

S. Piper

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

Case No. IPR2018-01054

PATENT NO. 8,936,177

CASE NO. IPR2018-01055

PATENT NO. 9,370,631

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3M COMPANY, MERCK & CO., )  
INC., and MERCK SHARP & )  
DOHME CORP., )  
Petitioners, )  
v. )  
APTAR FRANCE S.A.S., )  
Patent Owner, )

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DEPOSITION OF SAMUEL DAVID PIPER

Washington, D.C.

January 25, 2019

REPORTED BY: Barbara DeVico, CRR, RMR

JOB NO. 154348

Ex. 2019  
3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp., v. Aptar France SAS  
IPR2018-01055

S. Piper

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and MERCK SHARP & DOHME CORP., )  
Petitioners, )  
v. )  
APTAR FRANCE, S.A.S., )  
Patent Owner )

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Friday, January 25, 2019

9:04 a.m.

Deposition of SAMUEL DAVID PIPER, held at the law  
offices of AKIN GUMP, 1333 New Hampshire Avenue, N.W.,  
Washington, D.C., pursuant to Notice before Barbara  
DeVico, Certified Realtime Reporter and Certified  
Nationally Certified Realtime Reporter and Registered  
Merit Reporter and Notary Public of the District of  
Columbia and the state of Maryland and Commonwealth of  
Virginia.

S. Piper

APPEARANCES:

ON BEHALF OF PETITIONERS:

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ON BEHALF OF RESPONDENT:

RYAN HARGRAVE, ESQUIRE

McKOOL SMITH

300 Crescent Court

Dallas, TX 75201

1 S. Piper

2 P R O C E E D I N G S

3 SAMUEL DAVID PIPER,

4 having been called as a witness on behalf of the  
5 Petitioners and having been first duly sworn, was  
6 examined and testified as follows:

7 EXAMINATION BY

8 MS. HARGRAVE:

9 Q. Good morning. Good morning, Mr. Piper.  
10 Could you please state your name for the record?

11 A. Samuel David Piper.

12 Q. You've been deposed before, Mr. Piper,  
13 haven't you?

14 A. Yes, I have been deposed before.

15 Q. How many times have you been deposed  
16 before?

17 A. I've been deposed about three or four  
18 times. It's in my CV, the exact number.

19 Q. So you know the ground rules, but I'll go  
20 over them again just to refresh us.

21 You understand that you are under oath and  
22 giving testimony here today, correct?

23 A. I understand that.

24 Q. And the court reporter will be typing  
25 down everything we say so that it's important that you

1 S. Piper

2 and I don't talk at the same time. So if you agree to  
3 let me finish my question completely before beginning  
4 your answer, that will help her out quite a bit.

5 A. Not a problem.

6 Q. From time to time your lawyer may object  
7 to my questions. When he finishes his objection, you  
8 should answer the question unless he instructs you not  
9 to. Do you understand that?

10 A. I do.

11 Q. And then to help the court reporter,  
12 instead of saying things like "uh-huh" or nodding your  
13 head when you answer, try to say a verbal yes or no so  
14 that she can take down your answer.

15 A. Okay.

16 Q. And if you need a break, just let me  
17 know. We can take one.

18 Lastly, if I ask you a question and you give me  
19 an answer, I'm going to assume that you understood my  
20 question. So if you don't understand my question,  
21 please let me know and I'll try to ask it in a different  
22 way.

23 A. Okay.

24 Q. And I apologize, I'm nursing a cough this  
25 morning. So I'm going to have to water up a lot.

1 S. Piper

2 Is there any reason that you can't testify  
3 truthfully and accurately today, Mr. Piper?

4 A. No.

5 Q. Where are you currently employed?

6 A. Well, I run a business called Piper  
7 Medical Products. It is an S Corporation, and I'm an  
8 employee of that corporation.

9 Q. What is your title?

10 A. My title at Piper Medical Products is  
11 president.

12 Q. How long have you been the president of  
13 Piper Medical?

14 A. I started Piper Medical sometime around  
15 1996.

16 Q. Mr. Piper, you've served as an expert  
17 witness before; correct?

18 A. I have served as an expert witness  
19 before.

20 Q. About how many times have you served as  
21 an expert witness?

22 A. I've served as an expert witness at least  
23 four times, three or four times. Again, it's on my CV.  
24 I could give you a more specific answer if you give me  
25 my CV.

1 S. Piper

2 Q. That's fine, and we may enter that as an  
3 exhibit in a minute. I just want to kind of make sure  
4 that I understand what your experience is apart from  
5 what's on your CV to the extent that there are any  
6 differences.

7 Have you ever served as an expert witness in an  
8 IPR or an inter parties review?

9 A. Yes, I have.

10 Q. Apart from your work on these matters,  
11 have you served as an expert in an IPR?

12 A. Aside from the matter at issue today in  
13 the declarations that we're going to discuss?

14 Q. Yes.

15 A. Yes, I have.

16 Q. We'll go ahead and enter Exhibit 2003.

17 (Exhibit 1003, Curriculum  
18 Vitae, was marked for  
19 identification.)

20 Q. Mr. Piper, do you recognize this  
21 document?

22 A. Yes, this document is my CV.

23 Q. Let's go to the second page. We've got  
24 listed "Expert Witness" as the heading. You've got a  
25 number of matters here. Which of these is the IPR that

1 S. Piper

2 you worked on?

3 A. As I recall, both the second and the  
4 third matters, which both involved Fontem-involved IPRs.

5 Q. Okay. And in those matters, were you  
6 testifying on behalf of the petitioner or the patent  
7 owner?

8 A. I was -- well, there were -- both sides  
9 were suing the other side for infringement. So I was  
10 involved in the case. Some of the work I did was  
11 providing the declaration reports on why some of the  
12 patents were invalid.

13 Q. Okay. So then you were testifying on  
14 behalf of the petitioner in the IPR?

15 A. Right.

16 Q. And just to be clear, the technology in  
17 that case related to electronic cigarettes; correct?

18 A. Yes, that is correct.

19 Q. Have you ever done any IPR work related  
20 to inhalation products that were not electronic  
21 cigarettes?

22 A. No.

23 Q. And were these Fontem cases the only IPR  
24 matters that you have been engaged to testify in?

25 A. Yeah. I'm pretty sure the Ventronics



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2 versus Draeger one, I don't think that that involved an  
3 IPR.

4 Q. Mr. Piper, have you ever been retained as  
5 an expert witness for 3M in other matters?

6 A. No, I've never been retained as an expert  
7 witness by 3M.

8 Q. Have you ever been retained as an expert  
9 witness by Merck prior to your involvement on these  
10 matters?

11 A. No, I've never been retained by Merck as  
12 an expert witness, except for this matter, of course.

13 Q. Have you ever informally consulted or  
14 formally consulted for either 3M or Merck?

15 A. No, I don't remember doing any work for  
16 3M or Merck prior to this matter.

17 Q. None of the expert work that you've done  
18 previously involved meter dose inhalers, correct?

19 A. None of the expert work I've done  
20 involved meter dose inhalers that are powered by freon.  
21 The electronic cigarette is an aerosol delivery device,  
22 so it involved an inhalation device, so there's some  
23 variance on what a meter dose inhaler may or may not be.  
24 But as far as a freon-driven meter dose inhaler, none of  
25 my other expert witness work had bearing -- well, had

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2 bearing but was not in regard to devices that are  
3 freon-driven meter dose inhalers.

4 Q. Let me just ask the question again.

5 A. Okay.

6 Q. None of the expert work that you've done  
7 previously involved meter dose inhalers, correct?

8 A. None of the expert witness work I've done  
9 previously involved meter dose inhalers that are powered  
10 by freon.

11 Q. And it's not your testimony today that an  
12 electronic cigarette is a meter dose inhaler, right?

13 A. Well, there's some people who suggested  
14 that the condensation aerosolization process of an  
15 electronic cigarette could be used as a meter dose  
16 inhaler-type product, but I'm not aware of any products  
17 that have successfully made it to the market using that  
18 approach.

19 Q. Mr. Piper, do you remember when you were  
20 first retained by Petitioners to work on these IPR  
21 matters that we're talking about here today?

22 A. I don't remember the exact date. I have  
23 an approximate idea of when that was.

24 Q. What's your approximate idea of when you  
25 were first retained to work on these matters?

1 S. Piper

2 A. Sometime in 2018. More likely the  
3 earlier half of 2018 than the latter half.

4 Q. Do you remember who contacted you about  
5 possibly working on the matters that we're discussing  
6 here today?

7 A. I was originally contacted by expert  
8 search, expert witness search firm, and I think the  
9 first initial contact I had with the attorneys in the  
10 case was Jason Weill.

11 Q. Were you first retained to work --  
12 were you retained to perform any prior art searches in  
13 this case?

14 A. Well, I was retained as an expert witness  
15 for this work, so that involved doing, having  
16 discussions and looking at what possible prior art there  
17 might exist relevant to the case, yes.

18 Q. And you said that your involvement in  
19 this case began you thought in the earlier part of 2008,  
20 right?

21 A. 2018.

22 Q. Sorry about that, yes.

23 A. That's my recollection. I don't have the  
24 exact date for when that happened. That's obviously  
25 data that could be obtained. I can give it to you

1 S. Piper

2 today.

3 Q. You don't have any financial interest in  
4 the outcome of this case, do you, Mr. Piper?

5 A. No. I'm paid for my independent and  
6 expert opinion on this case regardless of what that is.  
7 So what the actual outcome of this case is or not has no  
8 economic bearing on my finance.

9 Q. What's your hourly rate for your work on  
10 this case?

11 A. My billing rate for this case is \$360 per  
12 hour.

13 Q. We'll go ahead and enter as an exhibit  
14 here each of your declarations in both the '631 and the  
15 '177 matters.

16 Let me back up.

17 You've been retained to provide testimony in IPR  
18 number -- let's see. Two IPR numbers. Let me restate  
19 the question.

20 You've been retained to provide expert testimony  
21 in IPR2018-01054 and IPR2018-01055. Is that correct?

22 A. I don't remember what the actual file  
23 numbers are for the IPRs. But it was in regard to IPR  
24 work regarding the, what I commonly refer to as the '631  
25 patent and the '177 patent.

1 S. Piper

2 Q. So just to be clear for the record, I'll  
3 state that your testimony relates to United States  
4 patent numbers 8,936,177, which you refer to as the '177  
5 patent and 9,370,631, which you refer to as the '631  
6 patent. Does that sound right?

7 A. That sounds right. As long as they are  
8 the patents referred to in the declaration, that would  
9 be correct.

10 Q. I just want to be sure for the record  
11 that when you and I are talking about the '177 patent  
12 we're talking about 8,936,177, and when we're talking  
13 about the '631 patent we're talking about 9,370,631.

14 A. If you give me my declaration, I will  
15 confirm those exact numbers for you.

16 Q. I just want to get some sort of shorthand  
17 that we can use together so we don't have to say the  
18 full IPR number and the full patent number each time we  
19 talk about it.

20 A. I would share your preference.

21 Q. Okay. So this is -- we'll mark this as  
22 Exhibit 1,002, '177, I think is how we should do that.  
23 And this is your declaration for the '177 matter.  
24 Coincidentally, the exhibit number for your '631  
25 declaration is also 1,002, so I don't want the record to

1 S. Piper

2 be unclear.

3 (Exhibit 1,002.1, Declaration,  
4 was marked for identification.)

5 MS. HARGRAVE: And then we'll mark as  
6 Exhibit 1,002.2 your declaration in the '631 matter.

7 (Exhibit 1,002.2, Declaration,  
8 was marked for identification.)

9 BY MS. HARGRAVE:

10 Q. Let's start with Exhibit 1,002.1.

11 A. Okay.

12 MR. SKLAR: Did you hear the 1,000 --

13 MS. HARGRAVE: We just have been  
14 marking them 1 and 2.

15 MR. SKLAR: One is for the '177?

16 MS. HARGRAVE: Yes.

17 BY MS. HARGRAVE:

18 Q. Mr. Piper, can you identify  
19 Exhibit 1,002.1 for me?

20 A. The 1,000 -- what's listed here as  
21 Exhibit 1,002.1 is my declaration, and for what I would  
22 commonly refer to as the '177 patent, which the patent  
23 number is 8,936,177.

24 MR. SKLAR: I just need to raise one  
25 objection to 1,002.1. It looks like 1,002.2 was

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2 properly printed in color. 1,002.1 is in black and  
3 white. I think it makes a little bit of a difference if  
4 we're getting into the technical aspects of the patent.  
5 I think we can, we would be happy to assist in providing  
6 a color copy if that would be helpful.

7 MS. HARGRAVE: That would be helpful.  
8 That would be great. Thank you.

9 BY MS. HARGRAVE:

10 Q. So if you and I refer to Exhibit 1,002.1  
11 as your '177 declaration, will you understand what I  
12 mean by that?

13 A. Yes.

14 Q. Okay. Let's take a look at  
15 Exhibit 1,002.2.

16 A. Okay, I have the 1,002.2 in front of me.

17 Q. Can you identify for the record  
18 Exhibit 1,002.2?

19 A. Exhibit 1,002.2 is my declaration  
20 regarding what I commonly refer to as the '631 patent,  
21 which the full number for that patent is 9,370,631.

22 Q. So if I refer to Exhibit 1,002.2 as your  
23 '631 declaration, you'll understand what I mean?

24 A. Correct.

25 Q. Mr. Piper, you submitted your exhibits to

1 S. Piper

2 the Patent and Trademark Office in May 2018; right? You  
3 can check your signature page on the back.

4 A. Yeah. I'm looking at the signature page.  
5 Yeah, Exhibit 1,002.2 has got a May 9, 2018, signature.  
6 And Exhibit 1,002.1 has a signature date of May 9, 2018.

7 Q. Mr. Piper, who wrote your declarations  
8 for the '631 and '177 matters?

9 A. I wrote the declaration.

10 Q. Did you write them with assistance of  
11 counsel at Akin Gump?

12 A. Yes, I did write them with assistance.

13 Q. Did you write them with the assistance  
14 from anyone else apart from attorneys at Akin Gump?

15 MR. SKLAR: Objection, foundation.

16 A. No, I did not.

17 Q. Mr. Piper, are the opinions in your  
18 declarations your opinions?

19 A. Yes, they are all mine.

20 Q. Are you aware of any changes or  
21 modifications that need to be made to either of your  
22 declarations?

23 A. No, I have no changes or modifications  
24 that I'm aware of that need to be made to either  
25 declaration.



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Q. About how many hours would you say that you spent preparing your declarations for these matters?

A. I don't have the exact number. Something of over a hundred hours or more.

Q. Would you say that's 100 matters total for both IPR matters?

A. Yeah, I don't have an exact number. I'm just giving an order of magnitude. More than ten, less than a thousand for both declarations.

Q. You likely submitted invoices for work that you performed on these matters, correct?

A. I did submit invoices for work on these matters, yes.

Q. Do you have an estimate how much money you have invoiced for work performed on these matters?

A. Well, I invoiced \$360 per hour times the number of hours plus whatever expenses were also incurred.

Q. Is it your testimony that you can't narrow for me the amount that you've invoiced for your work on these matters anything between one and a thousand hours? I mean --

A. I said --

MR. SKLAR: Just a moment. Objection

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2 to the form.

3 A. I said ten and 100 hours. What I said  
4 was that my, the number of hours I expended on this, on  
5 these, for these declarations was something in the order  
6 of 100 hours. I could certainly give you a more  
7 definitive number. If I have time to review the  
8 invoices, I could give you a very exact number.

9 Q. Could you do that on a break?

10 Mr. Piper, were you aware of either the '177  
11 patent or the '631 patent before you were contacted to  
12 work on this case?

13 A. No, I had no awareness. I hadn't  
14 reviewed either patent prior to this case.

15 Q. Just to be clear, you were not aware of  
16 either the '177 patent or the '631 patent prior to this  
17 case; correct?

18 A. I had not seen either patent prior to  
19 this case, and I had no knowledge of its existence prior  
20 to this case, no.

21 Q. Were you aware of the patent owner in  
22 this case, Aptar, before you started working on this  
23 case?

24 A. I did not have a familiarity with who  
25 Aptar was prior to this case. I would imagine I may

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2 have heard the name before as a possibility. I can't  
3 say that I didn't, but I never worked for Aptar and  
4 never had any business relations with Aptar prior to  
5 this case.

6 Q. Let's go back to your CV, Mr. Piper,  
7 which I believe is Exhibit 1,003.

8 A. Okay.

9 Q. Have you got it?

10 A. I do.

11 Q. Your CV was attached to each of your '631  
12 and '177 declarations for these matters, correct?

13 A. Yes, my CV was attached to both  
14 declarations.

15 Q. And the CV attached to each declaration  
16 was identical, right?

17 A. The CV that was attached to each  
18 declaration was identical.

19 Q. Okay. So we can refer to Exhibit 1,003,  
20 which was, I believe was attached to your '177  
21 declaration. All the testimony that you provide related  
22 to Exhibit 1,003 would apply equally to your declaration  
23 to your CV that was attached to the '631 declaration;  
24 right?

25 A. Well, the CV that was attached to both

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2 declarations was identical. So any testimony I give  
3 regarding my CV would equally apply in regards to the  
4 fact that the CV in both declarations is identical.

5 Q. Is the CV that you attached to your  
6 declaration in May still accurate?

7 A. Well, as of the date of -- as of the date  
8 of the declaration, yeah, it was accurate at the time.

9 Q. Are you aware of items that need to be  
10 updated on your CV as of today?

11 A. Well, for example, there's always  
12 additional work that one is involved with if they are in  
13 the working world. And so as an expert witness, I've  
14 now been deposed one additional time, for example.

15 Q. Well, why don't you tell me about the  
16 matter that you were deposed in. Was it one of the  
17 matters that's listed on your CV and you just haven't  
18 yet been deposed in that matter?

19 A. I'm talking about this deposition.

20 Q. Understood. So is there any additional  
21 work that you've been involved in since you submitted  
22 your CV as an attachment to your declaration in May 2018  
23 that you think is relevant to your work on this matter?

24 MR. SKLAR: Object to the form.

25 A. I do testing on MDI devices on a regular

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2 basis, so this is late January, and the date of  
3 submission for the declaration was May 9, so in that  
4 period of time I've had additional, you know, equivalent  
5 amount of extra additional testing work that involved  
6 aerosol delivery devices including meter dose inhalers.  
7 That would be one example.

8 Q. Well, I guess let's start with the  
9 testing that is on your CV, and then we can maybe get to  
10 the additional testing performed since you submitted it.

11 One thing I wanted to ask you, Mr. Piper, is  
12 this your standard CV that you would submit or circulate  
13 for any purpose, whether or not it's litigation?

14 A. You know, a CV is like a business card.  
15 So if I'm doing development, somebody is interested in a  
16 CV for development work, I might have a different CV  
17 that includes more details on development work. I don't  
18 remember having submitted such a CV to anybody within  
19 the last 12 months.

20 Q. So is this CV prepared especially for use  
21 for your work on these matters?

22 A. This is my CV, that's my standard CV with  
23 the occasional update for doing expert witness work.

24 Q. Okay. And you're not aware of any  
25 mistakes or inaccuracies in the CV that you attached to

1 S. Piper

2 your declaration in May 2018?

3 A. I'm not aware of any mistakes on my CV  
4 that was attached as of May 92018.

5 Q. Mr. Piper, you are a named inventor on a  
6 number of patents; correct?

7 A. I am a named inventor on a number of  
8 different patents, that's correct.

9 Q. And none of the patents on which you are  
10 a named inventor focus on dose counting technology for  
11 meter dose inhalers, right?

12 MR. SKLAR: Object to the form.

13 A. I'm involved in, what do we have, on the  
14 CV we show one, two, three, four, five, six, seven,  
15 eight, nine, ten patents, almost all of which are  
16 aerosol delivery patents. It includes also a powder  
17 inhaler aerosolization process which would be an MDI  
18 product. Does that answer your question?

