.</p> <p>18 Q. (BY MR. WEIL) I will strike that question,</p> <p>19 ask it differently.</p> <p>20 A. Thank you.</p> <p>21 Q. Is it your position that if we looked at the</p> <p>22 mechanism of Rhoades immediately before what's shown in</p> <p>23 figure 9, that gap would still be present?</p> <p>24 A. The differences in cam surfaces would be the</p> <p>25 same.</p>	<p style="text-align: right;">Page 93</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. Just to be clear, what you're saying there,</p> <p>3 the offset difference between the bottom of the stop</p> <p>4 member and the bottom of the finger would be the same?</p> <p>5 MS. HARGRAVE: Objection,</p> <p>6 mischaracterization of testimony.</p> <p>7 A. Well, again, I mean, these are, you know,</p> <p>8 schematics, but, you know, from what I can see, you</p> <p>9 know, the line thicknesses and everything, hopefully</p> <p>10 we're not splitting hairs here, but it appears that</p> <p>11 figure 9 and from the description of Rhoades, you know,</p> <p>12 you fully depress, and then the stop member releases the</p> <p>13 cam body and allows it to rotate. And so that's -- you</p> <p>14 know, that's what that's showing.</p> <p>15 Q. (BY MR. WEIL) When exactly does the stop</p> <p>16 member release the cam body?</p> <p>17 A. The stop member, as we previously discussed</p> <p>18 many times, the tip of 45 and 46 -- I am not sure how</p> <p>19 Rhoades characterizes it as leading or trailing --</p> <p>20 passes -- so the bottom tip obviously passes the upper</p> <p>21 tip of face -- came face 56 and 58.</p> <p>22 Q. And that point that you just described, the</p> <p>23 bottom surface of the finger and the bottom surface of</p> <p>24 the stop member would be colinear. Right?</p> <p>25 MS. HARGRAVE: Objection,</p>

<p style="text-align: right;">Page 94</p> <p>1 CHARLES E. CLEMENS</p> <p>2 mischaracterization of testimony.</p> <p>3 A. Well, let's put it all together.</p> <p>4 Q. (BY MR. WEIL) Okay.</p> <p>5 A. Give me the whole question.</p> <p>6 Q. Okay.</p> <p>7 A. So I make sure I'm connecting the dots the</p> <p>8 same way you are.</p> <p>9 Q. Okay. Let me just try to talk it through and</p> <p>10 you tell me when I'm wrong.</p> <p>11 Figure 8 shows the pen in the retracted state.</p> <p>12 Correct?</p> <p>13 A. Correct.</p> <p>14 Q. User begins to push down on the plunger,</p> <p>15 forces fingers 43 and 44 downwards. Right?</p> <p>16 A. Yes.</p> <p>17 Q. And that forces the cam body downwards?</p> <p>18 A. Yes.</p> <p>19 Q. And the cam body cannot yet rotate because the</p> <p>20 stop members are in those deep grooves?</p> <p>21 A. Yes.</p> <p>22 Q. You continue to push down the plunger which</p> <p>23 pushes the fingers down which pushes the cam body down</p> <p>24 until the moment when the stop member exits the deep</p> <p>25 grooves. Correct?</p>	<p style="text-align: right;">Page 95</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. That is the moment of full depression.</p> <p>3 Q. And at that point, the bottom of finger 43 and</p> <p>4 the bottom of finger 45 are colinear. Right?</p> <p>5 A. Say that again. 45 --</p> <p>6 Q. At the point that we just described, the</p> <p>7 bottom of finger 43 and the bottom of finger 45 form a</p> <p>8 straight line that's colinear, right, like we saw in the</p> <p>9 video?</p> <p>10 A. No, that -- I believe I've answered that</p> <p>11 particular question several times. That is not correct.</p> <p>12 I disagree with that.</p> <p>13 Q. Okay. And at the point when the bottom</p> <p>14 surface of the stop member 45 is colinear with the</p> <p>15 bottom surface of finger 43, what is holding the cam</p> <p>16 body 20 in place?</p> <p>17 A. The stop members.</p> <p>18 Q. When the stop members are colinear with the</p> <p>19 tooth, aren't they completely removed from the recess?</p> <p>20 A. That is --</p> <p>21 MS. HARGRAVE: Objection, vague.</p> <p>22 THE WITNESS: Sorry.</p> <p>23 MS. HARGRAVE: It's okay.</p> <p>24 A. That is not how Rhoades is describing.</p> <p>25 Q. (BY MR. WEIL) But setting aside Rhoades, as</p>
<p style="text-align: right;">Page 96</p> <p>1 CHARLES E. CLEMENS</p> <p>2 soon as those two surfaces are colinear, wouldn't a cam</p> <p>3 body be able to rotate?</p> <p>4 MS. HARGRAVE: Objection, vague, calls</p> <p>5 for speculation.</p> <p>6 A. You know, now you're going off into a</p> <p>7 different design, and what we're focusing on right now,</p> <p>8 my understanding is what we're focusing on is the</p> <p>9 Rhoades patent and how he's described the invention.</p> <p>10 Q. (BY MR. WEIL) All right. We won't set aside</p> <p>11 Rhoades. We'll stick with Rhoades.</p> <p>12 When the bottom surface of figure 43 and the</p> <p>13 bottom surface of the stop member are colinear, does</p> <p>14 Rhoades identify anything that is still in that groove</p> <p>15 that's holding the cam body from rotating?</p> <p>16 A. I would have to read through Rhoades to see if</p> <p>17 that particular positioning is described or, I mean, if</p> <p>18 you can point to it, I am happy to read through it.</p> <p>19 Q. But just sitting here without reading through</p> <p>20 it, you're not aware of it?</p> <p>21 A. No. No, sir.</p> <p>22 Q. All right. Let's turn to paragraph 25 of your</p> <p>23 report. Could you move on from Rhoades?</p> <p>24 A. All right.</p> <p>25 MS. HARGRAVE: Did you say "page" or</p>	<p style="text-align: right;">Page 97</p> <p>1 CHARLES E. CLEMENS</p> <p>2 "paragraph"?</p> <p>3 Q. (BY MR. WEIL) Paragraph 25 of the Patent '177</p> <p>4 IPR, and in paragraph 25 you say that petitioners do not</p> <p>5 explain how the cam body could be mounted to the inhaler</p> <p>6 or how the cam body could be modified to include</p> <p>7 numerals. Do you see that?</p> <p>8 In paragraph 25 you say that petitioners do</p> <p>9 not indicate how the cam body could be mounted to the</p> <p>10 inhaler or modified to include numerals. Do you see</p> <p>11 that?</p> <p>12 A. I do see it.</p> <p>13 Q. And we just spent a lot of time talking about</p> <p>14 figures 8 through 11 of Rhoades. Correct?</p> <p>15 A. Oh, yes.</p> <p>16 Q. And those same figures are in the petition at</p> <p>17 pages 25 to 27, the colored drawings we looked at. Is</p> <p>18 that right? Exhibit 1053.</p> <p>19 A. What did I do with it?</p> <p>20 Q. I think it's --</p> <p>21 A. This one.</p> <p>22 Q. This one, sorry. It's Exhibit 1054.</p> <p>23 A. And, yes, I see that these are the colored</p> <p>24 version. Okay.</p> <p>25 Q. And in paragraph 24 of your report, you</p>

25 (Pages 94 to 97)

<p style="text-align: right;">Page 98</p> <p>1 CHARLES E. CLEMENS</p> <p>2 explain the combination, as you understand it, as a</p> <p>3 simple substitution of the Rhoades mechanism into the</p> <p>4 Elliott inhaler, on the third line.</p> <p>5 Do you see that?</p> <p>6 MS. HARGRAVE: Objection,</p> <p>7 mischaracterization of the testimony.</p> <p>8 A. We're in paragraph 24?</p> <p>9 Q. (BY MR. WEIL) Correct.</p> <p>10 A. I see the second sentence that states that the</p> <p>11 combination is a simple substitution. Is that the</p> <p>12 sentence?</p> <p>13 Q. Sure.</p> <p>14 A. Okay. I do see that sentence, and it's</p> <p>15 referring to the description that the petitioners</p> <p>16 advanced.</p> <p>17 Q. And there's nothing in the petition that says</p> <p>18 that during operation of a combined device, the cam body</p> <p>19 stop members or fingers would interact in some way other</p> <p>20 than what was described in Rhoades, is there?</p> <p>21 A. I'm going to ask you to repeat that, if you</p> <p>22 could.</p> <p>23 Q. Sure.</p> <p>24 A. Or read it or whatever.</p> <p>25 Q. So I'll say there is nothing in the petition</p>	<p style="text-align: right;">Page 99</p> <p>1 CHARLES E. CLEMENS</p> <p>2 that states during the operation of the combination</p> <p>3 device that we're talking about, that the cam body stop</p> <p>4 members or the fingers would interact in any way</p> <p>5 differently than they do in Rhoades, is there?</p> <p>6 A. Let me just read through this again real quick</p> <p>7 just to make sure I form my answer correctly.</p> <p>8 Q. Sure.</p> <p>9 A. Okay. Yes. Yes, I agree that it would be the</p> <p>10 substitution of the cam body.</p> <p>11 Q. The cam body --</p> <p>12 A. And the stop members.</p> <p>13 Q. And the fingers?</p> <p>14 A. It would be on an analogous component having</p> <p>15 fingers, yes. I see that.</p> <p>16 Q. And you understand that cam body 20 is a small</p> <p>17 plastic component. Right?</p> <p>18 MS. HARGRAVE: Objection, vague.</p> <p>19 A. Well, it's small relative to a pen. Is that</p> <p>20 what I presume what your question is directed at?</p> <p>21 Q. (BY MR. WEIL) Earlier in your background</p> <p>22 section you talked about working with small plastic</p> <p>23 components. Would you characterize a cam body as a</p> <p>24 small plastic component?</p> <p>25 MS. HARGRAVE: Objection, vague.</p>
<p style="text-align: right;">Page 100</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. So "small" obviously is a relative term. I</p> <p>3 mean, this is still small. So -- but it's, you know, a</p> <p>4 vague term. Could be a small part relative to a part</p> <p>5 this size, for instance. I am pointing to my glass</p> <p>6 case.</p> <p>7 Q. (BY MR. WEIL) And your glass's case would not</p> <p>8 be placed inside of a pen, though. Correct?</p> <p>9 A. That is correct.</p> <p>10 Q. So maybe to your question, yes, would you</p> <p>11 characterize the cam body as a small plastic component</p> <p>12 with respect to the size of a pen?</p> <p>13 MS. HARGRAVE: Objection, vague.</p> <p>14 A. It is -- the cam body would be considered</p> <p>15 smaller.</p> <p>16 Q. (BY MR. WEIL) And it would be made of</p> <p>17 plastic?</p> <p>18 A. It certainly could be.</p> <p>19 Q. It would be well within the knowledge of one</p> <p>20 skilled in the art at the time of the invention to add</p> <p>21 numbers to a small plastic component like that, wouldn't</p> <p>22 it?</p> <p>23 A. So my response to that is that I'm not really</p> <p>24 sure how -- all these devices are very custom. They're</p> <p>25 very unique. So adding numbers to a part is a good</p>	<p style="text-align: right;">Page 101</p> <p>1 CHARLES E. CLEMENS</p> <p>2 general statement, but it does not actually describe how</p> <p>3 that would be done or accomplished. And petitioners and</p> <p>4 even expert Piper have offered no details whatsoever how</p> <p>5 that would be accomplished. And so without me having</p> <p>6 some information, I don't have an opinion on that. I</p> <p>7 don't have an opinion on how the petitioners or the</p> <p>8 expert Piper would accomplish that. That is information</p> <p>9 that I need.</p> <p>10 Q. You need information on how petitioners or</p> <p>11 expert Piper would accomplish that to determine whether</p> <p>12 the claims are obvious?</p> <p>13 MS. HARGRAVE: Objection, vague.</p> <p>14 A. That is correct.</p> <p>15 Q. (BY MR. WEIL) You can't tell me from the</p> <p>16 person of ordinary skill in the art that you've used if</p> <p>17 that person would be able to modify a component to add</p> <p>18 numbers to a small plastic piece?</p> <p>19 MS. HARGRAVE: Objection, asked and</p> <p>20 answered.</p> <p>21 A. Like I said, these are custom parts. They're</p> <p>22 all unique. The numbering of -- you know, counting</p> <p>23 doses isn't necessarily a simplified thing. And every</p> <p>24 proposed design would have its unique application of,</p> <p>25 you know, indicating the doses. So I think it's</p>

<p style="text-align: right;">Page 102</p> <p>1 CHARLES E. CLEMENS</p> <p>2 incumbent on the petitioners and expert Piper to</p> <p>3 describe exactly what -- how they would accomplish that.</p> <p>4 Q. (BY MR. WEIL) Does the specification of the</p> <p>5 "177 Patent describe how the numerals are included on</p> <p>6 the counter element in the claimed invention?</p> <p>7 A. I do not believe so. I could review it --</p> <p>8 Q. You can look if you want.</p> <p>9 A. -- and see, but-- .</p> <p>10 Q. I will just represent to you that it doesn't,</p> <p>11 is my understanding.</p> <p>12 A. Okay. I am not recalling it.</p> <p>13 Q. So how would someone know how to include the</p> <p>14 numbers on the counter in the "177 Patent?</p> <p>15 MS. HARGRAVE: Objection, calls for</p> <p>16 speculation.</p> <p>17 A. The -- so the "177 Patent schematically shows</p> <p>18 how everything functions and interacts and interrelates</p> <p>19 with one another. That helps to understand the</p> <p>20 functionality of it. And it is written in a broad sense</p> <p>21 so that it can be -- the invention can be generally</p> <p>22 understood. And from that information, that invention</p> <p>23 information, multiple approaches could be taken. And</p> <p>24 I'm sure they did not want to necessarily narrow it down</p> <p>25 to one particular way.</p>	<p style="text-align: right;">Page 103</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) So a couple of things in your</p> <p>3 answer there. It's your understanding that the "177</p> <p>4 Patent -- I'll use your exact words -- shows how</p> <p>5 everything functions and interacts and interrelates with</p> <p>6 one another. Is that right?</p> <p>7 A. That's correct.</p> <p>8 Q. And you said that the "177 Patent was written</p> <p>9 in a broad sense. So you don't think that they had to</p> <p>10 disclose how you would put numbers on to a counter?</p> <p>11 MS. HARGRAVE: Objection,</p> <p>12 mischaracterizes the witness's testimony.</p> <p>13 A. I'm saying that the inventor did not want to</p> <p>14 narrow his -- I believe my read of the patent, the</p> <p>15 inventor did not want to narrow his options in terms of</p> <p>16 how that would be done.</p> <p>17 Q. (BY MR. WEIL) So is it your understanding of</p> <p>18 the obviousness analysis that petitioners have to</p> <p>19 explain more than what the patent explains?</p> <p>20 A. No, that is not what I'm saying. What I am</p> <p>21 saying is petitioners have identified specific examples</p> <p>22 of inventions and designs that they are now modifying</p> <p>23 and trying to put together. And each of these designs</p> <p>24 is unique on its own and has its own descriptions and</p> <p>25 limitations in it. And what has been advanced by</p>
<p style="text-align: right;">Page 104</p> <p>1 CHARLES E. CLEMENS</p> <p>2 petitioners and Mr. Piper is so vague that it's -- that</p> <p>3 it is not possible to understand how they can -- how</p> <p>4 their modified new device would actually operate.</p> <p>5 Q. My questions here are specific to putting</p> <p>6 numbers on a small piece, not the device in total. So</p> <p>7 let me just make sure I understand this. Correct me if</p> <p>8 I'm wrong.</p> <p>9 You've concluded that the petitioners have not</p> <p>10 shown that the claims are obvious, and one reason is</p> <p>11 petitioners have not explained how you would put numbers</p> <p>12 on to a cam body. Correct?</p> <p>13 MS. HARGRAVE: Objection,</p> <p>14 mischaracterization of testimony.</p> <p>15 A. Ask your question again. I am not sure I</p> <p>16 actually heard --</p> <p>17 Q. (BY MR. WEIL) Let me just ask.</p> <p>18 Paragraph 25, you say "Petitioners do not</p> <p>19 indicate how the cam body could be mounted to the</p> <p>20 inhaler or modified to include numerals." Right?</p> <p>21 MS. HARGRAVE: Objection,</p> <p>22 mischaracterization of his testimony.</p> <p>23 A. But those words are in my report, correct.</p> <p>24 Q. (BY MR. WEIL) And you're telling me today</p> <p>25 that you don't think petitioners have explained how one</p>	<p style="text-align: right;">Page 105</p> <p>1 CHARLES E. CLEMENS</p> <p>2 would modify the cam body to include numerals. Right?</p> <p>3 That's your position today?</p> <p>4 A. They do not indicate how the cam body could be</p> <p>5 mounted to the inhaler or modified to include those</p> <p>6 numbers, correct, yes.</p> <p>7 Q. And we've already discussed the "177 Patent</p> <p>8 does not tell you how to put numerals on to a counter.</p> <p>9 Correct?</p> <p>10 MS. HARGRAVE: Objection,</p> <p>11 mischaracterization of testimony.</p> <p>12 A. I believe what I said was is that the claims</p> <p>13 have been broadly written so as to not limit their --</p> <p>14 the ways in which that might be achieved, but I believe</p> <p>15 you and I agreed earlier that in looking through the</p> <p>16 patent, specific words to how numbers would be applied</p> <p>17 are not in that patent.</p> <p>18 Q. (BY MR. WEIL) I guess what I'm struggling</p> <p>19 with is it sounds like you're requiring petitioners to</p> <p>20 explain how numbers would be included, but we're</p> <p>21 agreeing that that's not disclosed in the specification.</p> <p>22 Right?</p> <p>23 A. Yeah, my response to that is pretty much the</p> <p>24 same as what I've been saying, and that is the</p> <p>25 petitioners are taking specific designs and then they're</p>

27 (Pages 102 to 105)

<p style="text-align: right;">Page 106</p> <p>1 CHARLES E. CLEMENS</p> <p>2 modifying them and integrating them to perform the same</p> <p>3 functionality and requirements. And, you know, these</p> <p>4 are very unique designs. They have their own</p> <p>5 limitations, their own descriptions, their own</p> <p>6 idiosyncrasies. And when you combine them, that creates</p> <p>7 a whole set of questions that you need to answer in</p> <p>8 order for that to happen. So it's quite a different</p> <p>9 situation between the "177 Patent and what petitioners</p> <p>10 and the expert are trying to accomplish. More</p> <p>11 information is needed to understand what that is, what</p> <p>12 that modification -- all those modifications are. Could</p> <p>13 be quite complicated.</p> <p>14 Q. Okay. Can we turn to paragraphs 29 and 30 of</p> <p>15 your declaration "177 Patent IPR? If I understand your</p> <p>16 argument correctly, it is that if stop members were</p> <p>17 incorporated directly onto the inhaler body, it would be</p> <p>18 impossible to further assemble the device. Is that</p> <p>19 right?</p> <p>20 MS. HARGRAVE: Objection, vague.</p> <p>21 A. You know, once the stop members are shown,</p> <p>22 which are shown in blue, are molded into the body and</p> <p>23 protrude into the cavity of the inhaler body, there</p> <p>24 could be no further assembly of the device, and this is</p> <p>25 because the cam body would have to somehow get past</p>	<p style="text-align: right;">Page 107</p> <p>1 CHARLES E. CLEMENS</p> <p>2 these features which are blocking.</p> <p>3 Q. (BY MR. WEIL) But you would agree that the</p> <p>4 inhaler body with the teeth molded into the surface</p> <p>5 would be a stationary body including at least one</p> <p>6 stationary gear. Right?</p> <p>7 MS. HARGRAVE: Objection,</p> <p>8 mischaracterization of testimony.</p> <p>9 A. I am not sure I have a written opinion about</p> <p>10 that in my report. Can you point to it for me?</p> <p>11 Q. (BY MR. WEIL) Oh, so you don't have an</p> <p>12 opinion on whether or not --</p> <p>13 A. I don't have a written opinion --</p> <p>14 Q. Okay.</p> <p>15 A. -- in my report that I can remember, unless</p> <p>16 I'm missing something.</p> <p>17 Q. Okay. But the argument here is that it would</p> <p>18 be impossible to insert the components past the molded</p> <p>19 stop members. Right?</p> <p>20 MS. HARGRAVE: Objection, vague.</p> <p>21 A. I believe --</p> <p>22 THE WITNESS: Sorry.</p> <p>23 MS. HARGRAVE: It's okay.</p> <p>24 A. I believe that because of the interaction, the</p> <p>25 design interaction and the intent of these parts -- and</p>
<p style="text-align: right;">Page 108</p> <p>1 CHARLES E. CLEMENS</p> <p>2 if petitioners intend to create features on the inside</p> <p>3 diameter, that the assembly is not doable.</p> <p>4 Q. (BY MR. WEIL) And the plastic used in devices</p> <p>5 like Elliott is resilient. Right?</p> <p>6 MS. HARGRAVE: Objection, vague.</p> <p>7 A. Plastic -- plastic parts can be resilient,</p> <p>8 that is correct.</p> <p>9 Q. (BY MR. WEIL) Would you be able to come up</p> <p>10 with some way of getting the components into the inhaler</p> <p>11 body past the teeth?</p> <p>12 MS. HARGRAVE: Objection, calls for</p> <p>13 speculation.</p> <p>14 A. Again, I'm not really -- my purpose isn't to</p> <p>15 sit and analyze and figure out for the petitioners how</p> <p>16 this might be accomplished. And so, you know, from a</p> <p>17 perspective of a person skilled in the art and reading</p> <p>18 what the petitioners have proposed, I believe that this</p> <p>19 perspective is valid.</p> <p>20 MS. HARGRAVE: What was the last phrase?</p> <p>21 THE WITNESS: Valid. In the eyes of a</p> <p>22 person skilled in the art could not -- you know, could</p> <p>23 not assemble.</p> <p>24 Q. (BY MR. WEIL) You think that a person of</p> <p>25 skill in the art would not be able to assemble this</p>	<p style="text-align: right;">Page 109</p> <p>1 CHARLES E. CLEMENS</p> <p>2 device?</p> <p>3 MS. HARGRAVE: Objection, asked answered.</p> <p>4 A. Assembly is a problem. And if you wanted to</p> <p>5 mold -- even mold those parts on the inside diameter,</p> <p>6 that's a problem. There are multiple problems with</p> <p>7 this, as I pointed out in my report.</p> <p>8 Q. (BY MR. WEIL) We'll talk about the molding in</p> <p>9 a second. But specifically this -- in paragraphs 29 and</p> <p>10 30, this problem with assembly that you allege, you've</p> <p>11 done your analysis from, you said, the eyes of one</p> <p>12 skilled in the art. Correct?</p> <p>13 A. And at the time of the invention, correct.</p> <p>14 Q. So my question is would one skilled in the art</p> <p>15 know how to assemble this device?</p> <p>16 A. Again, it's not for me to speculate, you know,</p> <p>17 what could be in the minds of a lot of other people,</p> <p>18 so --</p> <p>19 Q. So now I'm asking you. Could you do it?</p> <p>20 MS. HARGRAVE: Objection, asked and</p> <p>21 answered.</p> <p>22 A. I haven't done it. I have not been asked to</p> <p>23 do it, and so, therefore, I can't answer that question</p> <p>24 with any -- any accuracy. But my opinion, as written in</p> <p>25 here, it would be a problem. It would be a big problem,</p>

<p style="text-align: right;">Page 110</p> <p>1 CHARLES E. CLEMENS</p> <p>2 assembly is not possible.</p> <p>3 Q. (BY MR. WEIL) Assembly is not possible to one</p> <p>4 skilled in the art. Correct?</p> <p>5 A. Well --</p> <p>6 MS. HARGRAVE: Objection, asked and</p> <p>7 answered.</p> <p>8 A. -- the report is written from the position of</p> <p>9 one skilled in the art at the time of the invention.</p> <p>10 Q. (BY MR. WEIL) So is it your understanding</p> <p>11 that petitioners had to address every technical</p> <p>12 challenge, like assembly of a device, to show the claims</p> <p>13 would have been obvious?</p> <p>14 A. I think it's -- I think the petitioners at</p> <p>15 least have the duty to show how a new custom combined</p> <p>16 modified design is capable of achieving what they claim</p> <p>17 it's achieving; and in order to make it an obvious</p> <p>18 combination, I believe that a person of skill in the art</p> <p>19 would presume that it would have to be assembleable,</p> <p>20 so --</p> <p>21 Q. Now set aside what petitioners told you about</p> <p>22 the combination. If a client comes to you and says "I</p> <p>23 would like to make this device with the stop members on</p> <p>24 the inside. I've got to get this cam body past." Would</p> <p>25 you tell them "Sorry, people can't do that"?</p>	<p style="text-align: right;">Page 111</p> <p>1 CHARLES E. CLEMENS</p> <p>2 MS. HARGRAVE: Objection, vague, calls</p> <p>3 for speculation.</p> <p>4 A. It's an incomplete hypothetical. There are --</p> <p>5 every bit of the design details that you're describing</p> <p>6 in a very general, vague way are unknown. That is not</p> <p>7 something that I would, you know, try to speculate on at</p> <p>8 this point. I really know knowing about a general</p> <p>9 situation that you're describing.</p> <p>10 Q. (BY MR. WEIL) But you would agree with me</p> <p>11 that the obviousness analysis just requires petitioners</p> <p>12 to show how the teachings of one reference would be</p> <p>13 combined with the teachings of another reference.</p> <p>14 Right?</p> <p>15 A. I don't believe they've done that.</p> <p>16 Q. And the reason you don't think they've done</p> <p>17 that is because they did not include detailed diagrams</p> <p>18 of how these components would be assembled?</p> <p>19 MS. HARGRAVE: Objection,</p> <p>20 mischaracterization of testimony.</p> <p>21 A. I believe I've captured in my report, you</p> <p>22 know, all the particular nuances of what information has</p> <p>23 been lacking in the -- you know, from the petitioners.</p> <p>24 But, you know, whenever you're creating a new custom</p> <p>25 combination of something, obviously there are the</p>
<p style="text-align: right;">Page 112</p> <p>1 CHARLES E. CLEMENS</p> <p>2 modifications, the customizations that need to occur,</p> <p>3 and those -- all those things need to be described so</p> <p>4 they could be understood, because the rest of it is</p> <p>5 already described but there are modifications and</p> <p>6 changes that need description.</p> <p>7 Q. (BY MR. WEIL) Okay. Let's look at paragraph</p> <p>8 31 of your declaration.</p> <p>9 A. Certainly.</p> <p>10 Q. And I think you started to get into this a</p> <p>11 little bit about the practical tooling design to create</p> <p>12 the features we were talking about. Right?</p> <p>13 A. Correct.</p> <p>14 Q. I am going to hand you what's marked as</p> <p>15 Exhibit 2018. Do you recognize Exhibit 2018,</p> <p>16 Mr. Clemens?</p> <p>17 A. Yes.</p> <p>18 Q. What is that exhibit?</p> <p>19 A. It's a reference to plastic part design</p> <p>20 injection molding by Malloy.</p> <p>21 Q. Okay. Turn to page number 99, if you look at</p> <p>22 the page numbers at the top of the book.</p> <p>23 A. Okay. I've got it.</p> <p>24 Q. So the picture on this page shows a few</p> <p>25 possible undercuts and holes. Right?</p>	<p style="text-align: right;">Page 113</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. It does.</p> <p>3 Q. And in this picture on the left you see where</p> <p>4 the mold movement and it shows that the mold pulls apart</p> <p>5 vertically? Am I understanding that correctly?</p> <p>6 A. To the left there?</p> <p>7 Q. Correct.</p> <p>8 A. Yes, I see that.</p> <p>9 Q. And I'm right that the way this works is the</p> <p>10 mold pulls apart in the directions of those two arrows?</p> <p>11 A. Correct.</p> <p>12 Q. So if we look kind of like on the back wall of</p> <p>13 that picture, there's some molded slots and a molded</p> <p>14 hole.</p> <p>15 Do you see those?</p> <p>16 A. I do.</p> <p>17 Q. And the molded slots, they don't require any</p> <p>18 special side action or difficult engineering, do they?</p> <p>19 A. It says here molded hole requires a side</p> <p>20 action.</p> <p>21 Q. I am talking about the two slots next to the</p> <p>22 hole molded slots.</p> <p>23 A. Oh, okay.</p> <p>24 Q. So the slots don't require --</p> <p>25 A. Slots? Right. There's no undercut.</p>