19 Q. No, it doesn't actually, but I'll ask it  
20 again.

21 None of the patents in which you are a named  
22 inventor -- let me say that again.

23 None of the patents on which you are a named  
24 inventor focus on meter dose inhaler dose counting  
25 technology, right?

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2 A. I'm not a patent holder of a dose  
3 counting technology that's used in a meter dose inhaler,  
4 that's correct.

5 Q. And none of the patents on which you are  
6 a named inventor focus on aerosol meter dose inhalers,  
7 meter dose inhalers, correct?

8 A. Powder inhalers is referred to in the  
9 industry as an PMDI and is used for delivering meter  
10 dose of medication. Just the form of the medication is  
11 in a powder form instead of provided in a propellant  
12 form through freon. So it is a meter dose inhaler.

13 Q. But that wasn't my question. Let me  
14 state my question again.

15 None of the patents on which you are a named  
16 inventor focus on aerosol meter dose inhalers, correct?

17 A. A powder inhaler -- the patent that's  
18 listed here is powder inhaler with aerosolization  
19 occurring with each individual powder receptacle.  
20 Patent No. 5,533,502, July 9, 1996, involves the unit  
21 dose delivery with each inhalation of a powder  
22 medicament. So therefore, it's a meter dose inhaler of  
23 sorts.

24 Q. So I appreciate that distinction. So in  
25 your prior answer you made a distinction between powder

1 S. Piper

2 dose inhalers and inhalers powered by freon, right?

3 A. Right. The powder inhaler of the patent  
4 I just referred to is a powder medicament device, and  
5 that is a different device than a meter dose inhaler  
6 that is powered by freon.

7 Q. Let's talk a little bit about your work  
8 history.

9 On your CV you have listed that you worked at  
10 Vortran Medical from 1990 to 1995, correct?

11 A. Correct.

12 Q. Tell me about the nature of that work.

13 MR. SKLAR: Objection to form.

14 A. I was hired initially to develop a low  
15 flow nebulizer for Vortran Medical Technology. Became  
16 their director of research and development and was  
17 involved in the development of a number of different  
18 aerosol technologies.

19 Q. What type of company is Vortran Medical?

20 A. It's a United States-based company.

21 Q. Are they in a product development type of  
22 engagement? When you say you developed devices for that  
23 company, what was the ultimate goal of your initial  
24 position there at Vortran Medical?

25 MR. SKLAR: Objection to the form.



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2 A. My initial goal was to develop products  
3 for Vortran technology that would produce revenue.

4 Q. Now, did any of the products that you  
5 developed at Vortran Medical make it to market?

6 A. Yes. Many of the products that I  
7 developed for Vortran Medical Technology made it to  
8 market.

9 Q. Tell me about some of those products.  
10 Let's start with one.

11 A. One product was what is branded as the  
12 heart nebulizer. It's a continuous nebulizer. It's  
13 covered under patent, Universal Nebulizer 5,287,847 is  
14 the patent number dated February 26 -- excuse me.  
15 February 22, 1994.

16 Q. Were the majority of the products that  
17 you developed at Vortran Medical nebulizers?

18 A. I was involved with development of  
19 nebulizers with Vortran Medical Technology, but I also  
20 helped with the development of inhaler products and  
21 other -- I looked at other unique aerosolization  
22 delivery approaches. If I wasn't involved with the  
23 development of aerosol-producing technologies in Vortran  
24 Medical Technology, I was involved with devices that  
25 assisted with the delivery of aerosol from aerosol

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2 delivery devices to patients under various settings.

3 Q. Tell me more about devices that would  
4 assist with the delivery of aerosol that you were just  
5 referring to.

6 A. Well, for example, one device was called  
7 the Vyzan 9. It was a device that was used -- it was a  
8 device that I was involved in, in charge of the  
9 development of that worked powering a nebulizer  
10 delivering large amounts of aerosol to patients who had  
11 ARDS for the delivery of surfactants, surfactants  
12 specifically produced by Burroughs Welcome as part of a  
13 large clinical trial. The patients we were delivering  
14 aerosol to for that particular project were on ICU  
15 ventilators.

16 Q. So the Vyzan 9 wasn't a meter dose  
17 inhaler?

18 A. No. Nobody in the industry would have  
19 classified the Vyzan 9 as a meter dose inhaler.

20 Q. Did the Vyzan 9 make it to market?

21 A. Well, we made it into clinical trials.  
22 It was a drug device/combo device, and the clinical  
23 trial was shut down due to -- the early indications of  
24 the clinical data indicated that the surfactant that  
25 Burroughs Welcome was delivering was, in fact, not

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2 actually effective as a molecule.

3 Q. So at the time of your work at Vortran  
4 Medical, did any of the meter dose inhalers that you  
5 worked on make it to market?

6 A. I worked on a, with Vortran Medical  
7 Technology on a product called the Gentle Inhaler. I  
8 had done a substantial amount of testing work, and I was  
9 not the inventor of that product and did not do the  
10 initial development on it. But I was involved in  
11 approving the manufacturing processes of the device.

12 That product was licensed. There was a license  
13 agreement at the time I was there, as I recall, with  
14 Schering-Plough, which at some subsequent point was  
15 canceled, so that product never made it to a point in  
16 which there was an FDA approval. But Vortran Medical  
17 Technology did receive substantial amounts of revenue as  
18 a result of the licensing agreement.

19 Q. And you said the nature of your work on  
20 that product was approving the manufacturing processes  
21 of the device, right?

22 A. No. I actually said I was involved with  
23 a lot of the testing of the device and the development  
24 would have been that I was involved with on the Gentle  
25 Inhaler was more in regards to things like improving the

1 S. Piper

2 manufacturing process of the device.

3 Q. What other types of development work  
4 would you do apart from work on the manufacturing  
5 processes?

6 A. Whether it was -- it was certainly  
7 development work involved around improving our ability  
8 to measure the performance in regards to not only the  
9 dose and the particle size but the plume geometry that  
10 came out of the device.

11 Q. What is plume geometry?

12 A. Plume geometry of an MDI is the  
13 characteristic velocity profile of the emitted cloud.  
14 It appears to be a cloud. It's drug particles and  
15 whatever other carriers are used.

16 So in the case of a normal MDI, meter dose  
17 inhaler powered by freon, the discharge is quite quick,  
18 and a lot of medication impacts the back of the throat  
19 of a patient, leaving an aftertaste resulting in side  
20 effects.

21 The Gentle Inhaler products had a slower plume  
22 geometry profile that came out from the device. And so  
23 there was less deposition of particles in the back of  
24 the throat if you used a Gentle Inhaler versus a normal  
25 inhaler product with the same freon canister.

1 S. Piper

2 Plume geometry also includes not only the  
3 velocity of the particles but what the particle  
4 velocities are at different points in the plume at  
5 different times. They also -- it also bears on the  
6 angle of dispersion of the aerosol cloud that's being  
7 emitted from the inhaler product.

8 Q. That process sounds complex.

9 A. It was an interesting project to be  
10 involved in trying to measure better and better, as it  
11 was.

12 Q. So as a company is in development of an  
13 MDI, you mentioned the manufacturing processes as  
14 something that you considered in development. You also  
15 mentioned plume geometry as something you considered in  
16 the development of an MDI.

17 What other factors are important in the  
18 development of an MDI?

19 MR. SKLAR: Objection to form.

20 A. Well, there are a lot of factors that are  
21 relevant in the development of an inhaler product, as  
22 there are a lot of factors that are relevant in any  
23 manufactured product that, for which commercialization  
24 is trying to be obtained.

25 Q. Tell me about the factors that are

1 S. Piper

2 relevant to the development of an inhaler product,  
3 specifically an MDI.

4 A. That's a really broad question. Can you  
5 narrow the question down at all?

6 Q. Could you tell me at a high level what  
7 big picture concerns a company that is developing an MDI  
8 considers when developing an MDI.

9 MR. SKLAR: Objection to the form.

10 A. Well, there are lots of considerations in  
11 manufacturing any product. There is a USP standard  
12 regarding meter dose inhalers, regarding consistency of  
13 dose and how to measure particle size, what the particle  
14 size is. And so that would be one example.

15 Q. Can you give me another?

16 A. Product constructions for the device.  
17 That would be -- that would be a consideration for a  
18 product.

19 Q. How about another?

20 A. User, user attractiveness, color of the  
21 plastic used. Branding of the product. Shipment of the  
22 product. Environmental storage parameters.  
23 Environmental operational parameters.

24 Q. In terms of the functionality of the  
25 device, I think maybe let's narrow in there. What types

1 S. Piper

2 of -- let me rephrase.

3 In your experience when a company is developing  
4 an MDI, what considerations are given to functionality  
5 of the device, and how does a company go about ensuring  
6 proper functionality of an MDI?

7 MR. SKLAR: Objection to form.

8 A. Well, again, there are all kinds of  
9 considerations a person would make to any product that's  
10 being manufactured. A meter dose inhaler is a medical  
11 device, and so there is an associated FDA approval  
12 process that is required. And so the regulatory pathway  
13 to achieving final approval of a product would certainly  
14 be a consideration.

15 Q. What about the injection molding process?  
16 Most MDIs are manufactured using injection molding,  
17 right?

18 A. Well, meter dose inhaler, the overall  
19 package is, consists of -- the standard MDI includes a  
20 plastic portion, which has a jet. It also has a  
21 canister that is filled with -- usually it's filled with  
22 freon and medication. And so there's a metering valve.  
23 So those are stamped metal components. The actuator  
24 boot itself, the vast majority of the time it is  
25 injectionable. And so manufacturing issues regarding

1 S. Piper

2 injection molding would bear on the development of the  
3 product.

4 Q. What type of manufacturing issues  
5 regarding injection molding would bear on the  
6 development of the product?

7 A. Well, injection mold apart, there's a lot  
8 of considerations. How the tool would actually, what  
9 the party lines would be, what the drafts and the tapers  
10 are so that the plastic can be injected, molded when  
11 it's hot and then be ejected from the machine.

12 Wall thicknesses is a certain consideration and  
13 a desire to have a desirable cycle time for your  
14 injection mold machine. Those would be some  
15 considerations. There are a lot of considerations for  
16 injection molding.

17 Q. Are you typically involved in that part  
18 of the development of an MDI when you do the work that  
19 you do presently?

20 A. I have a lot of experience doing  
21 injection molded product. The pattern medicament device  
22 that I developed, we did not get to a point where we did  
23 tooling for that product. It was certainly something I  
24 kept in mind while we did developments of the  
25 prototypes, and I expected the device ultimately would



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2 need to be injection molded.

3 I also worked on another device which was kind  
4 of a hybrid of a nebulizer MDI. That was -- that  
5 wasn't, had a lot of components in that device that were  
6 injection molded. And so I have a lot of experience in  
7 injection molding products. Nebulizers, just about all  
8 the nebulizers, not all the nebulizers I've developed  
9 have all been largely injection molded.

10 Q. So the part which you were just  
11 discussing which was the hybrid of the nebulizer and the  
12 MDI, you said it had a lot of components?

13 A. Well, it had more than two or three. It  
14 was powered by a CO2 canister. It aerosolized a liquid  
15 medication. It had a jet. It had a chamber. It had an  
16 inhalation check valve. It had a mouthpiece. It had a  
17 cap. It had a means for switching out CO2 canisters.

18 Q. What was the nature of your involvement  
19 on that product?

20 A. I was principal inventor of that product.

21 Q. So in a product like that that has a lot  
22 of components, what steps do you take to ensure  
23 interoperability between each component?

24 A. Are you talking about various components  
25 that fit together?

1 S. Piper

2 Q. Yes.

3 A. Okay. Well, I mean, it depends on how,  
4 what the nature of those components are and how they are  
5 expected to fit together. So if -- like for a water  
6 bottle with a cap, for an example, the cap has to be  
7 able to screw on and engage with the threads. And so in  
8 the case of threads, you have to have equal pitch and  
9 equivalent in maybe inside and outside diameter for the  
10 product to work.

11 Q. How does the number of components affect  
12 the ease of the manufacturing process of a product like  
13 that?

14 MR. SKLAR: Objection to the form.

15 A. Well, with an injection molded product,  
16 every additional component needs at least one additional  
17 cavity to produce a component. And so more components  
18 would necessarily result in more cavities in a tool.  
19 And to provide that the ultimate components are being  
20 put together into an assembly, it would increase the  
21 effort needed to assemble the product.

22 Q. How does the number of components in an  
23 inhalation product affect interoperability of each  
24 component?

25 MR. SKLAR: Operation to the form.

1 S. Piper

2 A. I don't understand that question. Can  
3 you restate it?

4 Q. Sure. If you have a product with a large  
5 number of components, is it harder to ensure  
6 interoperability between the components?

7 MR. SKLAR: Objection to the form.

8 A. It would depend on the components and  
9 what you mean by a lot of components. Generally the  
10 more components a product has, the more complicated it  
11 gets as a general rule, especially if they are part of  
12 an assembly.

13 Sometimes medical devices involve kits in which  
14 a large number of products may be simply put in a tray  
15 and then covered with a foil or Saran Wrap. So in those  
16 cases you could have a large number of parts in a  
17 product, and if you're talking about providing a kit,  
18 that wouldn't increase the complexity that much.

19 Q. Do meter dose inhalers typically involve  
20 kits?

21 A. Well, there are different types of meter  
22 dose inhalers. I've never seen a meter dose inhaler  
23 provided in the kit form that I just described, but a  
24 product to be legally marketed must include a case with  
25 product instructions, and most inhalers in the very

1 S. Piper

2 least contain a freon canister and an actuator boot.

3 So there are a number of items that are part of  
4 the full package, all of which is considered the product  
5 by the FDA. So they must all be packaged and sold  
6 together. So in a sense that is a kit.

7 Q. You described medical devices that  
8 involved kits that are put in a tray and covered with  
9 foil or Saran Wrap. All meter dose inhalers typically  
10 involve those types of kits?

11 A. I've never seen a meter dose inhaler that  
12 was put in a tray and packaged as a cover, you know,  
13 covered with foil and kitted out in that way, no. Those  
14 are relegated to things like for surgical kits.

15 Q. So let's get back. We waded in. Let's  
16 broaden out to you generally worked at Vortran Medical.  
17 Could you estimate for me the number of meter dose  
18 inhalers that you worked on when you were at Vortran  
19 Medical?

20 A. Well, I worked on various different  
21 aerosol technologies: electrodynamic,  
22 electrohydrodynamic, powder devices. A lot of different  
23 powder devices. My job -- part of my job description  
24 was to come up with innovative new ways to provide  
25 aerosolization, and there's -- there was an interest at

1 S. Piper

2 Vortran Medical Technology to not only new nebulizer  
3 technologies but new inhaler technologies.

4 So it's hard to estimate, and it's hard to  
5 answer your question. It depends on the degree of what  
6 you're considering development to be.

7 Q. Sure. Did you work on -- apart from the  
8 Gentile Inhaler, was that during your time at Vortran?

9 A. Yeah, I did work on the Gentle Inhaler  
10 while I was at Vortran, and I was also asked to do the  
11 work, some work regarding some feasibility issues of the  
12 dose counter with the Gentle Inhaler after I left  
13 Vortran Medical Technology.

14 Q. So apart from the Gentle Inhaler, what  
15 number of meter dose inhalers were brought to market  
16 during your time while working at Vortran Medical? Let  
17 me rephrase that question because I asked it in pieces.

18 Apart from the Gentle Inhaler, what number of  
19 meter dose inhalers were brought to market during your  
20 time at Vortran Medical?

21 A. Brought to market by who, by Vortran  
22 Medical Technology?

23 Q. By any company that you're aware of.

24 A. Oh, geez, I don't know.

25 Q. Apart from the Gentle Inhaler, what

1 S. Piper

2 percentage of meter dose inhalers were brought to market  
3 during your time at Vortran Medical by Vortran Medical?

4 MR. SKLAR: Objection, form,  
5 foundation.

6 A. Well, the Gentle Inhaler product had a  
7 license agreement with Schering at the time, but it did  
8 not reach the point where it got FDA approval. It  
9 depends on what you mean by "brought to market." So I  
10 don't know if that would classify.

11 Other products, there were people interested,  
12 there were discussions, licensing discussions around the  
13 powder medicament technology, but there were no  
14 licensing agreements around that as well. So I don't  
15 think that Vortran Medical Technology had any other  
16 inhaler products that made it to market while I was  
17 employed at Vortran Medical Technology.

18 I'm sorry, but I had some really good coffee  
19 this morning and I'd like to go to the bathroom. We can  
20 stop now?

21 MS. HARGRAVE: Sure, this is a good  
22 place to stop.

23 (Recess)

24 BY MS. HARGRAVE:

25 Q. Mr. Piper, we were talking about your

1 S. Piper

2 experience at Vortran Medical before the break. Let's  
3 talk about your experience at Evit Labs, Inc. Am I  
4 pronouncing that correctly?

5 A. Evit Labs.

6 Q. You were the president, CEO and founder  
7 of Evit Labs; correct?

8 A. That is correct.

9 Q. Tell me generally about the nature of  
10 Evit Labs' business.

11 A. I developed -- prior to starting Evit  
12 Labs as a legal entity, as part of my work at Piper  
13 Medical, I developed a unique aerosolization technology  
14 that can be characterized as a hybrid between a  
15 nebulizer and an inhaler product.

16 The relevant patent numbers are the Shock Wave  
17 aerosolization methods and apparatus, patent number  
18 6,981,660 and then the Shock Wave aerosolization method  
19 and apparatus, patent No. 6,742,721.

20 The aerosolization process was particularly  
21 well-suited compared to other aerosolization processes  
22 for delivering larger molecules, proteins, peptides,  
23 macromolecules in more of a meter dose inhaler-type  
24 format.

25 And so I started Evit Labs and obtained

1 S. Piper

2 investment for further development and attempted to  
3 commercialize the product technology.

4 Q. So your work at Evit Labs really focused  
5 on the one product that you were just discussing, right?

6 A. Yeah, the two patents. Yes, that's  
7 correct.

8 Q. Two patents that are related to the one  
9 product that you were just discussing, right?

10 A. That's correct, yes. We had one practice  
11 embodiment of the two patents.

12 Q. Was the product that you worked on at  
13 Evit Labs powered by freon?

14 A. No, it was powered by -- we never used  
15 freon.

16 Q. When you say "we," who is "we"?

17 A. Well, as part of the Evit Labs I hired a  
18 bunch of people to assist in bringing the product to  
19 market. So we functioned as a team. I was the chief  
20 technical officer, so I was primarily responsible for  
21 all of the development and advice. I never looked into  
22 using freon, because we wanted to use carbon dioxide and  
23 compressed air.

24 Q. What's the difference between using  
25 carbon dioxide and compressed air as compared to



1 S. Piper

2 traditional freon-powered meter dose inhaler?

3 A. Well, one of the reasons why proteins and  
4 peptides can't be delivered using freon is the way that  
5 meter dose inhalers are used for delivery of, say,  
6 albuterol sulfate -- which is branded, one of the brand  
7 names is Ventolin -- is that in the case of like  
8 Ventolin, the medication in the freon is premixed in a  
9 canister prior to delivery.

10 If you were to do that with a protein or a  
11 peptide, it would be very difficult to keep the  
12 medication in a stable form so that when the patient  
13 took the medication at some subsequent period of time  
14 after it had been packaged, you couldn't assure that  
15 they were going to actually get what you put into the  
16 device.

17 So we used compressed air and compressed CO2 to  
18 provide the energy needed for aerosolization, and a  
19 liquid that would contain the protein or the peptide was  
20 added to the device just prior to delivery of treatment.

21 Q. When did you found Piper Medical?

22 A. When did I found Piper Medical?

23 Q. Yes.

24 A. I found the Piper Medical sometime around  
25 1995.

1 S. Piper

2 Q. And that was just after you worked at  
3 Vortran Medical?

4 A. That's correct. Well, that's just after  
5 my employment at Vortran Medical Technology. I did work  
6 with Vortran Medical Technology after I left Vortran  
7 Technology and have a productive relationship with that  
8 company to this date.