<p style="text-align: right;">Page 114</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And that's because you could just pull the</p> <p>3 mold apart, and it would just come out of those slots?</p> <p>4 A. Slots.</p> <p>5 Q. And then the hole, which does require a side</p> <p>6 action, you can't just pull the mold apart. Correct?</p> <p>7 A. In what sense?</p> <p>8 Q. Without some sort of side action to get the</p> <p>9 piece out?</p> <p>10 A. Yes, that is how the side action works.</p> <p>11 Q. And if we look at the two internal cantilever</p> <p>12 snaps, it says the one to the left requires side action</p> <p>13 to remove from the mold. Right? Correct?</p> <p>14 A. That is correct.</p> <p>15 Q. And then the internal cantilever snap to the</p> <p>16 right does not require any special side action.</p> <p>17 Correct?</p> <p>18 A. Internal cantilever snap, no special mold</p> <p>19 action required when the slot is added. You add that</p> <p>20 slot, and then it can be accomplished.</p> <p>21 Q. And is that because a piece of the cavity</p> <p>22 comes through that slot and then when you pull them</p> <p>23 apart, it just pulls out through that slot?</p> <p>24 A. A piece of the tool.</p> <p>25 Q. A piece of the tool comes up there and then</p>	<p style="text-align: right;">Page 115</p> <p>1 CHARLES E. CLEMENS</p> <p>2 you just pull it apart?</p> <p>3 A. Yes, sir. Yes, sir.</p> <p>4 Q. And the size of that slot is the size of the</p> <p>5 undercut. Is that right?</p> <p>6 A. The size of the slot will be what it will be.</p> <p>7 It's -- you know, from a tooling standpoint, it would</p> <p>8 depend on the design of the part and where in the part</p> <p>9 the -- you know, this particular blade would have to be.</p> <p>10 So it's -- it could be anything, you know, depending</p> <p>11 upon the part.</p> <p>12 Q. If it was a simple design where you just put</p> <p>13 two undercuts into a tube and you just had to pull the</p> <p>14 piece off of the cavity through the slots, then the</p> <p>15 slots would be the same size as the undercut. Correct?</p> <p>16 MS. HARGRAVE: Objection, calls for</p> <p>17 speculation.</p> <p>18 A. So I think you're mixing metaphors. You're</p> <p>19 using the term "undercut," but in the case of the</p> <p>20 cantilever snap -- which this is what we're talking</p> <p>21 about, right?</p> <p>22 Q. (BY MR. WEIL) Yeah.</p> <p>23 A. If this particular design of a cantilever snap</p> <p>24 is accomplished like this, we would not consider that an</p> <p>25 undercut. Okay. This is just a snap. And with respect</p>
<p style="text-align: right;">Page 116</p> <p>1 CHARLES E. CLEMENS</p> <p>2 to your question on the tool and the slot, you know,</p> <p>3 obviously, the tool is going to be designed for the slot</p> <p>4 opening, and the tool, rigid part of the tool is what</p> <p>5 forms the slot. So, yeah, I mean, the slot would match</p> <p>6 the tool.</p> <p>7 Q. If we look at your declaration, paragraph 31.</p> <p>8 A. I note that in that paragraph it says ideally</p> <p>9 a plastic part should be designed so it could be ejected</p> <p>10 from the mold without any special mold actions.</p> <p>11 Q. Let's stay on that page for a second.</p> <p>12 And if you designed a part like the internal</p> <p>13 cantilever snap to the right, that part could be ejected</p> <p>14 from the mold without any special moldings. Right?</p> <p>15 MS. HARGRAVE: Objection, calls for</p> <p>16 speculation.</p> <p>17 A. If you molded an internal cantilever snap such</p> <p>18 as is shown in this diagram, it would eject from the</p> <p>19 tool.</p> <p>20 Q. (BY MR. WEIL) Without any special action?</p> <p>21 A. Without -- well, that's correct.</p> <p>22 Q. If we turn back to paragraph 31 of your</p> <p>23 declaration, you say "Additionally, there is no</p> <p>24 practical tooling design that could create molded</p> <p>25 undercut features with the required functional angled</p>	<p style="text-align: right;">Page 117</p> <p>1 CHARLES E. CLEMENS</p> <p>2 bottom surface on the inside diameter of the inhaler</p> <p>3 body and above the valve block mounting (shown in green)</p> <p>4 so as not to interfere with the inhalation flow path."</p> <p>5 Right?</p> <p>6 A. I believe you read that correctly.</p> <p>7 Q. What do you mean not interfere with the</p> <p>8 inhalation flow path?</p> <p>9 A. Well, as was alluded to in this reference and</p> <p>10 a person who is skilled in the art and is already</p> <p>11 working with plastic injection molding and knows</p> <p>12 tooling, some of these features -- and I even note in my</p> <p>13 report here to the extent that petitioners argue that</p> <p>14 you could put in some complex tooling, there may be a</p> <p>15 way of achieving some of these features, notwithstanding</p> <p>16 the assembling issues that would ensue upon doing that,</p> <p>17 but what would happen is you would -- these special side</p> <p>18 action slides, or whatever it could be. I don't know</p> <p>19 what it could be without disturbing this design, but</p> <p>20 because we're talking about the inside -- it's an inside</p> <p>21 corner of the inhaler actuator. And so you already</p> <p>22 have, essentially, a core that's coming out of the</p> <p>23 mouthpiece and a core that's coming out of the top of</p> <p>24 the actuator. These two cores have to come down and</p> <p>25 create the valve block down below.</p>

<p style="text-align: right;">Page 118</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Everything has been designed specifically so</p> <p>3 that when the drug is atomized into its droplets and</p> <p>4 then starts going through the flow path, which is</p> <p>5 essentially from the orifice through the mouthpiece and</p> <p>6 then into, you know, the person, has been very carefully</p> <p>7 designed and optimized. And I'm telling you they've</p> <p>8 been modeled and studied unbelievably amount of time.</p> <p>9 So coming in and creating side pulls, which</p> <p>10 would create draft holes within the side of the body --</p> <p>11 in most instances, it cannot be done. You cannot match</p> <p>12 up the cores in such a manner that you could create</p> <p>13 features that project inside the diameter which are now</p> <p>14 right around the block -- the valve block or above the</p> <p>15 valve block because you would create undercuts, and</p> <p>16 undercuts are features that are molded plastic that are</p> <p>17 stuck in the tool that can't be removed. So you would</p> <p>18 literally be stripping them out or the parts just simply</p> <p>19 wouldn't come off the tool.</p> <p>20 So modifications that -- you know, it may be</p> <p>21 possible to throw a bunch of expensive tooling and</p> <p>22 complicated tooling at this and create the features. In</p> <p>23 doing so, it's likely you would disturb the design of</p> <p>24 the flow path and so that's what I'm talking about, is</p> <p>25 the highly optimized, highly designed computational</p>	<p style="text-align: right;">Page 119</p> <p>1 CHARLES E. CLEMENS</p> <p>2 fluid dynamically analyzed flow path with other features</p> <p>3 or holes, you know, draft holes or things like that that</p> <p>4 would completely disturb the -- how the drug droplets</p> <p>5 are formed and how much composition of drug they have</p> <p>6 within them, et cetera.</p> <p>7 Q. And the inhalation flow path that you're</p> <p>8 referring to, that's from the stem block out the</p> <p>9 mouthpiece?</p> <p>10 A. So it's created -- literally it's created by</p> <p>11 the canister being in the way, whatever else, you know,</p> <p>12 parts of the design, your counter. All that stuff</p> <p>13 interferes with the flow path that's coming in and out,</p> <p>14 and it needs -- if you change it, it needs to be</p> <p>15 reverified, reanalyzed, because it's quite likely that</p> <p>16 that flow path has been disturbed, and now it changes</p> <p>17 the drug amount that is being inhaled. So these are</p> <p>18 very complicated little devices. They've been around</p> <p>19 forever and they look very simple, but trust me, there's</p> <p>20 been a lot of engineering that's gone into them.</p> <p>21 Q. So just so I understand, the flow path is from</p> <p>22 the top of the canister where air can enter the inhaler</p> <p>23 body, and it comes all the way down out the mouthpiece.</p> <p>24 That's what you were referring to?</p> <p>25 A. Yes, sir.</p>
<p style="text-align: right;">Page 120</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And you talked about if you added extra little</p> <p>3 holes or extra little features, you would have to -- I</p> <p>4 forget the word you used, but you would have to reverify</p> <p>5 that the drug all works directly. What if you were</p> <p>6 making a new MDI and you wanted to add a dose counter</p> <p>7 and put this type of thing in, you still have to go</p> <p>8 through all of that verification process in the new</p> <p>9 product. Right?</p> <p>10 MS. HARGRAVE: Objection, calls for</p> <p>11 speculation.</p> <p>12 A. You know, the petitioners are advancing that,</p> <p>13 hey, if you just take these two ideas and put them</p> <p>14 together, it's a simple substitution. And, you know, it</p> <p>15 would be very simple to -- it would be an obvious change</p> <p>16 that wouldn't take, you know, any testing to accomplish.</p> <p>17 You know, this is just not the case.</p> <p>18 Q. (BY MR. WEIL) If you're designing a new MDI</p> <p>19 to go to market, you would be testing it anyway. Right?</p> <p>20 MS. HARGRAVE: Objection, asked and</p> <p>21 answered.</p> <p>22 A. We're not talking about a brand new MDI from</p> <p>23 scratch. We're talking about a proposal that has been</p> <p>24 advanced that you could blend two designs together</p> <p>25 simply, easily and obviously and it would work, it would</p>	<p style="text-align: right;">Page 121</p> <p>1 CHARLES E. CLEMENS</p> <p>2 simply work, and that's just not the case.</p> <p>3 Q. (BY MR. WEIL) Okay. So if we go to page 15</p> <p>4 of the declaration, just above paragraph 32.</p> <p>5 A. I'm sorry. My brain is starting to click</p> <p>6 differently. Okay.</p> <p>7 Q. Page 15, you see just above paragraph 32</p> <p>8 there's a long element that begins "a dose indicator</p> <p>9 device"?</p> <p>10 A. Yes.</p> <p>11 Q. Well, let me just read this. This section</p> <p>12 relates to the element "A dose indicator device</p> <p>13 including a counter element 20 that is displaceable</p> <p>14 axially and in rotation relative to said body 1 for</p> <p>15 indicating the number of doses of fluid that have been</p> <p>16 dispensed or that remain to be dispensed from said</p> <p>17 reservoir." Right?</p> <p>18 A. Correct.</p> <p>19 Q. And paragraph 34 starts off "Second,</p> <p>20 petitioners point to the Rhoades cam body." Right?</p> <p>21 A. Yes, that's what it says.</p> <p>22 Q. So that paragraph you're addressing</p> <p>23 petitioners's argument that the Rhoades cam body meets</p> <p>24 this limitation. Right?</p> <p>25 A. It's saying that the petitioners are pointing</p>

<p style="text-align: right;">Page 122</p> <p>1 CHARLES E. CLEMENS</p> <p>2 to the Rhoades cam body stating that it would have been</p> <p>3 obvious for a person of ordinary skill in the art to</p> <p>4 incorporate the Rhoades mechanism of converting axial</p> <p>5 motion to rotational motion into the Elliott inhaler.</p> <p>6 Q. And in this paragraph specifically is in</p> <p>7 relation to the Elliott in view of Rhoades combination.</p> <p>8 Correct?</p> <p>9 A. I believe that's true.</p> <p>10 Q. You can find it at page 11, if it helps.</p> <p>11 A. Let me just see if that's where it began.</p> <p>12 Yes. Thank you.</p> <p>13 Q. In paragraph 36, you indicate that the</p> <p>14 proposed combination does not explain where the springs</p> <p>15 would be located. Right?</p> <p>16 A. Yes, and how they would interact with the</p> <p>17 inhaler, in other words, how they would -- you know,</p> <p>18 just basically operate the cam mechanism.</p> <p>19 Q. So the canister in the metered-dose inhaler</p> <p>20 generally has a spring inside of it to return the</p> <p>21 canister to its position after a depression. Right?</p> <p>22 MS. HARGRAVE: Objection, vague.</p> <p>23 A. There is a spring in the canister that's been</p> <p>24 designed and optimized for the valve action.</p> <p>25 Q. (BY MR. WEIL) So that's when you push the</p>	<p style="text-align: right;">Page 123</p> <p>1 CHARLES E. CLEMENS</p> <p>2 canister down and it shoots out medicine and then the</p> <p>3 canister goes back up?</p> <p>4 A. Right.</p> <p>5 Q. Okay. Like valves, canisters and how those</p> <p>6 components functioned was well-known to one of skill in</p> <p>7 the art at the time of the invention. Right?</p> <p>8 MS. HARGRAVE: Objection, vague.</p> <p>9 A. So I would just characterize it as there were</p> <p>10 hundreds of canisters and valves of different designs,</p> <p>11 obviously, different companies, what have you. So quite</p> <p>12 a bit of drug canister and integrated valves have been</p> <p>13 around for a while.</p> <p>14 Q. (BY MR. WEIL) And a person skilled in the art</p> <p>15 would understand how valves and canisters and those</p> <p>16 components worked. Right?</p> <p>17 A. So, again, I would characterize that as a</p> <p>18 person of skill in the art would have a general idea of</p> <p>19 how they work, you know, conceptually they would</p> <p>20 understand. But pretty much all this stuff is custom.</p> <p>21 So each and every canister would be unique unto itself</p> <p>22 and would have to be studied and characterized and</p> <p>23 designed with.</p> <p>24 Q. But you would agree that one of skill in the</p> <p>25 art at the time of the invention would be able to use a</p>
<p style="text-align: right;">Page 124</p> <p>1 CHARLES E. CLEMENS</p> <p>2 canister that moves axially within the housing. Right?</p> <p>3 A. At the time of the invention, they would have</p> <p>4 had probably multiple kinds of canister, drug canisters</p> <p>5 of that kind.</p> <p>6 Q. When you say they would have had them, one of</p> <p>7 skill in the art would understand how those things</p> <p>8 worked. Right?</p> <p>9 A. Again, they would have a general</p> <p>10 understanding, but they would have to literally</p> <p>11 characterize something that they intended to design</p> <p>12 with.</p> <p>13 Q. And there were various known techniques that</p> <p>14 could be used to connect valves, canisters and the</p> <p>15 inhaler body, right, at the time of the invention?</p> <p>16 A. The construction -- I'm sorry. Are you asking</p> <p>17 if the construction of the canisters and the valve</p> <p>18 mechanisms themselves are connected, that that would</p> <p>19 have been well-known?</p> <p>20 Q. No, not exactly.</p> <p>21 The components of the inhaler body, the valve,</p> <p>22 the canister, people skilled in the art knew how to</p> <p>23 connect all those things together by various mechanisms,</p> <p>24 right --</p> <p>25 MS. HARGRAVE: Objection, vague.</p>	<p style="text-align: right;">Page 125</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) -- various techniques?</p> <p>3 MS. HARGRAVE: Sorry.</p> <p>4 A. So in a general sense, not specifically</p> <p>5 related to any particular design, the basic</p> <p>6 configuration of an MDI was well-known at the time of</p> <p>7 the art.</p> <p>8 Q. And in the Rhoades reference the lower spring</p> <p>9 16 is biased against the writing unit. Correct?</p> <p>10 A. Are you referring to something in my report or</p> <p>11 Rhoades?</p> <p>12 Q. Rhoades, but I think you have the pictures in</p> <p>13 your report, whatever you want to look at.</p> <p>14 A. Yeah, I just want to take a look at what we're</p> <p>15 talking about again.</p> <p>16 So could you repeat your question?</p> <p>17 Q. Sure.</p> <p>18 In Rhoades, the lower spring 16 is biased</p> <p>19 against the writing unit, which is attached to the cam</p> <p>20 body. Right?</p> <p>21 A. I believe Rhoades characterizes it that it's</p> <p>22 floating between the two, the lower and the upper</p> <p>23 springs. So there's, you know, a bias -- there's a</p> <p>24 multiple bias, and that the reservoir tip, canister</p> <p>25 tip -- I can't remember how they referred to it -- with</p>

<p style="text-align: right;">Page 126</p> <p>1 CHARLES E. CLEMENS</p> <p>2 the attached cam body is floating.</p> <p>3 Q. And the upward bias is created by spring 16.</p> <p>4 Right?</p> <p>5 A. Let's just say that the ink cartridge and cam</p> <p>6 body are supported in both directions via springs in a</p> <p>7 sense where it happens to be balanced in whichever</p> <p>8 particular position it's been placed into.</p> <p>9 Q. Well, I am not trying to be tricky. If you</p> <p>10 look at figure 2 in Rhoades, you see spring 16 near the</p> <p>11 bottom?</p> <p>12 A. Yeah. This is when it's fully --</p> <p>13 Q. Sure. Spring 16 is always at the bottom of</p> <p>14 the pen. Correct?</p> <p>15 A. 16 is at the tip.</p> <p>16 Q. The tip.</p> <p>17 A. Yeah. Thank you.</p> <p>18 Q. And the writing -- the ink reservoir is</p> <p>19 rearward of the spring 16. Correct? Away from the tip?</p> <p>20 A. The what part?</p> <p>21 Q. Ink reservoir.</p> <p>22 A. Ink reservoir is away from it, yes.</p> <p>23 Q. And then the ink reservoir is directly</p> <p>24 connected to the cam body. Correct?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 127</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And that ink reservoir and cam body, the force</p> <p>3 that's pushing them rearward comes from spring 16.</p> <p>4 Right?</p> <p>5 A. Yes, there's a bias going, as we have agreed,</p> <p>6 back towards the reservoir, and then the spring above it</p> <p>7 is pressing the other direction 38, spring 38.</p> <p>8 Q. So in the combination of Elliott and Rhoades</p> <p>9 that we've been describing, if the spring that biases</p> <p>10 the cam body upward was placed around the valve stem</p> <p>11 between the stem block and the cam body, the upward</p> <p>12 force would function the same way as 16 in Rhoades,</p> <p>13 wouldn't it?</p> <p>14 MS. HARGRAVE: Objection, calls for</p> <p>15 speculation.</p> <p>16 A. I believe I've described that configuration in</p> <p>17 my report, haven't I? Let's just see if we can -- I</p> <p>18 can't remember exactly where, but --</p> <p>19 Q. (BY MR. WEIL) My guess is you think it's</p> <p>20 around paragraph 36ish.</p> <p>21 A. How about page 18? The image on the left</p> <p>22 there, is that what your question is?</p> <p>23 Q. No. I mean, that image doesn't show a cam</p> <p>24 body, does it?</p> <p>25 A. Oh, yes, that's correct. There's no cam body,</p>
<p style="text-align: right;">Page 128</p> <p>1 CHARLES E. CLEMENS</p> <p>2 but there's a spring that is around the valve body. Is</p> <p>3 that the description you're giving?</p> <p>4 Q. That's what I'm asking you about, but there's</p> <p>5 no spring in your picture. Correct?</p> <p>6 A. Well, that red triangle -- rectangle there.</p> <p>7 Q. That red rectangle. Is that just blowing up</p> <p>8 the picture to the right?</p> <p>9 A. Hold on a second here. Well, I don't see it</p> <p>10 identified on this picture. We can continue to describe</p> <p>11 it verbally if you would like if this picture is</p> <p>12 confusing, but I thought it captured the idea you were</p> <p>13 trying to describe to me, placing a spring around the</p> <p>14 valve body and allowing a force --</p> <p>15 Q. You say "valve body." That's the stem, right,</p> <p>16 just so I'm clear?</p> <p>17 A. Yes.</p> <p>18 Q. Yes, placing a spring around the stem that</p> <p>19 would create upward force on the cam body?</p> <p>20 A. Right. Right.</p> <p>21 MS. HARGRAVE: Sorry. I just wanted to</p> <p>22 make sure there wasn't a question pending there.</p> <p>23 Q. (BY MR. WEIL) So that configuration that</p> <p>24 we've been describing, that spring that creates the</p> <p>25 upward force on the cam body would have the same</p>	<p style="text-align: right;">Page 129</p> <p>1 CHARLES E. CLEMENS</p> <p>2 function as spring 16 in Rhoades that creates the upward</p> <p>3 force on the ink reservoir connected to the cam body.</p> <p>4 Right?</p> <p>5 MS. HARGRAVE: Objection, vague.</p> <p>6 A. So the difficult part of this is that there</p> <p>7 doesn't appear to be any description on how that would</p> <p>8 be accomplished in this combination. Obviously, it's</p> <p>9 clear that if you start putting springs around this</p> <p>10 area, you're going to start interfering with the</p> <p>11 inhalation path of the drugs. So yes, there is a spring</p> <p>12 in the valve area that's already been optimized for the</p> <p>13 valve action, so you can't mess with that.</p> <p>14 But I understand conceptually, you know,</p> <p>15 you're trying to put a spring bias on the cam body. Yet</p> <p>16 I see no details of how to put a cam body in this space</p> <p>17 along with a spring which, you know, is not going to</p> <p>18 interfere with the operation of this device. So I am</p> <p>19 looking for some detail, some information. You know,</p> <p>20 it's easy to just say -- make a comment and just say</p> <p>21 this is going to happen, but I think for there to be an</p> <p>22 understanding, there needs to be more information</p> <p>23 provided by the petitioners to reach some sort of</p> <p>24 obviousness position.</p> <p>25 Q. (BY MR. WEIL) Well, you understand that in</p>

<p style="text-align: right;">Page 130</p> <p>1 CHARLES E. CLEMENS</p> <p>2 this proposed combination, the cam body 20 is</p> <p>3 incorporated below the canister. Correct? Look at</p> <p>4 paragraph 24.</p> <p>5 A. Yeah, I'll get back to it. Yes.</p> <p>6 Q. So my question is pretty simple. If that's</p> <p>7 where the cam body is and there's a spring underneath</p> <p>8 the cam body, would that create the same upward bias</p> <p>9 that we see in Rhoades based on the spring 16 which is</p> <p>10 below the cam body?</p> <p>11 MS. HARGRAVE: Objection, calls for</p> <p>12 speculation.</p> <p>13 A. So paragraph 25, which follows that, fully</p> <p>14 describes the problems that I'm having with this, is</p> <p>15 that, you know, there's no indication of how the cam</p> <p>16 body would be mounted, modified or -- all the things</p> <p>17 that need to be done that we keep talking about in this</p> <p>18 combination, this modified new design that they're</p> <p>19 coming up with, there's no description on how this could</p> <p>20 be accomplished without the obvious problems of</p> <p>21 assembly, of creating the parts themselves, I mean,</p> <p>22 fabrication, and then the disturbance of the actual</p> <p>23 operation of the inhalation process. All that</p> <p>24 information is missing. So if that were -- that could</p> <p>25 be improved on, might be able to make a good analysis of</p>	<p style="text-align: right;">Page 131</p> <p>1 CHARLES E. CLEMENS</p> <p>2 how that could be done, but it's difficult. I can't see</p> <p>3 it from what's been described.</p> <p>4 Q. (BY MR. WEIL) So people skilled in the art,</p> <p>5 they understand how springs work. Right?</p> <p>6 A. A person of skill in the art during that time</p> <p>7 would know how springs work.</p> <p>8 Q. One of skill in the art at that time would</p> <p>9 know if they put a spring below a component, they could</p> <p>10 bias that component upwards with a spring. Correct?</p> <p>11 A. Again, that is such a vague comment that</p> <p>12 really, I can't comment on it because it does not really</p> <p>13 relate to a very specific instance of combining designs</p> <p>14 in such a manner that, you know, they create this custom</p> <p>15 modification. That requires customization of</p> <p>16 everything. So this needs to be described.</p> <p>17 You can't -- one can't apply a general thought</p> <p>18 to -- especially in design. Design, the devil is in the</p> <p>19 details. You know, this is modified. This is custom.</p> <p>20 We need to see -- we need to see more information how</p> <p>21 this is going to be accomplished.</p> <p>22 Q. Again, my question is more related to what you</p> <p>23 understand one of skill in the art knows. I asked you</p> <p>24 earlier what the definition is; you didn't have a</p> <p>25 specific opinion. I now get that one of skill in the</p>
<p style="text-align: right;">Page 132</p> <p>1 CHARLES E. CLEMENS</p> <p>2 art knows how springs work. We agree on that?</p> <p>3 A. We agree.</p> <p>4 Q. And aside from any particular combination, if</p> <p>5 you put a component pressing down on a spring below it,</p> <p>6 that spring will bias that component upwards. Can we</p> <p>7 agree on that?</p> <p>8 MS. HARGRAVE: Objection, calls for</p> <p>9 speculation.</p> <p>10 A. I agree that springs -- springs do apply</p> <p>11 force. You know, as a general matter, that is what a</p> <p>12 spring is designed to do. They have compliance.</p> <p>13 There's billions of them in the world.</p> <p>14 Q. (BY MR. WEIL) Just a little bit more, and</p> <p>15 then we can take a break.</p> <p>16 A. Sure, you bet.</p> <p>17 Q. Still talking about the springs, one of skill</p> <p>18 in the art at the time working with MDI -- let me back</p> <p>19 up. Let me start again.</p> <p>20 All the MDIs that we've looked at about all</p> <p>21 the prior references, they all require some sort of</p> <p>22 spring mechanism. Correct?</p> <p>23 A. There are many springs. As I sit here, and I</p> <p>24 don't have the documents in front of me, I don't</p> <p>25 necessarily recall that each and every thing we've</p>	<p style="text-align: right;">Page 133</p> <p>1 CHARLES E. CLEMENS</p> <p>2 looked at, all the prior arts have springs, but there</p> <p>3 were a lot of them.</p> <p>4 Q. And if one of skill in the art did incorporate</p> <p>5 a spring into an MDI, they would understand adjusting</p> <p>6 tolerances so the device would work properly. Correct?</p> <p>7 MS. HARGRAVE: Objection, calls for</p> <p>8 speculation.</p> <p>9 A. Well, so, again, you know, all these MDIs have</p> <p>10 springs. All the springs are unique and different, and</p> <p>11 they're specifically designed and tested to deliver a</p> <p>12 certain amount of force. So naturally in the process of</p> <p>13 designing, you know, there would be a lot of back and</p> <p>14 forth testing and characterizing to achieve its purpose,</p> <p>15 its design requirements.</p> <p>16 Q. (BY MR. WEIL) But one skilled in the art</p> <p>17 would be able to do that. Correct?</p> <p>18 MS. HARGRAVE: Objection, asked and</p> <p>19 answered.</p> <p>20 A. Let me just say that I would characterize that</p> <p>21 by saying designers all kind of approach their designs</p> <p>22 in different ways, but I would say, you know, one</p> <p>23 skilled in the art would have the basic skills, you</p> <p>24 know, to incorporate a spring, think about its</p> <p>25 requirements, you know, and make an attempt at a spring.</p>