9 Q. What's the nature of your continued work  
10 with Vortran Technology?

11 A. As of today?

12 Q. Yes.

13 A. I developed a ventilatory technology,  
14 which is a disposable ventilator product. Ventilators  
15 are normally capital equipment devices. I developed an  
16 innovative valve technology that could be made entirely  
17 out of injection molded plastic. Well, with a spring or  
18 two. And it was -- it could be used for providing  
19 emergency ventilation to patients. It could be used as  
20 an intrapulmonary percussion device.

21 Anyway, that technology I licensed to Vortran  
22 Medical Technology, and they market it and sell it to  
23 this day. And so I have ongoing conversations with them  
24 regarding that on a semi-regular basis. And I'm also  
25 open to other development projects with them from time

1 S. Piper

2 to time that we discuss.

3 Q. Your current work at Piper Medical, could  
4 you tell me on a general level what's the nature of your  
5 work now?

6 MR. SKLAR: Objection to the form.

7 A. The work that I perform at Piper Medical  
8 at this point, I do a lot of testing for people and  
9 normally in regards to trying to obtain FDA approval.  
10 If their product has deficiencies in performance that  
11 are going to prevent their approval, I will help them  
12 develop whatever solution may be necessary for them to  
13 have a better performing product and subsequently  
14 receive approval.

15 I consult with people and provide them guidance  
16 on how to do various things regarding usually testing.  
17 Sometimes I provide assistance to people on general  
18 regulatory issues such as what the manufacturing  
19 requirements are for a medical device business such as  
20 design history files and what documents are required by  
21 the FDA to manufacture a product.

22 I provide people with feedback on what current  
23 expectations are for the FDA on device approvals, mostly  
24 for aerosol -- mostly for respiratory devices and  
25 certainly for aerosol delivery devices.

1 S. Piper

2 Q. What percentage of your work currently  
3 relates to traditional meter dose inhalers?

4 A. Most of the work I do regarding meter  
5 dose inhalers involves currently, at Piper Medical,  
6 currently involves testing spacer chambers, which are a  
7 meter dose inhaler is, presents some issues with  
8 patients. One is coordination of ventilation and  
9 actuation. The other is a large amount of the  
10 medication that comes out of a meter dose inhaler will  
11 impact the back of the throat of a patient. A spacer  
12 chamber helps alleviate both those concerns.

13 A spacer chamber is basically an after-market  
14 device in which FDA approval is obtained through the  
15 CDRH of the FDA through a 510(k) application process.  
16 So currently right now I have a project that I'm working  
17 on that we're doing the testing that would be needed by  
18 the customer that they will submit to the FDA as part of  
19 their approval of their spacer chamber.

20 Q. Apart from your work on spacer chambers,  
21 have you worked on new product development at Piper  
22 Medical for meter dose inhalers?

23 A. I have worked on -- for what timeframe?  
24 Currently?

25 Q. I guess answer regarding your current

1 S. Piper

2 work to start.

3 A. I currently don't have a meter dose  
4 inhaler development project in process at Piper Medical.

5 Q. In the last five years, have you worked  
6 on new product development at Piper Medical for meter  
7 dose inhalers?

8 A. I have worked with -- patients on  
9 ventilators will need to receive aerosolized medication  
10 often. And it's done through a jet device and it's used  
11 with a freon canister right out of a meter dose inhaler  
12 project -- product. But the same boot is not used.

13 The boot that comes with the freon canister is  
14 discarded and a different boot is inserted into the  
15 ventilatory tubing line, inspiratory limb. And then the  
16 freon canister is engaged with that and the canister is  
17 actuated and aerosol is delivered to the patient while  
18 they are on the ventilator via the ventilator tubing.

19 And so in the last five years I've worked on at  
20 least two different projects regarding such devices.

21 Q. Would you classify the devices that you  
22 just described as a traditional meter dose inhaler?

23 A. What do you mean by "traditional"?

24 Q. A handheld meter dose inhaler that a  
25 patient would use.

1 S. Piper

2 A. Well, the device is made out of injection  
3 molded plastic. It's held in a hand, and it's used for  
4 delivering meter dose inhalers from an MDI canister.

5 Q. Is the answer to my question yes?

6 MR. SKLAR: Objection, form.

7 A. I answered. I gave you an answer. Do  
8 you want to reask the question?

9 Q. Would you classify the devices that you  
10 were just describing as a meter dose inhaler?

11 MR. SKLAR: Objection, form.

12 A. I would classify the device that I just  
13 described, which is the MDI inhaler product used in a  
14 ventilator inspiratory limb of a ventilator circuit for  
15 delivering ventilatory support to a patient and  
16 delivering aerosol to a patient at the same time as an  
17 alternative actuation body or boot and is used in  
18 conjunction with the exact same canister as a meter dose  
19 inhaler that may be used by an asthmatic patient who is  
20 able to breathe on their own without the assistance of a  
21 ventilator.

22 Q. Sir, yes or no: Would you classify the  
23 devices that you were just describing as a meter dose  
24 inhaler?

25 MR. SKLAR: Objection, form.

1 S. Piper

2 A. A meter dose inhaler involves what I -- a  
3 freon-driven meter dose inhaler involves a freon  
4 canister of a freon medication. Such a device would be  
5 used with such a canister. It has a jet that interacts  
6 with the stem of a canister just like any other actuator  
7 boot. And so I would say yeah, I would say yeah, I  
8 would classify that combination as a meter dose inhaler.

9 Q. At a high level can you describe the work  
10 that Piper Medical performed related to the device that  
11 you just described?

12 A. Are you talking about the meter dose  
13 inhaler products used with patients with ventilator  
14 circuits?

15 Q. You know what, we can just move on.

16 We've been talking a bit about the FDA. As  
17 we're speaking with one another today, if I refer to the  
18 FDA, you understand I'm referring to the Food and Drug  
19 Administration; right?

20 A. Yes.

21 Q. The FDA is a regulatory body, right?

22 A. The FDA is a branch of the government,  
23 and it provides regulatory oversight on medical devices  
24 and pharmaceutical compounds and foods and a number of  
25 other issues. There are many branches of the FDA.

1 S. Piper

2 Q. The FDA occasionally provides guidance  
3 for particular industries, right?

4 A. The FDA will sometimes issue guidance for  
5 a particular industry, yes.

6 Q. The FDA does not recommend any specific  
7 design approach for any medical device, right?

8 A. I can't speak for all the activities of  
9 the FDA. Can you narrow the question?

10 Q. Sure. For the FDA guidance that you're  
11 familiar with, the FDA does not typically recommend any  
12 specific design approach for a medical device; right?

13 A. Well, I'm familiar with more than one  
14 guidance. For example, there's a draft guidance for a  
15 nebulizer, FDA, dated 1993. I think you're referring to  
16 in this matter the 2001 draft guidance and the 2003 FDA  
17 guidance regarding dose counters and integrated dose  
18 counters as part of inhalers. Is in that nature of your  
19 question?

20 Q. No.

21 A. Oh.

22 Q. The nature of my question is just  
23 generally. For the FDA guidance that you are familiar  
24 with, the FDA typically does not recommend any specific  
25 design approach for a medical device; right?



1 S. Piper

2 MR. SKLAR: Objection to the form.

3 A. I'm not -- I can't recall a specific  
4 guidance by the FDA that would, that specifies exactly  
5 what, how something is to be achieved to address maybe  
6 some safety or performance concern. Usually they'll  
7 leave that up to manufacturers and developers to come up  
8 with the exact solution.

9 Their guidance is simply regarding issues that  
10 they think are relevant that you could expect to be  
11 confronted with as part of an approval process for such  
12 a device or drug or I guess food product. I have no  
13 experience with food products.

14 Q. To your knowledge, are there FDA-approved  
15 meter dose inhalers that do not include a dose counter  
16 or an indicator?

17 A. Yes, there are meter dose inhalers that  
18 are approved by the FDA that do not include integrated  
19 dose counters.

20 Q. Can you think of one by name?

21 A. Well, for example, there's an older  
22 formulation of albuterol with an earlier name of, brand  
23 name of Ventolin, and those -- once a product comes off  
24 patent -- by the FDA's term, not by the PTO term --  
25 other manufacturers can produce a product if they meet

1 S. Piper

2 certain requirements, and my understanding is that  
3 there's a number of albuterol meter dose inhaler  
4 products that are generics that don't include dose  
5 counters.

6 Q. So a company looking to introduce a meter  
7 dose inhaler on the market wouldn't be forced to include  
8 a dose counter or an indicator, correct?

9 MR. SKLAR: Objection to the form.  
10 Foundation.

11 A. What's your time frame of the question?

12 Q. I'm not sure what you're asking me.

13 A. Well, are you saying that if -- if I was  
14 going to bring a meter dose inhaler product to the  
15 market today, I could expect that the FDA would require  
16 that my device would have a counter.

17 Q. You say you could expect your device to  
18 have a counter. What does that mean?

19 A. That means if I submitted an application  
20 to the FDA without a dose counter product and the FDA  
21 said You need to count doses, I should have fully  
22 expected that. I mean, it would be silly to submit and  
23 invest the time and money for such a submission without  
24 including a dose counter.

25 Q. But there are meter dose inhalers

1 S. Piper

2 currently on the market that don't include dose counters  
3 and indicators, correct?

4 A. Yeah. There are products that were  
5 approved prior to the guidance that are on the market.

6 Q. So with all the meter dose inhalers that  
7 you're familiar with that do not include a dose counter  
8 or indicator, is it your position that they were all  
9 approved prior to the guidance in 2003?

10 A. I don't know of any meter dose inhaler,  
11 inhalers on the market that don't include dose counters  
12 that were not already approved prior to 2001 or about  
13 that time frame.

14 Q. Does a company who intends to maintain a  
15 product on the market over a long period of time have to  
16 engage in updated regulatory forms?

17 MR. SKLAR: Objection, form.

18 A. What is that? That question is really  
19 kind of vague. Can you restate it.

20 Q. Sure. If a company has a product on the  
21 market and it's been on the market for a long time, are  
22 there additional regulatory processes other than the  
23 initial approval process that a company has to undergo  
24 to maintain a product on the market?

25 MR. SKLAR: Objection, form.

1 S. Piper

2 A. There are all kinds of manufacturing  
3 requirements that medical device and drug manufacturers  
4 need to be current with. And most medical device and  
5 pharmaceutical manufacturers are audited by the FDA on a  
6 regular basis. And they are expected to meet what are  
7 generally called as good manufacturing practices.

8 So there's a substantial amount of regulatory  
9 requirements for a company to continue to manufacture  
10 and sell a product after they receive their initial  
11 approval on a particular device or drug.

12 Q. We can just do some housekeeping here. I  
13 have the updated color copy thanks to you-all of the  
14 '177 declaration, which I believe is Exhibit 1,002.1.

15 A. Okay.

16 MS. HARGRAVE: So I think if we can  
17 replace the black-and-white copy with the color copy.

18 (Exhibit 1,002 withdrawn)

19 (Exhibit 1,002.1, Color copy of  
20 declaration, was marked for  
21 identification.)

22 BY MS. HARGRAVE:

23 Q. Let's turn to Paragraph 74 of  
24 Exhibit 1,002.1.

25 A. Is that Paragraph 74?

1 S. Piper

2 Q. Yes.

3 A. Okay.

4 Q. Let me know when you get there.

5 A. All right. Paragraph 74 of the '177  
6 declaration.

7 Q. So in Paragraph 74 of your '177  
8 declaration, you state, the third sentence you state,  
9 "In fact, sometime around 1998 but before 2001 in my  
10 role at Piper Medical I was asked to look into building  
11 a dose indicator for an inhaler."

12 And you go on to explain that you looked to the  
13 mechanism of a simple plastic inexpensive mechanical pen  
14 that converted axial motion into rotational motion.

15 Do you see that?

16 A. Yeah. I see Paragraph 74 in which I  
17 described a mechanical pen, and yes. The sentence here  
18 is, "In fact, some time around 1998 but before 2001 in  
19 my role at Piper Medical I was asked to look into  
20 building a dose indicator for an inhaler."

21 Q. You didn't identify that dose indicator  
22 by name here in your declaration, did you?

23 A. No.

24 Q. You didn't identify the manufacturer of  
25 that dose indicator here in your declaration, did you?

1 S. Piper

2 A. No, I did not indicate a manufacturer for  
3 the dose indicator in the declaration.

4 Q. And you don't describe in your  
5 declaration the structure or particular components for  
6 that dose indicator, do you?

7 A. No. I was asked to do a feasibility  
8 study by Vortran Medical Technology. They were in talks  
9 with a pharmaceutical company regarding their Gentle  
10 Inhaler product. And they wanted to know if I thought  
11 building a dose indicator was feasible, and I took a  
12 look at it. As part of that process I looked at a pen  
13 which has simple axial displacement of one piece  
14 resulted in a rotational turn of another piece. So my  
15 response back to them was that it was certainly  
16 feasible.

17 Q. Just to get a clean record here, you do  
18 not ascribe the structure or a particular component of  
19 the dose inhaler dose indicator that you describe in  
20 your declaration; right?

21 MR. SKLAR: Operation to the form.

22 A. What's the question?

23 Q. You do not ascribe the structure or a  
24 particular component of the dose indicator that you  
25 discuss in your declaration, right?

1 S. Piper

2 A. Well, I describe the fact that a  
3 ballpoint pen had an axial moving portion like a  
4 ballpoint pen like an MDI canister and that the, a  
5 ballpoint pen has a turning piece as a result of that  
6 axial motion. And that that turning piece could be  
7 incorporated with a simple window in the body to  
8 indicate the number of times the axial piece had been  
9 actuated.

10 Q. You don't discuss a turning piece in your  
11 declaration, do you, Mr. Piper?

12 A. I discuss a piece that's a rotational  
13 turning piece.

14 Q. You don't discuss a rotational turning  
15 piece in the context of the dose indicator that you were  
16 asked to develop around 1998.

17 A. What's the question?

18 Q. You don't discuss a turning piece in your  
19 declaration relating to the dose indicator that you were  
20 asked to develop around 1998, do you?

21 A. So near the bottom of page 38 of  
22 Paragraph 44 -- or 74, sorry. "For example, both  
23 products converted an axial motion of one part into a  
24 rotational motion of another part and contained a fluid  
25 reservoir that could be used axially and rotationally.

1 S. Piper

2 Furthermore, both devices, both devices had the design  
3 requirement that they be capable of being mass produced  
4 and be primarily made of plastic and could be relatively  
5 inexpensive and be portable.

6 "Thereupon, being asked to look into building a  
7 dose counter, I took apart and examined a mechanical pen  
8 more closely to see how the mechanical components work.  
9 I designed the dose indicator that I was asked to build  
10 by using the same type of mechanism that was disclosed  
11 inside the mechanical pen," which as described include a  
12 rotational part.

13 Q. So the last sentence of that paragraph  
14 says, "I designed a dose indicator that I was asked to  
15 build by using the same type of mechanism that was  
16 disclosed inside a mechanical pen."

17 Right, did I read that correctly?

18 A. The last sentence states, "I designed the  
19 dose indicator that I was asked to build by using the  
20 same type of mechanism that was disclosed inside the  
21 mechanical pen."

22 Q. For the dose indicator that you were  
23 asked to build, you have not produced any notes relating  
24 to your development of that product; right?

25 MR. SKLAR: Objection to the form.



1 S. Piper

2 A. Well, the declaration describes the work  
3 that I did.

4 Q. I'm talking about notes that you may have  
5 made while you were developing your product. You didn't  
6 produce any notes like that, did you?

7 A. I had sketches and notes that I made at  
8 the time.

9 Q. Did you produce those in the context of  
10 your declaration?

11 A. I did not include them as part of the  
12 context of the declaration.

13 Q. Did you include any lab notebooks that  
14 you may have used while developing this product in  
15 conjunction with your declaration?

16 MR. SKLAR: Objection, foundation.

17 A. No. I did not include any lab books,  
18 notes as part of the declaration. But certainly the  
19 work I did, it wasn't very difficult to remember. And  
20 as I indicated in the declaration, it wasn't unusual for  
21 people to refer to ballpoint pens in regards to  
22 designing medical devices.

23 MS. HARGRAVE: Objection,  
24 nonresponsive.

25 Q. You didn't include any drawings, pictures

1 S. Piper

2 or diagrams that you may have produced -- scratch that.

3 You didn't produce any drawings, pictures or  
4 diagrams relating to the dose indicator device that you  
5 were asked to develop some time around 1998, did you?

6 MR. SKLAR: Objection, form.

7 A. I did not include any drawings or  
8 pictures of the work I did in regards to developing a  
9 dose indicator for Vortran Medical Technology in regards  
10 to their inhaler product.

11 Q. You don't include any documentary  
12 evidence of your design of the dose indicator that we  
13 were just discussing some time around 1998, do you?

14 A. No. I provide substantial -- I have a  
15 full description here, and I think it's fully described  
16 what I did, so I would consider that documentation. The  
17 declaration is certainly a document.

18 Q. You don't include any contemporaneous  
19 documentary evidence of your design of the dose  
20 indicator that we were just discussing sometime around  
21 1998, do you?

22 A. I'm not -- contemporaneous --

23 Q. That's all right.

24 A. I know vaguely, can you use a different,  
25 ask a different question.

S. Piper

Q. Sure. In your declarations you don't provide any evidence that the inhaler that you designed was ever manufactured, right?

A. I don't provide any evidence that the inhaler that I designed was ever manufactured? That's correct. In fact --

Q. In your declarations you don't provide any evidence that the inhaler you designed was ever brought to market, right?

MR. SKLAR: Objection, form.

A. I don't provide any evidence that the inhaler work, indicator work that I did as part of the Vortran inhaler was ever manufactured or brought to market.

Q. I want to talk specifically about your opinions relating to the Elliott and Rhoades combination in your '177 declaration. Let's start with Paragraph 79.

Are you there with me?

A. Not quite. All right. I'm there. Seventy-nine.

Q. Why don't you just read, skim or orient yourself to the section of your declaration that we're discussing here so I can ask you some questions about

1 S. Piper

2 it.

3 A. (Witness complies with request.) Okay,  
4 I've read Paragraph 79.

5 Q. This section of your declaration is  
6 discussing your opinion that a person with ordinary  
7 skill in the art would have been motivated to  
8 incorporate the entire Rhoades mechanism into Elliott,  
9 right?

10 A. Right. I mean, to make the above  
11 substitution of the -- would have incorporated the body  
12 of Rhoades. You know, there's a whole paragraph here.  
13 I can read it if you like.

14 Q. No, no, no. I just want to make sure  
15 we're both talking about the same thing.

16 So you just read that first sentence or a  
17 portion of that first sentence, and you call the  
18 modifications that a person would have made a  
19 substitution; right?

20 A. The word "substitution" is used in the  
21 Paragraph 79, yes.

22 Q. So if you're substituting, you'd be  
23 removing components from one device and replacing them  
24 with components from another; right?

25 A. Yeah, it's an obviousness combination of

1 S. Piper

2 two products, it's not anticipation argument. So yeah,  
3 I mean, to make, to make the above substitution of the  
4 elements of the Rhoades patents so they worked with the  
5 Elliott device, you would substitute some of the  
6 components of the Rhoades device into the Elliott  
7 device.

8 Q. And so in this particular combination of  
9 Elliott and Rhoades, Elliott's counting mechanism is  
10 removed; right?

11 A. In this particular description, yes.

12 Q. Is there another combination of Elliott  
13 and Rhoades that you're familiar with where the Elliott  
14 counting mechanism is not removed?

15 A. Do you mean in the declaration itself?

16 Q. Yes. Well, you're not testifying here  
17 today that Petitioners have asserted that there would be  
18 some combination of Elliott and Rhoades that would  
19 invalidate the '177 patent where the Elliott counting  
20 mechanism is not removed from this, right?