<p style="text-align: right;">Page 134</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Obviously, all the testing would occur afterwards to see</p> <p>3 if everything worked out.</p> <p>4 Q. (BY MR. WEIL) And when you mention all the</p> <p>5 testing, one of skill in the art would understand how to</p> <p>6 adjust other tolerances within the device to make them</p> <p>7 work in conjunction with that spring. Correct?</p> <p>8 MS. HARGRAVE: Objection, calls for</p> <p>9 speculation.</p> <p>10 A. Within reason. Some might do it better than</p> <p>11 others, but within reason they would, certainly from a</p> <p>12 nominal standpoint, and it really depends on the design</p> <p>13 itself, how many you're manufacturing, how you're</p> <p>14 manufacturing, how the parts are made. There's a lot of</p> <p>15 variables.</p> <p>16 Q. (BY MR. WEIL) But those skilled in the art</p> <p>17 who have the knowledge of conventional reservoirs,</p> <p>18 dispenser members, indicator devices and know how</p> <p>19 they're shaped and structured, they would understand how</p> <p>20 to shape and structure gears, and the interactions of</p> <p>21 those gears make to create a device that works.</p> <p>22 Correct?</p> <p>23 MS. HARGRAVE: Objection, calls for</p> <p>24 speculation.</p> <p>25 A. So I would agree that a person of skill in the</p>	<p style="text-align: right;">Page 135</p> <p>1 CHARLES E. CLEMENS</p> <p>2 art, you know, would possess -- some would possess good</p> <p>3 gear designing skills. Some would have good spring</p> <p>4 designing skills, you know, various capabilities. And</p> <p>5 you know, they would be experienced in creating parts</p> <p>6 based on a design and then testing it and trying to</p> <p>7 modify it in ways that would make it work better. So I</p> <p>8 would say in a general sense that, yes, that they would</p> <p>9 be able to -- you might have to have a couple guys that</p> <p>10 have a couple of expertise, but they would generally</p> <p>11 know how to pull that together.</p> <p>12 Q. And again, I'm asking this because you applied</p> <p>13 the analysis to the eyes of the person skilled in the</p> <p>14 art. So just to make sure I understand the answer,</p> <p>15 those skilled in the art who have knowledge of</p> <p>16 conventional reservoirs, dispenser members and</p> <p>17 structures, they would know how to shape and structure</p> <p>18 the gears to interact and create a device that works?</p> <p>19 And I'm talking about a person of skill in the art that</p> <p>20 you used in your analysis.</p> <p>21 MS. HARGRAVE: Objection, asked and</p> <p>22 answered, calls for speculation.</p> <p>23 A. Well, yes, but it would be able to create a</p> <p>24 design. Now when we say it works, you know, that's kind</p> <p>25 of a broad term there, but they would be able to create</p>
<p style="text-align: right;">Page 136</p> <p>1 CHARLES E. CLEMENS</p> <p>2 designs which could then be tested against requirements</p> <p>3 and so works is like a separate issue.</p> <p>4 Q. (BY MR. WEIL) Gotcha. But this is a</p> <p>5 mechanical technology. It's considered to be</p> <p>6 predictable art. Correct?</p> <p>7 MS. HARGRAVE: Objection, vague.</p> <p>8 A. What aspect of this are you -- are you</p> <p>9 characterizing as being predictable?</p> <p>10 Q. We're talking about one of skill in this art.</p> <p>11 Right?</p> <p>12 A. A person skilled in the art of mechanical</p> <p>13 engineering.</p> <p>14 Q. This technology, it's a mechanical technology.</p> <p>15 Correct?</p> <p>16 A. Yeah, the inhaler technology is a mechanical</p> <p>17 nature.</p> <p>18 Q. And the dose counter technology?</p> <p>19 A. Some dose counters are mechanical, yes.</p> <p>20 Q. And that type of technology you would consider</p> <p>21 to be a predictable art. Right?</p> <p>22 MS. HARGRAVE: Objection, vague.</p> <p>23 A. So when we apply -- when you suggest that term</p> <p>24 to me, it is indicating that conceptually, generally it</p> <p>25 is known. And you know, that would allow somebody to,</p>	<p style="text-align: right;">Page 137</p> <p>1 CHARLES E. CLEMENS</p> <p>2 again, go into a custom design, which these are all</p> <p>3 custom designs, and they would have to be highly</p> <p>4 designed and characterized and tested and, you know,</p> <p>5 altered until they were able to meet their goals.</p> <p>6 So the predictable aspect of it is that, you</p> <p>7 know, I think in a general sense that's true, that it</p> <p>8 would be generally understood. But trying to then make</p> <p>9 the leap from that to a custom design or a custom</p> <p>10 modification, that would require -- that requires some</p> <p>11 information, some detail that needs to be expressed.</p> <p>12 MR. WEIL: All right. Are you guys ready</p> <p>13 for a break?</p> <p>14 THE WITNESS: Yes, I am.</p> <p>15 (Break from 2:02 p.m. to 2:21 p.m.)</p> <p>16 Q. (BY MR. WEIL) Mr. Clemens, can you turn back</p> <p>17 to the "177 Patent? That's Exhibit 1001. Earlier we</p> <p>18 were discussing the inhalation flow path and how</p> <p>19 modifications can affect the inhalation flow path. Does</p> <p>20 the "177 Patent describe the effect of these components</p> <p>21 on the inhalation flow path?</p> <p>22 A. Again, no, I don't believe -- I believe that</p> <p>23 the patent is directed towards an invention which has</p> <p>24 been broadly -- broadly claimed, and so I believe that</p> <p>25 the intent is that you would have a flow path but that</p>

<p style="text-align: right;">Page 138</p> <p>1 CHARLES E. CLEMENS</p> <p>2 the interactions and, you know, the various components</p> <p>3 and interactions to create these safety systems in terms</p> <p>4 of counting are covered. So it's a counting -- it's an</p> <p>5 invention on a counter, so they're not trying to modify</p> <p>6 a flow path.</p> <p>7 Q. So it doesn't disclose anything about the flow</p> <p>8 path of that device. Is that right?</p> <p>9 MS. HARGRAVE: Objection, asked and</p> <p>10 answered.</p> <p>11 A. It's generally, or I should say broadly,</p> <p>12 written in terms of its claims relative to the safety</p> <p>13 features of a counter -- of a counting system. So I</p> <p>14 believe the intent is that the invention would apply to,</p> <p>15 you know, all the flow paths that you would design</p> <p>16 around it.</p> <p>17 Q. (BY MR. WEIL) And it's your understanding</p> <p>18 that one of skill in the art would understand those flow</p> <p>19 paths at the time of the invention?</p> <p>20 A. One skilled in the art would certainly be</p> <p>21 fully aware of the fact that the flow paths are</p> <p>22 important and very highly designed and that sort of</p> <p>23 thing.</p> <p>24 Q. And one of skill in the art would know how to</p> <p>25 make a -- design an inhaler to preserve the necessary</p>	<p style="text-align: right;">Page 139</p> <p>1 CHARLES E. CLEMENS</p> <p>2 air flow path. Correct?</p> <p>3 MS. HARGRAVE: Objection, calls for</p> <p>4 speculation.</p> <p>5 A. So we are talking about a very complicated</p> <p>6 topic of the inhalers, and each inhaler is unique and</p> <p>7 specific, as I have mentioned in the past. So that's --</p> <p>8 you know, when we start proposing designs and simple</p> <p>9 modifications and that sort of thing for obviousness, I</p> <p>10 think it has to be shown that your modifications in the</p> <p>11 combinations are going to meet these necessary</p> <p>12 requirements for the device. They just can't be glossed</p> <p>13 over. So that is, you know, my position, my opinion on</p> <p>14 it.</p> <p>15 Q. (BY MR. WEIL) Do the claims of the "177</p> <p>16 Patent say anything about a flow path?</p> <p>17 A. The "177 Patent does not -- is not claiming</p> <p>18 the combination of existing art in specific designs to</p> <p>19 create, you know, a design that's very limited. So it's</p> <p>20 not the same. It's not nearly the same.</p> <p>21 Q. And I just want to make sure I understand your</p> <p>22 obviousness analysis. At the time of the invention,</p> <p>23 you're assuming a person of ordinary skill in the art</p> <p>24 looks at two references and the analysis is whether</p> <p>25 those references would be combined to teach all elements</p>
<p style="text-align: right;">Page 140</p> <p>1 CHARLES E. CLEMENS</p> <p>2 of the claim. Is that your understanding of the</p> <p>3 analysis?</p> <p>4 A. Well, my analysis is that for an obviousness</p> <p>5 analysis to be shown, the elements of the combinations</p> <p>6 are -- they're taught as shown in the patent itself, and</p> <p>7 those descriptions can be, you know, substituted and</p> <p>8 combined in such a way that it is, you know, a simple</p> <p>9 straightforward, completely understandable. You don't</p> <p>10 have to recharacterize -- it's not going to complicate</p> <p>11 things. So if the petitioners and expert Piper would</p> <p>12 have shown some detail or could actually show that that</p> <p>13 is an actual case, been able to analyze that. But</p> <p>14 there's so little detail, so little information that --</p> <p>15 and much of what they've suggested looks problematic in</p> <p>16 terms of combining.</p> <p>17 Q. And back to my question is about the</p> <p>18 obviousness analysis, not what petitioners or expert</p> <p>19 Piper have said about these specific combinations. Is</p> <p>20 your understanding of the obviousness analysis that at</p> <p>21 the time of the invention, one of skill in the art needs</p> <p>22 to fit two references together? I will just stop there.</p> <p>23 MS. HARGRAVE: Objection, asked and</p> <p>24 answered.</p> <p>25 A. So what's the question?</p>	<p style="text-align: right;">Page 141</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) Let me ask a different one.</p> <p>3 Is your understanding of the obviousness</p> <p>4 analysis that at the time of the invention, the question</p> <p>5 is whether one of skill in the art would modify an</p> <p>6 existing device based on components in another</p> <p>7 reference?</p> <p>8 A. I think the point is that what the petitioners</p> <p>9 and expert Piper have advanced lacked sufficient</p> <p>10 information, detail, description to meet the burden that</p> <p>11 it's an obvious substitution. They simply have failed</p> <p>12 to do that, in my opinion.</p> <p>13 Q. So I keep asking you questions about how you</p> <p>14 did your analysis, and you keep saying what petitioners</p> <p>15 and Mr. Piper said. I'm asking you as an expert. I was</p> <p>16 trying to figure out when claims are or are not obvious.</p> <p>17 Your understanding of the analysis you have to do,</p> <p>18 that's what my question is about.</p> <p>19 A. Well, I'm sure there is a very good and</p> <p>20 complete legal definition of the obviousness test, but I</p> <p>21 think the point is is that in my analysis it is my</p> <p>22 opinion that petitioners have failed to make that</p> <p>23 burden.</p> <p>24 Q. But you understand my concern is you did the</p> <p>25 wrong analysis. That's why I'm asking you these</p>

<p style="text-align: right;">Page 142</p> <p>1 CHARLES E. CLEMENS</p> <p>2 questions about what is the analysis you did, not what</p> <p>3 petitioners have shown.</p> <p>4 A. Well, I am an expert. I have, as we</p> <p>5 discussed, at least 38 years of experience in the field</p> <p>6 of medical device product development. And I have</p> <p>7 reviewed all the information and viewed it through a</p> <p>8 person of skill in the art, and my conclusion is that</p> <p>9 it's -- what they've shown does not make an obvious case</p> <p>10 for the combination.</p> <p>11 Q. Are you a lawyer?</p> <p>12 A. No, sir, I am not a lawyer. I have relied on</p> <p>13 the attorneys that I am working with to inform me.</p> <p>14 Q. And the -- your understanding of the</p> <p>15 analysis -- the obviousness analysis, that's included in</p> <p>16 your declaration. Is that right?</p> <p>17 MS. HARGRAVE: Objection, vague.</p> <p>18 Q. (BY MR. WEIL) Let me just ask it a little</p> <p>19 more clearly. Is your understanding of the obviousness</p> <p>20 analysis included in your declaration?</p> <p>21 A. I do not believe I created a specific</p> <p>22 definition of that in my report.</p> <p>23 Q. So there's no way for me to know how you</p> <p>24 carried out this analysis. Is that right?</p> <p>25 A. Well, I carried it out as I was informed by</p>	<p style="text-align: right;">Page 143</p> <p>1 CHARLES E. CLEMENS</p> <p>2 attorneys.</p> <p>3 Q. And is that included in your report, is my</p> <p>4 question?</p> <p>5 A. I thought I answered it. I don't believe that</p> <p>6 I formalized that -- that specific procedure.</p> <p>7 MS. HARGRAVE: I am just going to object</p> <p>8 to this line where you're asking him what's in his</p> <p>9 report, and he hasn't been given the opportunity to</p> <p>10 review his report.</p> <p>11 MR. WEIL: He's got it in front of him.</p> <p>12 He can review it if he likes. And again, Ryan, please</p> <p>13 the PTAB is very clear on objections. It's objection,</p> <p>14 form; objection, foundation.</p> <p>15 Q. (BY MR. WEIL) You can review your declaration</p> <p>16 if you would like.</p> <p>17 A. Well, there's at least one area where I've put</p> <p>18 together a rather brief bit of information which was in</p> <p>19 paragraph 46. A little tidbit there of formalized.</p> <p>20 There's another little tidbit in paragraph 87</p> <p>21 in terms of the differences between dependent and</p> <p>22 independent claims in terms of obviousness. There's</p> <p>23 another mention of motivation or encouraged to combine</p> <p>24 in paragraph 90.</p> <p>25 Q. And Mr. Clemens, I'm not trying to be tricky.</p>
<p style="text-align: right;">Page 144</p> <p>1 CHARLES E. CLEMENS</p> <p>2 So if you look at paragraph 27, I believe you say</p> <p>3 something about obviousness there.</p> <p>4 A. Probably. Yeah, there's another little bit of</p> <p>5 information there. So, you know, within both of these</p> <p>6 reports, you know, I have captured snippets, but I</p> <p>7 believe your question was have I put in my report a</p> <p>8 complete understanding of obviousness, the test for</p> <p>9 obviousness, and I do not -- off the top of my head, I</p> <p>10 don't think I did. There are bits and pieces here and</p> <p>11 there.</p> <p>12 Q. Okay. And back to the "177 Patent, does</p> <p>13 that -- does the disclosure, the specification, discuss</p> <p>14 the dimensions of the canister that's used in the</p> <p>15 invention?</p> <p>16 A. No, I didn't think so. You know, the patent</p> <p>17 is written -- the claims are written in a very broad</p> <p>18 sense. I didn't see any specific canister dimensions</p> <p>19 outlined.</p> <p>20 Q. And if we look at the figures in the "177</p> <p>21 Patent, if you look at figure 1, do you see the number</p> <p>22 3? Is it your understanding that's the dispenser member</p> <p>23 of the canister?</p> <p>24 A. That's correct.</p> <p>25 Q. I guess my question is how does this device</p>	<p style="text-align: right;">Page 145</p> <p>1 CHARLES E. CLEMENS</p> <p>2 dispense medication if the dispenser member is, you</p> <p>3 know, up there in the middle?</p> <p>4 A. So obviously, you know, a lot of these patents</p> <p>5 are schematic. They're also two-dimensional. They're</p> <p>6 planar. So, you know, we really can't see what's</p> <p>7 happening in-depth, but these are schematics by their</p> <p>8 nature. I believe it's even stated so in the patent</p> <p>9 itself. So, you know, the combination of being a</p> <p>10 schematic and the fact that it's not three-dimensional,</p> <p>11 you're going to see some what appears to be anomalous</p> <p>12 information, you know, to our three-dimensional minds.</p> <p>13 But, you know, a person of skill in the art would be</p> <p>14 looking at the -- you know, the schematic. The</p> <p>15 important thing about this is that each and every</p> <p>16 element is described and the interactions are described</p> <p>17 and there are diagrams, information showing how the</p> <p>18 interactions work. So this is quite different than</p> <p>19 what's been presented thus far for the obviousness case.</p> <p>20 Q. So your position is that the disclosure in the</p> <p>21 "177 Patent -- oh, we already talked about that.</p> <p>22 Strike that question.</p> <p>23 But even looking at these schematics, if I</p> <p>24 understood what you were saying, one of skill in the art</p> <p>25 would have to use some of your own creativity to</p>

37 (Pages 142 to 145)

<p style="text-align: right;">Page 146</p> <p>1 CHARLES E. CLEMENS 2 understand how this works. Correct? 3 MS. HARGRAVE: Objection, 4 mischaracterizes the testimony. 5 A. There is obviously always going to be some 6 information -- I mean, this is not a complete CAD 7 drawing and design package. So, you know, by its nature 8 it lacks certain information, but one of skill in the 9 art would have a certain amount of knowledge for any 10 patent that is going to be required. 11 Q. (BY MR. WEIL) And that person of skill in the 12 art is the same person who is trying to determine 13 whether this patent -- these claims are obvious in view 14 of the references we were discussing. Correct? 15 MS. HARGRAVE: Objection, calls for 16 speculation. 17 A. Well, both are taken from the perspective of 18 one skilled in the art. 19 Q. (BY MR. WEIL) And that's the same person of 20 skill in the art for each analysis. Right? 21 MS. HARGRAVE: Objection, asked and 22 answered. 23 A. Assuming everybody agrees on person of skill 24 in the art, but, yes, it's the same person. 25 Q. (BY MR. WEIL) Does the '177 Patent describe</p>	<p style="text-align: right;">Page 147</p> <p>1 CHARLES E. CLEMENS 2 how -- the size of the teeth that are used in these 3 gears? 4 A. Let me see if there's a specific requirement. 5 No, I did not find a reference or a narrowing 6 of any of the claims specific to a size of a particular 7 gear and that, I guess, is in line with the fact that 8 it's broadly -- the claims are broadly stated. 9 Q. You keep saying the claims are broadly stated. 10 I'm asking about the disclosure specification. Is that 11 what you mean when you're answering these questions? 12 A. I'm sorry. I thought you said in the patent. 13 Q. Yeah. 14 A. But, yes, so I reviewed the disclosure and the 15 claims. 16 Q. Okay. I just want to go back to something you 17 had said earlier. I think you testified a few minutes 18 ago that within both of your reports you captured 19 snippets, but you did not put the complete understanding 20 of obviousness into your report. Is that right? 21 A. I did not formalize a complete understanding. 22 I believe that was your original question. A complete 23 understanding of the test for obviousness. 24 Q. And you relied on the attorneys to provide the 25 obviousness analysis for you?</p>
<p style="text-align: right;">Page 148</p> <p>1 CHARLES E. CLEMENS 2 MS. HARGRAVE: Objection. 3 A. No. 4 Q. (BY MR. WEIL) Sorry. That's not what I 5 meant. Strike that question. 6 A. Okay. Good. 7 Q. You relied on the attorneys to provide the 8 legal framework for the obviousness analysis. Is that 9 correct? 10 A. That is correct. 11 Q. Can you articulate for me on the record today 12 the obviousness analysis you performed that's not listed 13 in your declaration but that the attorneys informed you 14 of? 15 A. I actually can't recall. 16 Q. Okay. I want to ask you a little bit about 17 that video we watched earlier. 18 A. Okay. 19 Q. I think it's Exhibit 2020 you submitted with 20 your report. Do you know who made that video? 21 A. Off the top of my head, I don't recall the 22 exact author. 23 Q. And that author, I'll just tell you, it's in 24 the video. His name is Bill Hammack. Do you know 25 anything about Mr. Hammack?</p>	<p style="text-align: right;">Page 149</p> <p>1 CHARLES E. CLEMENS 2 A. Not a whole lot. 3 Q. Do you know something about him? 4 A. Yeah. Just, you know, that what I saw on the 5 video and the information, but, you know, he is a person 6 who puts on media in various forms to help people 7 understand certain things, a bit of a teacher. 8 Q. Do you know whether he has any experience with 9 fluid dispensers? 10 A. I do not have a detailed background on him. 11 Q. And you've never spoken to him. Correct? 12 A. I have never personally spoke with him. 13 Q. Do you know whether he's an expert in 14 mechanical pen art? 15 A. I do not know that. 16 Q. I think you said he makes -- like a teacher. 17 Do you know whether he has produced any other videos? 18 A. I don't know the answer to that question. 19 Q. How did you find the video? 20 A. Just through an Internet search. 21 Q. So you were not aware of that video before you 22 started working on this case? 23 A. It was something that I learned in the process 24 of learning about this case. 25 Q. When you decided to rely on that video in your</p>

<p style="text-align: right;">Page 150</p> <p>1 CHARLES E. CLEMENS</p> <p>2 declaration, did you do any further investigation into</p> <p>3 the facts that are presented in the video?</p> <p>4 A. Other than the fact that it on its face is</p> <p>5 a -- it is an expression of the Rhoades patent, and</p> <p>6 after viewing it, studying it myself and analyzing what</p> <p>7 I saw in the video versus the patent itself, it to me is</p> <p>8 authentic.</p> <p>9 Q. Sorry. What do you mean by authentic?</p> <p>10 A. It is an example of the Rhoades invention.</p> <p>11 Q. Did you do any further investigation into</p> <p>12 Mr. Hammack?</p> <p>13 A. No, I did not.</p> <p>14 Q. I think in that video there's a statement that</p> <p>15 it took 66 people to create the pen. Do you recall</p> <p>16 that?</p> <p>17 A. That is correct.</p> <p>18 Q. Did you do any investigation into whether that</p> <p>19 was the case?</p> <p>20 A. I did not.</p> <p>21 Q. Do you know are there 66 inventors on the</p> <p>22 Rhoades patent?</p> <p>23 A. There is not.</p> <p>24 Q. Did the petitioners cite that video as prior</p> <p>25 art against the "177 Patent?</p>	<p style="text-align: right;">Page 151</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. They did not.</p> <p>3 Q. Did the petitioners cite that video as prior</p> <p>4 art against the '631 Patent?</p> <p>5 A. No, they did not.</p> <p>6 Q. The petitioners specifically relied on the</p> <p>7 Rhoades reference itself. Correct?</p> <p>8 A. It's unknown to me what the petitioners</p> <p>9 considered.</p> <p>10 Q. But the --</p> <p>11 A. Other than what's been listed on --</p> <p>12 Q. Yeah, sorry, I didn't mean what the</p> <p>13 petitioners considered. Petitioners relied on in their</p> <p>14 invalidity grounds, petitioners relied on the actual US</p> <p>15 patent for the Rhoades reference. Correct?</p> <p>16 A. Yes, I would say I agree to that.</p> <p>17 Q. All right. Could we turn to paragraph 42 of</p> <p>18 your declaration?</p> <p>19 A. '177?</p> <p>20 Q. Yeah.</p> <p>21 A. 42, right?</p> <p>22 Q. Paragraph 42. I'm really going to talk about</p> <p>23 the heading just above it.</p> <p>24 A. Oh.</p> <p>25 Q. I just want to orient us. We're going to talk</p>
<p style="text-align: right;">Page 152</p> <p>1 CHARLES E. CLEMENS</p> <p>2 about claim 2 of the "177 Patent. Okay?</p> <p>3 A. Okay.</p> <p>4 Q. And looking at paragraph 43, do you see</p> <p>5 petitioners do not describe how the height of the teeth</p> <p>6 could be designed to cause chamber refilling to occur</p> <p>7 after the valve has been sufficiently released, kind of</p> <p>8 in the middle.</p> <p>9 Do you see that?</p> <p>10 A. Yes, I do. So I am just trying to orient</p> <p>11 myself again to where we are. Okay. Okay.</p> <p>12 Q. So my question is about in the canister,</p> <p>13 there's a set distance that a depressed canister must</p> <p>14 return before the metering chamber refills. Correct?</p> <p>15 A. They're all -- they're all different, and in</p> <p>16 each manufactured canister and valve combination, it</p> <p>17 varies as well. So with the proviso that there's a lot</p> <p>18 of variables involved, to that extent there is a set</p> <p>19 distance, plus a lot of variation.</p> <p>20 Q. And when you say "each manufactured valve and</p> <p>21 canister, it varies," are you talking about the</p> <p>22 tolerances of it refills at? For example,</p> <p>23 fifty-thousandths of an inch, plus or minus</p> <p>24 two-thousandths, and the plus or minus is the variance?</p> <p>25 MS. HARGRAVE: Objection, calls for</p>	<p style="text-align: right;">Page 153</p> <p>1 CHARLES E. CLEMENS</p> <p>2 speculation.</p> <p>3 A. Yes, that would be the variance, you know, but</p> <p>4 in the actual manufacturing process, there's going to be</p> <p>5 some variances there. So from part to part -- even of</p> <p>6 the same brand, it's going to vary. So, yeah, there's</p> <p>7 generally a set distance for whatever canister you're</p> <p>8 designing for, but there is going to be some variation</p> <p>9 there.</p> <p>10 Q. (BY MR. WEIL) But if it varies outside of</p> <p>11 that set tolerance, the canister is considered not to</p> <p>12 be -- to be successfully made. Correct?</p> <p>13 A. I would characterize that as something that</p> <p>14 didn't meet the design specification.</p> <p>15 Q. So within the design specification, there's a</p> <p>16 point at which the metering chamber would refill. Is</p> <p>17 that correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And one of skill in the art who knows what</p> <p>20 that point is would be able to design teeth -- let me</p> <p>21 start that again.</p> <p>22 A person of ordinary skill in the art who</p> <p>23 knows what that point is would be able to design an MDI</p> <p>24 that counts again after the chamber has refilled. Is</p> <p>25 that correct?</p>