21 A. No. I'm just saying it would have been  
22 obvious. There are any number of different ways that  
23 you could do this. This is one particular, one  
24 particular way.

25 Q. You haven't described any other ways of

1 S. Piper

2 combining Elliott and Rhoades that don't involve  
3 removing Elliott's counting mechanism from the inhaler,  
4 right?

5 A. In the declaration for the '177 there are  
6 two grounds for obviousness. One is Elliott in view of  
7 Rhoades, and the other one is Bason in view of Rhoades.

8 Q. My question was, you haven't described  
9 any other ways of combining Elliott and Rhoades that  
10 don't involve removing Elliott's dose indicator  
11 mechanism from the inhaler; right?

12 A. Well, the primary description here, as is  
13 stated like in Paragraph 79, does include putting the  
14 mechanism of Rhoades -- well, I'll just read the  
15 paragraph.

16 "To make the above substitution a person of  
17 ordinary skill would have incorporated cam body 20 of  
18 Rhoades immediately below the canister where the  
19 counting mechanism of Elliott resides. The stop members  
20 of Rhoades" --

21 Q. You don't have to keep reading the whole  
22 thing, because that's not really my question. My  
23 question is, to your knowledge is there any other place  
24 in your declaration where you describe a combination of  
25 Elliott and Rhoades where the counting mechanism of

1 S. Piper

2 Elliott is not removed? Can you think of anything like  
3 that? And I don't need you to read me your declaration.  
4 Just to your recollection.

5 MR. SKLAR: Objection, form.

6 A. I mean, there's two developed grounds  
7 here for obviousness. One is Elliott and Rhoades. The  
8 other one is Bason and Rhoades. So those are the  
9 primary grounds. There are any number of ways to do the  
10 combination and achieve the same objective.

11 Q. You don't describe any of these  
12 combinations here in your declaration, do you?

13 A. I have not described all the possible  
14 combinations, no, because there are a lot of them.

15 Q. So you agree with me, though, that in the  
16 Elliott and Rhoades combination that you described in  
17 your declaration, Elliott's counting mechanism is  
18 removed; right?

19 A. That I would -- as it's described here,  
20 the elements of Rhoades are placed in the Elliott device  
21 in place of some of the Elliott components. That's  
22 correct.

23 Q. So, for example, in the Elliott-Rhoades  
24 combination you describe here in Paragraph 79 of your  
25 '177 declaration, Elliott's number wheel is not present;

1 S. Piper

2 right?

3 A. Well, as it says here, a person of  
4 ordinary skill in the art would have easily included  
5 numbers around the circumference of the rotating Rhoades  
6 cam body to include displayable values.

7 Q. So I'm not asking you about components of  
8 Rhoades. I'm asking you about components of Elliott  
9 that may or may not be present in the combination that  
10 you describe here in Paragraph 79.

11 So here in Paragraph 79, Elliott's number wheel  
12 is not present in the combination of Elliott and Rhoades  
13 that you described; correct?

14 A. Well, the intent was to show the elements  
15 of Elliott and Rhoades could be placed combined with  
16 Elliott, and as described here, a number wheel, the  
17 component -- a person of ordinary skill would have  
18 easily included numbers around the circumference of the  
19 rotating Rhoades cam body including displayable values.

20 Q. So can you tell me or can you not tell me  
21 whether or not Elliott's number wheel is included in the  
22 combination that you assert invalidates the '177 patent?

23 MR. SKLAR: Objection to the form.

24 A. There's no mention of Elliott's counting  
25 wheel in this paragraph. So I'm saying that the -- to



1 S. Piper

2 make the above substitution. Yeah. In regards to the  
3 elements of Elliott that are substituted out, as it says  
4 near the end of Paragraph 78, "A person of ordinary  
5 skill would have been motivated to incorporate the  
6 entire Rhoades mechanism into the Elliott device to take  
7 advantage of the features of the Rhoades device."

8 Q. So -- okay. Go ahead.

9 A. You know, there's, including the Elliott  
10 wheel counter still there, it's being substituted out,  
11 there's no indication that the Elliott counter wheel is  
12 part of that resulting combination as described.

13 Q. So let's get the record really clear.  
14 You agree that in the combination of Elliott and Rhoades  
15 that you described in your Paragraph 79 of your '177  
16 declaration, Elliott's number wheel is not present?

17 A. I am not stating that the number wheel is  
18 present, Elliott's number wheel is present in that  
19 combination, no.

20 Q. So Elliott's number wheel was removed in  
21 that combination, right?

22 A. There are a number of elements including  
23 the number wheel which was substituted with functioning  
24 components of the Rhoades device.

25 Q. In the combination of Elliott and Rhoades

1 S. Piper

2 that you describe here in Paragraph 79 of your '177  
3 declaration, Elliott's drive member 34 is also not  
4 present; right?

5 A. The drive member of the Elliott device is  
6 not included in the described combination of Rhoades and  
7 Elliott.

8 Q. In the Elliott reference, the counting  
9 mechanism is at the bottom of the inhaler; correct?

10 A. How would you define -- I mean, just for  
11 sake of asking me to give a full and complete answer,  
12 how do you define "bottom"?

13 Q. We can just use your language. Let me  
14 find that for you. I think at the beginning of  
15 Paragraph 79 you describe that the counting mechanism of  
16 Elliott resides below the canister; is that correct?

17 A. Immediately below the canister, yes. So  
18 if you look at figure 3B, it's on page 29 of my  
19 declaration, there's a mouthpiece, an inhaler body and a  
20 vial.

21 So the counter window is indicated as 14 in that  
22 figure, so yeah, with the mouthpiece at the bottom and  
23 the canister at the top, the indicator display window is  
24 below the canister.

25 Q. In the combination of Elliott and Rhoades

1 S. Piper

2 that you describe in your declaration, the cam body of  
3 Rhoades that's incorporated into that product is not  
4 secured to anything at the bottom of the inhaler; right?

5 A. Well, it wouldn't fall out if you tipped  
6 it over. So it's secured in some way or form. It's a  
7 rotational piece, and it translates, but it doesn't just  
8 come out if somebody sticks an inhaler in their product.  
9 Pocket, sorry about that.

10 Q. You said in your testimony just now that  
11 it's secured in some way or form. In what way or form  
12 is the cam body secured to the inhaler?

13 A. Well, it's engaged with the stop numbers  
14 and the figures as described, and so it's therefore sort  
15 of encapsulated by those components in the overall body  
16 of the inhaler, described inhaler.

17 Q. So if we're conceptualizing the Elliott  
18 and Rhoades combination you have, the canister and then  
19 below that you have the mechanism of Rhoades that has  
20 been incorporated and then the mouthpiece below that, is  
21 there anything between Rhoades and the mouthpiece? I  
22 mean -- sorry. Let me restate that question.

23 In the Elliott and Rhoades combination, you have  
24 the canister, and immediately below the canister are the  
25 components of Rhoades that were incorporated, and then

1 S. Piper

2 you have the mouthpiece. Is there any component between  
3 the mouthpiece and the cam body?

4 A. Well, the mouthpiece isn't vertically  
5 directly below anything. So it's just, that's generally  
6 the bottom end. But as described, the stop members of  
7 Rhoades would have been molded directly into the Elliott  
8 inhaler body. So those could be between. It depends on  
9 the orientation. And --

10 Q. You state "it depends on the  
11 orientation." What orientation is it? Are you saying  
12 that depending on whether or not the inhaler is oriented  
13 with the canister up or down?

14 A. I guess the point of my comment is the  
15 question is kind of vague. I mean --

16 Q. Why don't you tell me what's confusing  
17 you about my question.

18 A. Well, you're asking if it's between the  
19 mouthpiece -- you were asking me if any components of  
20 the Rhoades substitution would be between the canister  
21 and the mouthpiece? Is that the exact question?

22 Q. Yes.

23 A. Okay. So the mouthpiece is off-angle  
24 from the axis of the canister and the counting  
25 mechanism. So there would be -- I mean, there are

1 S. Piper

2 clearly components below the canister that engage with  
3 the canister and the inhaler body. It indicates here  
4 Item 10 in the figure on page 29.

5 So it's just that the mouthpiece isn't in direct  
6 line with the canister, so -- with the axis of the  
7 canister. So yes, there are components in between. It  
8 just seems like an obscure question. So I guess I'm  
9 just not clear on where you're going with it or what  
10 exactly you're asking.

11 Q. Sure. So why don't you just describe for  
12 me the sequence of components following the canister.

13 MR. SKLAR: Objection to the form.

14 Q. What comes directly below the canister?

15 A. Below the canister would be the fingers  
16 of the Rhoades device, which would engage with the cam  
17 body, which would have the indicated numerals on it.  
18 The stop members would be integratedly molded into the  
19 body of 10. That entire assembly would occur for the  
20 most part underneath the canister as described in the  
21 declaration.

22 Q. So apart from the components that you  
23 just described, were there any other components that are  
24 attached to the cam body to secure it in place?

25 MR. SKLAR: Objection, form.

1 S. Piper

2 A. The cam body needs to, needs to be able  
3 to move when engaged with the fingers of the -- of the  
4 fingers of the Rhoades device. And needs to rotate to  
5 indicate numbers so it's assembled in place but it's  
6 able to move as part of its normal function. I think  
7 that's totally described in the Rhoades patent, and  
8 everybody who has taken the time to look at it would  
9 understand.

10 Q. So you said the cam body wouldn't fall  
11 out easily, right?

12 A. No.

13 Q. What keeps it from falling out of the  
14 inhaler?

15 A. It's encapsulated between the fingers in  
16 the canister and the inhaler body, which the stop  
17 members are molded into.

18 Q. So are you saying that the contact  
19 between the cam body and the stop members are what keep  
20 the cam body from falling out of the inhaler?

21 A. Well, the cam -- the cam body is engaged  
22 by the fingers, and it is also engaged by the stop  
23 members which are molded into the inhaler body.

24 Q. So apart from the fingers and the stop  
25 members which are molded on to the inhaler body, are

1 S. Piper

2 there any other components in the Elliott-Rhoades  
3 combination that secure the cam body in place?

4 A. Well, the stem would -- the stem of the  
5 canister would travel through the center of the  
6 assembly. And so that would prevent the cam body from  
7 just falling out of the device as well.

8 Q. You described here in Paragraph 79 how  
9 the stem provides -- scratch that.

10 You don't describe here in Paragraph 79 how the  
11 stem traveling through the center of the assembly  
12 prevents the cam body from falling out of the device,  
13 right?

14 A. I don't -- I don't -- in 79?

15 Q. Correct.

16 A. Well, I mean what's described here is the  
17 canister would sit on a component analogous to the  
18 Rhoades plunger having fingers 43 and 44 of Rhoades, and  
19 that would engage with the cam body. And since the  
20 canister is sitting on top of the fingers, the desire is  
21 to have an inhaler that is tracking the number of doses  
22 and is able to deliver an inhaled dose, I think it's  
23 obvious to somebody skilled in the art that the stem of  
24 the canister would travel through the cam body in the  
25 Rhoades device. It's part of the design that's

1 S. Piper

2 described.

3 Q. You don't describe it here in your  
4 declaration in Paragraph 79, do you?

5 A. Well, I think it is described, as  
6 somebody skilled in the art would look at the Rhoades  
7 device which is a reference and look at the Elliott  
8 device as a reference, and based on this description I'd  
9 say yeah, I understand what is being said here and the  
10 valve stem wouldn't necessarily travel through the cam  
11 body of the Rhoades device.

12 Q. You testified earlier that there are lots  
13 of different ways to combine these components. Is it  
14 your testimony right now that necessarily a person of  
15 ordinary skill in the art looking at these two  
16 references would have decided that this is the  
17 particular way they must be combined?

18 A. What I'm saying is that what's described  
19 here is a way to substitute in the Rhoades mechanisms  
20 into the Elliott device such that the counting mechanism  
21 is below the canister as shown in figure on page 29,  
22 figure 3B of the Elliott patent; and thereby because  
23 there's a canister and there's a counter below the  
24 canister and then there's a mouthpiece, there needs to  
25 be a clear path for the jet to come out when the



1 S. Piper

2 canister is actuated.

3 And so what I'm saying, therefore, is that  
4 you're going to have to have some means of having the  
5 aerosol come out of the inhaler, otherwise it's not a  
6 very functional inhaler. And a person of ordinary skill  
7 in the art would understand that.

8 Q. So it's your testimony that that's the  
9 only way that the design that is described here in your  
10 declaration --

11 A. I am not --

12 MR. SKLAR: Object to the form. Just  
13 give me a chance to make my objection. Objection to  
14 form. You can answer.

15 A. I'm not suggesting any particular  
16 embodiment in which, in this combination, in which the  
17 exit of aerosol from the jet would be impeded. So as  
18 part of the design requirements of an inhaler device, it  
19 is understood that whatever combination is described  
20 will also allow for the straightforward emission of the  
21 desired dose from the inhaler.

22 Q. Does adding a hole into the can body to  
23 allow the valve stem to proceed through it affect how  
24 the component would interact with the other components  
25 you described here?

1 S. Piper

2 MR. SKLAR: Objection, form.

3 A. No. The part needs to translate and  
4 rotate. As long as it's able to do that, it could have  
5 a passage through the center.

6 Q. Do you describe having passage through  
7 the center here in your declaration?

8 A. As I answered previously, I think it's  
9 very clear to somebody skilled in the art that they  
10 would understand that the canister has a stem, has to be  
11 engaged with a jet in some way and allow direct emission  
12 of aerosol through the mouthpiece. I think one of skill  
13 in the art would understand that that's what's being  
14 described.

15 Q. So my question is not whether one with  
16 skill in the art would understand it. My question is  
17 whether or not you described it in Paragraph 79. So let  
18 me ask my question again.

19 Do you describe in your combination of Elliott  
20 and Rhoades having a passage through the cam body to  
21 allow the valve stem to go through it?

22 A. I think that given the description that's  
23 here, I think it would be understood by somebody skilled  
24 in the art.

25 Q. Again, sir, I'm not asking about what

1 S. Piper

2 someone reading this would understand. I'm asking if  
3 you describe in your own words a hole through the cam  
4 body to allow a valve stem to pass through it. Are  
5 those words included here in your declaration?

6 MR. SKLAR: Objection, form.

7 A. I don't see in Paragraph 79, I don't see  
8 the words "hole through a cam body." So therefore  
9 they're not there.

10 Q. Anywhere else in your declaration do you  
11 use words to describe having a hole through Rhoades' cam  
12 body in the combination of Elliott and Rhoades?

13 A. I could review the declaration if you'd  
14 like me to.

15 Q. To your recollection, do you recall any  
16 language describing a passage through the cam body in  
17 your Elliott and Rhoades combination for the '177  
18 patent?

19 MR. SKLAR: Objection, form.

20 A. Well, I think again what -- I describe  
21 what I thought was relatively obvious. I mean, the  
22 combination of Rhoades and Elliott device, for example.  
23 Whether I used language or not, I would have to go  
24 through the declaration sentence by sentence to give you  
25 a full and complete answer one way or the other.

1 S. Piper

2 Q. Do you recall, Mr. Piper, in your '177  
3 declaration describing an alternative modification that  
4 a person of ordinary skill in the art could have made to  
5 Elliott in view of Rhoades? And I can just direct you  
6 to -- if it's not coming directly to mind, you can go  
7 into Paragraph 81 of your '177 declaration.

8 A. Yeah.

9 Q. So you describe a modification that a  
10 person of ordinary skill in the art would have made to  
11 the Rhoades mechanism here in Paragraph 81.

12 In that modification, cam body 20 would have a  
13 first row of teeth all the same height and separately a  
14 second row of teeth also the same height; correct?

15 A. As it states here, a person of ordinary  
16 skill would have used a single row of teeth all at the  
17 same height and separately incorporated a second row of  
18 teeth at the same height to interact with the stop  
19 numbers, yes.

20 Q. Mr. Piper, do you include any diagram  
21 showing two separate and even rows of teeth?

22 A. As a description to this particular  
23 alternative?

24 Q. Yes.

25 A. No.

1 S. Piper

2 Q. And nothing in Rhoades describes a  
3 component with two separate and even rows of teeth,  
4 right?

5 A. Well, the Rhoades device is described in  
6 how it functions. So it doesn't teach a ballpoint pen  
7 that is either always, you click it and it's either  
8 always retracted or it's always extended. But a person  
9 of ordinary skill in the art could understand the  
10 mechanism and at the end of the day a translatable axial  
11 movement of one component results in a rotational motion  
12 of another component, and that would obviously be very  
13 useful and indicating a number of doses of a meter dose  
14 inhaler.

15 MS. HARGRAVE: Objection,  
16 nonresponsive.

17 Q. As you state here, you're modifying  
18 Rhoades to include a component with two separate and  
19 even rows of teeth; right?

20 A. This alternative, you could do it either  
21 way. You could have it the way as it's first described  
22 and have a meter dose inhaler that you click to dispense  
23 medication and then click to refill the meter volume.

24 Or you can make this slight modification to the  
25 Rhoades device and have a single-click meter dose

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2 inhaler that in the course of a click in allowing a  
3 return would dispense medication, perform a count and be  
4 ready for the next dose. So you would need a refill.

5 Q. To your knowledge, nothing in Elliott  
6 describes a component with two separate and even rows of  
7 teeth; right?

8 A. The Elliott device -- well, let me look  
9 before I answer the question. The Elliott device shows  
10 parts with evenly distributed rows of teeth.

11 Q. Which figure are you looking at? What  
12 page are you on?

13 A. I'm on page 28, Paragraph 55, there's a  
14 diagram there, it's figure 1 as part of the Elliott  
15 patent.

16 Q. Which component do you contend in Elliott  
17 that includes two separate and even sets of teeth?

18 A. Well, the number wheel has teeth on the  
19 bottom and teeth on the inside, indicated with the  
20 numbers 26 and 24 that appears.

21 Q. You're referring to numbers 26 and 24 in  
22 the figure on page 29?

23 A. Twenty-eight.

24 Q. I'm sorry.

25 A. Figure 1 of the Elliott patent.

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2 Q. Is there anywhere else in your '177  
3 declaration where you include further explanation of the  
4 modification that you proposed?

5 A. Which, which modification are you talking  
6 about?

7 Q. We were just talking earlier about  
8 Paragraph 81.

9 A. Okay.

10 Q. In your '177 declaration where you  
11 describe making a modification to the cam surfaces of  
12 cam body 20. And rather than two gears of separate  
13 height, a person of ordinary skill in the art would have  
14 used a single row of teeth all at the same height and  
15 separately incorporate a second row of teeth of the same  
16 height to impact the stop.

17 Do you see that?

18 A. Yes.

19 Q. Are you aware of any other place in your  
20 declaration where you describe this modification that we  
21 just discussed in Paragraph 81 in any further detail?

22 A. There's a similar paragraph, 143.

23 Q. And that's addressing modifications to  
24 the Rhoades and Bason combination, right, not Rhoades  
25 and Elliott?

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2 A. Right. That's based on the Rhoades  
3 combination, that's correct.

4 Q. So with respect to Elliott and Rhoades,  
5 you're not aware of any other explanation in your  
6 declaration that further describes the modification that  
7 you've referred to in Paragraph 81?

8 A. The further modification is described in  
9 81. That certainly represents the primary description  
10 of that modification, yeah.

11 Q. So --

12 A. That particular modification.

13 Q. Sure. And so if I wanted to find  
14 additional description of that particular modification,  
15 you can't point me to anywhere else in your declaration  
16 where I would go to find that?

17 A. No. I think that it's sufficient,  
18 there's sufficient description right here to understand  
19 what's being described.

20 Q. Go ahead and go to Paragraph 96 of your  
21 declaration. And for the record, this is the '177  
22 declaration, Exhibit 1,002.1. Let me know when you're  
23 there.