<p style="text-align: right;">Page 154</p> <p>1 CHARLES E. CLEMENS 2 MS. HARGRAVE: Objection, calls for 3 speculation. 4 A. So conceptually, you know, all us people of 5 skill in the art, we generally know -- conceptually, we 6 know that the design needs to do this. That's a design 7 requirement. Converting that design requirement into an 8 actual hard design requires analysis of all the 9 interacting parts that go into making that happen. 10 As it is, you know, in these counters, there 11 is a lot of interaction between the counting means and 12 the actuation means, you know, the valving and, you 13 know, where all these interdependencies occur. That is 14 the detail -- you know, conceptually, I know how it's 15 all supposed to work, but unless it's described on how 16 this can occur, in particular when trying to prove 17 something that's obvious, there needs to be a lot more 18 detail on how the interaction and interoperability of 19 all these components occur for that to happen. 20 Q. (BY MR. WEIL) Yeah, and my question wasn't at 21 all about what's required for obviousness. It's could 22 one of skill in the art at the time of the invention, 23 would that person know how to design an MDI with a dose 24 counter that could count again at that point after the 25 meter chamber has refilled?</p>	<p style="text-align: right;">Page 155</p> <p>1 CHARLES E. CLEMENS 2 MS. HARGRAVE: Objection, asked and 3 answered, calls for speculation. 4 A. Well, it depends. It depends on, you know, 5 what your design is. If it were a very -- you know, a 6 two-part system, that would be, you know, a level that 7 would be quite simple. We're talking about here, you 8 know, a unique approach which is decomposing two ideas 9 and synthesizing a third. You know, there's a lot of 10 details here. There are some difficult design 11 requirements. So, you know, it's -- what has been 12 presented here is -- what I am saying is a person of 13 skill in the art couldn't make that -- couldn't make 14 that leap with the lack of information. 15 Q. (BY MR. WEIL) So we're talking about an MDI 16 with a dose counter where you push down on the canister 17 and linear motion converts to rotational motion of the 18 dose counter. Is that correct? 19 MS. HARGRAVE: Objection, vague. 20 A. You know, this is, you know, a very simplistic 21 view of what's going on, but, you know, we've seen 22 several different kinds of inhalers and counters. So I 23 am not sure where to go with that. I mean, my last 24 statement about your other question I think stands as I 25 stated it.</p>
<p style="text-align: right;">Page 156</p> <p>1 CHARLES E. CLEMENS 2 Q. (BY MR. WEIL) Well, let's talk about a dose 3 counter that you push down a canister axially, which 4 causes a piece to move rotationally. Okay. What's 5 unique about that device that -- let me start again. 6 Talking about a dose counter where you push 7 down a canister axially, which causes a piece to move 8 rotationally, isn't that just a simple conversion of 9 linear to rotational movement? 10 A. But that isn't what we're talking about here. 11 Q. That's what I'm talking about from my 12 question. 13 A. So you're talking about a completely 14 hypothetical example which has nothing to do with what's 15 in my reports? 16 Q. So you think that the conversion of linear to 17 rotational movement has nothing to do with what's in 18 your report? 19 MS. HARGRAVE: Objection, 20 mischaracterization of testimony. 21 A. Right, that's not at all what I said. I was 22 asking you if you were attempting to simplify what I am 23 talking about in, let's say, paragraph 43 into, you 24 know, a simplistic statement, and it just can't be done. 25 Q. (BY MR. WEIL) Would one of skill in the art</p>	<p style="text-align: right;">Page 157</p> <p>1 CHARLES E. CLEMENS 2 at the time of the invention know different various 3 techniques for converting linear to rotational movement? 4 A. So yes, earlier we spoke about this a person 5 skilled in the art would have general knowledge, you 6 know, for instance of springs and gears and, you know, 7 components. Conceptually, they would understand that, 8 you know, there are ways to convert linear motion to 9 rotary motion. That's obviously been around for a 10 while. So in general conceptually, absolutely, they 11 would -- they would have that knowledge. 12 Q. And the Rhoades patent converts linear to 13 rotational movement. Correct? 14 A. The Rhoades invention, indeed, does do that. 15 Q. And back to my question about coordinating 16 dose counting and metering chamber refilling. I am not 17 asking about what's been proposed in the petitions. I 18 am asking your understanding of one of skill in the art 19 at the time of the invention, what their abilities would 20 be in relation to this. Would they be able to 21 coordinate a dose count and metering chamber refilling? 22 A. I believe that it depends. It depends on the 23 design. 24 Q. So there's some designs where they could? 25 A. Well, as I stated earlier, there's obviously</p>

<p style="text-align: right;">Page 158</p> <p>1 CHARLES E. CLEMENS</p> <p>2 some very simplistic designs, you know, that have, let's</p> <p>3 say, two components and you're, you know, trying to</p> <p>4 coordinate them. You know, we're kind of talking in the</p> <p>5 abstract here, but my point is that it depends on the</p> <p>6 design.</p> <p>7 Q. But with a given design, one of skill in the</p> <p>8 art would have understood how to structure the gears and</p> <p>9 gear teeth to coordinate chamber refilling. Right?</p> <p>10 MS. HARGRAVE: Objection, asked and</p> <p>11 answered, calls for speculation.</p> <p>12 A. It depends on the design in front of a POSITA.</p> <p>13 Q. (BY MR. WEIL) Okay. So in your declaration</p> <p>14 if we look at paragraph 47, you first state that Rhoades</p> <p>15 is not analogous art.</p> <p>16 Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. And then in paragraph 53 you refer to some</p> <p>19 references that petitioners cite where you say that they</p> <p>20 teach away from this invention. Is that right?</p> <p>21 A. Yes, that's correct.</p> <p>22 Q. Just so -- sorry.</p> <p>23 A. I was clearing my throat, sorry.</p> <p>24 Q. Okay. And I just want to be sure I understand</p> <p>25 what your analysis is. Is your opinion that one of</p>	<p style="text-align: right;">Page 159</p> <p>1 CHARLES E. CLEMENS</p> <p>2 skill in the art would not even ever look at Rhoades, or</p> <p>3 is your opinion that one of skill in the art would look</p> <p>4 to these references but then be taught away?</p> <p>5 MS. HARGRAVE: Objection, compound.</p> <p>6 A. Okay. So to the first part, which is --</p> <p>7 Q. (BY MR. WEIL) Do you want to break it down?</p> <p>8 A. Yeah, let's break it down. So I'm referring</p> <p>9 to paragraph 47. Obviously, you know, the statement</p> <p>10 here first, Rhoades is not analogous art, I mean, that's</p> <p>11 my opinion. It just -- almost all of it is not</p> <p>12 applicable, not useful. So I believe it's not analogous</p> <p>13 art.</p> <p>14 The second part of the question with respect</p> <p>15 to patents that teach away, when in reading the</p> <p>16 specification and/or the claims, if a patent indicates</p> <p>17 that the very thing that you believe it's teaching, it's</p> <p>18 actually saying that this would not work, that would be</p> <p>19 an indication of the specifications teaching away from</p> <p>20 what you're trying to say that it's teaching.</p> <p>21 Q. And to the first part, you answered about</p> <p>22 paragraph 47, is your understanding that a reference is</p> <p>23 not analogous art if almost all of it is not applicable,</p> <p>24 not useful?</p> <p>25 MS. HARGRAVE: Objection,</p>
<p style="text-align: right;">Page 160</p> <p>1 CHARLES E. CLEMENS</p> <p>2 mischaracterization of testimony.</p> <p>3 A. So, you know, I tried to lay out a little bit</p> <p>4 of, you know, rationale here. It should be from the</p> <p>5 same field of endeavor or at least reasonably pertinent</p> <p>6 to the particular problem that the inventor is trying to</p> <p>7 solve. So, you know, and then further on I go on to</p> <p>8 kind of explain about the different -- the stated</p> <p>9 purposes, the fields of endeavor. You know, they're so</p> <p>10 vastly different. They're solving completely different</p> <p>11 problems. Rhoades is completely uninterested in how</p> <p>12 much fluid is in the reservoir. It counts nothing,</p> <p>13 et cetera, et cetera. There's many reasons why there's</p> <p>14 just not analogous art.</p> <p>15 Q. (BY MR. WEIL) And in paragraph 48, that's</p> <p>16 where you say the stated purpose of the "177 Patent is</p> <p>17 to provide a fluid dispenser including a dose indicator</p> <p>18 device that prevents any risk of undercounting, i.e.,</p> <p>19 that guarantees that the indicator device is actuated,</p> <p>20 counted, each time liquid is dispensed by the fluid</p> <p>21 dispenser. Is that right?</p> <p>22 A. I believe you read that correctly.</p> <p>23 Q. And that looks like that's a quote from</p> <p>24 something. There's some quotation marks.</p> <p>25 A. To the patent.</p>	<p style="text-align: right;">Page 161</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. Okay. Just to make sure we've got the right</p> <p>3 spot. In the "177 Patent, is that -- the quote is</p> <p>4 column 1, lines 47 to 51. Is that right?</p> <p>5 A. Let me just check here. I am sorry. Did you</p> <p>6 say --</p> <p>7 Q. Column 1, 47 through 51.</p> <p>8 A. I believe that is, yeah.</p> <p>9 Q. And that language which you call the stated</p> <p>10 purpose, that's identified as an object of the present</p> <p>11 invention. Correct?</p> <p>12 A. It is stated as an object, yes.</p> <p>13 Q. And there are other objects stated in the</p> <p>14 specification. Right?</p> <p>15 A. Yes.</p> <p>16 Q. If you look at column 1, lines 57 to 59, that</p> <p>17 states another object of the present invention is to</p> <p>18 provide such a fluid dispenser that a simple and</p> <p>19 inexpensive to manufacture and to assemble and that it</p> <p>20 is reliable in use.</p> <p>21 Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. So that's another stated purpose of the</p> <p>24 Rhoades device. Right?</p> <p>25 A. Indeed, yes.</p>

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<p style="text-align: right;">Page 162</p> <p>1 CHARLES E. CLEMENS</p> <p>2 MS. HARGRAVE: Objection, vague. I don't</p> <p>3 think you meant to say "Rhoades."</p> <p>4 A. Did you say "Rhoades"?</p> <p>5 MS. HARGRAVE: I didn't mean to fix your</p> <p>6 record for you, but --</p> <p>7 MR. WEIL: Thank you.</p> <p>8 Q. (BY MR. WEIL) That's another stated purpose</p> <p>9 of the "177 Patent. Right?</p> <p>10 A. Correct.</p> <p>11 Q. And if we go to paragraph 49 of your report,</p> <p>12 there you're discussing the Rhoades reference. Right?</p> <p>13 A. Correct.</p> <p>14 Q. And there you state that Rhoades's stated</p> <p>15 purpose is to, quote, "provide a ballpoint writing</p> <p>16 instrument having an improved push button operated</p> <p>17 projecting and retracting mechanism." Right?</p> <p>18 A. Yes, that's what I wrote in my report.</p> <p>19 Q. And just to make sure we have the right spot</p> <p>20 in Rhoades, is that in column 1, lines 15 to 17?</p> <p>21 A. Correct.</p> <p>22 Q. And that's also listed as an object of the</p> <p>23 present invention?</p> <p>24 A. Yes.</p> <p>25 Q. And you see there's other objects of the</p>	<p style="text-align: right;">Page 163</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Rhoades invention as well?</p> <p>3 A. There are other objects.</p> <p>4 Q. If we look at the 1 -- lines 35 to 41 of</p> <p>5 column 1, it says a further object of the invention is</p> <p>6 to provide a simple and reliable projecting and</p> <p>7 retracting mechanism for a ballpoint writing instrument</p> <p>8 which mechanism may be readily manufactured and</p> <p>9 assembled which operates positively to project and</p> <p>10 retract the writing point upon successive depressions of</p> <p>11 a push button and which will operate satisfactorily for</p> <p>12 a long period of time. Do you see that? Sorry, long</p> <p>13 period of use.</p> <p>14 A. Yes, I see that in the patent.</p> <p>15 Q. And that's another object of the Rhoades</p> <p>16 invention. Right?</p> <p>17 A. Yes. Both of these references have multiple</p> <p>18 objects, but the field of endeavor or, you know, the</p> <p>19 main purpose and objective of these patents are directed</p> <p>20 to a field of endeavor. And you know, the point --</p> <p>21 while there may be a lot of common objectives among</p> <p>22 everything -- I mean, nowadays everything has got to be</p> <p>23 cheap, you know, low cost, but -- motherhood and apple</p> <p>24 pie. But, you know, what they're directed towards is</p> <p>25 really the point that I'm making here. And you know,</p>
<p style="text-align: right;">Page 164</p> <p>1 CHARLES E. CLEMENS</p> <p>2 the "177 Patent is directed towards, you know, a very</p> <p>3 sophisticated, you know, highly tuned medical device</p> <p>4 that, you know, applies, you know, in some cases, you</p> <p>5 know, safety related therapies; and in the other case</p> <p>6 the field of endeavor is, you know, a pen that, you</p> <p>7 know, billions are made and they're -- you know, they</p> <p>8 really have nothing to do with one or the other. Very,</p> <p>9 very little to do.</p> <p>10 Q. Back to my questions about the express</p> <p>11 disclosures in the reference. You agree with me that</p> <p>12 another stated purpose of Rhoades is what I read into</p> <p>13 the record from lines 35 to 41. Correct?</p> <p>14 MS. HARGRAVE: Objection, asked and</p> <p>15 answered.</p> <p>16 A. I agree that those are expressly stated in the</p> <p>17 patent.</p> <p>18 Q. (BY MR. WEIL) You agree with me that fluid</p> <p>19 dispensers operate by moving a canister axially to cause</p> <p>20 liquid to be dispensed. Right?</p> <p>21 MS. HARGRAVE: Objection, vague.</p> <p>22 A. Well, fluid dispensers are a very broad topic.</p> <p>23 Q. (BY MR. WEIL) Let me make it a little</p> <p>24 different.</p> <p>25 Fluid dispensers can operate by moving</p>	<p style="text-align: right;">Page 165</p> <p>1 CHARLES E. CLEMENS</p> <p>2 axially -- by moving a canister axially to cause liquid</p> <p>3 to be dispensed. Correct?</p> <p>4 MS. HARGRAVE: Objection, vague.</p> <p>5 A. I do believe that, you know, in our world</p> <p>6 there are those kinds of dispensers.</p> <p>7 Q. (BY MR. WEIL) And that's how an MDI works.</p> <p>8 Is that right?</p> <p>9 A. An MDI --</p> <p>10 MS. HARGRAVE: Objection, vague.</p> <p>11 A. Well, would you qualify that a little bit?</p> <p>12 Q. (BY MR. WEIL) Sure.</p> <p>13 We've looked at a number of -- we've looked</p> <p>14 at, for example, the Elliott reference.</p> <p>15 A. Okay.</p> <p>16 Q. And in there we saw an inhaler body with a</p> <p>17 canister in it. That was an MDI. Correct?</p> <p>18 A. Correct.</p> <p>19 Q. And that type of device works by moving the</p> <p>20 canister axially to dispense a dose of fluid. Right?</p> <p>21 A. Elliott functions in that fashion, correct.</p> <p>22 Q. At the time of the invention, there were lots</p> <p>23 of devices that operated in that function. Right?</p> <p>24 A. There were many devices that had similar</p> <p>25 operation, yes.</p>

<p style="text-align: right;">Page 166</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. You would agree that at the time of the</p> <p>3 invention dose counters that converted linear motion</p> <p>4 into rotational motion were well-known. Right?</p> <p>5 MS. HARGRAVE: Objection, vague.</p> <p>6 A. Off the top of my head, I can't remember what</p> <p>7 the specific prior arts were that -- that referenced in</p> <p>8 the patent, but, you know, there were devices that were</p> <p>9 making those conversions.</p> <p>10 Q. (BY MR. WEIL) And they would have been known</p> <p>11 to one of skill in the art?</p> <p>12 A. Certainly the ones that were identified at the</p> <p>13 time of the invention by the inventors, you know, a</p> <p>14 person of skill in the art would know that.</p> <p>15 Q. Just a few more questions about the video,</p> <p>16 Exhibit 2020. We talked a little bit about that before,</p> <p>17 and we talked about the video refers to the Rhoades</p> <p>18 mechanism requiring 66 people to create. Right?</p> <p>19 A. That's correct.</p> <p>20 Q. And do you know whether the video was</p> <p>21 referring to people who would be qualified as one</p> <p>22 skilled in the art?</p> <p>23 A. I do not have a way of knowing that.</p> <p>24 Q. Do you think it would have taken over 60</p> <p>25 people to design Rhoades in 2003?</p>	<p style="text-align: right;">Page 167</p> <p>1 CHARLES E. CLEMENS</p> <p>2 MS. HARGRAVE: Objection, calls for</p> <p>3 speculation.</p> <p>4 A. I guess I don't really have a way of answering</p> <p>5 that with any -- any ability.</p> <p>6 Q. (BY MR. WEIL) Well, you're a mechanical</p> <p>7 engineer and you understand the mechanism of Rhoades.</p> <p>8 Right?</p> <p>9 A. Well, but, you know, we're talking about a</p> <p>10 creative moment, you know, an invention. And whether,</p> <p>11 you know, two people could have done it or 20 or 30, you</p> <p>12 know, that's another question. You know, it's -- you</p> <p>13 know, I don't have a crystal ball how that could have</p> <p>14 been done, but it's not information that would -- you</p> <p>15 know, that is like just looking it up in a book. It's a</p> <p>16 creative moment.</p> <p>17 Q. Let's look at paragraph 51 in the '177</p> <p>18 declaration, and there you discuss a number of things</p> <p>19 that are important for drug delivery by an MDI.</p> <p>20 Correct?</p> <p>21 A. Yes, I would say that general statement is</p> <p>22 true.</p> <p>23 Q. And you cite to Exhibit 2008. Do you see</p> <p>24 that?</p> <p>25 A. I do.</p>
<p style="text-align: right;">Page 168</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. I am going to hand you an exhibit that's been</p> <p>3 marked as Exhibit 2008 in IPR 2018-01054, and I believe</p> <p>4 this is the same as 2008 in the other IPR. And do you</p> <p>5 recognize the exhibit I just handed you?</p> <p>6 A. Yes, it looks like the one.</p> <p>7 Q. This is the article you were referring to?</p> <p>8 A. I believe so.</p> <p>9 Q. Can you go to page 330?</p> <p>10 A. Oh, yes. Okay.</p> <p>11 Q. And you see the picture at the upper</p> <p>12 right-hand part of that page?</p> <p>13 A. Yeah, I do.</p> <p>14 Q. And does that device have the components that</p> <p>15 you were talking about that are important for drug</p> <p>16 delivery?</p> <p>17 A. Yes. You know, it appears to. I am not sure</p> <p>18 what it relates to or what particular product it relates</p> <p>19 to. It's a schematic. I mean, you know, whether this</p> <p>20 is an actual produced design that's been optimized for</p> <p>21 drug delivery for a particular drug delivery, that is</p> <p>22 something I have no idea about, but it says it's</p> <p>23 schematic. So it could be just a generic drawing, and</p> <p>24 it could possibly relate to nothing that's on the market</p> <p>25 or, you know, delivering drugs.</p>	<p style="text-align: right;">Page 169</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. But you're pointing to this reference as an</p> <p>3 example of the features that are necessary for</p> <p>4 accurately dispensing drug. Correct?</p> <p>5 A. In my report, I detail out several aspects of</p> <p>6 design, you know, for these metered-dose inhalers that</p> <p>7 all have an effect on creating a respirable dose. And</p> <p>8 so -- and the point here is that, you know, here is at</p> <p>9 least one bit of reference, you know, that confirms that</p> <p>10 a lot of these, you know, aspects of designing an MDI,</p> <p>11 they do have an effect on respirable dose, so they have</p> <p>12 to be taken into consideration. So, you know, that's, I</p> <p>13 think, the important point here is you don't just slap</p> <p>14 something together and it works. You know, all these</p> <p>15 factors and variables enter into a design that will</p> <p>16 actually deliver drugs.</p> <p>17 MR. WEIL: All right. Do you guys want</p> <p>18 to take a break?</p> <p>19 MS. HARGRAVE: Sure.</p> <p>20 (Break from 3:22 p.m. to 3:31 p.m.)</p> <p>21 Q. (BY MR. WEIL) Okay. Mr. Clemens, so before</p> <p>22 the break we were talking about your opinion that</p> <p>23 Rhoades is not analogous art. Right?</p> <p>24 A. Right.</p> <p>25 Q. I believe you testified that two of those</p>

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<p style="text-align: right;">Page 170</p> <p>1 CHARLES E. CLEMENS</p> <p>2 reasons are that Rhoades doesn't count anything and it's</p> <p>3 not interested in how much fluid is in the reservoir.</p> <p>4 Is that right?</p> <p>5 A. I believe it's -- yeah, those were some of</p> <p>6 the -- some of the reasons why it's not analogous. Of</p> <p>7 course, my report has got --</p> <p>8 Q. Sure.</p> <p>9 A. -- more of a complete opinion, but --</p> <p>10 Q. But a pen can be an analogous art for a</p> <p>11 medical device. Is that correct?</p> <p>12 MS. HARGRAVE: Objection, calls for</p> <p>13 speculation.</p> <p>14 A. So I know that there is -- it's popular to</p> <p>15 make that kind of statement. The reality is that pen</p> <p>16 injectors, other than being long, oblong shapes and</p> <p>17 perhaps having springs, other than that they really have</p> <p>18 almost nothing to do with each other.</p> <p>19 Q. (BY MR. WEIL) I will hand you what I have</p> <p>20 marked as Exhibit 1055.</p> <p>21 (Exhibit 1055 marked.)</p> <p>22 Q. (BY MR. WEIL) Mr. Clemens, do you recognize</p> <p>23 this document?</p> <p>24 A. It certainly looks like I authored it. Yes.</p> <p>25 Q. What is this document?</p>	<p style="text-align: right;">Page 171</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Well, this is a declaration that I produced in</p> <p>3 a matter between West Pharmaceutical and Sanofi-Aventis,</p> <p>4 and I believe it was regarding -- I will have to look at</p> <p>5 it again, but I believe it was -- I believe it's related</p> <p>6 to safety -- safety devices for needles.</p> <p>7 Q. If you look at the last page, page 90 of this</p> <p>8 declaration, is that your signature?</p> <p>9 A. Yes, it is.</p> <p>10 Q. And you signed that on May 9, 2018. Is that</p> <p>11 right?</p> <p>12 A. Correct.</p> <p>13 Q. Were you still working on the West</p> <p>14 Pharmaceutical's IPR at the time you were retained for</p> <p>15 this matter?</p> <p>16 A. I do not believe so.</p> <p>17 Q. Would you look at paragraph 11. In that</p> <p>18 paragraph you state your specific areas of expertise.</p> <p>19 Right?</p> <p>20 A. Oh, yes. As it relates to this matter, yes,</p> <p>21 correct.</p> <p>22 Q. And you don't mention anything about</p> <p>23 respiratory devices, though. Right?</p> <p>24 A. I don't. I don't list all of my background.</p> <p>25 Q. But as we discussed this morning, all that</p>
<p style="text-align: right;">Page 172</p> <p>1 CHARLES E. CLEMENS</p> <p>2 background contributed to your opinions in the IPR.</p> <p>3 Correct?</p> <p>4 MS. HARGRAVE: Objection,</p> <p>5 mischaracterization of testimony.</p> <p>6 A. Yes, I mean, the entirety of my career and</p> <p>7 experience is what I possess. Of course, when I do a</p> <p>8 lot of these analyses, I do them through the eyes of a</p> <p>9 person skilled in the art at the time of the invention;</p> <p>10 but in terms of my total background, yes, you know, I</p> <p>11 have quite a bit in a wide range of medical devices.</p> <p>12 Q. (BY MR. WEIL) And in paragraph 12 you talk</p> <p>13 about some of those same specific devices that you</p> <p>14 mentioned earlier today. I see Twinject, EpiPen.</p> <p>15 Do you see those?</p> <p>16 A. I do.</p> <p>17 Q. And those were all types of pen injector</p> <p>18 devices. Right?</p> <p>19 A. They're different injector devices,</p> <p>20 autoinjectors. I mean, they give them a lot of</p> <p>21 different names, EpiPens. But, as we discussed earlier,</p> <p>22 I've had a fair amount of experience with some of these.</p> <p>23 Q. If we look at paragraph 47, in that paragraph</p> <p>24 you're referring to the safety mechanism claimed by the</p> <p>25 challenged claims. And you state, Such a mechanism can</p>	<p style="text-align: right;">Page 173</p> <p>1 CHARLES E. CLEMENS</p> <p>2 be found in age old mechanisms of a retractable</p> <p>3 ballpoint pen. Is that right?</p> <p>4 A. That is correct.</p> <p>5 Q. So in this IPR, you refer to the ballpoint pen</p> <p>6 as something that an engineer would know about at the</p> <p>7 time of the invention. Right?</p> <p>8 MS. HARGRAVE: Objection, vague.</p> <p>9 A. There's a significant difference here as</p> <p>10 opposed to what we're talking -- the matters that we're</p> <p>11 talking about there. In these matters, there is a</p> <p>12 retracting and projecting mechanism. That's an</p> <p>13 objective of Rhoades.</p> <p>14 Q. (BY MR. WEIL) Right. So the objective of</p> <p>15 Rhoades is to extend and retract the pen, as you</p> <p>16 described it. Correct?</p> <p>17 A. That's correct.</p> <p>18 Q. And these devices, if I just understood you,</p> <p>19 they operate in the same way, extending and retracting a</p> <p>20 needle. Is that correct?</p> <p>21 A. Yes. They all are concerned about the</p> <p>22 needle -- moving the needle, projecting it into its</p> <p>23 injection position and then retracting it into a safe</p> <p>24 zone.</p> <p>25 Q. And we also discussed earlier that Rhoades</p>