24 A. Okay, I'm at 96.

25 Q. In this portion of your declaration



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2 you're addressing the last claim element of Claim 1 of  
3 the '177 patent, right?

4 MR. SKLAR: Objection. This is the  
5 last claim element of Claim 1.

6 Before you go on any further, we've  
7 been going for a little over an hour. Take a quick  
8 break?

9 MS. HARGRAVE: Sure.

10 (Recess)

11 BY MS. HARGRAVE:

12 Q. Mr. Piper, I think before the break we  
13 had begun to look at Paragraph 96 of your '177  
14 declaration.

15 Do you remember that?

16 A. Yeah.

17 Q. Okay. And we agreed that this was your  
18 discussion of the last claim element of Claim 1 of the  
19 '177 patent for the Elliott and Rhoades combination,  
20 right?

21 A. Right, this is the last claimed element  
22 of Claim 1 regarding the Elliott and Rhoades  
23 combination.

24 Q. So in this of your declaration you're  
25 discussing Petitioner's position that the

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2 Elliott-Rhoades combination meets this particular claim  
3 limitation, right?

4 A. I'm sorry, I just don't understand.

5 Q. I just want to establish what we're  
6 talking about. I think what we're talking about is your  
7 opinions relating to Petitioner's contention that the  
8 Elliott-Rhoades combination meets this particular claim  
9 limitation, right?

10 A. I mean, what's described here is that I  
11 think that the '177 patent Claim 1, all the elements of  
12 Claim 1 are met by combining Rhoades and Elliott, and so  
13 it's a piece-by-piece breakdown of the claim. And this  
14 represents the last part of the claim as I've broken it  
15 down for the declaration.

16 Q. Okay. Let's go down to Paragraph 99.

17 A. Okay. I'm at 99.

18 Q. In the very last sentence you say,  
19 "Moreover, as explained in Paragraph 81, the POSA" --  
20 or person of ordinary skill in the art -- "would also  
21 have made a device based on the Rhoades design that  
22 would not have required additional depression to extend  
23 and retract the canister."

24 Do you see that?

25 A. Yeah.

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2 Q. So are you referring here to the  
3 modification that we discussed earlier where you would  
4 have two even sets of teeth rather than Rhoades' cam  
5 body design as is disclosed in Rhoades?

6 MR. SKLAR: Objection, form.

7 A. So I'd like to clarify. There was a  
8 question regarding the Elliott counter in regards to  
9 whether the Rhoades device, you know, completely  
10 replaced everything and whether -- I think there had  
11 been a question on whether there were any other places  
12 that that had been described.

13 So in Paragraph 99 a person of ordinary skill  
14 would have been motivated to improve Elliott in view of  
15 Rhoades, and a person would have substituted the Rhoades  
16 mechanism into Elliott at the position of Elliott's  
17 counter. In such a configuration, the Elliott canister  
18 would have sat on top of the Rhoades plunger with the  
19 Elliott canister valve extending through the counter  
20 like it does in Elliott.

21 There was some previous conversation we were  
22 having, and I just thought that this is a relevant topic  
23 obviously to address some of those answers, which now  
24 seeing this I just wanted to make sure there's a more  
25 complete answer.

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2 Q. Okay. So do you want me to restate my  
3 question, my previous question?

4 A. Yeah, please.

5 Q. In Paragraph 99 you discuss a  
6 modification that could have been made to the device  
7 that would not have required additional depression to  
8 extend and retract the canister, right?

9 A. Right.

10 Q. Is that modification, the modification  
11 that is explained in 81, where the device would be  
12 modified so that it had two even rows of teeth?

13 A. Well, it says as in Paragraph 81, and 81  
14 is the description of a person could have done it with  
15 single rows of teeth, as we discussed.

16 Q. So that's yes in an answer to my  
17 question?

18 A. Well, yeah. Moreover as explained in 81,  
19 yes.

20 Q. Okay. So as we were just discussing,  
21 this section is where you laid out the proof that the  
22 Elliott and Rhoades combination together meets this  
23 particular claim limitation; right?

24 MR. SKLAR: Objection, form.

25 A. This section here from Paragraph 96

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2 through 99, this describes how the limitations of, the  
3 limitations of the claim are met by combining Elliott  
4 and Rhoades.

5 Q. So apart from the sentence here at the  
6 very bottom of Paragraph 99, is there any other  
7 discussion in this section of your declaration that  
8 describes how that particular modification meets this  
9 particular claim element?

10 MR. SKLAR: Objection, form.

11 A. Can you include more specifics in that  
12 question?

13 Q. Okay. Apart from describing -- let me  
14 rephrase.

15 Apart from referring to your discussion in  
16 Paragraph 81, is there anyplace here in this section of  
17 your declaration where you describe how that  
18 modification meets this particular claim limitation?

19 MR. SKLAR: Objection, form.

20 A. Well, I'm discussing this claim  
21 limitation here. So I mean, it's fully described in 93,  
22 Paragraphs 93 through 99. So if you're focusing on one  
23 last sentence -- oh, not 99. Yeah. I'm sorry, yes, 99.

24 Q. Well, I'm just asking you to point me  
25 where in your declaration you discuss how the

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2 modification to the Elliott-Rhoades combination that  
3 we've just been discussing meets this particular claim  
4 limitation.

5 MR. SKLAR: Objection, form.

6 A. Well, there's a pretty full description  
7 on how the Rhoades device works. And so I think it's --  
8 you know, previously in the declaration -- so I think  
9 it's pretty clear about how this particular claim  
10 limitation is met by the geometry of the Rhoades device,  
11 which is previous in the declaration.

12 Q. Sure, but we're not talking about the  
13 geometry of the Rhoades device. We're talking about the  
14 modification that you say you would make to Rhoades so  
15 that there are two sets of even teeth, right?

16 A. Well, I think the modification is pretty  
17 straightforward. And so there's a lot of description on  
18 how the Rhoades device is described and how it works and  
19 how that would meet as part of these, this limitation.  
20 And so I don't think you just take this language right  
21 here and say this is the only thing, because there's  
22 quite a substantial amount of description on Rhoades on  
23 how it works and how it would meet this particular part  
24 of the limitation in regards to how the overall Rhoades  
25 device works. Simply making one little minor

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2 modification is just part of that bigger picture.

3 Q. So apart from your description of how  
4 Rhoades works and your discussion here in Paragraph 96  
5 through 99, you can't point me today to any other  
6 description in your declaration that discusses  
7 specifically how your modification to Rhoades meets this  
8 claim limitation; right?

9 MR. SKLAR: Objection, form.

10 A. I don't agree with that. I think that's  
11 a -- I don't agree with the assessment because I think  
12 that in the description of Rhoades there's a description  
13 of how these particular parts of the elements are met.  
14 And that adding a second row of teeth so that you would  
15 have a single clickable device is a minor modification  
16 of what has already been described. I think it's pretty  
17 straightforward.

18 Q. So from your perspective adding the  
19 additional rows of teeth doesn't change the  
20 functionality of the device essentially that you needed  
21 to do a specific analysis for that particular  
22 modification? Is that your testimony?

23 A. So for an example, like Paragraph 78, "A  
24 person skilled in the art would have known that if the  
25 tolerances of the Rhoades stop members were coordinated

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2 to the tolerances of valve travel and refillings, as  
3 explained in Paragraphs 19 through 22, one could further  
4 decrease the possibility of undercounting, which is  
5 obviously part of the elements of the claim limitation  
6 we're talking about.

7 "For example, in Rhoades, figure 9, there's a  
8 noticeable gap between the bottom surface of the stop  
9 members and surfaces 50 and 52. Cam body 20 will begin  
10 to rotate as soon as the lower edge of the bottom  
11 surfaces of stop members clear the top surfaces of 50  
12 and 52.

13 "However, to account for the tolerances of the  
14 device, the mechanism is designed so that the plunger  
15 can continue to press cam body 20 even after it's  
16 cleared the stop members. Thus, Rhoades demonstrates  
17 that the cam body 20 will begin to rotate even prior to  
18 the completion of the actuation stroke. A person  
19 skilled in the art would have been motivated to  
20 incorporate the entire Rhoades mechanism into the  
21 Elliott device to take advantage of this feature."

22 And so that's part of what bears on the claim  
23 limitation here at the end of Paragraph 95. So it's  
24 that geometry, using that geometry and the way that the  
25 Rhoades device works meets, satisfies, is in part how



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2 this limitation is satisfied.

3 Q. So that description related to this  
4 disclosure in Rhoades, right?

5 A. There's a description -- what was the  
6 question?

7 Q. So Paragraph 78 you were just discussing,  
8 that's a discussion of what's disclosed in Rhoades;  
9 right?

10 A. Right. And how the Rhoades device works,  
11 yes, correct. And that's particularly relevant to the,  
12 obviously, the, you know, the declaration of the  
13 combination of Elliott in terms of Rhoades and why the  
14 claim limitations are satisfied.

15 Q. Okay. Are you aware of any meter dose  
16 inhalers available on the market that use a retractable  
17 mechanism as the e-pen in Rhoades does?

18 MR. SKLAR: Objection, form.

19 A. Use a retractible mechanism like in the  
20 Rhoades device? What was the question?

21 Q. Sure, I'll read it again.

22 A. Sorry.

23 Q. That's all right. Are you aware of any  
24 meter dose inhaler available on the market that uses a  
25 retractible mechanism as the pen in Rhoades does?

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2 MR. SKLAR: Objection, form.

3 A. Well, the retractible mechanism in the  
4 Rhoades device is the simple force of the spring, so I  
5 would say that all meter dose inhalers have a spring  
6 component included into their canister; when you push  
7 it, it retracts automatically.

8 Q. That's not quite what I'm asking about.

9 You make a distinction in Paragraph 81 of your  
10 declaration between what you describe as the combination  
11 of Elliott and Rhoades and a simple press-and-release  
12 inhaler like the one depicted in Elliott, right?

13 A. Correct.

14 Q. So there's a distinction between the  
15 retraction and extension that you describe in the  
16 Elliott and Rhoades combination and a simple  
17 press-and-release inhaler, right?

18 A. Right. The Rhoades device is a ballpoint  
19 pen that you click it and it extends a writing point and  
20 you can click it again and it will retract the point.  
21 You can do an inhaler that way and it would have some  
22 advantages.

23 Q. Are you aware of any inhaler on the  
24 market that operates that way?

25 A. Well, there's some breath-actuated

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2 devices that -- I haven't done any -- I've seen them and  
3 tested them. I haven't really delved into all the  
4 mechanics, but they're essentially cocked and spring  
5 loaded in advance of a person inhaling; and then when a  
6 person inhales it, it actuates the device by the force  
7 of inhalation. And then as I recall the devices have to  
8 be recocked to be reused again. So they may essentially  
9 be similar to a dual-action as described as a first  
10 description in the Rhoades device.

11 Q. But you're not aware of any meter dose  
12 inhaler on the market that operates in the way that you  
13 describe for the Elliott and Rhoades combination, right?

14 A. Well, the breath -- what I'm trying to  
15 say is a breath-actuated inhaler device has a cocking  
16 mechanism so that the force needed to actuate it is  
17 preloaded. So when a patient inhales, the devices, the  
18 canister is actuated and a dose is dispensed in  
19 coordination with the patient's inhalation.

20 And then there's a subsequent mechanical motion  
21 that happens to recock the device, which I believe would  
22 be a second action that would cause the refilling of the  
23 priming volume.

24 And like I said, I think that it might function  
25 that way. Other than that, I don't know of an inhaler

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2 which you'd click once to dispense medication and then  
3 you click a second time to refill the metering volume.

4 Q. The breath actuator inhaler device that  
5 you were just describing, is that available on the  
6 market?

7 A. It used to be. I don't know if it's been  
8 taken off the market. I haven't seen one in a while.

9 Q. And for the breath-actuator inhaler  
10 device that you were just speaking of, is the user  
11 responsible for cocking and dispensing the fluid?

12 A. Yeah. Something the user does. They  
13 will cock the device, which provides a preloaded spring  
14 force that could be applied to the canister when they  
15 inhale. When they inhale, a flapper valve moves out of  
16 the way which allows the force to be applied to the  
17 canister, and the canister dispenses medication in  
18 coordination with their inhalation.

19 Like I said, I haven't actually taken one of  
20 those apart to some great degree or developed one  
21 myself. But it does require two actions, and it does  
22 seem like the recocking action would be when the  
23 canister would be refilled.

24 Q. But you can't tell me that for sure  
25 because you haven't observed the product in detail to

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2 say one way or the other?

3 A. I can't say for absolute certainty, no.

4 Q. So apart from the product that we were  
5 just discussing, you can't recall a commercially  
6 produced meter dose inhaler that uses a retractible  
7 mechanism as the e-pen in Rhodes; right?

8 MR. SKLAR: Objection, form. Asked and  
9 answered.

10 A. I can't recall a device, although there  
11 is some powder inhaler devices that function various  
12 ways. But I can't recall one that functions in a -- for  
13 sure, I can't say with any authority one way or the  
14 other that there is an inhaler device that the first  
15 click will dispense the medication and then a second  
16 click would refill it. The metering valve, refill the  
17 metering valve, that is.

18 Q. Do you describe in your declaration  
19 anywhere how a patient who is using, extending and  
20 retracting the meter would be able to tell by looking  
21 which configuration the inhaler was in?

22 A. Well, I don't know. I don't recall that  
23 there's exact language, but I mean, where obviously the  
24 pen is. You can tell when it's been, you know, in the  
25 down or the up position.

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2 Q. In the inhaler that you've described as a  
3 combination of Elliott and Rhoades, you don't explain in  
4 your declaration anywhere how a patient who is using the  
5 extending and retracting inhaler would have been able to  
6 tell by looking which configuration the inhaler is in;  
7 right?

8 A. Well, I think that would be pretty  
9 straightforward. I don't recall a place where that's  
10 exactly indicated, no.

11 Q. Let's turn now to your discussion of the  
12 Bason and Rhoades combination in the '177 declaration,  
13 and I believe that begins at Paragraph 127. Let me know  
14 when you've found it.

15 A. Okay, I'm there.

16 Q. So now that you kind of know which  
17 portion of the declaration we're talking about, can you  
18 flip to Paragraph 141 where you're discussing how a  
19 person of ordinary skill in the art would have combined  
20 Bason with Rhoades.

21 A. Okay.

22 Q. Just as we discussed earlier with  
23 Elliott, your position is that a person of ordinary  
24 skill in the art would have incorporated the Rhoades  
25 mechanism into the Bason inhaler; right?

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2 A. Correct. I'm saying that combining  
3 Rhoades and Bason gives you the limitations of the  
4 stated claims of the '177 patent.

5 Q. And so if a person of ordinary skill in  
6 the art incorporated the Rhoades mechanism into Bason,  
7 the dose counting components of Bason would be removed;  
8 right?

9 A. Many of the components would be replaced  
10 with Rhoades components.

11 Q. You didn't include in your declaration  
12 any diagrams showing the components of Rhoades as they  
13 purportedly would have been incorporated into the Bason  
14 inhaler, right?

15 A. I included -- I have a description here  
16 of how Rhoades would have been incorporated with Bason  
17 to achieve the desired objective.

18 Q. But you don't include any diagrams  
19 showing how it would have been incorporated into Bason;  
20 right?

21 A. No diagrams other than the diagrams that  
22 are in the Rhoades and the Bason patents.

23 Q. You can use for reference one of the  
24 figures from Bason that you used in your declaration. I  
25 believe it's at the bottom of Paragraph 129. Let me

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2 give you a page number. That's on page 67.

3 A. I got it.

4 Q. Let's just walk through each of the  
5 elements in this figure for Bason, and you can confirm  
6 for me whether or not they are present in the proposed  
7 combination of Bason and Rhoades.

8 So in the Bason and Rhoades combination, Bason's  
9 base 1 is removed; right?

10 A. Base, the combination of base 1 as  
11 described of Rhoades and Bason, base 1 is not included.

12 Q. And the same is true for Bason's ring 8,  
13 it's also been removed?

14 A. As described in the declaration, the  
15 combination of Rhoades and Bason, the ring 8 of Bason  
16 would not be included.

17 Q. And as described in your declaration  
18 regarding the combination of Rhoades and Bason, Bason's  
19 ring 4 would also be removed; correct?

20 A. As described in combination of Bason and  
21 Rhoades, ring 4 would be replaced. Ring 4 of Bason  
22 would be replaced.

23 Q. And Bason's Central Bush 15 would also be  
24 replaced, right?

25 A. As described in the combination, Central



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2 Bush 15 of Bason would be replaced.

3 Q. So Central Bush 15 would not be present  
4 in the Bason-Rhoades combination, right?

5 A. Not as described no.

6 Q. Well, are you saying that some version of  
7 Bason in Central Bush 15 be included in the  
8 Bason-Rhoades combination?

9 A. Well, what's described as taking the  
10 components of Rhoades, which specifically the fingers,  
11 the cam body and the stop members, and including  
12 those -- printing numbers on the cam body and including  
13 those as the working combination.

14 Q. Sure. And if you do that, you'd have to  
15 take the counting components of Bason out; right?  
16 You're not contending that somehow the components of  
17 Bason remain and they interact with those components  
18 from Rhoades, right?

19 A. No, no, no. The Rhoades device, an axial  
20 moving device results in a rotational moving device.  
21 And the Bason device has a counter with indicated  
22 numerals on it. So you would include those numbers as  
23 part of that cam body 20.

24 Q. You're saying you would include numbers,  
25 but you're not saying that any of the components of

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2 Bason that relate to the counting mechanism would be  
3 retained in the Bason-Rhoades combination; right?

4 A. Well, I'm saying that one could combine  
5 the two into an obvious configuration to achieve the  
6 desired result. And it would largely -- as described,  
7 it would largely include the Rhoades components in place  
8 of the Bason component.

9 Q. We've got to be really precise with our  
10 language here, because when you say "it would largely  
11 include," that suggests to me that you think that it  
12 would partially include some of the counting components  
13 of Bason, so let's be really clear.

14 Are there any counting components of Bason apart  
15 from the numerals that you described might be  
16 incorporated on the Rhoades components, are there any  
17 counting components of Bason that remain in the  
18 Bason-Rhoades combination?

19 MR. SKLAR: Objection, form.

20 A. Well, there's a window obviously in the  
21 Bason device. That would be included as part of the  
22 Rhoades device.

23 Q. So apart from the window and the  
24 numerals, are there any other components of Bason's  
25 counting mechanism that would remain in the

1 S. Piper

2 Bason-Rhoades combination?

3 A. The elements that are described in Bason  
4 would be replaced with the Rhoades elements. There  
5 would be indicated numbers and a window, but other than  
6 that, no.

7 Q. So Bason's cap 14 would also not be  
8 present in the Bason-Rhoades combination, right?

9 A. Well, the cap could be modified to  
10 include the fingers. A cap would be included to have  
11 fingers. So parts of the element of the component would  
12 still exist. But the cap 14 as described does not  
13 include fingers as it is. You have to add fingers to  
14 get 14.

15 Q. I didn't mean to cut you off. I was just  
16 going to say is that the only modification that you have  
17 to make to cap 14 to achieve the design that you  
18 described for the Bason-Rhoades combination?

19 A. Well, as described you would increase the  
20 height of the body of the Bason device to include stop  
21 members --

22 Q. Why?

23 A. -- into the inhaler body.

24 Q. I'm sorry. I keep interrupting you and I  
25 don't mean to do that.

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2 I'm not talking about modifications to the  
3 inhaler specifically. I'm talking about specific  
4 modifications to cap 14. Are there any other -- let me  
5 restate.

6 So apart from the window and the numerals, are  
7 there any other -- scratch that.

8 Apart from including fingers, are there any  
9 other modifications that you would have to make to  
10 Bason's cap 14 to achieve the combination of Elliott and  
11 Rhoades?