<p style="text-align: right;">Page 174</p> <p>1 CHARLES E. CLEMENS</p> <p>2 mechanism converts axial motion into rotational motion.</p> <p>3 Correct?</p> <p>4 MS. HARGRAVE: Objection,</p> <p>5 mischaracterization of testimony.</p> <p>6 A. There are several instances in our</p> <p>7 conversation before which talked about the fact that</p> <p>8 Rhoades is a device that converts linear motion to</p> <p>9 rotary motion. So if that's your question, that's</p> <p>10 correct, yeah.</p> <p>11 Q. (BY MR. WEIL) So am I to understand you</p> <p>12 correctly that engineers thinking of the linear motion</p> <p>13 in these pen injectors might look to a mechanical pen,</p> <p>14 but it's your position that an engineer looking to solve</p> <p>15 the problem of converting axial into rotational motion</p> <p>16 would not look to a pen?</p> <p>17 MS. HARGRAVE: Objection,</p> <p>18 mischaracterization of testimony.</p> <p>19 A. So, again, going back to my report, in looking</p> <p>20 at the objective of the invention and what it's actually</p> <p>21 trying to do, in the case of Rhoades, that there is no</p> <p>22 objective of Rhoades which is really applying and has</p> <p>23 anything to do with the '177 or the '613. So -- whereas</p> <p>24 in this case, all of these designs relate to projecting</p> <p>25 and retracting. So that's -- you know, that's a huge</p>	<p style="text-align: right;">Page 175</p> <p>1 CHARLES E. CLEMENS</p> <p>2 distinction. So there could be some analogous art that</p> <p>3 you can see in the comparison between these two.</p> <p>4 Q. (BY MR. WEIL) So the mechanical engineer</p> <p>5 skilled in the art at the time of the invention working</p> <p>6 on this type of medical device wouldn't be aware of how</p> <p>7 a pen works. Correct?</p> <p>8 MS. HARGRAVE: Objection, vague.</p> <p>9 A. When you say "this," which one are you</p> <p>10 referring to?</p> <p>11 Q. (BY MR. WEIL) Thank you. "This" being the</p> <p>12 pen type injector that we're discussing in your --</p> <p>13 A. The safety pens --</p> <p>14 Q. Correct.</p> <p>15 A. -- or the safety devices?</p> <p>16 Q. Yeah. Let me just ask it again so it's clear.</p> <p>17 So the person of ordinary skill in the art at</p> <p>18 the time of the invention working on the safety types of</p> <p>19 pens, they would be aware how a mechanical pen works.</p> <p>20 Correct?</p> <p>21 A. So I would characterize it as obviously pens,</p> <p>22 you know, are -- there's billions of them. We all use</p> <p>23 them. So there's going to be a general understanding of</p> <p>24 pens for everybody. So that's true. We're going to be</p> <p>25 aware of that, but the question of whether or not that</p>
<p style="text-align: right;">Page 176</p> <p>1 CHARLES E. CLEMENS</p> <p>2 has any usefulness or analogy to a particular design is</p> <p>3 a totally different question that needs to be asked and</p> <p>4 answered.</p> <p>5 Q. Well, would one of skill in the art understand</p> <p>6 that a pen converts linear motion into rotational</p> <p>7 motion?</p> <p>8 MS. HARGRAVE: Objection, vague.</p> <p>9 A. Ask the question again.</p> <p>10 Q. (BY MR. WEIL) Sure.</p> <p>11 Would one of skill in the art at the time of</p> <p>12 the invention know that a mechanical pen like Rhoades</p> <p>13 converts linear motion into rotational motion?</p> <p>14 MS. HARGRAVE: Objection, vague.</p> <p>15 A. So, you know, a person skilled in the art, you</p> <p>16 know, would have had access to lots of pens. And so it</p> <p>17 would be impossible for a person of skill in the art or</p> <p>18 anybody else, you know, not to, you know, notice, you</p> <p>19 know, what a pen does.</p> <p>20 Q. (BY MR. WEIL) And you would agree with me</p> <p>21 that those skilled in the art often apply these simple</p> <p>22 mechanisms to other projects that they're working on.</p> <p>23 Right?</p> <p>24 MS. HARGRAVE: Objection, calls for</p> <p>25 speculation and vague.</p>	<p style="text-align: right;">Page 177</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. So I would say, once again, that conceptually</p> <p>3 these things, you know, make sense at a high level. You</p> <p>4 know, you could say, well, you know, I am going to use</p> <p>5 something that converts linear to rotary motion, and</p> <p>6 you -- conceptually, you can accept that. I know</p> <p>7 through many years of experience that all these designs</p> <p>8 are custom. They're highly optimized for their purpose.</p> <p>9 And, you know, rarely do you get the benefit of</p> <p>10 something dropping in. Sometimes you might get lucky,</p> <p>11 but, you know, when you see -- when you look at and</p> <p>12 analyze the combinations that petitioner is suggesting</p> <p>13 and then you actually look at a pen -- the Rhoades</p> <p>14 reference and you try to glean from the Rhoades</p> <p>15 reference what they could possibly use from it, you</p> <p>16 could see it's just not analogous. It's not analogous</p> <p>17 art. The petitioners have proposed some modifications.</p> <p>18 Perhaps if there was more information, more substance to</p> <p>19 the combined design that can be analyzed, but from my</p> <p>20 reading, it isn't.</p> <p>21 Q. (BY MR. WEIL) So Mr. Clemens, that was not at</p> <p>22 all my question. I was not asking about proposed</p> <p>23 combination. I asked whether engineers skilled in the</p> <p>24 art, the person who you applied for your analysis,</p> <p>25 whether they adopt simple mechanisms like converting</p>

<p style="text-align: right;">Page 178</p> <p>1 CHARLES E. CLEMENS</p> <p>2 linear to rotational motion into other projects beyond</p> <p>3 the specific one they're looking at?</p> <p>4 MS. HARGRAVE: Objection, asked and</p> <p>5 answered.</p> <p>6 Q. (BY MR. WEIL) Is that something that a person</p> <p>7 of skill in the art can do?</p> <p>8 MS. HARGRAVE: Objection, asked and</p> <p>9 answered, calls for speculation.</p> <p>10 A. Without going through the exercise of</p> <p>11 rereading my answer, which I did answer your question,</p> <p>12 maybe you can be more specific to a particular modality</p> <p>13 of design that was used and dropped into something else.</p> <p>14 Then I could be more specific with my answer.</p> <p>15 Q. (BY MR. WEIL) I guess one thing that's</p> <p>16 confusing. You keep saying "dropped into something</p> <p>17 else." What do you mean by that?</p> <p>18 A. So when I hear some of your questions, my</p> <p>19 perception is that you're describing something about the</p> <p>20 Rhoades pen or anything -- any design -- I am sorry, not</p> <p>21 just the Rhoades, but any design which can be just</p> <p>22 simply utilized as is in another design, you know,</p> <p>23 dropped in without modification.</p> <p>24 Q. And is that your understanding of the</p> <p>25 obviousness analysis?</p>	<p style="text-align: right;">Page 179</p> <p>1 CHARLES E. CLEMENS</p> <p>2 MS. HARGRAVE: Objection,</p> <p>3 mischaracterization.</p> <p>4 A. I believe we discussed that at length earlier,</p> <p>5 the two of those comments. Lines of questions don't</p> <p>6 make sense to me to connect.</p> <p>7 Q. (BY MR. WEIL) Let's go back to the first</p> <p>8 line. I am not talking about just dropping a device</p> <p>9 into another device. I am saying we've agreed that one</p> <p>10 of skill in the art would understand that a pen like</p> <p>11 Rhoades converts linear to rotational motion.</p> <p>12 MS. HARGRAVE: Objection,</p> <p>13 mischaracterization of the testimony.</p> <p>14 Q. (BY MR. WEIL) We've also -- my question now</p> <p>15 is -- well, let me strike that last part.</p> <p>16 We've talked about how the Rhoades pen works,</p> <p>17 converts linear to rotational motion. We've talked</p> <p>18 about dose counters that convert linear motion of a</p> <p>19 canister into rotational motion of a counter. Correct?</p> <p>20 MS. HARGRAVE: Objection,</p> <p>21 mischaracterization of the testimony.</p> <p>22 A. So, you know, those -- in a general sense, I</p> <p>23 had a very high level, and in the abstract that is true.</p> <p>24 These things appear at the surface to be doing similar</p> <p>25 things, but at the design level, at the detail level,</p>
<p style="text-align: right;">Page 180</p> <p>1 CHARLES E. CLEMENS</p> <p>2 you know, they are -- they're accomplished in sometimes</p> <p>3 vastly different ways. So conceptually, you know, from</p> <p>4 an outside viewpoint, they may appear to be doing the</p> <p>5 same thing, but on the inside, it's totally different.</p> <p>6 Q. (BY MR. WEIL) So conceptually at a high level</p> <p>7 one might understand that they could take the type of</p> <p>8 linear to rotational motion in a mechanism like in</p> <p>9 Rhoades and use it in a fluid dispenser to effectuate</p> <p>10 the rotational motion of the counter?</p> <p>11 MS. HARGRAVE: Objection, vague, calls</p> <p>12 for speculation.</p> <p>13 A. So the abstract theoretical question that</p> <p>14 you've posed to me is what it is. It's -- you know, if</p> <p>15 you're a person who believes anything is possible, I</p> <p>16 suppose you could apply that. But in terms of what I</p> <p>17 attempted to do in my reporting was to look at specific</p> <p>18 instances of design that were modified and combined and</p> <p>19 to try to analyze that.</p> <p>20 Q. (BY MR. WEIL) So in the needle injector</p> <p>21 systems we're looking at in Exhibit 1055 --</p> <p>22 So there are similar components in Rhoades and</p> <p>23 in an MDI. Correct?</p> <p>24 MS. HARGRAVE: Objection, vague.</p> <p>25 A. Which MDI are we referring to?</p>	<p style="text-align: right;">Page 181</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) Let's say Elliott. Do you</p> <p>3 recall Elliott?</p> <p>4 A. Sure. And which elements are you speaking to?</p> <p>5 Q. Well, I am really asking at a higher level.</p> <p>6 Do you understand both of these types of devices have</p> <p>7 gears. Correct?</p> <p>8 A. Yes. They do employ a gearing --</p> <p>9 Q. In both the MDIs and the pens have a fluid</p> <p>10 reservoir. Correct?</p> <p>11 MS. HARGRAVE: Objection, calls for legal</p> <p>12 opinion.</p> <p>13 A. They both have a reservoir of fluid, that's</p> <p>14 correct.</p> <p>15 Q. (BY MR. WEIL) And we've now discussed several</p> <p>16 times that they both in their mechanisms can convert the</p> <p>17 axial motion of the reservoir into rotational motion of</p> <p>18 a counter -- sorry. Let me strike that.</p> <p>19 They both can convert -- the mechanical</p> <p>20 mechanism of the MDI and the pen each converts linear</p> <p>21 motion of a piece into rotational motion of another</p> <p>22 piece. Is that correct?</p> <p>23 MS. HARGRAVE: Objection,</p> <p>24 mischaracterization of the testimony and vague.</p> <p>25 A. Yeah. So I mean like we've discussed at a</p>

<p style="text-align: right;">Page 182</p> <p>1 CHARLES E. CLEMENS</p> <p>2 high level, you know, from a basic mechanics standpoint,</p> <p>3 I can say that Rhoades converts a linear motion to a</p> <p>4 rotary motion. And, you know, Elliott is performing</p> <p>5 completely different methodology, components and design.</p> <p>6 So again -- and this is something I brought up much</p> <p>7 earlier, is that, you know, these characterizations that</p> <p>8 you would like to talk about are very -- in a design</p> <p>9 world, those are all very high level requirements. You</p> <p>10 know, essentially we have to somehow create a linear</p> <p>11 motion and a rotary motion, but inside there's a whole</p> <p>12 bunch of magic. And, you know, Rhoades, Elliott, all</p> <p>13 these designs are highly optimized, and they're unique,</p> <p>14 custom designs. And so when you're trying to make an</p> <p>15 analogy from one design to the other or trying to modify</p> <p>16 them and combine them, there's just a whole lot of</p> <p>17 detail in the design level that needs to happen in order</p> <p>18 for it to function and achieve that highest level design</p> <p>19 requirement. So unless we can get into more details of</p> <p>20 what this combination actually is, we can have a</p> <p>21 discussion about the -- you know, how these extremely</p> <p>22 high-level requirements get achieved at the design</p> <p>23 level.</p> <p>24 Q. (BY MR. WEIL.) One more question about the</p> <p>25 Exhibit 1055. In that IPR, you were testifying on</p>	<p style="text-align: right;">Page 183</p> <p>1 CHARLES E. CLEMENS</p> <p>2 behalf of the petitioner. Is that right?</p> <p>3 A. I was -- yes, the petitioner, that's correct.</p> <p>4 Q. It was your opinion that the claims were</p> <p>5 invalid?</p> <p>6 A. I know this says 2018, but I've actually got</p> <p>7 to go back. I haven't, you know, read this since then,</p> <p>8 but --</p> <p>9 Q. I guess if it helps, I can direct you to</p> <p>10 page 28.</p> <p>11 A. That's probably going to be helpful. Yes,</p> <p>12 that's correct.</p> <p>13 Q. I'm going to hand you what we've marked as</p> <p>14 Exhibit 1056.</p> <p>15 (Exhibit 1056 marked.)</p> <p>16 Q. (BY MR. WEIL.) Mr. Clemens, do you recognize</p> <p>17 Exhibit 1056?</p> <p>18 A. I believe -- I mean, I remember, you know, the</p> <p>19 timeframe and the -- and vaguely the lawsuit, but yes,</p> <p>20 this was a while ago.</p> <p>21 Q. This is an excerpt of a deposition transcript</p> <p>22 from the Novo Nordisk versus Sanofi lawsuit. Is that</p> <p>23 right?</p> <p>24 A. One of them. One of them, yes.</p> <p>25 Q. And was the product in that case or one of the</p>
<p style="text-align: right;">Page 184</p> <p>1 CHARLES E. CLEMENS</p> <p>2 products the SoloStar injection pen that you mentioned</p> <p>3 earlier?</p> <p>4 A. This is going to be challenging. I don't</p> <p>5 recall. I believe -- well, I guess it's best for me to</p> <p>6 say I'm not entirely sure.</p> <p>7 Q. Do you recall the subject matter of this</p> <p>8 lawsuit?</p> <p>9 A. Well, obviously it had to do with injector</p> <p>10 pens.</p> <p>11 Q. If we look at page 4 of Exhibit 1054 -- this</p> <p>12 is the one with page 98 of the transcript at the top.</p> <p>13 A. Okay.</p> <p>14 Q. Do you see the attorney asked you, How else</p> <p>15 would an engineer or one of ordinary skill in the art</p> <p>16 connect the tubular part to the nut, starting at line</p> <p>17 15? Oh, I'm sorry. I think I said the wrong exhibit</p> <p>18 number. Page 4 of Exhibit 1056. Do you see that</p> <p>19 question?</p> <p>20 A. The question is, How else would an engineer?</p> <p>21 That one?</p> <p>22 Q. Yeah. And in your answer, you're discussing</p> <p>23 trying to translate linear motion through a coupling. I</p> <p>24 am looking at the top of page 99.</p> <p>25 A. 99.</p>	<p style="text-align: right;">Page 185</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And whatever that connection means is backed</p> <p>3 down into a plunger.</p> <p>4 Do you see that?</p> <p>5 A. I am sorry. I am just taking a moment to read</p> <p>6 it.</p> <p>7 Q. Go ahead and read it if you would like.</p> <p>8 A. Okay.</p> <p>9 Q. And page 99 part of your answer you say "There</p> <p>10 may be at least a few more approaches that you might</p> <p>11 take to translate, you know, linear to rotational to</p> <p>12 linear or rotational to linear motion." Is that right?</p> <p>13 A. That is correct.</p> <p>14 Q. And you say "You can do that through gearing,</p> <p>15 you could do that through threads, those are basically</p> <p>16 typically basic machines that mechanical engineers use</p> <p>17 to do this kind of thing." Right?</p> <p>18 A. That's what's written in my report, yes.</p> <p>19 Q. And gears are used in the Rhoades whatever.</p> <p>20 Correct?</p> <p>21 MS. HARGRAVE: Objection, vague.</p> <p>22 A. You know, we're calling them cams, but gears</p> <p>23 essentially, you know, mechanically considered a gear.</p> <p>24 Q. (BY MR. WEIL.) If we keep reading at the</p> <p>25 bottom of that page?</p>

47 (Pages 182 to 185)

<p style="text-align: right;">Page 186</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Sure.</p> <p>3 Q. The attorney asks you for any other ways to</p> <p>4 convert linear and rotational and vice versa, and you do</p> <p>5 point out cams with springs at line 22.</p> <p>6 Do you see that?</p> <p>7 MS. HARGRAVE: Objection,</p> <p>8 mischaracterization.</p> <p>9 A. I am just reading it through. I do see that,</p> <p>10 yes. You might use cams with springs. That's what</p> <p>11 you're referring to, that sentence?</p> <p>12 Q. (BY MR. WEIL) And you were telling him ways</p> <p>13 that you might convert linear to rotational or</p> <p>14 rotational to linear motion. Is that right?</p> <p>15 MS. HARGRAVE: Objection,</p> <p>16 mischaracterization.</p> <p>17 Q. (BY MR. WEIL) Let me rephrase that.</p> <p>18 A. I was just trying to read it from context.</p> <p>19 That's all.</p> <p>20 Q. Sure. And take your time to read it if you</p> <p>21 need to, but you're explaining to him there are other</p> <p>22 ways of converting rotational motion into linear motion.</p> <p>23 Is that right?</p> <p>24 A. In this case there was a reference to a</p> <p>25 gearbox which one of the designs was utilizing. And so</p>	<p style="text-align: right;">Page 187</p> <p>1 CHARLES E. CLEMENS</p> <p>2 I was admitting, yes, there are other ways of converting</p> <p>3 rotational motion into linear motion.</p> <p>4 Q. And the other ways, here you say cams with</p> <p>5 springs is another way?</p> <p>6 A. And then I say you might use cams with</p> <p>7 springs.</p> <p>8 Q. And I am looking on page 100. You say there</p> <p>9 are almost always several approaches to convert. Right?</p> <p>10 MS. HARGRAVE: Objection,</p> <p>11 mischaracterization.</p> <p>12 A. So in general, you know, yes, that's -- in</p> <p>13 design, typically, you know, you have to take alternate</p> <p>14 approaches to achieving at the design level, at the</p> <p>15 detail level to achieve the higher level requirement. I</p> <p>16 mean, that's what engineers do, is they -- you know,</p> <p>17 they try to figure this out and invent something, but --</p> <p>18 Q. (BY MR. WEIL) So what you're saying -- I am</p> <p>19 just going to read from your testimony here,</p> <p>20 Engineers -- I am looking at line 10 of page 100.</p> <p>21 Engineers take these basic mechanisms and they apply it</p> <p>22 to whatever the product or whatever they are trying to</p> <p>23 achieve in a product. Right?</p> <p>24 A. Yes, as a general statement, that's true.</p> <p>25 Q. So we talked a lot about the Rhoades</p>
<p style="text-align: right;">Page 188</p> <p>1 CHARLES E. CLEMENS</p> <p>2 mechanism. Right?</p> <p>3 A. We have.</p> <p>4 Q. And we've discussed its axial and rotational</p> <p>5 motion. Correct?</p> <p>6 A. We have discussed that it's a retractable and</p> <p>7 a projecting mechanism, and it does have a cam that</p> <p>8 rotates.</p> <p>9 Q. And that cam is rotated after axial depression</p> <p>10 of a plunger?</p> <p>11 A. That's correct.</p> <p>12 Q. So is it your position that one skilled -- an</p> <p>13 engineer, one skilled in the art at the time of</p> <p>14 invention would not take that basic mechanism and try to</p> <p>15 apply it to other products such as, for example, an</p> <p>16 inhaler?</p> <p>17 MS. HARGRAVE: Objection, calls for</p> <p>18 speculation.</p> <p>19 A. So, again, you know, there are many -- as I</p> <p>20 point out in this declaration, of course there are many</p> <p>21 ways of attempting, you know, some high-level design</p> <p>22 requirements. Could you apply those? Well, most cases,</p> <p>23 you attempt to apply them, but, you know, you modify</p> <p>24 them at the detail level to somehow make them work.</p> <p>25 So -- and so is it possible to do -- you know,</p>	<p style="text-align: right;">Page 189</p> <p>1 CHARLES E. CLEMENS</p> <p>2 to do some of these things? Of course it's possible,</p> <p>3 but my point all along has been, so many of these</p> <p>4 details are missing. Sure, you can just make comments</p> <p>5 about, well, we're just going to convert linear to</p> <p>6 rotational, but that's not enough to make an obviousness</p> <p>7 analysis and that's the distinction. So --</p> <p>8 Q. (BY MR. WEIL) And you again brought it back</p> <p>9 to the obviousness analysis, and I am talking about --</p> <p>10 you've taken the position that Rhoades is not analogous</p> <p>11 art, one of skill would not look to that. But you said</p> <p>12 here that at a high level, your words, There are many</p> <p>13 ways of attempting, you know, some high-level design</p> <p>14 requirements. Could you apply those? Well, most cases</p> <p>15 you attempt to apply them.</p> <p>16 I'm not asking would you take the Rhoades</p> <p>17 mechanism out and plop it in. Would one of skill in the</p> <p>18 art know about the mechanism of Rhoades, how it converts</p> <p>19 axial to rotational motion and consider that they might</p> <p>20 use that in an inhaler to operate a dose counter?</p> <p>21 MS. HARGRAVE: Objection, calls for</p> <p>22 speculation.</p> <p>23 A. Anybody skilled in the art having knowledge of</p> <p>24 all of these mechanisms certainly could at a high level</p> <p>25 make that -- make that leap, but when you look at the</p>

<p style="text-align: right;">Page 190</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Rhoades and you see what its objective is and what it's</p> <p>3 achieving and you compare that to what the MDIs are</p> <p>4 attempting to do, in particular the '177, which is</p> <p>5 adding critical safety capability to a counting</p> <p>6 mechanism, in an inhaler it's very hard to make that</p> <p>7 analogy.</p> <p>8 Q. (BY MR. WEIL) Okay. You can set that exhibit</p> <p>9 aside for now.</p> <p>10 A. Okay.</p> <p>11 Q. And can we turn to paragraph 53 of your</p> <p>12 report? And again, we're still on the '177 report. Are</p> <p>13 you there?</p> <p>14 A. Yes. I am sorry.</p> <p>15 Q. And in this paragraph, you're discussing</p> <p>16 additional references that the petitioner cited to that</p> <p>17 mention pen mechanisms. Correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And the first one is the Ambrosio patent. Is</p> <p>20 that right?</p> <p>21 A. Correct.</p> <p>22 Q. And that patent discusses a U.K. patent named</p> <p>23 Auvinent. Right?</p> <p>24 A. Yes.</p> <p>25 Q. I will just hand you Ambrosio so you'll have</p>	<p style="text-align: right;">Page 191</p> <p>1 CHARLES E. CLEMENS</p> <p>2 it in case you need it, and this is an exhibit that's</p> <p>3 been marked as Exhibit 1031, in the '177 IPR. And do</p> <p>4 you recognize that this is the Ambrosio patent that</p> <p>5 we're talking about?</p> <p>6 A. Yes, it is.</p> <p>7 Q. So setting aside your teaching away, we can at</p> <p>8 least agree that these inventors in Ambrosio knew of</p> <p>9 mechanical pens as potential mechanisms. Correct?</p> <p>10 MS. HARGRAVE: Objection, vague.</p> <p>11 A. Well, I totally agree that these -- all these</p> <p>12 people were familiar with pens certainly.</p> <p>13 Q. (BY MR. WEIL) So your criticism of Ambrosio</p> <p>14 in paragraph 53 is that it teaches away from the</p> <p>15 mechanism disclosed in Auvinent. Right?</p> <p>16 A. I believe -- I would have to read it again to</p> <p>17 see the specific paragraphs, but I believe it is</p> <p>18 referring to Auvinent, you know, which actually is the</p> <p>19 reference that teaches away.</p> <p>20 Q. And if you look at column 2, line -- probably</p> <p>21 35 of Ambrosio, that's the paragraph that discusses</p> <p>22 Auvinent. Is that correct?</p> <p>23 A. Well, yes, it references U.K. patent, right --</p> <p>24 Q. Uh-huh.</p> <p>25 A. -- to Auvinent.</p>
<p style="text-align: right;">Page 192</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And Auvinent uses a rotatable rod to deliver</p> <p>3 the medicinal powder. Right?</p> <p>4 A. Yes, I believe it does.</p> <p>5 Q. And according to Ambrosio, the mechanism for</p> <p>6 rotating that rod is an indexing mechanism much like the</p> <p>7 ballpoint pen. Right?</p> <p>8 A. I am just trying to remember. Where is that</p> <p>9 stated?</p> <p>10 Q. It would be line 45, it starts.</p> <p>11 A. Let's see here. Okay. I see that. Right.</p> <p>12 And then it follows by saying that this arrangement is</p> <p>13 disadvantageous from a delivery standpoint.</p> <p>14 Q. And it's disadvantageous from a delivery</p> <p>15 standpoint because the dry powder sticks to the cup like</p> <p>16 plastic rod. Correct?</p> <p>17 A. Well, I think that when you consider what</p> <p>18 they're using it for, that has to be part of its</p> <p>19 delivery process. So, yes, I see that as one aspect of</p> <p>20 the -- what they call out, but is that -- you know, is</p> <p>21 that because of the means by which it's operating? I</p> <p>22 mean, I think that's essentially what this is saying, is</p> <p>23 that this mechanism of delivery is not effective.</p> <p>24 Q. And that mechanism is disadvantageous because</p> <p>25 the powder sticks to the plastic. Right?</p>	<p style="text-align: right;">Page 193</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Well, that's an aspect of it.</p> <p>3 Q. If you rotated the rod with your fingers and</p> <p>4 the powder still stuck to it, would it be equally</p> <p>5 disadvantageous?</p> <p>6 MS. HARGRAVE: Objection, calls for</p> <p>7 speculation.</p> <p>8 A. Yeah, I mean, I haven't done any design work</p> <p>9 with this. I would be speculating on anything I would</p> <p>10 say relative to, you know, the fine design details of</p> <p>11 it. But, you know, it's indicating to me that, you</p> <p>12 know, cup like features on a rod rotating isn't working</p> <p>13 out. It's not advantageous.</p> <p>14 Q. (BY MR. WEIL) But that statement has nothing</p> <p>15 to do with the mechanism of how the rod is being</p> <p>16 rotated. Correct?</p> <p>17 MS. HARGRAVE: Objection, calls for</p> <p>18 speculation.</p> <p>19 A. It's -- it is a particular design that is</p> <p>20 described and it is not effective. So I would have to</p> <p>21 take it at its face.</p> <p>22 Q. (BY MR. WEIL) Let's just go step by step</p> <p>23 then. The device for rotating the rod is much like a</p> <p>24 pen. Correct?</p> <p>25 MS. HARGRAVE: Objection, vague.</p>

CHARLES E. CLEMENS

A. Well, you know, it's just -- you know, like it says here, it's an indexing mechanism much like a ballpoint pen. So we can agree on that.

Q. (BY MR. WEIL) Okay. And it's your understanding of when a reference teaches away -- let me restart that.

It's your understanding that a reference teaches away if it indicates that a certain confirmation is disadvantageous for any reason at all. Is that right?

MS. HARGRAVE: Objection, mischaracterization.

A. I don't presume to know exactly, you know, how the writer was necessarily putting this excerpt in, but what -- the read I take off of it is that this method of rotating a cup like feature, it didn't work out from a delivery standpoint. So that's usually a sign that you should probably avoid, you know, what the mechanism is, you know, if your goal is to have good delivery, good drug delivery.

Q. (BY MR. WEIL) Does a fluid dispenser deliver powder?

MS. HARGRAVE: Objection, vague.

A. Which dispenser are you talking about?

CHARLES E. CLEMENS

Q. (BY MR. WEIL) The '177 Patent claims covers fluid dispensers. Correct?

A. Oh, does it include fluids? Yes.

Q. Not does it include fluids, does it include powders?

A. Oh, well, that's obviously -- the '177 Patent doesn't mention any powder drugs.

Q. And a fluid dispenser that's claimed in the '177 Patent would not be dispensing powder. Correct?

A. So it's vague. It's a little abstract. I would have to say that in one sense maybe you certainly wouldn't consider it. In another sense, it's intriguing. It may work. I don't know. That's me speculating on the potential of, you know, what you're proposing.

Q. But you understand what the claims cover. Correct?

A. The '177 claims?

Q. Correct.

A. Yes.

Q. And they cover a fluid dispenser. Correct?

A. They cover a fluid dispenser.

Q. They don't cover a dry powder dispenser, right?

CHARLES E. CLEMENS

A. The claims do not have the words "dry powder."

Q. But your understanding of this discussion in Ambrosio is because this mechanism did not work for delivering dry powder, one wouldn't try to rotate a component using a pen like mechanism?

MS. HARGRAVE: Objection, mischaracterization.

A. All I'm saying is that this particular reference is saying that it is disadvantageous.

Q. (BY MR. WEIL) Delivery is disadvantageous. Is that right?

A. From a delivery standpoint.

Q. And it's delivering powder. Correct?

A. It is delivering powder.

Q. And when a reference says that it's disadvantageous, it's your understanding that that reference teaches away. Is that correct?

MS. HARGRAVE: Objection to mischaracterization.

A. Well, off the top of my head, I can't say that I have the complete legal definition in my head, but when a patent says that something is disadvantageous, that is a clear sign that that's something that's not -- that is to be avoided.

CHARLES E. CLEMENS

Q. (BY MR. WEIL) And if we go to paragraph 54, you're discussing the Wimpenny reference.

Do you see that?

A. Yes.

Q. And Wimpenny was cited by petitioners for its discussion of the ballpoint pen principle disclosed in the prior art Patent DE 3,814,023. Correct?

A. Correct.

Q. But then Wimpenny states -- according to paragraph 54 you say "Wimpenny states that the ballpoint pen mechanism does not address the problem of incorrect dose setting by the user." Is that right?

A. Yes, that's what's written. Correct.

Q. So why does Wimpenny's distinction over their prior art about setting the problem of incorrect dose setting have anything to do with the ballpoint pen principle that it's discussing?

A. I'm sorry. Ask again.

Q. Sure.

Why does Wimpenny's distinction over the prior art, this DE 3,814,023, about to set the problem of incorrect dose setting have anything to do with the ballpoint pen principle that it's discussing?

A. I would have to refresh my memory and take a

<p style="text-align: right;">Page 198</p> <p>1 CHARLES E. CLEMENS</p> <p>2 look at this citing again so I could be accurate.</p> <p>3 Q. But according to your declaration, your</p> <p>4 opinion is that because Wimpenny states that the</p> <p>5 ballpoint pen mechanism does not address the problem of</p> <p>6 incorrect dose setting, that's why it teaches away. Is</p> <p>7 that right?</p> <p>8 A. Well, you know, it just comes out and states</p> <p>9 it, that, you know, the ballpoint pen mechanism doesn't</p> <p>10 address the problem of incorrect dose setting by a user.</p> <p>11 Q. And you're talking about teaching away in this</p> <p>12 section. Correct?</p> <p>13 A. Yes.</p> <p>14 Q. So that's your reason why you think this</p> <p>15 reference teaches away. Correct?</p> <p>16 A. That's what's written in paragraph 54.</p> <p>17 Q. Do the claims of "177 Patent require use of</p> <p>18 an MDI?</p> <p>19 MS. HARGRAVE: Objection, vague.</p> <p>20 A. As opposed to what?</p> <p>21 Q. (BY MR. WEIL) A fluid dispenser generally.</p> <p>22 Let me start it differently and maybe we can go faster.</p> <p>23 It's your understanding that the claims of the</p> <p>24 "177 Patent cover a fluid dispenser. Correct?</p> <p>25 A. That's correct.</p>	<p style="text-align: right;">Page 199</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. Does that fluid dispenser have to be an MDI?</p> <p>3 A. Well, I would say that the inventors meant for</p> <p>4 this to be a fluid products dispenser in general, but in</p> <p>5 particular or more particularly, to such a dispenser</p> <p>6 included in a dose indicator device for indicating their</p> <p>7 use -- the user of the number of doses that have been</p> <p>8 dispensed or remain to be dispensed from a reservoir of</p> <p>9 a said fluid dispenser, which sounds suspiciously like</p> <p>10 an MDI.</p> <p>11 Q. Right. My question is about the challenge</p> <p>12 claims in this IPR. Do those claims require use of an</p> <p>13 MDI?</p> <p>14 A. I would say no. I would say they are broadly</p> <p>15 written, referring to a fluid dispenser.</p> <p>16 Q. Do the claims, the challenge claims of the</p> <p>17 patents require close manufacturing tolerances?</p> <p>18 A. I do not believe that close tolerances are in</p> <p>19 the claim language.</p> <p>20 Q. And do the claims require the use of a drug?</p> <p>21 A. I do not -- it's referring to a dose, but I do</p> <p>22 not see where a drug is specifically in the claim</p> <p>23 language.</p> <p>24 Q. If we jump ahead to paragraph 61 there in the</p> <p>25 last sentence you say that Rhoades expressly teaches</p>
<p style="text-align: right;">Page 200</p> <p>1 CHARLES E. CLEMENS</p> <p>2 away from the use of close manufacturing tolerances.</p> <p>3 Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. And is that based on the passage of Rhoades</p> <p>6 that says "None of the operating parts of the projecting</p> <p>7 retracting mechanism in accordance with my invention</p> <p>8 requires close manufacturing tolerances for dependable</p> <p>9 operation." And that is column 8, lines 14 to 16, if</p> <p>10 you want to look. And that's what you cited --</p> <p>11 A. Yeah, that's what I cited there.</p> <p>12 MS. HARGRAVE: Just so the record is</p> <p>13 clear, you just referred to lines 14 to 16.</p> <p>14 MR. WEIL: Correct.</p> <p>15 MS. HARGRAVE: And he cited lines 6 to</p> <p>16 16.</p> <p>17 Q. (BY MR. WEIL) Okay. Let me ask a different</p> <p>18 question.</p> <p>19 In the passage between lines 6 to 16, what in</p> <p>20 that passage tells you that Rhoades teaches away?</p> <p>21 A. Yeah, so the lines obviously that I'm</p> <p>22 referring to are talking about the construction of this</p> <p>23 mechanism, and it essentially finishes with none of the</p> <p>24 operating parts, which they've previously described of</p> <p>25 this projecting and retracting mechanism in accordance</p>	<p style="text-align: right;">Page 201</p> <p>1 CHARLES E. CLEMENS</p> <p>2 with my invention requires close manufacturing</p> <p>3 tolerances.</p> <p>4 Q. And it's your understanding that if the</p> <p>5 reference says close manufacturing tolerances are not</p> <p>6 required, that teaches away from using them?</p> <p>7 MS. HARGRAVE: Objection,</p> <p>8 mischaracterization.</p> <p>9 A. What it tells a person of skill in the art is</p> <p>10 that the parts and the manufacturing processes that are</p> <p>11 being used are intentionally avoiding designs and</p> <p>12 processes that use close manufacturing tolerances, so</p> <p>13 the opposite.</p> <p>14 Q. (BY MR. WEIL) So you understand that that</p> <p>15 teaches other people not to use close manufacturing</p> <p>16 tolerances. Is that right?</p> <p>17 MS. HARGRAVE: Objection,</p> <p>18 mischaracterization.</p> <p>19 A. It is teaching that the design approach that</p> <p>20 has been taken for that mechanism has been intentionally</p> <p>21 used to avoid such tight manufacturing needs.</p> <p>22 Q. (BY MR. WEIL) Okay. Let's jump ahead to</p> <p>23 Bason in view of Rhoades. I just have a couple of</p> <p>24 questions about paragraph 77.</p> <p>25 A. Okay.</p>

<p style="text-align: right;">Page 202</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And my question is -- and you understand that</p> <p>3 here we're discussing if the cam body was bonded to the</p> <p>4 canister and they both rotated, that's what we're</p> <p>5 discussing in this paragraph. Is that right?</p> <p>6 A. Uh-huh. That's correct.</p> <p>7 Q. And it's your understanding that that would</p> <p>8 rotate the stem within the stem block?</p> <p>9 A. That's correct.</p> <p>10 Q. Can the canister rotate about the stem?</p> <p>11 A. In the valve designs certainly that I've seen</p> <p>12 and am familiar with, that isn't how they're</p> <p>13 constructed. I haven't looked at and analyzed all of</p> <p>14 the valve designs, but as it was described here, it</p> <p>15 would cause the stem to rotate and that would be a</p> <p>16 problem.</p> <p>17 Q. Well, the petition doesn't say anything about</p> <p>18 the stem rotating. Correct?</p> <p>19 A. Generally, that is -- that is how these valves</p> <p>20 work.</p> <p>21 Q. So if the canister was able to rotate around</p> <p>22 the stem, you would not have these concerns about</p> <p>23 frictional wear on the ceiling surfaces between the</p> <p>24 valve stem and valve block that you're referring to</p> <p>25 here?</p>	<p style="text-align: right;">Page 203</p> <p>1 CHARLES E. CLEMENS</p> <p>2 MS. HARGRAVE: Objection, calls for</p> <p>3 speculation, mischaracterization.</p> <p>4 A. Well, yes, as with any set of assumptions that</p> <p>5 you would like to make, you know, if this, not that. If</p> <p>6 all the negative aspects that I'm calling out don't</p> <p>7 occur, then that particular aspect wouldn't matter then.</p> <p>8 Q. (BY MR. WEIL) Let me ask you a little more</p> <p>9 straightforward. If the stem does not rotate in the</p> <p>10 valve stem -- if the valve stem does not rotate in the</p> <p>11 valve block, you would not have these problems which you</p> <p>12 identify frictional wear on the sealing surfaces.</p> <p>13 Correct?</p> <p>14 MS. HARGRAVE: Objection, calls for</p> <p>15 speculation, mischaracterization.</p> <p>16 A. So if the canisters and the valve systems</p> <p>17 that -- you know, that I'm familiar with as a person</p> <p>18 skilled in the art at the time of the invention, they</p> <p>19 did not rotate independently; therefore, the stem would</p> <p>20 be attempting to rotate in its fitment and that would be</p> <p>21 a problem for delivery.</p> <p>22 Q. (BY MR. WEIL) And when you say the canisters</p> <p>23 you're familiar with, which ones did you look at that</p> <p>24 you're talking about?</p> <p>25 A. Well, again, I didn't do an exhaustive</p>
<p style="text-align: right;">Page 204</p> <p>1 CHARLES E. CLEMENS</p> <p>2 research on all of the canisters, but in my experience</p> <p>3 back in this timeframe in the early 2000s, all the</p> <p>4 canisters that I was familiar with as a person of skill</p> <p>5 in the art did not have that functionality that you're</p> <p>6 describing.</p> <p>7 Q. So you can't identify by name for me any of</p> <p>8 the canisters you're referring to?</p> <p>9 A. Back in 2003, off the top of my head, I can't</p> <p>10 remember.</p> <p>11 Q. And just so I'm clear, are you saying that</p> <p>12 those canisters could not rotate around the stem or that</p> <p>13 wasn't the intention of the canisters or you don't know?</p> <p>14 MS. HARGRAVE: Objection, compound.</p> <p>15 Q. (BY MR. WEIL) Do you want me to ask it in</p> <p>16 separate questions?</p> <p>17 A. Okay.</p> <p>18 Q. Just so I'm clear, are you saying those</p> <p>19 canisters could not rotate around the stem?</p> <p>20 A. That is the design aspect of the canisters,</p> <p>21 yes, at that time.</p> <p>22 Q. And do you know if they actually were able to</p> <p>23 rotate and they just weren't designed that way?</p> <p>24 A. So from my analysis, I would say that they</p> <p>25 just did not operate that way.</p>	<p style="text-align: right;">Page 205</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. Did you ever try to rotate a canister about a</p> <p>3 stem?</p> <p>4 A. Actually, yes, of course. You know, as an</p> <p>5 engineer, you're always playing around with them.</p> <p>6 Q. And were you unable to rotate it around the</p> <p>7 stem?</p> <p>8 A. Oh, without causing it damage.</p> <p>9 Q. Do you remember which canister you tried to</p> <p>10 rotate?</p> <p>11 A. I'm sorry, I don't. I don't have memory of</p> <p>12 specific names or brands.</p> <p>13 Q. If we look at paragraph 78, in that paragraph</p> <p>14 you say that petitioners do not describe the connections</p> <p>15 between counting rings 4 and 5 and cap 14, including</p> <p>16 various features. Is that right?</p> <p>17 A. I am just going to read it through real</p> <p>18 quick --</p> <p>19 Q. Sure. Go for it.</p> <p>20 A. Okay. Thank you. I've got it.</p> <p>21 Q. And so you're referring to Bason rings 4 and 5</p> <p>22 and cap 14. Correct?</p> <p>23 A. Yeah, essentially all of the counting -- the</p> <p>24 components that relate to the counting means which, of</p> <p>25 course, would include all these other features.</p>

<p style="text-align: right;">Page 206</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And you're saying petitioners do not describe</p> <p>3 the connections between them. Is that right?</p> <p>4 A. There is no description of how any of the --</p> <p>5 there's almost no description whatsoever how to -- how a</p> <p>6 user would be able to visually see the dose counts on</p> <p>7 the outside of the device and all of the interconnecting</p> <p>8 components that would replicate what is happening, you</p> <p>9 know, with all these connections of Bason's rings and</p> <p>10 cap and the -- I can't remember the specific names, but</p> <p>11 all these other components that are required to count.</p> <p>12 So none of that detail is present. Just a high level,</p> <p>13 it could happen.</p> <p>14 Q. Well, if you look at paragraph 75, you say</p> <p>15 "Bason ring 4 cannot meet this claim element because</p> <p>16 Bason ring 4 is not present in the asserted Bason</p> <p>17 Rhoades combination."</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. So why is it you expect the described</p> <p>21 connections to a component that's not present?</p> <p>22 A. Well, did I list four there? I mean, you</p> <p>23 know, there's seven other parts that need to be</p> <p>24 connected; but if I added that four there, that's</p> <p>25 probably -- shouldn't be there because it's replaced by</p>	<p style="text-align: right;">Page 207</p> <p>1 CHARLES E. CLEMENS</p> <p>2 the cam.</p> <p>3 Q. In paragraph 86, you say that the cam body</p> <p>4 cannot cooperate with the ink reservoir.</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do see that now.</p> <p>7 Q. Would you agree that two pieces cooperate with</p> <p>8 each other when the movement of one causes the other to</p> <p>9 also move in the same direction with respect to the</p> <p>10 other components?</p> <p>11 MS. HARGRAVE: Objection, vague.</p> <p>12 A. The configuration that is proposed by</p> <p>13 petitioners bonds the cam body to their ink reservoir so</p> <p>14 it acts as one single part. So there's no cooperation.</p> <p>15 It's been forced to be one part.</p> <p>16 Q. (BY MR. WEIL) And it's your position that</p> <p>17 that means that they don't cooperate. Is that right?</p> <p>18 A. They're acting in unison.</p> <p>19 Q. So if you look at paragraph 93, page 43 of</p> <p>20 your '177 declaration.</p> <p>21 A. 93?</p> <p>22 Q. Yeah.</p> <p>23 A. Got it.</p> <p>24 Q. And here you're discussing secondary</p> <p>25 considerations of nonobviousness. Correct?</p>
<p style="text-align: right;">Page 208</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Yes, that's the section, yeah.</p> <p>3 Q. Now are you familiar with the FDA's guidance</p> <p>4 in 2003?</p> <p>5 A. Yes, I'm aware of it.</p> <p>6 Q. Just so you have a copy of it, let me hand you</p> <p>7 what's Exhibit 1013 from the '177 Patent IPR.</p> <p>8 A. Thank you.</p> <p>9 Q. And if we look at your paragraph 91 --</p> <p>10 A. 91?</p> <p>11 Q. Yeah.</p> <p>12 A. Okay.</p> <p>13 Q. I'm sorry, not 91.</p> <p>14 A. 93?</p> <p>15 Q. I think so.</p> <p>16 MR. WEIL: Actually, could we take a</p> <p>17 quick break?</p> <p>18 MS. HARGRAVE: Sure.</p> <p>19 (Break from 4:45 p.m. to 4:52 p.m.)</p> <p>20 Q. (BY MR. WEIL) Okay. Mr. Clemens, so I handed</p> <p>21 you the Exhibit 1013 from the '177 Patent IPR.</p> <p>22 Correct?</p> <p>23 A. That's correct.</p> <p>24 Q. You recognize that as the 2003 guidance</p> <p>25 document. Is that right?</p>	<p style="text-align: right;">Page 209</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. I do.</p> <p>3 Q. So if we look at page -- page number on the</p> <p>4 document itself, page number 2. In the background</p> <p>5 section, about five lines down, maybe six, do you see it</p> <p>6 says a currently available MDIs offer no practical way</p> <p>7 for patients to track the remaining numbers of doses or</p> <p>8 amount of medication?</p> <p>9 Do you see that?</p> <p>10 A. I do see that.</p> <p>11 Q. Do you know whether any commercially available</p> <p>12 MDI at the time of the 2003 guidance included a dose</p> <p>13 counter?</p> <p>14 A. As of March 2003?</p> <p>15 Q. Correct.</p> <p>16 A. I do not think so.</p> <p>17 Q. But you are aware of a number of prior art</p> <p>18 dose counters. Right?</p> <p>19 A. There are patents that we're considering have</p> <p>20 prior art, yes.</p> <p>21 Q. And fluid dispensers having counting</p> <p>22 mechanisms were well-known at the time of the invention.</p> <p>23 Right?</p> <p>24 MS. HARGRAVE: Objection, vague.</p> <p>25 A. At least conceptually.</p>

<p style="text-align: right;">Page 210</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) The FDA --</p> <p>3 A. Nothing that had been produced, though, I</p> <p>4 think is what we're saying.</p> <p>5 Q. Does the FDA's 2003 guidance state that those</p> <p>6 counters that were known at that time were not accurate?</p> <p>7 A. I will just take a minute to read it.</p> <p>8 Q. Sure. Go for it.</p> <p>9 A. Okay. I have read the -- I have read the</p> <p>10 background section. What was your question?</p> <p>11 Q. The guidance does not state that those dose</p> <p>12 counters that were known at the time were not accurate,</p> <p>13 does it?</p> <p>14 MS. HARGRAVE: Objection, vague.</p> <p>15 A. That the dose counter -- well, I think we</p> <p>16 established that there were not any dose counters.</p> <p>17 Q. (BY MR. WEIL) Not commercially available dose</p> <p>18 counters. Right?</p> <p>19 A. Correct.</p> <p>20 Q. But there were some known in the prior art.</p> <p>21 Correct?</p> <p>22 A. There were some conceptual ones in patents in</p> <p>23 the prior art, that's correct.</p> <p>24 Q. And does the guidance say that those were not</p> <p>25 accurate?</p>	<p style="text-align: right;">Page 211</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. The guidance, to my knowledge and just sitting</p> <p>3 here today, doesn't make reference to anything that has</p> <p>4 to do with patents.</p> <p>5 Q. Let's look at paragraph 91 of your report.</p> <p>6 It's the very last few words on page 42. Do you see it</p> <p>7 says "Further, the Bason design already reflected the</p> <p>8 FDA's recommendation for dose counting."</p> <p>9 Do you see that?</p> <p>10 A. Yes, I see that.</p> <p>11 Q. And that was your opinion; it's in your</p> <p>12 report. Right?</p> <p>13 A. Correct.</p> <p>14 Q. So you agree with me that there were known</p> <p>15 methods of dose counting that were accurate enough for</p> <p>16 the FDA. Right?</p> <p>17 MS. HARGRAVE: Objection,</p> <p>18 mischaracterization.</p> <p>19 A. Well, you know, Bason obviously is a</p> <p>20 conceptual design. At that time it had not been</p> <p>21 produced, but it is a design that included a counter</p> <p>22 which was what the FDA was recommending. So, you know,</p> <p>23 it had the design itself. The concept, the invention</p> <p>24 possessed a counter. So if it had a counter, what would</p> <p>25 be the motivation to give it another one?</p>
<p style="text-align: right;">Page 212</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. (BY MR. WEIL) So in 2003, there were designs</p> <p>3 like the Bason design already known. Correct?</p> <p>4 A. There were some -- there were patented</p> <p>5 concepts that were out there as prior art, yes, that's</p> <p>6 correct.</p> <p>7 Q. And they just were not being used</p> <p>8 commercially. Correct?</p> <p>9 A. They had not been reduced to a commercial</p> <p>10 product, correct.</p> <p>11 Q. Have you reviewed or are you aware of any</p> <p>12 evidence that Merck tried but failed to develop an</p> <p>13 accurate dose counter as of 2003?</p> <p>14 MS. HARGRAVE: Objection, calls for</p> <p>15 speculation.</p> <p>16 Q. (BY MR. WEIL) And maybe just to be clear in</p> <p>17 my question, I am asking if you have reviewed any</p> <p>18 evidence that Merck tried but failed to develop an</p> <p>19 accurate dose counter as of 2003?</p> <p>20 A. I do not have any personal evidence to that.</p> <p>21 Q. And have you reviewed any evidence that 3M</p> <p>22 tried but failed to develop an accurate dose counter as</p> <p>23 of 2003?</p> <p>24 A. I am not knowledgeable to any inside company</p> <p>25 information for 3M, other than what's been published.</p>	<p style="text-align: right;">Page 213</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And before the FDA's guidance, were</p> <p>3 manufacturers permitted to sell MDIs without dose</p> <p>4 counters?</p> <p>5 A. Before the guidance, none of them had</p> <p>6 counters, so obviously they were sold.</p> <p>7 Q. And after the FDA's guidance, that's when</p> <p>8 manufacturers began developing products that included</p> <p>9 dose counters. Is that right?</p> <p>10 A. Yes, that is correct.</p> <p>11 Q. Okay.</p> <p>12 MS. HARGRAVE: Objection, vague to the</p> <p>13 previous question.</p> <p>14 Q. (BY MR. WEIL) So let's go to your other</p> <p>15 declaration. Again, we've covered all the duplicative</p> <p>16 material, so I am not going to ask you again about how</p> <p>17 Rhoades works.</p> <p>18 A. All the same --</p> <p>19 Q. All the same stuff.</p> <p>20 You agree with me that the things that are</p> <p>21 common we don't have to talk about again. Right?</p> <p>22 A. Yes, I agree. I would say insofar as the</p> <p>23 additional information somehow doesn't affect it, but as</p> <p>24 long as they're completely transferable, yes, I agree.</p> <p>25 Q. Okay. That's fair.</p>