12 A. No. You would have an element with  
13 fingers on it, and you would have a cam body 20 as  
14 described in the Rhoades device. You would have stop  
15 members as part of the body of the inhaler itself. You  
16 would have a window, there would be indicated numbers on  
17 the cam body. Those are the necessary components to  
18 achieve the desired effect.

19 MR. SKLAR: Objection, nonresponsive.

20 Q. Apart from including fingers, are there  
21 any other modifications that you would have to make to  
22 Bason's cap 14 to achieve the -- that's not right.  
23 Scratch that.

24 Apart from including fingers, are there any  
25 other modifications that you would have to make to

1 S. Piper

2 Bason's cap 14 to achieve the design of the Elliott and  
3 Rhoades combination?

4 MR. SKLAR: Objection, form.

5 A. Well, the inhaler body has to be modified  
6 with, and it has to include the stop members. I mean,  
7 that's an integral component of the device.

8 Q. I'm not talking about integral components  
9 of the device. I'm speaking specifically about cap 14,  
10 and I want to understand which portions of cap 14 as  
11 they're originally described in Bason remain in a  
12 combination and which were removed.

13 Why don't you tell me if there are any other  
14 modifications to Bason's cap 14 that you would need to  
15 make to achieve the combination of Bason-Rhoades.

16 MR. SKLAR: Objection, form.  
17 Mischaracterizes the witness's testimony.

18 A. No, there's no other modification. As  
19 long as there are fingers that engage with the cam body  
20 and also the stop members, there's no other described  
21 modifications here in this section of the declaration of  
22 the cap 14 of the Bason patent.

23 Q. As disclosed in Bason itself, base 1 is  
24 bonded to the medication canister; right?

25 A. Yes.

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Q. And Bason's base 1 includes teeth, right?

A. Base 1 includes teeth 2.

Q. Teeth 2 are fixed on Bason's base 1, right?

A. Teeth 2 are, you know, an integrated component of 1. They are features of 1, base 1, yes.

Q. And it's your position that Bason's teeth 1 -- sorry. Let me rephrase that.

It's your position that Bason's teeth 2 are stationary, right?

A. Well, teeth 2 are integral to piece 1, so teeth 2 do not move relative to the rest of piece 1. So if piece 1 is stationary, then teeth 2 would be stationary.

Q. When you describe the proposed combination of Bason and Rhoades, it's your opinion that Rhoades' cam body 20 would be bonded to the canister; right?

A. That's how it's described, yeah. The cam body 20 would be bonded to the canister.

Q. And in the Rhoades reference, the cam body 20 is secured to the ink reservoir tank; right?

A. That's correct.

Q. So just as we were discussing earlier --

1 S. Piper

2 and I think you actually referred to this particular  
3 paragraph -- in your '177 declaration you describe an  
4 alternative modification that a person of ordinary skill  
5 in the art could have made to Bason, right? That's  
6 included in Paragraph 142, correct, and that's on  
7 page 78.

8 A. Yeah, I mean the paragraph starts out,  
9 "Alternatively the POSA" -- person of skill in the  
10 art -- "wanted to incorporate the Rhoades mechanism into  
11 a simple depress and release inhaler as the one depicted  
12 in Bason, he or she would have made a simple and  
13 predictable modification of cam services in cam body  
14 20," as we previously discussed.

15 Q. Just as we discussed with Elliott, you  
16 don't include any diagrams or figures here in your  
17 declaration showing the two separate and even rows of  
18 teeth; right?

19 A. The modification of the -- incorporate  
20 into -- if -- there's a sentence here, "He or she would  
21 have made a simple and predictable modification to the  
22 cam services of cam body 20 for a simple depress and  
23 release inhaler." There is not a specific drawing  
24 showing those gears in the declaration.

25 Q. Are you aware of a component in Bason

1 S. Piper

2 that discloses two separate and even rows of teeth?

3 A. Well, there's a set of teeth on base  
4 1 labeled No. 2, and there's a set of teeth on ring  
5 4 labeled 7. Those are two rows of teeth.

6 Q. Is there a single component in Bason that  
7 discloses two separate and even rows of teeth?

8 A. There's also -- there's also a component  
9 15 that includes a set of teeth, and when the device is  
10 assembled teeth 15 and teeth 2, those pieces are, you  
11 know, they don't move relative to each other, as  
12 described in the Bason patent.

13 Q. Those are two separate components, right?

14 A. It's shown as two separate components.  
15 One is listed as component 1, and one is listed as  
16 component 15. But they're described as being assembled  
17 together; and if you look at figure 5, it's understood  
18 that part 15 and part 1 aren't moving relative to each  
19 other relative to teeth 7 which are on ring 4.

20 Q. So for purposes of our claim-by-claim  
21 analysis, it's your position that any two components  
22 that are fixed with respect to one another we can  
23 consider them a single component together?

24 MR. SKLAR: Objection.  
25 Mischaracterizes the witness's testimony.



1 S. Piper

2 A. Well, in overall to this question of --  
3 so in Paragraph 30 I state that "The '177 patent does  
4 not explicitly define the term 'stationary body,' 1,  
5 including at least one stationary gear. I understand  
6 the PTAB, however, already construed this term during  
7 the prosecution under the BRI standard as a stationary  
8 body including as a unitary or monolithic part of the  
9 stationary body, at least one stationary gear. That  
10 construction was based on the specification drawings  
11 with the Appellant's contentions. The PTAB relied on  
12 its construction to determine the pending claims were  
13 patentable over the Bason publication."

14 So that was more my understanding is that the  
15 stationary body was going with that understanding of it,  
16 if that's the question of moving parts.

17 Q. That wasn't my question, because I wasn't  
18 asking you about stationary body.

19 A. Okay.

20 Q. But that's all right.

21 A. It was a unitarian -- maybe I'm not  
22 looking at the right part. Anyway, go ahead, ask your  
23 question and I'll try and do better.

24 Q. Well -- let's move on.

25 So let's move on to your '631 declaration. For

1 S. Piper

2 the record, that's Exhibit 1,002.2. --

3 MR. SKLAR: Before we go on, can we  
4 take a break for lunch?

5 MS. HARGRAVE: Yes.

6 (Recess)

7 BY MS. HARGRAVE:

8 Q. Mr. Piper, this you can tell me when  
9 you're ready to get going.

10 A. I am ready.

11 Q. Excellent.

12 So before the break we were just about to look  
13 at your '631 declaration, I believe. We can start at  
14 Paragraph 52. And I've heard you say this, but I would  
15 orient you to know where we are in your declaration so  
16 we know what portion of your analysis we're talking  
17 about.

18 I think I have actually that paragraph number  
19 wrong. Oh, that's correct. Paragraph 52.

20 This is the beginning of your analysis of the  
21 Allsop reference. Does this look familiar to you  
22 generally?

23 A. Yes, ground 1, yeah, anticipation by  
24 Allsop of the '631 patent.

25 Q. So let's flip down to Paragraph 62.

1 S. Piper

2 A. (Witness complies with request.)

3 Q. And this Paragraph relates to your  
4 discussion the claim element, "A first member that is  
5 displaceable axially relative to said stationary body."

6 Do you see that?

7 A. Yeah.

8 Q. Flip over to the next page, there's a  
9 figure there that you've included. I want to ask you  
10 about that.

11 So the figure here on page 33 of your '631  
12 declaration, this was originally a figure that was taken  
13 from the Allsop patent; right?

14 A. Well, I mean, it looks like, it looks  
15 like figure 3 in the Allsop patent, right.

16 Q. Sure. And then color, the components  
17 have been color coded and labeled as this figure is here  
18 in your declaration; right?

19 A. Right. Yeah. The patent, the actual  
20 patent specification doesn't include color drawings.

21 Q. You said does not include color drawings?

22 A. Right, does not include color drawings.

23 Q. In this figure you have added "push  
24 button cap" in green at the top.

25 Do you see that?

1 S. Piper

2 A. Yes.

3 Q. The push button cap was not originally  
4 included in the figure in the Allsop reference, right?

5 A. Correct. It was described in the text,  
6 but it wasn't included in the figures.

7 Q. Let's go ahead and take a look at Allsop.  
8 Well, we'll see if we can get to where I want to get to  
9 without looking at the reference.

10 Just generally an Allsop inhaler is actuated  
11 when a user presses down on the push button cap, right?

12 A. Yes. It also disclosed the use of a push  
13 button cap that covers the upper portion of the  
14 pressurized container. So you push on the cap to  
15 actuate the inhaler.

16 Q. So if you wouldn't mind for me, we're  
17 going back to the figure that you have there on page 33  
18 of your declaration. I'll give you a pen. Could you  
19 mark for me how far down the pushdown on the push cap,  
20 how far down does it extend into the inhaler? You can  
21 just draw a line at the distance at which it would  
22 travel down the inhaler.

23 MR. SKLAR: Object to the form.

24 A. I don't know if the drawing is to scale.

25 So --

1 S. Piper

2 Q. Do you have an understanding as to how  
3 far down the pushdown cap would extend into the cap or  
4 into the body of the inhaler?

5 MR. SKLAR: Objection to the form.

6 A. I think as long as the push button cap is  
7 on top of the canister, you can push it, it would  
8 actuate push down on the canister.

9 Q. I don't think that's quite what my  
10 question was.

11 Do you have an understanding as to how far down  
12 the pushdown cap -- let me repeat that.

13 Do you have an understanding as to how far down  
14 the push cap would extend into the inhaler when you  
15 press it?

16 MR. SKLAR: Object to the form. Asked  
17 and answered.

18 A. Pressed into the canister and the inhaler  
19 itself or what the travel distance is?

20 Q. The travel distance, that's exactly what  
21 I'm looking for.

22 A. Well, it would depend on the canister and  
23 the stem. Many of the freon-driven MDI canisters that  
24 I've worked with have a travel distance of approximately  
25 100,000s of an inch. I haven't taken an exact

S. Piper

measurement of it.

Q. So you don't have an opinion one way or the other --

A. I do.

MR. SKLAR: Let her finish the question.

Q. You don't have an opinion one way or another as to the travel distance of the push button cap in the Allsop reference?

A. Well, I think it would --

MR. SKLAR: Objection, form.

A. The push button cap would cover the upper portion of the pressurized container as is described. So the button could be depressed actually moving the canister axially. So the push button cap would move with the canister.

Q. And I understand that the push button cap would move with the canister, but my particular question is, you don't have an opinion one way or the other as to the travel distance of the push button cap as it's pressed down during actuation; is that correct?

MR. SKLAR: Objection, form. Asked and answered.

A. I think the push button cap would make

1 S. Piper

2 the same travel distance as the canister, which can vary  
3 from canister to canister.

4 Q. So then you agree that as to the  
5 description included in Allsop there is -- let me  
6 rephrase.

7 You would agree that based upon the description  
8 in Allsop you can't identify a particular travel  
9 distance of the push button cap?

10 MR. SKLAR: Objection.  
11 Mischaracterizes the witness's testimony.

12 A. I think that there is enough in the  
13 specification of Allsop to know how to make the  
14 described inhaler-type product. The exact dimensions  
15 would depend on the meter dose inhaler canister you're  
16 using as part of that overall design.

17 Q. So sitting here today you can't identify  
18 a travel distance for the push button cap in the Allsop  
19 reference; right?

20 MR. SKLAR: Objection.  
21 Mischaracterizes the witness's testimony.

22 A. Well, based on what I see, I know that  
23 the travel distance of the cap would equal the travel  
24 distance of the canister. What else do I need to know?  
25 I guess the travel distance would necessarily be less

1 S. Piper

2 than that if the patient didn't actuate the device all  
3 the way down.

4 So probably the maximum distance that it could  
5 be, that the cap could travel would be equal to the  
6 maximum distance that the canister can actually be moved  
7 as part of the actuation and dispensing of the  
8 medication.

9 Q. And as you just stated, the actuation,  
10 the distance -- let me rephrase.

11 The distance that the canister travels could  
12 vary across all different kinds of meter dose inhalers,  
13 right?

14 A. Yeah. If you're building an integrated  
15 meter dose inhaler with an integrated counter, you would  
16 make the design of the counter consistent with the  
17 dimensions of the canister, including the travel  
18 distance of the canister and the corresponding distance  
19 to actuate the canister so that it releases medication.

20 MS. HARGRAVE: Objection.  
21 Nonresponsive.

22 Q. The distance that the canister travels  
23 could vary across all different kinds of meter dose  
24 inhalers, right?

25 MR. SKLAR: Objection to the form.



1 S. Piper

2 A. A particular canister will actuate based  
3 on its own dimensions. If you take the canister and put  
4 it in another inhaler body, the canister actuation  
5 distance would be the same. But two different canisters  
6 made by two different manufacturers may certainly have  
7 two different travel distances needed for release of  
8 medication.

9 Q. Let's flip to page 43 of your '631  
10 declaration.

11 A. (Witness complies with request.)

12 Q. At the very bottom of that page you can  
13 see that this is where your analysis for purported  
14 anticipation by Marelli for the '631 patent begins.

15 Do you see that?

16 A. Yeah, ground 2, claims on 24 of the '631  
17 patent are anticipated by Marelli, Exhibit 1008.

18 Q. Marelli includes, among other components,  
19 nasal 8, ring nut 4 and intermediate part 20; correct?

20 A. Intermediate part --

21 Q. Twenty?

22 A. Twenty. Yeah, there is a part 20, yeah,  
23 uh-huh.

24 Q. And Marelli also includes nasal 8 and  
25 ring nut 4, right?

1 S. Piper

2 A. There is a ring nut 4 and nasal 8, that  
3 is correct.

4 Q. Intermediate part 20 integrally includes  
5 rotating element 9, right?

6 A. Rotating element 9 and 20 are connected  
7 to each other, yes.

8 Q. Let's look at the figure that you had  
9 included on page 45 of your declaration.

10 A. Okay.

11 Q. And bear with me.

12 A. Yes.

13 Q. You've got a color copy, right?

14 A. I do.

15 Q. Do you see a jagged, dotted line going  
16 across about the top two-fifths of this figure?

17 A. The top two-fifths. I see a red, per the  
18 figure in my declaration there's a red shaded region,  
19 the border of which indicates a series of teeth.

20 Q. And so if you go just below that parallel  
21 to that line that you were just discussing, do you see a  
22 shaded line that looks a lot like the one you just  
23 described?

24 A. Near the bottom there's a green-shaded  
25 area with a corresponding set of teeth.

1 S. Piper

2 Q. I'm trying to identify accurately for the  
3 record, but let me point it out for you and I'll try to  
4 identify it for the record.

5 So I'm pointing to this shaded line that mirrors  
6 the look of this particular line of the teeth. Do you  
7 see what I'm talking about now?

8 A. Yeah. I don't see that line as being  
9 shade, dotted.

10 Q. Dotted. That's the word.

11 And so then below that dotted line there is a  
12 series of two additional parallel dotted lines below  
13 that.

14 Do you see those?

15 A. Yes, indicated as 9. Is that what you're  
16 talking about?

17 Q. Yes.

18 A. Okay.

19 Q. So let's start with the first dotted  
20 line, I'm not sure that's indicated by a number, but as  
21 we discussed it, mimics the outline of line 12 above it.

22 What does that dotted line represent in that  
23 figure?

24 MR. SKLAR: Objection, form.

25 A. That indicates a second position of 12

1 S. Piper

2 with respect to 13 or part 3. Actually it's an  
3 indicated position of 8 with respect to 3 in a squeezed  
4 position.

5 Q. So the first dotted line that we were  
6 just discussing represents the position of 8 when the  
7 device is compressed?

8 A. When -- yeah. When -- yeah, when the  
9 device is compressed, yes.

10 Q. So the second set of dotted lines below  
11 it which we discussed as representing the rotating  
12 element 9, tell me what that series of dotted lines  
13 represents in this figure.

14 A. That represents the position of 9 in  
15 relation to 3 in the same squeezed position as the  
16 dotted lines above it.

17 Q. As you read this figure, is the distance  
18 between teeth 2 and rotating element 9 maintained when  
19 the device is compressed?

20 MR. SKLAR: Objection to the form.

21 A. Did you say "element 2"? I'm sorry, I  
22 don't see an element 2.

23 Q. Well, I did say "element 2." Let me  
24 rephrase.

25 Is the distance between teeth 12 and rotating

1 S. Piper

2 element 9 maintained when the device is compressed?

3 MR. SKLAR: Objection, foundation.

4 A. Well, when you -- based on the  
5 description in the specification of this patent, when  
6 the two pieces are squeezed together, items 3 and 8, the  
7 drawing shows a clear flexing of leg 16. And thus,  
8 there's movement of 9 and element 8 toward 3.

9 The drawing doesn't necessarily show much  
10 flexing of legs 14 or 20, the upper leg above rotating  
11 element 9. But any time you put a squeeze force on  
12 something, you're going to get some flex. So there's  
13 going to be some difference in distance between  
14 item 9 and 8 in the squeezed position.

15 But the way the drawing is drawn, there's  
16 clearly much more change in the distance between 9 and  
17 3 than there is between 9 and 8 in the squeezed  
18 position.

19 Q. So is your answer to my question no?

20 MR. SKLAR: Objection, form.

21 A. I thought I answered the question. Maybe  
22 if you can restate it I'll try and do better this time.

23 Q. Sure. Is the distance between teeth 12  
24 and rotating element 9 maintained when the device is  
25 compressed?

1 S. Piper

2 MR. SKLAR: Objection. Asked and  
3 answered.

4 THE WITNESS: Is that asked not to  
5 answer?

6 MR. SKLAR: I didn't instruct you not  
7 to answer. I objected that it was asked and you had  
8 already answered.

9 THE WITNESS: Okay, sorry. It's not  
10 clearly indicated in the drawing what is or isn't true  
11 as far as the distance of 12 to 9. Any expectation is  
12 there might be some change in distance between 12 and 9,  
13 but the drawing really isn't indicating much of a change  
14 in distance between 12 and 9.

15 But my clear expectation, especially  
16 the way the device works is that there will be some flex  
17 and so the distance between 12 and 9 would be expected  
18 to change to some degree or another.

19 BY MS. HARGRAVE:

20 Q. But that's not necessarily represented  
21 here in the figure, right?

22 A. Well, it's not necessarily a figure to  
23 scale. And there's certainly no dimensions given.

24 Q. Your understanding of the way that the  
25 device works is not necessarily reflected in this

1 S. Piper

2 figure, right?

3 MR. SKLAR: Objection.

4 Mischaracterizes the witness's testimony.

5 A. I think this figure is illustrative of  
6 how the device works. It's a very helpful component  
7 along with the written specification of the other  
8 figures of the patent to indicate to me how the device  
9 works.

10 Q. Your understanding of the distance  
11 between components 12 and 9 would be expected to change  
12 is not necessarily reflected in this figure, right?

13 MR. SKLAR: Objection.

14 Mischaracterizes the witness's testimony.

15 A. No. I'm saying that you can't draw that  
16 kind of conclusion. I have stated that clearly the  
17 distance between 9 and 3 have changed substantially  
18 during the squeeze. And as you can see, feature 16 of  
19 the patent clearly is indicating a large amount of flex.

20 I would also expect that the upper arm may flex  
21 as well. Nothing doesn't not ever flex at all when  
22 applied -- well, I would say in general my expectation  
23 is that there's likely to be some flex of that arm. But  
24 it's not a drawing that's to scale. So -- and there are  
25 no dimensions given.

1 S. Piper

2 Q. So you can't tell one way or the other  
3 just by looking at this figure whether or not the  
4 distance between teeth 12 in rotating element 9 is  
5 maintained when the device is compressed, right?

6 MR. SKLAR: Objection.  
7 Mischaracterizes the witness's testimony.

8 A. I think that there's likely to be some  
9 change in that distance for flex. You're talking about  
10 plastic molded parts, and I would expect some flex of  
11 that arm with some, when force is applied to it.

12 Q. I understand that you would expect there  
13 to be flex, but looking at the figure you cannot tell  
14 one way or the other whether or not the distance between  
15 teeth 12 and element 9 is maintained during compression;  
16 right?