<p style="text-align: right;">Page 214</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Let me hand you the '631 Patent. I am handing</p> <p>3 you what's been marked Exhibit 1001 in the '631 Patent's</p> <p>4 IPR. I know we've talked about the "177 Patent</p> <p>5 earlier. Is it your understanding that the specs of</p> <p>6 these patents are the same except for the related -- the</p> <p>7 information at the beginning of column 1?</p> <p>8 A. I believe that is true.</p> <p>9 Q. Do the claims -- I am talking about the</p> <p>10 claims -- do the claims -- let's start off. You</p> <p>11 understand that all the claims, claims 1 through 4, were</p> <p>12 challenged in the IPR. Correct?</p> <p>13 A. Yes, I agree.</p> <p>14 Q. Do the claims require any specific safety</p> <p>15 feature?</p> <p>16 A. You mean, are safety features described as</p> <p>17 such in the claims?</p> <p>18 Q. I mean -- let me break it down a little bit.</p> <p>19 Let's look at claim 1, for example. Claim 1 describes</p> <p>20 several components and how they move axially and/or in</p> <p>21 rotation. Correct?</p> <p>22 A. Yes, I see that 1 and 2 are describing the two</p> <p>23 members that displace and rotate.</p> <p>24 Q. And do those motions necessarily provide any</p> <p>25 particular safety feature?</p>	<p style="text-align: right;">Page 215</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. I agree that there is nothing mentioned in the</p> <p>3 claims here that specifically call out a safety feature.</p> <p>4 Q. I am going to hand you what's been marked as</p> <p>5 Exhibit 1006 in the '631 IPR. This is the ALLSOP</p> <p>6 reference. Mr. Clemens, do you recognize this exhibit?</p> <p>7 A. I do.</p> <p>8 Q. If we turn to paragraph 34 of your</p> <p>9 declaration, and this is the declaration in this IPR.</p> <p>10 A. Got it.</p> <p>11 Q. You see there are pictures of 1 and 3 that you</p> <p>12 have annotated just below paragraph 34. Right?</p> <p>13 A. That's correct.</p> <p>14 Q. Did you make those annotations?</p> <p>15 A. I believe I took them from Piper.</p> <p>16 Q. So if we look at page 18, do you see that</p> <p>17 figure?</p> <p>18 A. Okay.</p> <p>19 Q. Do you recognize that as the figure from</p> <p>20 Mr. Piper's --</p> <p>21 A. Yes, I see that.</p> <p>22 Q. And then the figures on page 20, are those the</p> <p>23 ones that you made?</p> <p>24 A. Yes, those are the ones that are -- that I</p> <p>25 have made, yeah.</p>
<p style="text-align: right;">Page 216</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And do you see you've drawn the cap in black.</p> <p>3 Is that correct?</p> <p>4 A. Correct.</p> <p>5 Q. Is that your understanding of what a push</p> <p>6 button cap looks like?</p> <p>7 A. So, you know, I was sort of rendering or</p> <p>8 trying to capture, you know, this idea that Piper had,</p> <p>9 but I believe what is described in ALLSOP is -- it's a</p> <p>10 cap that's -- well, ALLSOP says it's a part of the</p> <p>11 housing, but it's something that just covers the top for</p> <p>12 protection against dust. So it's sort of like a dust</p> <p>13 cover.</p> <p>14 Q. We can look at ALLSOP. Specifically, it's</p> <p>15 page 8, line 22. Do you see it's specifically referring</p> <p>16 to a push button cap? Correct?</p> <p>17 A. So I'll just read it so that we can have the</p> <p>18 same information. A push button cap not shown may be</p> <p>19 provided as part of the main housing 10 to cover the</p> <p>20 upper portion of the pressurized dispensing container</p> <p>21 15. So it somehow is part of housing 10 and it's</p> <p>22 covering, you know, the whole top of this container</p> <p>23 here. So advantageously, this prevents the ingress of</p> <p>24 dust contaminants and moisture into the apparatus. So I</p> <p>25 imagine it's covering the whole top.</p>	<p style="text-align: right;">Page 217</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. I guess my question is really it sounds to me</p> <p>3 like you're just describing a cap on the top, but this</p> <p>4 is called a push button cap. Right?</p> <p>5 A. That's -- that's what's written in the patent.</p> <p>6 Q. Does your picture have a button included on</p> <p>7 it?</p> <p>8 MS. HARGRAVE: Objection, vague.</p> <p>9 A. Well, I am sorry, the black part?</p> <p>10 Q. (BY MR. WEIL) Yeah.</p> <p>11 A. Are we referring to that picture?</p> <p>12 Q. Yeah.</p> <p>13 A. And you're saying does it have a push button?</p> <p>14 Q. Is there a button on the black part of the cap</p> <p>15 you've drawn? A push button, yes.</p> <p>16 A. Well, from what I'm reading here, they're just</p> <p>17 calling that a push button cap. It's a name.</p> <p>18 Q. So your understanding of cap and push button</p> <p>19 cap are exactly the same?</p> <p>20 A. My understanding is coming from reading from</p> <p>21 the patent from somebody skilled in the art. You know,</p> <p>22 the inventor states a push button cap not shown may be</p> <p>23 provided. So he's giving this a name, just like all the</p> <p>24 other parts of the device.</p> <p>25 Q. If we look back to Mr. Piper's drawing, which</p>

<p style="text-align: right;">Page 218</p> <p>1 CHARLES E. CLEMENS</p> <p>2 is on page 18 of your report, do you see his cap is</p> <p>3 drawn in green?</p> <p>4 A. Yes.</p> <p>5 Q. And his cap has an additional rectangle at the</p> <p>6 top.</p> <p>7 Do you see that?</p> <p>8 A. Okay. Yes, I see that.</p> <p>9 Q. And yours does not have that component</p> <p>10 picture. Correct?</p> <p>11 A. The image on the next page black does not show</p> <p>12 us an additional top to it, and nor does -- is anything</p> <p>13 like that described in ALLSOP.</p> <p>14 Q. And a push button was something that was</p> <p>15 well-known to those skilled in the art at the time of</p> <p>16 the invention. Right?</p> <p>17 MS. HARGRAVE: Objection, vague.</p> <p>18 A. I mean, holy cow, that's so broad. A push</p> <p>19 button of what kind?</p> <p>20 Q. (BY MR. WEIL) Well, Rhoades refers to a push</p> <p>21 button we've already talked about at length. Right?</p> <p>22 A. Well, there's thousands and thousands of push</p> <p>23 button designs. What are you referring to?</p> <p>24 Q. I think you answered it. Those skilled in the</p> <p>25 art would know of this type of component. Right?</p>	<p style="text-align: right;">Page 219</p> <p>1 CHARLES E. CLEMENS</p> <p>2 MS. HARGRAVE: Objection,</p> <p>3 mischaracterization of testimony.</p> <p>4 A. ALLSOP doesn't state in this patent that a</p> <p>5 particular push button is indicated here. It's just a</p> <p>6 name.</p> <p>7 Q. (BY MR. WEIL) Right.</p> <p>8 A. And it's intended to be to prevent the ingress</p> <p>9 of dust, contaminants and moisture. It doesn't say</p> <p>10 anything about having a functionality, and I think</p> <p>11 you're reading functionality into this which doesn't</p> <p>12 exist. All this is saying is it's to cover the upper</p> <p>13 portion of the pressurized dispensing container and it</p> <p>14 prevents the ingress of dust contaminates and moisture.</p> <p>15 Q. It says advantageously it prevents the ingress</p> <p>16 of dust contaminants and moisture. Right?</p> <p>17 A. You read that correctly.</p> <p>18 Q. So it doesn't necessarily have to do that.</p> <p>19 Right?</p> <p>20 A. No, I think that's the intent. The intent is</p> <p>21 it has the advantage of doing this, and that's, you</p> <p>22 know, the intent of the component.</p> <p>23 Q. Let me just ask a pretty simple question. If</p> <p>24 you saw a device with just a cap fixed on top and it</p> <p>25 could not be pushed, is your understanding that that's a</p>
<p style="text-align: right;">Page 220</p> <p>1 CHARLES E. CLEMENS</p> <p>2 push button cap?</p> <p>3 MS. HARGRAVE: Objection, calls for</p> <p>4 speculation, vague.</p> <p>5 A. If I told you the number of times I thought</p> <p>6 names that, you know, patent inventors used, that drives</p> <p>7 me crazy, but it's just a term. It's just a name that</p> <p>8 the inventor gave to it.</p> <p>9 Q. (BY MR. WEIL) And you don't think that name</p> <p>10 means anything?</p> <p>11 MS. HARGRAVE: Objection,</p> <p>12 mischaracterization of the testimony.</p> <p>13 A. I read nothing in the patent where the</p> <p>14 inventor intended any functionality of this, other than</p> <p>15 to cover the upper portion of the pressurized dispensing</p> <p>16 container for the advantages of the ingress of dust,</p> <p>17 contaminants and moisture. That's the long and short of</p> <p>18 it.</p> <p>19 Q. (BY MR. WEIL) And if you look at Mr. Piper's</p> <p>20 drawing on page 18 of your declaration --</p> <p>21 A. Yes, sir.</p> <p>22 Q. -- and you see that additional rectangle that</p> <p>23 he drew on the top. If that additional rectangle is a</p> <p>24 button that can be pushed, you would agree with me that</p> <p>25 pushing that button could depress the canister.</p>	<p style="text-align: right;">Page 221</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Correct?</p> <p>3 MS. HARGRAVE: Objection, calls for</p> <p>4 speculation.</p> <p>5 A. You mean as in the proposed combination?</p> <p>6 Q. (BY MR. WEIL) So we're just talking about</p> <p>7 ALLSOP here, right? Not a combination with anything.</p> <p>8 Is that correct?</p> <p>9 A. Well, I'm asking you.</p> <p>10 Q. Okay.</p> <p>11 A. I am just trying to clarify.</p> <p>12 Q. I am asking: So Mr. Piper drew his</p> <p>13 understanding of what the push button cap is, and that's</p> <p>14 drawn in green. Correct?</p> <p>15 A. That is correct, yes.</p> <p>16 Q. And Mr. Piper believes that there's a button</p> <p>17 on top that you can push down to force the canister</p> <p>18 down. Is that correct?</p> <p>19 A. I guess one of the questions I have is why is</p> <p>20 there an extra feature on top?</p> <p>21 Q. The button?</p> <p>22 A. I mean, because the whole thing could be --</p> <p>23 could also be a button.</p> <p>24 Q. And I'm asking you about how Mr. Piper drew</p> <p>25 it. If that extra feature on top is a button and is</p>

<p style="text-align: right;">Page 222</p> <p>1 CHARLES E. CLEMENS</p> <p>2 pushed down, that will push the canister down. Correct?</p> <p>3 MS. HARGRAVE: Objection, calls for</p> <p>4 speculation.</p> <p>5 A. I think it would cause -- well, it depends.</p> <p>6 Let's -- as part of the issues that I'm having with</p> <p>7 Mr. Piper's report and also petitioners's information is</p> <p>8 it lacks so much information and detail to really</p> <p>9 understand how this is intended to work. I mean, does</p> <p>10 this -- you say it's -- Piper believes it's to push the</p> <p>11 canister, but it looks like it's, you know, colliding</p> <p>12 with the housing. There's so little information, so</p> <p>13 little description, it's very difficult to analyze this.</p> <p>14 Q. (BY MR. WEIL) So you don't understand how the</p> <p>15 picture that Mr. Piper drew would work?</p> <p>16 MS. HARGRAVE: Objection,</p> <p>17 mischaracterization.</p> <p>18 A. Well, I see even if you could push that down,</p> <p>19 I mean, you're going to cause -- you're going to bind</p> <p>20 the whole device.</p> <p>21 Q. (BY MR. WEIL) So why does the rest of the cap</p> <p>22 have to move if there's a button in the center that can</p> <p>23 be pushed like a button in a pen?</p> <p>24 MS. HARGRAVE: Objection, calls for</p> <p>25 speculation.</p>	<p style="text-align: right;">Page 223</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. I have to -- have to say that there is so</p> <p>3 little information there, it's -- one is incapable of</p> <p>4 analyzing exactly what the mystery is inside that green</p> <p>5 part.</p> <p>6 Q. (BY MR. WEIL) So you can't give any opinion</p> <p>7 on how Mr. Piper's picture might work?</p> <p>8 A. Well, I do have opinion, and I put it in my</p> <p>9 report, and it's right here.</p> <p>10 Q. In your report -- and your position was that</p> <p>11 the cap would be attempted to be pushed down into the</p> <p>12 device. Is that right?</p> <p>13 A. Well, I mean, let's just find a section here</p> <p>14 that you're asking a question about.</p> <p>15 Q. I think it's paragraph 32.</p> <p>16 A. Okay. Here. Depiction. Yes. Okay.</p> <p>17 Correct.</p> <p>18 Q. If we look at your pictures that you provided</p> <p>19 on page 20 -- I'm looking specifically at figure 1 on</p> <p>20 the left -- the ring with pin 164 is not at the very top</p> <p>21 of the outer housing, is it?</p> <p>22 A. The outer ring meaning the 160?</p> <p>23 Q. 164 shows a pin.</p> <p>24 A. A pin, yeah, in the yellow part 160. Okay.</p> <p>25 And --</p>
<p style="text-align: right;">Page 224</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And if I understand what you said in paragraph</p> <p>3 32, Mr. Piper could not depress the cap because it would</p> <p>4 interfere with ring 160 with pins 161 and 162. Right?</p> <p>5 A. That is correct. That's correct. I mean,</p> <p>6 there's also other parts in this assembly that it would</p> <p>7 interfere with. Like I said, if you attempted to, you</p> <p>8 know, push a button down anywhere near the inside</p> <p>9 diameter of the housing, you're going to cause several</p> <p>10 problems, binding, interference with the ring, binding</p> <p>11 of the canister.</p> <p>12 Q. Well, in paragraph 32 you say that pushing the</p> <p>13 cap down could cause one of two things to occur, the</p> <p>14 ring 160 with pins, 161, 162, would prevent the cap from</p> <p>15 being depressed or, two, the depression of the cap would</p> <p>16 cause the pins 161, 162 of ring 160 to be pushed</p> <p>17 downward resulting in -- indicating an inaccurate number</p> <p>18 of doses remaining. Right?</p> <p>19 A. Those are at least two things, two problematic</p> <p>20 things that would happen.</p> <p>21 Q. And for those two things, if we look at figure</p> <p>22 1 that you've annotated at the bottom of page 20,</p> <p>23 there's space in that white rectangle drawn on top of</p> <p>24 the outer housing for the cap to move downwards, isn't</p> <p>25 there?</p>	<p style="text-align: right;">Page 225</p> <p>1 CHARLES E. CLEMENS</p> <p>2 MS. HARGRAVE: Objection, vague.</p> <p>3 A. Well, I mean, first of all, this is a</p> <p>4 schematic, but I can't, you know, comment on the</p> <p>5 relative size and spacing of, you know, these diagrams,</p> <p>6 but I think if you can see that attempting to put</p> <p>7 something in between these parts would, you know, cause</p> <p>8 the ring to fall, to be pushed down, to bind. I mean --</p> <p>9 and again, there are other parts within this assembly</p> <p>10 that interfere. So, I mean, yes, I point out two things</p> <p>11 here that would probably happen, but there's actually</p> <p>12 several things that would happen that make this not</p> <p>13 obvious.</p> <p>14 Q. (BY MR. WEIL) And how far does a canister</p> <p>15 have to be depressed to actuate and dispense medication.</p> <p>16 Do you know?</p> <p>17 MS. HARGRAVE: Let me just object to</p> <p>18 calls for speculation.</p> <p>19 A. We spoke earlier that there are many -- many</p> <p>20 brands, many kinds of canisters and valves out there. I</p> <p>21 believe Mr. Piper speculated that it was a</p> <p>22 hundred-thousandths in his report. You know, it</p> <p>23 certainly could be smaller, but it could also be larger.</p> <p>24 Off the top of my head, I wouldn't be able to, you know,</p> <p>25 give you an exact or, you know, a real good read on</p>

<p style="text-align: right;">Page 226</p> <p>1 CHARLES E. CLEMENS</p> <p>2 that, but there are so many of them.</p> <p>3 Q. (BY MR. WEIL) Well, I am not asking you to</p> <p>4 speculate. You can look at paragraph 76 of this same</p> <p>5 declaration. You say "typically traveling only a few</p> <p>6 millimeters in distance." Right?</p> <p>7 A. That's my guess at -- and it's probably pretty</p> <p>8 close to what Mr. Piper is suggesting.</p> <p>9 Q. And I guess just to close the loop on this,</p> <p>10 looking at annotated figure 1 at the bottom of page 20,</p> <p>11 it's your testimony that one could not push this cap</p> <p>12 you've drawn down in that space of that white rectangle</p> <p>13 to actuate the inhaler?</p> <p>14 MS. HARGRAVE: Objection, asked and</p> <p>15 answered.</p> <p>16 A. I -- my opinion in my report is that would</p> <p>17 interfere with the operation of the device. It would</p> <p>18 cause an improper operation.</p> <p>19 Q. (BY MR. WEIL) In your opinion in your report,</p> <p>20 do you refer to this white rectangle in figure 1?</p> <p>21 A. You're talking about the space between the</p> <p>22 black part and the red part?</p> <p>23 Q. No. The space between the black part and the</p> <p>24 blue part. There's a white rectangle separating what</p> <p>25 you've drawn as the cap from the rest of the housing.</p>	<p style="text-align: right;">Page 227</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Sorry, maybe I wasn't clear.</p> <p>3 A. Yes. So that's also a cap, by the way. That</p> <p>4 white part there, that's a cap, and it has -- it has</p> <p>5 legs, by the way. And those legs, they -- it's sort of</p> <p>6 a mystery part, but those legs actually go down the ID</p> <p>7 of this part and get wedged. So the legs literally</p> <p>8 would be covering any kind of space that something could</p> <p>9 be pushed down into it. I mean, it would immediately</p> <p>10 bind. So that's another problem.</p> <p>11 Q. So the canister can be pushed up and down,</p> <p>12 though, right?</p> <p>13 A. The canister, the button would bind if --</p> <p>14 Q. Pretend there's no button. This white cap</p> <p>15 that you're talking about now --</p> <p>16 A. Yes.</p> <p>17 Q. -- you say you couldn't you push something</p> <p>18 down because it would bind. The canister could be</p> <p>19 pushed down. Correct?</p> <p>20 A. Well, that is a question actually. I am not</p> <p>21 sure.</p> <p>22 Q. Okay. If we look at paragraph 33 of your</p> <p>23 declaration.</p> <p>24 A. 33.</p> <p>25 Q. And the element that relates to is a second</p>
<p style="text-align: right;">Page 228</p> <p>1 CHARLES E. CLEMENS</p> <p>2 member being engageable with said first member and said</p> <p>3 stationary body.</p> <p>4 Do you see that?</p> <p>5 A. Okay. Yes.</p> <p>6 Q. Is the entire scope of your opinion on that</p> <p>7 element here in paragraph 33?</p> <p>8 A. Let me read it. Yes, I believe it is.</p> <p>9 Q. And then one more thing about ALLSOP.</p> <p>10 Paragraph 35 you say that the claim language of the '631</p> <p>11 Patent is specific to require changing a displayed value</p> <p>12 from displayable values. Is that right?</p> <p>13 A. If we could read the claim actually --</p> <p>14 Q. Well, we don't have to read it --</p> <p>15 A. But yes, I agree with my report.</p> <p>16 Q. Yes. And you did not suggest in your report</p> <p>17 that either term "displayed" or "displayable" needed to</p> <p>18 be specifically construed by the Board?</p> <p>19 A. I did not specifically construe the terms. My</p> <p>20 opinions in this area, really, they don't depend on a</p> <p>21 specific construction. It's taken directly from the</p> <p>22 claim and viewed by someone skilled in the art.</p> <p>23 Q. Does the specification of the '631 Patent say</p> <p>24 anything about how the dose number has to be viewed?</p> <p>25 A. I don't recall.</p>	<p style="text-align: right;">Page 229</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. And you understand that the claim terms in</p> <p>3 this IPR are construed according to the broadest</p> <p>4 reasonable interpretation. Correct?</p> <p>5 A. Well, I think my understanding is that perhaps</p> <p>6 the parties haven't totally agreed on the construction</p> <p>7 of any of these terms.</p> <p>8 Q. My question was just for any term that's in</p> <p>9 these claims, the standard is the broadest reasonable</p> <p>10 interpretation. Correct? Do you know one way or the</p> <p>11 other?</p> <p>12 A. It would be viewed from terms of how a person</p> <p>13 of skill in the art would be -- would understand the</p> <p>14 terms.</p> <p>15 Q. But one skilled in the art would give it its</p> <p>16 broadest reasonable construction. Correct?</p> <p>17 A. I believe that's true.</p> <p>18 Q. And you think it's unreasonable to understand</p> <p>19 the term "display" to include a series of numbers where</p> <p>20 an indicator points to the current number?</p> <p>21 MS. HARGRAVE: Objection,</p> <p>22 mischaracterization.</p> <p>23 A. That would be an indicator.</p> <p>24 Q. (BY MR. WEIL) And does that indicator display</p> <p>25 a value?</p>

<p style="text-align: right;">Page 230</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. It indicates. There is a distinction and a</p> <p>3 big difference.</p> <p>4 Q. So the distinction you're drawing is between</p> <p>5 indicating and displaying?</p> <p>6 A. That's what you were indicating. You</p> <p>7 described the example.</p> <p>8 Q. Sure. And in my example, you distinguished it</p> <p>9 and said that's indicating, not displaying. Correct?</p> <p>10 A. That's correct.</p> <p>11 Q. So you think it's unreasonable to say that a</p> <p>12 clock displays a time?</p> <p>13 MS. HARGRAVE: Objection, vague,</p> <p>14 mischaracterization.</p> <p>15 A. I'm saying that a specific read of this claim</p> <p>16 would -- the broadest reasonable interpretation is</p> <p>17 that -- especially changing a -- you know, a singular</p> <p>18 displayed value from more than one, display a bold</p> <p>19 values. So this means that, you know, only one can be</p> <p>20 seen although there are many to choose from.</p> <p>21 Q. (BY MR. WEIL) Okay. Let's flip forward a</p> <p>22 bit. Let's go to the obviousness combination. Let's</p> <p>23 first look at Bason in view of Rhoades and, if you will</p> <p>24 look at paragraph 47.</p> <p>25 Do you see on the next page, page 28, you</p>	<p style="text-align: right;">Page 231</p> <p>1 CHARLES E. CLEMENS</p> <p>2 provide a drawing of how you think that combination</p> <p>3 would be made according to the description in the</p> <p>4 petition. Is that right?</p> <p>5 A. My best shot, yes.</p> <p>6 Q. In paragraph 47, second to last sentence, you</p> <p>7 say "Petitioners state that the rest of the components</p> <p>8 would be connected in the same way they are connected in</p> <p>9 Bason."</p> <p>10 Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. I am going to hand you the petition from the</p> <p>13 '631 Patent IPR. If you could turn to page 55. Looking</p> <p>14 at the fourth line from the bottom, the petition says</p> <p>15 "The rest of the components could be connected in the</p> <p>16 same way they are connected in Bason or other ways well</p> <p>17 understood in the art."</p> <p>18 Do you see that?</p> <p>19 A. I do.</p> <p>20 Q. Your opinion does not include that last</p> <p>21 clause, does it?</p> <p>22 A. It does not.</p> <p>23 Q. Paragraph 48 of your '631 IPR declaration, you</p> <p>24 say "Petitioners do not indicate how teeth 2 will be</p> <p>25 integrated into the inhaler body."</p>
<p style="text-align: right;">Page 232</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Do you see that?</p> <p>3 A. Yes, I do see that.</p> <p>4 Q. And the same page of the petition that we were</p> <p>5 just looking at, page 55 --</p> <p>6 A. Yeah.</p> <p>7 Q. -- states that one would injection mold the</p> <p>8 actuator with a stationary gear already included,</p> <p>9 decreasing the number of parts.</p> <p>10 Do you see that? It's a few lines up from</p> <p>11 where we were looking before.</p> <p>12 A. Okay. I see that, yes.</p> <p>13 Q. So the petition does say how they would be</p> <p>14 added to the body, right, they would be injection</p> <p>15 molded?</p> <p>16 MS. HARGRAVE: Objection, vague.</p> <p>17 A. So the petitioners do indicate it would be</p> <p>18 injection molded. It doesn't say how or where or what.</p> <p>19 It just makes a blanket statement.</p> <p>20 Q. (BY MR. WEIL) As for where, they would be</p> <p>21 injection molded onto the inhaler body. Correct?</p> <p>22 A. Yeah, where.</p> <p>23 Q. And one of skill in the art wouldn't be able</p> <p>24 to figure out where they might put these components?</p> <p>25 A. Well, there is -- the rest of the analysis is</p>	<p style="text-align: right;">Page 233</p> <p>1 CHARLES E. CLEMENS</p> <p>2 that the rest of the counting means of Bason would then</p> <p>3 be connected the same way. So it's one thing to just</p> <p>4 blanket statement that you would do this, but how it</p> <p>5 would actually be done or if it could be done is an</p> <p>6 entirely different matter. Requires a whole lot more</p> <p>7 detail, a lot more explanation. All of that's missing,</p> <p>8 you know, from this suggestion. So that's the essence</p> <p>9 of this critique here, my critique, is that injection</p> <p>10 molded, that doesn't tell you enough, doesn't give you</p> <p>11 anywhere near enough information to understand how it's</p> <p>12 all integrated.</p> <p>13 Q. You wanted petitioners to show precisely where</p> <p>14 those teeth would be placed on to the inhaler body. Is</p> <p>15 that fair to say?</p> <p>16 A. And in relation to other components that they</p> <p>17 say are just connected.</p> <p>18 Q. Well, you know how those components interact</p> <p>19 in Bason. Right?</p> <p>20 A. Bason is a separate custom design, which it</p> <p>21 has been specifically designed to interact with their</p> <p>22 particular components that are especially designed.</p> <p>23 What's happened here is petitioners have modified it.</p> <p>24 They've changed it. And they're making a broad</p> <p>25 statement, well, I would just put this here. But if</p>