17 MR. SKLAR: Objection.  
18 Mischaracterizes the witness's testimony.

19 A. As I've stated, figure 4 shows  
20 substantial change in the distance between 3 and 20  
21 during the squeeze of the device. And the corresponding  
22 flex of 16, it does not show the same degree of flex in  
23 item 14, that part of 14 above 20 during that same  
24 squeeze portion.

25 Q. It can't be both things. You can't both



1 S. Piper

2 say that the figure shows you that the distance between  
3 9 and 12 changes and also that it's not to scale. So  
4 it's either got to be one or the other. You can either  
5 tell by looking at this figure whether the distance  
6 between 9 and 12 is maintained or you can't.

7 MR. SKLAR: Objection, form.

8 A. Was that a question?

9 Q. Do you agree with that?

10 MR. SKLAR: Objection, form.

11 A. Can you ask a question, please.

12 Q. Do you agree that you can't both take the  
13 position that the figure is not to scale so you can't  
14 tell what the distance is at all and also take the  
15 position that this figure shows you that the distance  
16 between 9 and 12 isn't maintained?

17 MR. SKLAR: Objection, form.

18 A. I think the drawing is illustrative, is  
19 trying to show how the device functions. These parts  
20 are actually cylindrically shaped. So this is a  
21 sectional view, and I think they are trying to  
22 illustrate -- it's trying to illustrate when I read the  
23 specification in the patent, it's showing that when  
24 8 and 3, the device is squeezed together, 8 and 3 become  
25 closer. There's clearly a deflection of 16. And that

1 S. Piper

2 deflection of 16 is far less than the deflection  
3 indicated by 14. My experience with plastic molded  
4 parts is if you squeeze on them, you will get some  
5 deflection.

6 Q. Let's look figure at the bottom of your  
7 Paragraph 87, and that figure is on page 44 of your '631  
8 declaration.

9 A. Figure 1?

10 Q. Yes. We may need to get out Marelli  
11 because I think figure 1 is blown up, but we'll see with  
12 our eyes just by looking at the smaller version of the  
13 figure and identify the feature that I want to talk to  
14 you about.

15 So if you look at nasal 8, which is outlined in  
16 red, right.

17 A. The sectional component of nasal 8 is  
18 outlined in red, right.

19 Q. Do you see two vertical lines outlined in  
20 red on the edges of the device?

21 A. I see some vertical lines as part of the  
22 outlying section of nasal 8.

23 Q. For example, let's look at the one to the  
24 right of the device. You see the red line that says  
25 "rotating element 9"?

S. Piper

A. Yes.

Q. And there is -- sorry.

A. I see the words "rotating element 9" as indicating, it's pointing through the window that's in nasal 8.

Q. Okay. So just below that arrow there's a red vertical line that represents nasal 8, correct?

A. Yeah. That's part of the sectional view of nasal, 8, correct.

Q. So at the top of that red vertical line, can you see that there's an outcropping on this piece, nasal 8 where the two lines that make up this portion are not perfectly parallel and at the top it juts out, the left line juts out to the left a little bit as it meets up with rotating element 9?

MR. SKLAR: Objection to the form.

A. Yes, I see that.

Q. If it's okay with you, let's call that a ridge unless you can think of a better word to describe that piece that juts out to the left. Are you okay with "ridge"?

A. Sure, I'm okay with "ridge."

Q. Can you tell me what is the purpose of that ridge?

1 S. Piper

2 A. Can I see the patent?

3 Q. Sure.

4 MS. HARGRAVE: We'll mark it as  
5 Exhibit 1,008.

6 (Exhibit 1,008, European patent  
7 specification, was marked for  
8 identification.)

9 A. This is in -- oh, there we go.

10 Q. There are ridges on both sides?

11 A. Yeah, I actually saw that.

12 Q. I just want to make sure when we're  
13 talking about one, I assume we can talk about both  
14 equally unless you tell me there's some difference  
15 between the two.

16 A. Okay. Okay. So it looks like it's a  
17 support to, supporting shoulder or supporting ridge, so  
18 that rotating element 9 is captivated in nasal 8 there.

19 Q. So you're saying you think the ridges are  
20 holding 9 in place?

21 MR. SKLAR: Objection.  
22 Mischaracterizes the witness's testimony.

23 A. Nine is a rotating piece.

24 Q. Right. But they are maintaining 9 at the  
25 location it's located in inside nasal 8, is that what

1 S. Piper

2 you said?

3 MR. SKLAR: Objection, form.  
4 Mischaracterizes the testimony.

5 A. The shoulders are helping to encapsulate  
6 what is called rotating element 9 as in the nasal 8.

7 Q. When you say "encapsulate," what do you  
8 mean?

9 A. It means obviously a piece can rotate,  
10 but if piece 9 cannot be, would not likely fall out of  
11 eight due to the force of the weight of its, force of  
12 gravity by its weight. So it's roughly held in place.

13 Q. And just so we're clear because I know  
14 our descriptions, particularly mine may be a little less  
15 than desirable, can you mark a star on your copy of  
16 Marelli on both places where we've been speaking about  
17 as a ridge.

18 A. (Witness complies with request.)

19 Q. Thank you. So let's move on to the  
20 portion of your declaration that discusses the  
21 Bason-Allsop combination.

22 A. The Bason what?

23 Q. Allsop.

24 A. Allsop, yes.

25 Q. Look at page 92.

1 S. Piper

2 A. Okay.

3 Q. Your position is that a person of  
4 ordinary skill in the art would have modified Bason in  
5 view of Allsop, right?

6 A. Yes.

7 Q. So let's look specifically at  
8 Paragraph 172 where you describe a modification.

9 A. Paragraph what?

10 Q. 172, page 93.

11 A. Okay.

12 Q. So in Paragraph 172 of the '631  
13 declaration, you describe that a person of ordinary  
14 skill in the art would have moved the Bason dose counter  
15 below the canister; right?

16 A. Yeah, 172 says, "To improve the Bason  
17 device as described in Paragraphs 1178 through 120 in  
18 light of the device disclosed in Allsop, a person with  
19 skill in the art would have simply moved the Bason dose  
20 counter below the Bason canister."

21 Q. You describe that a person of ordinary  
22 skill in the art would have integrally molded the teeth  
23 2 into the inhaler counter?

24 A. Yeah, I mean, further that sentence  
25 reads, "Where the rotational mechanism, (outer housing

1 S. Piper

2 collar 155 and in the inner housing flange 142), is  
3 located in Allsop and integrally molded the teeth 2 into  
4 the inhaler housing just as Allsop teaches."

5 Q. I think you start that by saying yes. So  
6 you agree with my question?

7 MR. SKLAR: Objection to the form.

8 A. It says the integrally molded teeth 2  
9 into the inhaler housing just as Allsop teaches, yeah.  
10 Does that answer your question?

11 Q. Yes. In the Bason-Allsop combination,  
12 what happens to Bason's cap?

13 MR. SKLAR: Objection, form.

14 Q. Let me rephrase the question. In the  
15 Bason-Allsop combination as you describe it in your  
16 declaration, what happens to Bason's cap?

17 MR. SKLAR: Objection, form.

18 A. The Bason cap would be placed underneath  
19 the canister.

20 Q. Are there any other modifications that  
21 are being made to Bason cap so that it would function in  
22 the Bason-Allsop combination?

23 MR. SKLAR: Objection to the form.

24 A. Well, as it says here in the declaration,  
25 the valve will extend through the counting mechanism

1 S. Piper

2 just as it does in Allsop so there would have to be a  
3 passage for the stem to pass through the cap.

4 Q. So apart from moving the cap and adding a  
5 hole for the stem, valve stem to pass through, are there  
6 any other ways in which the cap in the Bason-Allsop  
7 combination is different from the cap that's disclosed  
8 in Bason?

9 MR. SKLAR: Objection, form.

10 A. Can I see the Bason patent?

11 Q. Sure.

12 (Discussion held off the  
13 record.)

14 MS. HARGRAVE: We'll mark as Bason,  
15 it's patent 6,283,365, as Exhibit 1,005.

16 (Exhibit 1,005, Bason patent,  
17 was marked for identification.)

18 Q. Let me know if you need me to repeat my  
19 question. Actually I think I'll just go ahead and  
20 repeat it so that the record is clear.

21 Apart from moving the cap and adding a hole for  
22 the stem valve -- scratch that.

23 Apart from moving the cap and adding a hole for  
24 the valve stem to pass through, are there any other ways  
25 in which the cap in the Bason-Allsop combination is



1 S. Piper

2 different from the cap that's disclosed in Allsop?

3 MR. SKLAR: Objection to the form.

4 A. Well, I mean in general there are  
5 probably a number of modifications made to the parts to  
6 fit a slight different arrangement than is described in  
7 Bason, so I think a reasonable expectation would be that  
8 there would be other modifications.

9 But in addition, there's at least one other  
10 specific modification that has to be made, and that is  
11 that there's a window 13 in Bason that indicates a count  
12 of the doses, and obviously that arrangement would have  
13 to be made on the side of the device that a patient  
14 would see the number of actuations.

15 Q. So apart from moving the cap, adding a  
16 hole for the valve stem and adding a window, you can't  
17 identify any particular modifications that would also  
18 need to be made?

19 MR. SKLAR: Objection, form,  
20 Mischaracterizes the witness's testimony.

21 A. Well, a number of other general  
22 modifications would have to be made to move it down  
23 below to fit a particular canister arrangement.

24 Q. Can you describe those particular  
25 modifications in your declaration?

1 S. Piper

2 A. Not fully. I haven't certainly done  
3 detailed drawings of the arrangement to be made.

4 Q. Can you identify this particular  
5 modification for me sitting here today?

6 A. Not likely all of them, no.

7 Q. Your position is that in the Bason-Allsop  
8 combination the components of Bason all interact to  
9 change the dose value the same way that they do in  
10 Bason, right?

11 MR. SKLAR: Objection, form.  
12 Mischaracterizes the testimony.

13 A. What was the question again?

14 Q. Let's just find the relevant portion of  
15 your declaration that talks about that. Take a look at  
16 Paragraph 175 of your declaration on page 95. There you  
17 state, "A POSA" -- a person of ordinary skill in the  
18 art -- "would further have had a reasonable expectation  
19 of success because in such a modification all the  
20 components would have retained their same function."

21 Do you see that?

22 A. Yeah.

23 Q. So you're referring to the components of  
24 Bason there, right?

25 A. As the sentence further reads,

1 S. Piper

2 "Depressing the canister of the Bason would depress the  
3 cap that it would now be sitting on top of. The cap  
4 would depress rings 4 and 8, causing teeth 7 of ring  
5 4 to interact with stationary teeth 2 and rotate ring 4  
6 to change the dose value the same way that they do in  
7 Bason. The valve would extend through the counting  
8 mechanism just as it does in Allsop. The resulting  
9 inhaler would have been predictable, less expensive to  
10 manufacture," so on and so forth.

11 Q. So let me ask my question again. When  
12 you state here in Paragraph 175 that all of the  
13 components would have retained their same functions,  
14 you're referring to Bason components; correct?

15 A. Well, I'm talking about the general  
16 mechanism of Bason as combined with -- as combined with  
17 Allsop.

18 Q. You're not suggesting that any particular  
19 components of Allsop are incorporated into the Bason  
20 inhaler, right?

21 MR. SKLAR: Objection, form.

22 A. Well, it does involve moving the Bason  
23 counting mechanism below the canister as described, but,  
24 for example, it does include things that are already  
25 taught by Allsop such as integrally molding the teeth

1 S. Piper

2 2 into the inhaler housing. But in such an arrangement  
3 the teeth 2 would have the same function in the combined  
4 arrangement as they do in the Bason device.

5 Again, furthermore as it's described in Allsop,  
6 the base 1 of Bason and the gear teeth 2 would have been  
7 also molded into the walls of the inhaler as it's taught  
8 in Allsop. So there would be components of both, but  
9 the functions of the mechanisms in Bason would remain  
10 the same.

11 Q. Allsop doesn't teach any component  
12 entitled "teeth 2," right?

13 A. Well, there's a reference to teeth 2 in  
14 Bason.

15 Q. Right. But I'm asking specifically,  
16 there's not a component titled "teeth 2" in Allsop;  
17 right?

18 A. May I see Allsop?

19 Q. I knew you were going to ask me that, and  
20 that is a fair question. And I don't have it,  
21 unfortunately. So I'll withdraw that question.

22 What we'll do is -- we'll do that at a break.

23 Mr. Piper, you would agree that meter dose  
24 inhalers are sophisticated aerosol delivery devices with  
25 a wide array of unique issues, right?

1 S. Piper

2 MR. SKLAR: Objection to the form.

3 A. Relative to what?

4 Q. I'm just asking if you agree with that  
5 statement as I stated it, and I'm happy to restate it  
6 for you if you'd like.

7 A. Yeah, please do.

8 Q. Would you agree that meter dose inhalers  
9 are sophisticated aerosol delivery devices with a wide  
10 array of unique issues?

11 MR. SKLAR: Objection to the form.

12 A. The statement is, I wouldn't agree with  
13 the statement exactly as it is, because what is  
14 sophisticated relative to what? To a cup? I would say  
15 meter dose inhaler is more complicated than --  
16 "sophisticated" was the word you used -- than this cup.

17 Q. So as it's written you think the  
18 statement is unclear?

19 MR. SKLAR: Objection.  
20 Mischaracterizes the witness's testimony.

21 A. Sophisticated is a, is not a quantifiable  
22 statement by itself. I'm not sure what that's meant by  
23 the word "sophisticated." So in relative to something  
24 else, I can answer the question whether something is  
25 sophisticated or not relative to something else.

1 S. Piper

2 Q. Would you agree that meter dose inhalers  
3 must meet stringent requirements to obtain regulatory  
4 approval?

5 MR. SKLAR: Objection to the form.

6 A. I would agree that meter dose inhalers  
7 are required to meet certain requirements by the FDA to  
8 get FDA approval.

9 Q. Are those requirements stringent, in your  
10 opinion?

11 MR. SKLAR: Objection, form.

12 A. Stringent relative to what?

13 Q. So you're unwilling to opine whether or  
14 not the requirements to meet FDA approval for a meter  
15 dose inhaler are stringent, right?

16 MR. SKLAR: Objection, form. Asked and  
17 answered.

18 A. There are requirements that if they are  
19 not met by a meter dose inhaler product the FDA will not  
20 grant its approval.

21 Q. So that statement is also unclear, right?

22 MR. SKLAR: Objection, form.

23 A. Well, I'm just clarifying what my opinion  
24 is and saying it in such a way that I think it's clear.

25 Q. So it's not clear to say that the

1 S. Piper

2 requirements to meet FDA approval are stringent, in your  
3 opinion?

4 MR. SKLAR: Objection, form.  
5 Mischaracterizes the testimony.

6 A. The term "stringent," again, is relative.  
7 I mean, if the requirements to market an MDI, meter dose  
8 inhaler product, are more stringent than is required to  
9 manufacture and market a coffee cup.

10 Q. Would you agree that with MDI gears, the  
11 gears must fit together with precision?

12 MR. SKLAR: Objection, form.

13 A. Again, I would say that a meter dose  
14 inhaler product with gears that work together, there  
15 will be certain level of tolerances that are required  
16 for the gears to work together. And if those tolerances  
17 aren't met, the gears may not actually work together.

18 Q. You have substantial experience in  
19 designing meter dose inhalers, right?

20 A. I have substantial experience in  
21 developing and testing meter dose inhalers.

22 Q. In your experience when designing a meter  
23 dose inhaler, do the components have to be coordinated  
24 together with precision?

25 MR. SKLAR: Objection, form.

1 S. Piper

2 A. My experience with designing a meter dose  
3 inhaler is, as with any product, involves multiple  
4 components that the dimensions of the various components  
5 need to be in agreement with each other to function the  
6 intended way.

7 Q. What does "in agreement with each other"  
8 mean?

9 A. For example, the water bottle, it has a  
10 cap with a threaded component for those parts to be  
11 agreeable with each other, work with each other. For  
12 example, the pitch of the thread needs to be the same  
13 and the diameter, the inside diameter of the thread of  
14 the cap needs to be at least slightly bigger than the  
15 inside diameter of the threads on the bottle.

16 MR. SKLAR: Want to take another quick  
17 break? We've been going about an hour.

18 MS. HARGRAVE: Okay.

19 (Recess)

20 BY MS. HARGRAVE:

21 Q. Mr. Piper, are you ready?

22 A. Yeah, I'm ready, thank you.

23 Q. Mr. Piper, can you tell me what is the  
24 approximate distance of the actuation stroke of an MDI?

25 MR. SKLAR: Objection, form.



1 S. Piper

2 A. By memory it takes approximately -- you  
3 have to depress the canister about 100,000s of an inch  
4 to, for a full actuation of the canister.

5 Q. What's the approximate distance of the  
6 actuation stroke of a retractable e-pen?

7 A. Well, for this particular pen that I hold  
8 in my hand the pen is in the exposed direction. And  
9 when I push it out, fully out, I would say it's about  
10 100 -- about 125,000s of an inch.

11 Q. So what about if you're going from the  
12 retracted position to the extended position? Then  
13 what's the actuation stroke, approximately?

14 A. Do you have a pair of calipers?

15 Q. I unfortunately do not.

16 A. Okay. My eyesight is legendary for  
17 its -- but I'm not calibrated to NC standards. So when  
18 the pen is fully retained within the pen as it's  
19 intended to be when you're not using it and I push on  
20 it, it looks like it travels around 300,000s of an inch.  
21 And that's, you know, a necessary distance for the pen  
22 to be fully exposed so that you can write with it. But  
23 the actual clicking part to get it to go from one to the  
24 next is about 125,000s, as I previously estimated.

25 So there's an additional amount of travel

1 S. Piper

2 required to have, over the 125,000s to get the pen to  
3 actually be exposed out of the body.

4 Q. Would you agree that the particle size of  
5 medication contained within a meter dose inhaler as it's  
6 dispensed can affect the efficacy of the drug?

7 A. I would say that the particle size of an  
8 aerosol emitted by an MDI, the deposition rates of that  
9 medication to the patient's lung would vary based on  
10 particle size.

11 Q. My question was actually a little bit  
12 different than that. So I'll ask it again.

13 Would you agree that the particle size of a  
14 medication contained within a meter dose inhaler as it's  
15 dispensed can affect the efficacy of the drug?

16 A. Well, there actually isn't any aerosol  
17 particle size contained within the meter dose inhaler in  
18 the freon canister prior to it exiting the jet. That's  
19 why I answered the question a little bit differently.  
20 You said "within the MDI inhaler."

21 Q. I understand exactly the distinction that  
22 you're making, and so I'll ask my question better.

23 Would you agree that the particle size of  
24 medication as it's dispensed from a meter dose inhaler  
25 can affect the efficacy of the drug?

1 S. Piper

2 A. I would agree that the particle size  
3 emitted by an MDI affects the deposition rate of the  
4 patient, thus the efficacy of the medication. I would  
5 not suggest that MDIs deliver a majority of the  
6 medications dispensed to the patient's lungs.

7 Q. Would you agree that the spray pattern of  
8 a meter dose inhaler can have as big an effect on the  
9 dose of medication that reaches the patient's lungs as  
10 the dose in the particle size can?

11 MR. SKLAR: Objection to the form.

12 A. I think the more important component of  
13 measuring the performance of a meter dose inhaler and  
14 predicting its possible efficacy is more dependent on  
15 the dose and the particle size than it is on the spray  
16 pattern of the MDI.

17 Q. So you disagree that the spray pattern of  
18 an MDI can have as big an effect on the dose of the  
19 medication that reaches the patient's lungs as the dose  
20 and particle size?

21 MR. SKLAR: Objection to the form.

22 Asked and answered.

23 A. The measurable effect of one variable or  
24 another depends on the degree of variation, in my  
25 opinion. The sensitivity of the efficacy of a meter

1 S. Piper

2 dose inhaler can be better measured by the dose in the  
3 particle size than by the spray pattern.