<p style="text-align: right;">Page 234</p> <p>1 CHARLES E. CLEMENS</p> <p>2 you're going to make a combination and make it obvious,</p> <p>3 if it's so obvious, all these details should be</p> <p>4 available. But there's obviously -- well, if I take it</p> <p>5 straight from the way it's stated, it would act the</p> <p>6 same, which is essentially what I did in my report. You</p> <p>7 know, my conclusion was, well, if you did that, they</p> <p>8 wouldn't even come close to each other. So, you know, it</p> <p>9 wouldn't function.</p> <p>10 Q. So they wouldn't act the same in your picture</p> <p>11 as they would in Bason. Correct?</p> <p>12 MS. HARGRAVE: Objection,</p> <p>13 mischaracterization.</p> <p>14 A. What I have portrayed is my understanding</p> <p>15 through the petitioners's description following the</p> <p>16 sense, the strict sense and the direction that</p> <p>17 petitioners and Piper give, it's not workable. It</p> <p>18 doesn't work.</p> <p>19 Q. (BY MR. WEIL) And you say you followed the</p> <p>20 strict sense and the direction that petitioners gave.</p> <p>21 So you didn't apply any sort of creativity to figure out</p> <p>22 how, for example, in your picture on 28 the red</p> <p>23 component could maintain its interaction with the teeth,</p> <p>24 the blue teeth. Correct?</p> <p>25 A. Well, that would require me to make the case</p>	<p style="text-align: right;">Page 235</p> <p>1 CHARLES E. CLEMENS</p> <p>2 for obviousness for petitioners. Petitioners need to do</p> <p>3 that, provide that information. I am here to analyze</p> <p>4 what the petitioners are suggesting is going to be a</p> <p>5 combined design that achieves what the claims are</p> <p>6 intending. So that was not put together by the</p> <p>7 petitioners. This is -- what is shown, illustrated here</p> <p>8 is actually what was written and described.</p> <p>9 Q. And your understanding of the obviousness</p> <p>10 analysis is that petitioners have to explain that to one</p> <p>11 skilled in the art. Correct?</p> <p>12 MS. HARGRAVE: Objection,</p> <p>13 mischaracterization.</p> <p>14 A. Yeah, maybe if you restate that.</p> <p>15 Q. (BY MR. WEIL) Sure.</p> <p>16 I guess my question is -- it sounds to me like</p> <p>17 you're saying you just tried to replicate precisely what</p> <p>18 you understood the petition to say the modification was.</p> <p>19 Correct?</p> <p>20 A. What I said was that from just reading the --</p> <p>21 what the petitioners described as the combination and</p> <p>22 considering the expert Piper, his explanation as well,</p> <p>23 the understanding that you get from this combination is</p> <p>24 illustrated here on page 28.</p> <p>25 Q. Just one more question. On page 56 of the</p>
<p style="text-align: right;">Page 236</p> <p>1 CHARLES E. CLEMENS</p> <p>2 petition, the first sentence of the second -- the first</p> <p>3 full paragraph. In such a modification, all of the</p> <p>4 components would retain their same functions.</p> <p>5 Do you see that?</p> <p>6 A. Page 56?</p> <p>7 Q. Correct.</p> <p>8 A. The second paragraph "Moreover," that one?</p> <p>9 Q. Yeah.</p> <p>10 A. Let's see. Where are we here? So I do see</p> <p>11 that sentence.</p> <p>12 Q. And my question is simple. In what you've</p> <p>13 drawn on page 28, do all the components retain their</p> <p>14 same functions?</p> <p>15 A. No, they do not.</p> <p>16 Q. Let's look at the paragraph 24 of your</p> <p>17 declaration, and just above that paragraph there's two</p> <p>18 pictures.</p> <p>19 A. Sure.</p> <p>20 Q. And on the right-hand picture, it's a</p> <p>21 figure -- I guess it's figure 4 from the reference. Can</p> <p>22 you see how the cap is prevented from falling off the</p> <p>23 top of the inhaler from this figure?</p> <p>24 A. How the cap is falling off?</p> <p>25 Q. It doesn't fall off. Right?</p>	<p style="text-align: right;">Page 237</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Okay. So part 14 we're talking about. Right?</p> <p>3 Q. Right.</p> <p>4 A. Right. It's captured by base one and would</p> <p>5 now slide between the canister and the housing.</p> <p>6 Q. And you see base one has little projections</p> <p>7 that -- I guess it's a little rib along the bottom of</p> <p>8 the cap.</p> <p>9 Do you see that?</p> <p>10 A. Yeah, they would be, you know, all around,</p> <p>11 yeah.</p> <p>12 Q. And that's what prevents the cap from falling</p> <p>13 off the top?</p> <p>14 A. That prevents the spring from pushing it away,</p> <p>15 uh-huh.</p> <p>16 Q. So let's go to paragraph 60. I guess I'm</p> <p>17 going to look at the figure at the top of page 33.</p> <p>18 Actually, I guess maybe it's easier to look at the</p> <p>19 picture at the top of page 34 on the right, and it's</p> <p>20 your belief that the ring 4 cannot be the second member</p> <p>21 in this combination because, as you've drawn it here, it</p> <p>22 will not rotate when you push down the cap. Correct.</p> <p>23 MS. HARGRAVE: Objection,</p> <p>24 mischaracterization.</p> <p>25 A. So in the combination as I have understood it,</p>

60 (Pages 234 to 237)

<p style="text-align: right;">Page 238</p> <p>1 CHARLES E. CLEMENS</p> <p>2 based on descriptions from petitioner, the first problem</p> <p>3 is the cap doesn't go down because it interferes with</p> <p>4 the teeth, the teeth 2 which have been modified to be</p> <p>5 moved to the inside diameter of the housing. And then</p> <p>6 ring 4 doesn't rotate. There's nothing to rotate it.</p> <p>7 Plus, it can't be axially moved, so --</p> <p>8 Q. (BY MR. WEIL) And that's based on how you've</p> <p>9 drawn the picture here at the top of page 34. Correct?</p> <p>10 MS. HARGRAVE: Objection,</p> <p>11 mischaracterization.</p> <p>12 A. It's based on the description given by the</p> <p>13 petitioner and described also by expert Piper.</p> <p>14 Q. (BY MR. WEIL) All right. So if we look at</p> <p>15 paragraph 75, the last sentence of that paragraph you</p> <p>16 say "Petitioners failed to explain why a person seeking</p> <p>17 to improve the accuracy of an MDI would look to</p> <p>18 nonprecision components like those of an ink pen."</p> <p>19 Do you see that sentence?</p> <p>20 A. I see that sentence, correct.</p> <p>21 Q. Is it your understanding that petitioners's</p> <p>22 argument is that one would be motivated to improve the</p> <p>23 accuracy of an MDI in their combination?</p> <p>24 A. I am just reading the paragraph for context.</p> <p>25 Q. Yeah. Let me give it a little more context.</p>	<p style="text-align: right;">Page 239</p> <p>1 CHARLES E. CLEMENS</p> <p>2 This is in the context of the section D, page 35 of your</p> <p>3 report, a post that would not have been motivated to</p> <p>4 combine -- sorry, page 35.</p> <p>5 A. Yeah.</p> <p>6 Q. And the heading says a POSITA would not have</p> <p>7 been motivated to combine Bason with Rhoades?</p> <p>8 A. That is correct.</p> <p>9 Q. So for the sentence we're looking at, is your</p> <p>10 understanding of the motivation petitioners are</p> <p>11 proposing that one would make that combination to</p> <p>12 improve the accuracy of an MDI?</p> <p>13 MS. HARGRAVE: Objection, vague.</p> <p>14 Q. (BY MR. WEIL) The sentence we're looking at</p> <p>15 at the bottom of paragraph 75 that we have already read,</p> <p>16 is it your understanding from petitioners's arguments</p> <p>17 that the motivation to combine these references is</p> <p>18 because one would be looking to improve the accuracy of</p> <p>19 an MDI? Is that your understanding of the motivation?</p> <p>20 A. Okay. I think I understand the question. The</p> <p>21 point that I'm making in the report in this area is</p> <p>22 given the nature of MDIs and counters and making sure</p> <p>23 that you're dispensing and counting accurately with the</p> <p>24 safety features that are involved in order to create an</p> <p>25 accurate counting device, which the FDA has recommended,</p>
<p style="text-align: right;">Page 240</p> <p>1 CHARLES E. CLEMENS</p> <p>2 given those things -- those kinds of designs entail</p> <p>3 accuracy of parts and assembly and operation</p> <p>4 interoperability.</p> <p>5 So given that these designs inherently have</p> <p>6 these requirements, in order for them to be safe and to</p> <p>7 count accurately, as required by the FDA, the</p> <p>8 petitioners have failed to explain why you would apply a</p> <p>9 non -- a reference such as Rhoades which states that it</p> <p>10 is not a precise device and actually it's not required,</p> <p>11 the processing, the expense of the processing and tight</p> <p>12 tolerances are not required.</p> <p>13 So that's what this statement is referring to</p> <p>14 is the petitioners fail to explain why a person who</p> <p>15 actually needs to create an accurate device for all the</p> <p>16 reasons I just explained would try to attempt to do that</p> <p>17 with an ink pen reference such as Rhoades. That's</p> <p>18 what's that's saying.</p> <p>19 Q. Let me just ask what hopefully will not</p> <p>20 require a long answer.</p> <p>21 You understand in the obviousness analysis</p> <p>22 petitioners have to describe some motivation why one</p> <p>23 would combine two references. Correct?</p> <p>24 A. Well, I mean, again, you know, what the</p> <p>25 complete definition for the complete test for</p>	<p style="text-align: right;">Page 241</p> <p>1 CHARLES E. CLEMENS</p> <p>2 obviousness is -- you know, I don't have that on the top</p> <p>3 of my head right now, but it sounds like you're asking a</p> <p>4 specific question about obviousness test. So --</p> <p>5 Q. Yeah. And if you can't answer it, that's</p> <p>6 fine. Your understanding of the obviousness test, do</p> <p>7 the petitioners have to explain some sort of motivation</p> <p>8 why one would combine the two references?</p> <p>9 A. I don't know.</p> <p>10 Q. You just don't know?</p> <p>11 A. I don't know that.</p> <p>12 Q. And I know we talked about this about the</p> <p>13 '177 Patent. Just to be sure that we covered it for</p> <p>14 the '631 also, the claims of the '631 Patent, they cover</p> <p>15 a fluid dispenser. Correct?</p> <p>16 A. I am just going to do a quick check.</p> <p>17 Q. Yeah.</p> <p>18 MS. HARGRAVE: Objection, vague.</p> <p>19 A. The invention and the claims are directed</p> <p>20 towards a fluid dispenser.</p> <p>21 Q. (BY MR. WEIL) And the claims of the '631</p> <p>22 Patent, they do not require including a drug in a fluid</p> <p>23 dispenser, do they?</p> <p>24 A. The word "drug" does not show up in the</p> <p>25 claims.</p>

<p style="text-align: right;">Page 242</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. Is a nasal spray a fluid dispenser?</p> <p>3 MS. HARGRAVE: Objection, calls for</p> <p>4 speculation.</p> <p>5 A. Obviously you're referring to the product, but</p> <p>6 nasal spray devices are intended to be used with liquid.</p> <p>7 Q. (BY MR. WEIL) And do nasal spray devices</p> <p>8 require close manufacturing tolerances?</p> <p>9 MS. HARGRAVE: Objection, calls for</p> <p>10 speculation.</p> <p>11 A. Okay. Nasal sprays would be considered an</p> <p>12 over-the-counter device, delivery device and whereas</p> <p>13 MDIs would be considered a prescription device. So</p> <p>14 they're really quite different.</p> <p>15 Q. (BY MR. WEIL) And again, I think we talked</p> <p>16 about this in the '177, but just to cover it in the</p> <p>17 '631, the claims of the '631 do not require any specific</p> <p>18 tolerances. Correct?</p> <p>19 A. They do not have any dimensions or tolerances.</p> <p>20 Q. I want to talk a little bit about the</p> <p>21 combination of Bason in view of ALLSOP. So maybe we</p> <p>22 could turn to paragraph 85.</p> <p>23 MS. HARGRAVE: I will just say you're now</p> <p>24 about 15 minutes over seven hours.</p> <p>25 MR. WEIL: Okay.</p>	<p style="text-align: right;">Page 243</p> <p>1 CHARLES E. CLEMENS</p> <p>2 MS. HARGRAVE: Do you have -- I'm just</p> <p>3 going to say we're going to hit a hard stop at about</p> <p>4 6:10.</p> <p>5 MR. WEIL: I think I'll be done by 6:10.</p> <p>6 I'll try to get done by 6:10. I'll talk to Ron and see</p> <p>7 if there's anything else, and if we're not, we'll talk</p> <p>8 at 6:10.</p> <p>9 MS. HARGRAVE: Okay.</p> <p>10 MR. WEIL: But I am close.</p> <p>11 Q. (BY MR. WEIL) Okay. So paragraph 85 Bason in</p> <p>12 view of ALLSOP. Just so we're on the same page of this</p> <p>13 combination, this is the combination where it's proposed</p> <p>14 that the Bason counter is moved below the canister.</p> <p>15 Correct?</p> <p>16 A. That is correct.</p> <p>17 Q. And fluid dispensers with dose counters below</p> <p>18 the canister were known in the prior art at the time of</p> <p>19 the invention. Right?</p> <p>20 A. Yeah, that's correct.</p> <p>21 Q. So in this proposed combination, what</p> <p>22 modifications to the cap would be necessary to allow the</p> <p>23 stem of the canister to pass through it?</p> <p>24 MS. HARGRAVE: Objection, calls for</p> <p>25 speculation.</p>
<p style="text-align: right;">Page 244</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Well, again, it's not my -- you know, I</p> <p>3 haven't been asked to analyze and make a design work.</p> <p>4 What I am doing is analyzing a design that's been</p> <p>5 proposed or described by petitioners and based on what,</p> <p>6 you know, I've read and tried to understand from their</p> <p>7 description.</p> <p>8 Q. (BY MR. WEIL) We looked at Elliott much</p> <p>9 earlier today and looked at the components in that red</p> <p>10 box. Do you recall that?</p> <p>11 A. Yes.</p> <p>12 Q. And we talked about how in the Elliott device</p> <p>13 the canister sits on top of the counting mechanism, the</p> <p>14 stem passes through the center. Right?</p> <p>15 A. That's correct.</p> <p>16 Q. So that confirmation was known prior to the</p> <p>17 invention. Right?</p> <p>18 A. Elliott was known for quite a while, but</p> <p>19 Elliott obviously is. You know, it's unique to its own</p> <p>20 design, and this is a unique design unto itself. So</p> <p>21 there's more work to do in terms of how this kind of</p> <p>22 combination might work. As it is, as it's described, it</p> <p>23 doesn't work. I mean, the cap doesn't even move. The</p> <p>24 parts aren't really moldable. I mean, there's many</p> <p>25 issues that need to be reworked in order for this kind</p>	<p style="text-align: right;">Page 245</p> <p>1 CHARLES E. CLEMENS</p> <p>2 of a combination to work.</p> <p>3 (Brief interruption.)</p> <p>4 Q. (BY MR. WEIL) The picture at the top of page</p> <p>5 47, did you create that picture?</p> <p>6 A. So on many of these pictures, I would create</p> <p>7 hand sketches and then, you know, a PowerPoint Ninja</p> <p>8 would help to create some of the images.</p> <p>9 Q. Understood. And does your image at the top of</p> <p>10 page 47 show the stem block?</p> <p>11 A. It does not.</p> <p>12 Q. And this is your understanding of the</p> <p>13 combination that petitioners proposed. Correct?</p> <p>14 A. As I read the petition and also Piper's</p> <p>15 description.</p> <p>16 Q. And it's your understanding from the petition</p> <p>17 and Piper's description that the canister would be up</p> <p>18 near the very top of the inhaler as it's drawn here?</p> <p>19 A. Well, it obviously would be --</p> <p>20 (Brief interruption.)</p> <p>21 Q. (BY MR. WEIL) We were looking at the picture</p> <p>22 at the top of page 47, and my question was it's your</p> <p>23 understanding from the petition and Mr. Piper's</p> <p>24 description that the canister would be up near the very</p> <p>25 top of the inhaler as you've drawn it here. Is that</p>

<p style="text-align: right;">Page 246</p> <p>1 CHARLES E. CLEMENS</p> <p>2 correct?</p> <p>3 A. So there -- obviously there is some depth, you</p> <p>4 know, size to the Bason counter. So it necessarily</p> <p>5 would have to reside somewhere above the valve block.</p> <p>6 So, you know, the proportions, you know, may be a little</p> <p>7 off here, but there is quite a bit of size to the Bason</p> <p>8 counter. So it would necessarily be a little bit higher</p> <p>9 in terms of how it would be mounted. Let's see. Let me</p> <p>10 just think about that a little bit more, because --</p> <p>11 yeah, no, that's my complete answer.</p> <p>12 Q. Let's turn ahead to page 53, and I am looking</p> <p>13 at the figure, and this is the figure where I think your</p> <p>14 argument is if this combination was made, the numbers</p> <p>15 that are seen through the window, which I think is this</p> <p>16 highlighted yellow box, would not be visible. Is that</p> <p>17 correct?</p> <p>18 A. That is correct.</p> <p>19 Q. And just this simple question. Do you believe</p> <p>20 that making this combination one of skill in the art</p> <p>21 would have the ability to move that window to the side</p> <p>22 of the inhaler button?</p> <p>23 MS. HARGRAVE: Objection, calls for</p> <p>24 speculation.</p> <p>25 A. There is many components that interact in</p>	<p style="text-align: right;">Page 247</p> <p>1 CHARLES E. CLEMENS</p> <p>2 order to create the functionality of counting, and none</p> <p>3 of the descriptions or explanation as to how that could</p> <p>4 possibly be done was not given. So it's impossible for</p> <p>5 me to analyze something that isn't described and/or if</p> <p>6 it would have been obvious to somebody skilled in the</p> <p>7 art. So based on what I was able to understand, with</p> <p>8 these complications here, you know, I don't see how</p> <p>9 that -- obviously, you wouldn't be able to read, you</p> <p>10 know, the doses. So --</p> <p>11 Q. (BY MR. WEIL) I understand you wouldn't be</p> <p>12 able to read the doses if you just bodily incorporated</p> <p>13 the counter underneath the inhaler and made no</p> <p>14 modification. Is that your point?</p> <p>15 MS. HARGRAVE: Objection,</p> <p>16 mischaracterization.</p> <p>17 A. Yeah, my point is if you read and take in what</p> <p>18 the petitioners and expert Piper have described as the</p> <p>19 combination of this is the result that I get when I'm</p> <p>20 looking at it and understanding it from a person of</p> <p>21 skill in the art and it doesn't work.</p> <p>22 Q. (BY MR. WEIL) All right. Paragraph 97 you</p> <p>23 state that Bason teaches away from the concept of fewer</p> <p>24 components, expressly teaching that preferably the</p> <p>25 entire device, with the possible exception of spring 3,</p>
<p style="text-align: right;">Page 248</p> <p>1 CHARLES E. CLEMENS</p> <p>2 is made from individual pieces.</p> <p>3 Do you see that?</p> <p>4 A. Yes. And there's a citing there.</p> <p>5 Q. Yes. And it cites to Exhibit 1007 at 350 to</p> <p>6 60. And the device in the Bason reference is meant to</p> <p>7 be affixed at the top of the canister. Correct?</p> <p>8 A. That's correct.</p> <p>9 Q. So is it your understanding that Bason's</p> <p>10 preference to make the components for its top mounted</p> <p>11 counter from individual pieces expressly teaches away</p> <p>12 from making an integrated dose counter with fewer</p> <p>13 components?</p> <p>14 A. I think what I'm saying is that Bason</p> <p>15 expressly teaches, you know, exactly what is stated</p> <p>16 here. So the entire device with the possible exception</p> <p>17 of spring 3 is made from individual pieces. You know,</p> <p>18 that's directly taken right from Bason.</p> <p>19 Q. And again, Bason is talking that he's saying</p> <p>20 that about using a top mounted dose counter. Correct?</p> <p>21 A. Well, he's talking about his invention, that</p> <p>22 is correct, and the petitioners are saying, you know,</p> <p>23 we're going to take Bason and we're going to try to</p> <p>24 modify it. So that's what Bason teaches.</p> <p>25 MR. WEIL: All right. Ryan, just give us</p>	<p style="text-align: right;">Page 249</p> <p>1 CHARLES E. CLEMENS</p> <p>2 a minute or two.</p> <p>3 MS. HARGRAVE: Okay. Do you want us to</p> <p>4 step out.</p> <p>5 MR. SKLAR: I don't think so.</p> <p>6 (Break from 6:08 p.m. to 6:09 p.m.)</p> <p>7 MR. WEIL: Okay. So I understand we have</p> <p>8 a time limit. If you can tell me you're not going to do</p> <p>9 any redirect, I can stop here.</p> <p>10 MS. HARGRAVE: I have about three</p> <p>11 redirect questions, but they are not going to affect</p> <p>12 anything that you do.</p> <p>13 MR. WEIL: And it's okay for me to</p> <p>14 re-cross after?</p> <p>15 MS. HARGRAVE: Yes.</p> <p>16 MR. WEIL: In that case, I have no</p> <p>17 questions at this moment.</p> <p>18 MS. HARGRAVE: Okay.</p> <p>19 EXAMINATION</p> <p>20 BY MS. HARGRAVE:</p> <p>21 Q. Mr. Clemens, you were asked a number of</p> <p>22 questions about your experience in the relevant</p> <p>23 technology here. Do you remember those questions by</p> <p>24 Mr. Weil?</p> <p>25 A. Sort of, yes.</p>

<p style="text-align: right;">Page 250</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. Mr. Clemens, despite whether or not you have</p> <p>3 been a named inventor on a patent claiming inhalation</p> <p>4 technology, would you say you're an expert in inhalation</p> <p>5 devices?</p> <p>6 A. Of course I would, based on all the direct</p> <p>7 experience that I have had and applied to the designs</p> <p>8 that I've created. You know, having a particular patent</p> <p>9 is not a necessary requirement to be an expert in</p> <p>10 something that you're highly skilled and have years of</p> <p>11 experience in.</p> <p>12 Q. Are you qualified -- strike that.</p> <p>13 Are you an expert in fluid dispensers?</p> <p>14 MR. WEIL: Objection, leading.</p> <p>15 THE WITNESS: Is it okay if I answer?</p> <p>16 MR. WEIL: Sure.</p> <p>17 THE WITNESS: Okay.</p> <p>18 A. In my many years of experience, I have had</p> <p>19 years of experience working with different dispensers</p> <p>20 and containers. A great deal of my experience relates</p> <p>21 to fluid delivery and fluid containment, fluid</p> <p>22 management. So I have many, many years of experience in</p> <p>23 this area.</p> <p>24 Q. (BY MS. HARGRAVE) Are you qualified as a</p> <p>25 person of ordinary skill in the art under petitioners's</p>	<p style="text-align: right;">Page 251</p> <p>1 CHARLES E. CLEMENS</p> <p>2 proposed level of skill in the art?</p> <p>3 MR. WEIL: Objection, leading.</p> <p>4 A. Yes, I am.</p> <p>5 Q. (BY MS. HARGRAVE) Would you have been a</p> <p>6 person of ordinary skill in the art under petitioners's</p> <p>7 proposed level of skill in the art at the time of the</p> <p>8 invention?</p> <p>9 MR. WEIL: Same objection.</p> <p>10 A. Yes, I would have.</p> <p>11 Q. (BY MS. HARGRAVE) Are there any errors that</p> <p>12 you noticed in your report that you need to correct?</p> <p>13 A. I did find a few typos.</p> <p>14 MR. WEIL: Objection, outside the scope.</p> <p>15 Q. (BY MS. HARGRAVE) Go ahead.</p> <p>16 A. Yeah, I did find a few typos that I could --</p> <p>17 Q. Can you just identify them on the record?</p> <p>18 A. Let y'all know.</p> <p>19 MR. WEIL: Same objection.</p> <p>20 A. I mean, I don't have them off the top of my</p> <p>21 head. I've got them written down.</p> <p>22 MS. HARGRAVE: Can we go off the record</p> <p>23 for 30 seconds for me to grab that?</p> <p>24 THE WITNESS: I know where it is.</p> <p>25 (Break from 6:12 p.m. to 6:13 p.m.)</p>
<p style="text-align: right;">Page 252</p> <p>1 CHARLES E. CLEMENS</p> <p>2 A. Okay. In the '177 declaration, my</p> <p>3 declaration, page 35 in the heading 8, it says "Ground</p> <p>4 1," and it should say "Ground 2." That's one error.</p> <p>5 In the Clemens declaration for the '631,</p> <p>6 page 24, paragraph 41, there is a sentence, Marelli</p> <p>7 specifically teaches that the fixed distance. And then</p> <p>8 the next word is "element 9," and there should be a word</p> <p>9 "between" that's added between distance and element.</p> <p>10 Okay. And then the last error I found was in</p> <p>11 my '631 declaration, page 8, paragraph 16 it says "in</p> <p>12 shaded blue." The word "in" is -- shouldn't be in</p> <p>13 there. It should just say shaded blue.</p> <p>14 And I believe that's in a sentence there.</p> <p>15 MS. HARGRAVE: I don't have any more</p> <p>16 questions.</p> <p>17 MR. WEIL: And I have just one to</p> <p>18 clarify.</p> <p>19 FURTHER EXAMINATION</p> <p>20 BY MR. WEIL:</p> <p>21 Q. The middle correction, it's paragraph 41?</p> <p>22 A. Marelli.</p> <p>23 Q. I didn't catch exactly what word are you</p> <p>24 adding between distance and element?</p> <p>25 A. The word "between."</p>	<p style="text-align: right;">Page 253</p> <p>1 CHARLES E. CLEMENS</p> <p>2 Q. I gotcha.</p> <p>3 MR. WEIL: Okay. Nothing further from</p> <p>4 me. Thank you, Mr. Clemens.</p> <p>5</p> <p>6</p> <p>7</p> <p>8 (Proceedings ended at 6:15 p.m.)</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

ERRATA SHEET

Case Name:

Deposition Date:

Deponent:

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Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

THIS ____ DAY OF _____, 2019.

(Notary Public) MY COMMISSION EXPIRES: _____

I, CHARLES E. CLEMENS, have read the foregoing deposition and hereby affix my signature that same is true and correct, except as noted above.

CHARLES E. CLEMENS

THE STATE OF _____)

COUNTY OF _____)

Before me, _____, on this day personally appeared CHARLES E. CLEMENS, known to me (or proved to me under oath or through _____) (description of identity card or other document) to be the person whose name is subscribed to the foregoing instrument and acknowledged to me that they executed the same for the purposes and consideration therein expressed.

Given under my hand and seal of office this _____ day of _____, _____.

NOTARY PUBLIC IN AND FOR

THE STATE OF _____

COMMISSION EXPIRES: _____

REPORTER'S CERTIFICATE

The undersigned Certified Shorthand Reporter licensed in the State of Texas does hereby certify:

I am authorized to administer oaths or affirmations, and prior to being examined, the witness was duly administered an oath by me.

I am not a relative or employee or attorney or counsel of any of the parties, nor am I a relative or employee of such attorney or counsel, nor am I financially interested in the outcome of this action.

I am the deposition officer who stenographically recorded the testimony in the foregoing deposition, and the foregoing transcript is a true record of the testimony given by the witness.

Before completion of the deposition, review of the transcript [X] was [] was not requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

In witness whereof, I have subscribed my name this 1st day of May, 2019.

Julie C. Brandt, CSR, RMR, CRR
TX CSR No. 4018, Exp. 10/31/21

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