4 If you put a -- there are components of the  
5 spray pattern that could be varied substantially enough  
6 that they would have a bigger impact on the efficacy of  
7 the device as well. It's a matter of degree of  
8 variation because of the plume geometry of meter dose  
9 inhalers, very, very large percentage of the medication  
10 dispensed from the meter dose inhaler is actually  
11 impacted in the patient's mouth and back of their  
12 throat.

13 Q. Let's go back to our discussion of  
14 Allsop.

15 MS. HARGRAVE: Let's mark this as  
16 Exhibit 1,006.

17 (Exhibit 1,006, Patent  
18 application, was marked for  
19 identification.)

20 MS. HARGRAVE: For the record, what's  
21 been marked as Exhibit 1,006 is International  
22 publication number W0059806, otherwise referred to as  
23 Allsop.

24 BY MS. HARGRAVE:

25 Q. What I want to do, Mr. Piper, is to look

1 S. Piper

2 at -- let's look at page 17 of this document, which  
3 contains figures 1 through 4.

4 A. (Witness complies with request.)

5 Q. And if you'll remember, you described the  
6 Bason-Allsop combination in your declaration that you  
7 were talking about. The modifications that you proposed  
8 to be made would be found in your declaration around  
9 Paragraphs 172, 173, 174.

10 So I want to ask you now looking -- well, let me  
11 refresh your --

12 A. Those are Paragraphs 172, -3 and -4?

13 Q. Yes. You can confirm that that's the  
14 declaration where you're talking about how a person of  
15 ordinary skill in the art would purportedly have  
16 modified Bason in light of Allsop.

17 A. Okay, yes.

18 Q. So let's look at figures 1, 2, 3 and 4 --

19 A. Okay.

20 Q. -- of Allsop, Exhibit 1,006. And can you  
21 tell me which of the components identified in any of  
22 these figures would be present in the Bason-Allsop  
23 combination?

24 MR. SKLAR: Objection, form.

25 A. So the body, certainly the body of Allsop

1 S. Piper

2 would be, would be part of the proposed design combining  
3 Bason and Allsop. The teeth 2 would be integrally  
4 molded as it's taught by Allsop as far as a ring or part  
5 No. 155 of Allsop, although the teeth that would be  
6 molded would be teeth 2 of Bason.

7 Q. So you're saying that Bason's teeth --  
8 excuse me. You're saying that Bason's teeth 2 would be  
9 modified in view of Allsop's component 155?

10 A. Well, instead of it being -- the teeth  
11 would be molded as an integral part of the body, which I  
12 think is 10 in Allsop, looking at figure 3.

13 Q. Are there any other components of Allsop  
14 that you contend would have been incorporated into the  
15 Bason-Allsop combination?

16 MR. SKLAR: Objection, form.

17 A. Generally speaking, the components of  
18 Bason would replace many of the components in Allsop,  
19 and they would be placed under the canister in Allsop,  
20 and the components such as the teeth 2 would be  
21 integrally molded into the body 10 of Allsop. Allsop or  
22 Bason. Bason has a vertical --

23 Q. Before we move on, I just want to make  
24 sure I understand your last sentence.

25 So it's your position that instead of modifying

1 S. Piper

2 Bason in view of Allsop, you would, in fact, take  
3 Bason's component and incorporate them into Allsop?

4 MR. SKLAR: Objection, form.

5 A. Maybe I didn't say the sentence very  
6 well. I'm simply saying that somebody would have moved  
7 the Bason dose counter below the Bason canister, as  
8 where the rotational mechanism is located, such as in  
9 the Allsop device.

10 Q. Okay. So back to the question that I was  
11 asking you, which was you discussed that you think  
12 Allsop's body would be incorporated into the  
13 Allsop-Bason combination. Are there any other  
14 components of Allsop that would be incorporated into the  
15 Allsop-Bason combination?

16 MR. SKLAR: Objection to the form.  
17 Mischaracterizes the testimony.

18 A. There are elements that are taught by  
19 Allsop that would be part of the modification, but the,  
20 specifically part number 140 would not -- for example,  
21 would not be included.

22 Q. And so I need you to identify  
23 specifically for me which components of Allsop would be  
24 incorporated into the Allsop-Bason combination.

25 MR. SKLAR: Objection to the form.

1 S. Piper

2 Asked and answered.

3 A. Well, certainly component 10, which  
4 includes feature 13. Component 16. I think it looks  
5 like a stem. Dispensing container 15 would also be  
6 included.

7 Q. And that's the canister?

8 A. Correct.

9 Q. So the Bason-Allsop combination would  
10 include Allsop's canister, not Bason's canister?

11 MR. SKLAR: Objection, form.  
12 Mischaracterizes the testimony.

13 A. I think the idea as described -- actually  
14 the idea is to improve Bason, so I think we're generally  
15 talking about the same canister, but no, I think we've  
16 used the canister -- what's described here is an  
17 improved Bason device. And so, and it's modified by the  
18 teachings of Allsop.

19 Q. Right. So you see what I'm getting at  
20 here. There appears to be a bit of confusion as to  
21 which components of Allsop are incorporated and which  
22 components of Bason remain. So I just want to get  
23 cleared on that. So I want you to list for me which  
24 components of Allsop are incorporated into the  
25 Bason-Allsop combination.



1 S. Piper

2 MR. SKLAR: Objection, form.

3 A. I think some of the confusion is simply  
4 the result of the fact that both Bason, they are both  
5 meter dose inhaler devices with counters. They both  
6 have bodies. They both use canisters. They both have  
7 valve stems. They both have some of corresponding jet  
8 that interacts with it. So those components obviously  
9 need to be retained for a meter dose inhaler. So if  
10 there are elements of both, they would still, of course,  
11 be included.

12 Q. Do you think that that's what's reflected  
13 here in your declaration?

14 A. An idea -- the idea is to improve Bason  
15 in view of Allsop.

16 Q. Mr. Piper, I just want to do a couple of  
17 housekeeping-type matters. I don't believe that we have  
18 introduced the patent owner's notice of deposition for  
19 either of the IPRs, and I just wanted to put it in the  
20 record and make sure it's clear.

21 MS. HARGRAVE: So let's mark -- I'm  
22 just going to estimate we're up to 1,010. Does that  
23 sound about right for exhibits?

24 (Discussion held off the  
25 record.)

1 S. Piper

2 MS. HARGRAVE: We'll mark Patent  
3 Owner's Notice of Deposition of S. David Piper for case  
4 IPR 2018-01054 for Patent No. 8,936,177.

5 (Exhibit 1,009, Patent Owner's  
6 Notice of Deposition of S.  
7 David Piper, was marked for  
8 identification.)

9 Q. So you understand, Mr. Piper, that you're  
10 here giving testimony today relating to case IPR  
11 2018-01054 relating to Patent No. 8,936,177; correct?

12 A. Correct.

13 MS. HARGRAVE: Can you mark Patent  
14 Owner's Notice of Deposition of S. David Piper for case  
15 IPR2018-01055, Patent No. 9,370,631 as Exhibit 1,010.

16 (Exhibit 1,010, Patent owner's  
17 notice of deposition of S.  
18 David Piper, was marked for  
19 identification.)

20 Q. So you understand, Mr. Piper, that you're  
21 here giving testimony today also relating to case IPR  
22 2018-01055, Patent No. 9,370,631, correct?

23 A. Correct.

24 Q. Did you meet with your counsel to prepare  
25 for your deposition today?

1 S. Piper

2 A. Yes.

3 Q. When did you meet with counsel to prepare  
4 for your deposition today?

5 A. Yesterday.

6 Q. For how many hours did you meet with  
7 counsel to prepare for your deposition today?

8 A. I also met with him on Tuesday.

9 Q. So approximately how many hours did you  
10 spend preparing for your deposition on Tuesday?

11 A. On Tuesday, about eight hours.

12 Q. And approximately how many hours did you  
13 spend preparing for your deposition yesterday?

14 A. About eight hours.

15 Q. Who did you meet with to prepare for your  
16 deposition today?

17 A. The attorneys that are present. Jason,  
18 Ron and Greg.

19 Q. Did you meet with anybody else in  
20 preparation for your deposition today?

21 A. No. Those are the people I worked with  
22 on preparation for my deposition that I recall.

23 Q. Did you meet with anybody in-house at  
24 either Drohme or Merck to prepare for your deposition  
25 today?

1 S. Piper

2 A. I met with -- I forgot your name. Emily.  
3 She seems to be more of an observer than anything else.

4 Q. Let's look at your '177 declaration,  
5 Exhibit 1,002.1. So if you look at Pages 3 through 5,  
6 you've included a list of materials which you have  
7 considered.

8 Do you see those?

9 A. Yes.

10 Q. Are there any other materials that you  
11 reviewed and considered in forming your opinions  
12 relating to the '177 IPR?

13 A. Not in this specific case. I obviously  
14 have a substantial amount of experience in the area of  
15 aerosol delivery devices. So I have a vast background  
16 information that's been collected over lots of events,  
17 experiences and publications and texts and so on and so  
18 forth. What the list here represents is the primary  
19 items I viewed in preparation for this declaration.

20 Q. You can't identify particularly any other  
21 materials that you would have reviewed in forming your  
22 opinions for the '177 IPR, right?

23 A. No.

24 Q. And now let's look at Exhibit 1,002.2,  
25 which is your declaration for the '631 patent. And

1 S. Piper

2 again, turn to your list of materials considered and  
3 reviewed. It begins on page 3 and ends on page 6.

4 A. (Witness complies with request.) Okay.

5 Q. And you can't identify particularly any  
6 other materials that you would have reviewed in forming  
7 your opinions for the '631 IPR, correct?

8 A. Similarly as stated in the '177, yes.

9 Q. Mr. Piper, you're not a lawyer; right?

10 A. No, I'm not a lawyer.

11 Q. And you're not a legal expert, correct?

12 A. I'm not a legal expert.

13 Q. So you relied on Petitioner's attorneys  
14 to instruct you as to the law that's relevant to the  
15 issues in your report, right?

16 A. I relied on the attorneys that I worked  
17 with on the legal issues.

18 Q. And you prepared claim constructions for  
19 certain terms in the '177 and '631 patents, right?

20 A. Right.

21 Q. And you applied those claim constructions  
22 in your analysis for those patents, correct?

23 A. What was the question?

24 Q. You applied those claim constructions in  
25 your analysis for the '631 and '177 patents, correct?

1 S. Piper

2 A. Well, the claim constructions were part  
3 of the declaration. So it's part of the analysis. I  
4 guess I don't understand the question.

5 Q. You didn't perform analysis assuming any  
6 other claim constructions that weren't included in your  
7 declaration, correct?

8 A. No, my declarations are a full and  
9 complete record of my analysis.

10 Q. So if we look at your '177 declaration on  
11 page 17. You discuss a proposed claim construction for  
12 the term a "stationary body including at least one  
13 stationary gear."

14 Do you see that?

15 A. At the top of the page?

16 Q. Yes.

17 A. Yes, the '631 patent does not explicitly  
18 define the term "stationary body" comprising one gear.

19 MR. SKLAR: Please clarify. Are you  
20 talking about the '177 declaration?

21 MS. HARGRAVE: Yes.

22 A. I'm sorry.

23 Q. Yes, the '177 declaration. And that's  
24 Exhibit 1,002.1.

25 A. What was the page number?

1 S. Piper

2 Q. Page 20.

3 A. Okay, yes, stationary body including at  
4 least one stationary gear. Yeah. There's a claim  
5 construction there, yes.

6 Q. Did you come up with a construction for  
7 the term "stationary body"?

8 MR. SKLAR: Objection to the form.

9 A. It's my declaration, so there was a lot  
10 of conversation on, with the people I worked with in  
11 preparing the declarations. But at the end of the day  
12 it is my declaration, and I've read all the drafts and  
13 helped create the document and thoroughly reviewed the  
14 final draft, made sure that it represented what I  
15 thought and signed and dated it. It was my document.

16 Q. Was the construction for a stationary  
17 body provided to you by your lawyers?

18 MR. SKLAR: Again, I'll object based on  
19 privilege. You do not have to answer it based on any  
20 direct conversation that you had with attorneys or  
21 reveal any of the content of any conversation you had  
22 with the attorneys.

23 A. So I won't answer. If I don't have to  
24 answer a question, I won't.

25 Q. Did you personally review the

1 S. Piper

2 specification in the file history to come up with a  
3 proposed construction for the term "stationary body"?

4 A. I reviewed the file history.

5 Q. That's not really what I asked, so I'll  
6 ask it again.

7 Did you review the specification and the file  
8 history to come up with a proposed construction for the  
9 term "stationary body"?

10 A. I've reviewed the specification and the  
11 file history. The overall document including the claim  
12 construction was a teamwork effort of which --

13 MR. SKLAR: Again, I'll instruct you  
14 not to discuss any specific contents of the  
15 conversations with the attorneys.

16 A. Can you restate the question?

17 Q. Sure. Did you review the specification  
18 and the file history --

19 A. Yes.

20 Q. That's not the end of the question.

21 A. Sorry.

22 Q. That's okay. Did you review the  
23 specification and the file history to come up with a  
24 proposed construction for the term "stationary body"?

25 A. I did review the claim or the file



1 S. Piper

2 history and the specification to come up with the  
3 limitation, you know, as part of creating the limitation  
4 and the whole declaration.

5 Q. So apart from the term "stationary body,"  
6 there are no other claims -- let me check.

7 Apart from the term "a stationary body including  
8 at least one position area gear," there are no other  
9 terms in the claims of the '177 patent for which you  
10 believe construction is necessary; right?

11 MR. SKLAR: Objection, form.

12 A. Well, I mean, that was simply one of the  
13 more explicit terms that were defined out for the claim  
14 construction. I mentioned -- for example, I mentioned  
15 in Paragraph 110 that a person with skills understanding  
16 the gear under the broadest reasonable interpretation in  
17 light of the '177 patent specification, a specification  
18 is a set of surfaces of teeth that either restrict or  
19 cause movement of another part.

20 So I'm just making clear what my interpretations  
21 of what certain terminology meant based on my reading of  
22 the specification and what I think a person of ordinary  
23 skill in the art would understand in that light.

24 Q. So is it your position that you proposed  
25 a construction for the term "gear"?

1 S. Piper

2 A. I'm just making clear how my, what my  
3 interpretation was or what I thought a person of  
4 ordinary skill would have taken the term "gear" to mean.

5 Q. You haven't proposed any constructions  
6 for any other term in the '177 patent, right?

7 MR. SKLAR: Objection, form.

8 A. Well, this one proposal on page 20,  
9 "stationary body including at least one stationary  
10 gear," that is certainly the only explicit -- I'm sorry.  
11 Can you ask the question again?

12 Q. Sure.

13 A. I'm just getting a little tired.

14 Q. That's all right. I'm nearly done.

15 You haven't proposed any constructions for any  
16 other term in the '177 patent except for the term "a  
17 stationary body including at least one stationary gear,"  
18 correct?

19 MR. SKLAR: Objection to the form.  
20 Mischaracterizes the witness's testimony.

21 A. I guess I'm not sure exactly what the,  
22 what the legal nuances are of construction or not.  
23 Certainly the construction of stationary body, one,  
24 including at least one stationary gear, that  
25 construction is listed here on page 20 as explicit

1 S. Piper

2 construction.

3 There are other places where I communicate what  
4 I think was meant by say a certain term or how I  
5 construed a term or how I thought somebody of person of  
6 skill in the art would have interpreted a term as more  
7 of a fuller explanation.

8 But I don't know if that meets your requirements  
9 for construction that you're asking. It's simply a  
10 matter of fact that my expertise is in the area of meter  
11 dose inhalers and aerosol delivery devices and not law.

12 Q. Did your lawyers explain to you that in  
13 performing your analysis of the claims in this patent  
14 you either need to propose a particular construction for  
15 a term or otherwise give it its plain and ordinary  
16 meaning?

17 MR. SKLAR: Again, I'll caution you not  
18 to disclose any particular conversations or discussions  
19 that you had with attorneys.

20 Q. Let me rephrase my question. Do you  
21 understand that in performing your analysis of the  
22 claims in this patent you either need to propose a  
23 particular construction for a term or otherwise give it  
24 its plain and ordinary meaning?

25 A. Yes, I do. I understand that.

1 S. Piper

2 Q. Where you have not ascribed a particular  
3 construction for a term, you have applied the term's  
4 plain and ordinary meaning; right?

5 A. Yes, and this other explanation of the  
6 gear is an explanation of what there may be in case  
7 there was any confusion.

8 Q. Just to be clear, you didn't apply any  
9 other construction or any other term in the '177 patent  
10 apart from stationary body including at least one  
11 stationary gear?

12 MR. SKLAR: Objection to form.  
13 Mischaracterizes the witness's testimony.

14 A. In the formal sense as I understand it.  
15 In regards to the plain and ordinary meaning of the  
16 words, there are claims where I've clarified what that  
17 might be. This is the one specific example on page 20  
18 on which there is a claim construction.

19 Q. Apart from explanation that you may have  
20 included in your declaration, what the plain and  
21 ordinary meaning of a particular term might be, there  
22 are no other terms in the '177 patent that you believe  
23 needs special construction to be understood; correct?

24 A. No. I think my declaration is pretty  
25 clear as it's written and spelled out and written out.

1 S. Piper

2 Q. So let's look again at your '631  
3 declaration, Exhibit 1,002.2.

4 So for the '631 patent, the proposed  
5 constructions for the term "a stationary body comprising  
6 at least one stationary gear" in Claim 1, and in Claim 3  
7 the term "disposed on"; is that right?

8 A. That's correct.

9 Q. So again, apart from the term "stationary  
10 body" and "disposed on," there are no other terms in the  
11 claims of the '631 patent for which you applied a  
12 different claim construction?

13 A. Other than --

14 MR. SKLAR: Objection to the form. Go  
15 ahead.

16 A. Other than plain and ordinary meaning  
17 that I applied and may have explained in the declaration  
18 throughout, but no.

19 Q. And you consider yourself a person of  
20 ordinary skill in the art of the '177 and '631 patents,  
21 correct?

22 A. Yeah, at least a person skilled in the  
23 art at least.

24 Q. And you understand the terms of the '177  
25 and '631 patents apart from the terms that you proposed

1 S. Piper

2 construction for without further understanding of what  
3 they mean?

4 MR. SKLAR: Objection. Form.  
5 Mischaracterizes the witness's testimony.

6 A. I don't understand the question. First  
7 off, we're talking about the '177?

8 Q. Sure. I'll break it down.

9 A. Okay.

10 Q. You understand the terms in the claims of  
11 the '631 patent without further explanation of what they  
12 mean, correct?

13 MR. SKLAR: Objection. Form.

14 A. Well, I took the plain and ordinary  
15 meaning of the words and as would be understood as  
16 somebody with skill in the art.

17 Q. And you applied the plain and ordinary  
18 meaning of the words except for the terms that we just  
19 discussed, which were "stationary body" and "disposed  
20 on"; correct?

21 MR. SKLAR: Objection, form.

22 A. In the '631 patent?

23 Q. Yes.

24 A. Yes.

25 MS. HARGRAVE: I don't have any further

1 S. Piper

2 questions.

3 MR. MORRIS: Let's take a quick break.

4 (Recess)

5 EXAMINATION BY

6 MR. SKLAR:

7 Q. Just, Mr. Piper, a couple questions as  
8 well from me.

9 Can I direct you to Paragraph 74 of  
10 Exhibit 1,002.1. That is your declaration for the '177  
11 IPR.

12 A. Okay. Paragraph 74?

13 Q. Yes. Why don't you just take a moment to  
14 reread Paragraph 74 and let me know when you're done.

15 A. (Witness complies with request.) Okay, I  
16 read Paragraph 74.

17 Q. Okay. And do you recall earlier this  
18 morning Aptar counsel was asking you some questions  
19 about the sentence in that paragraph that begins, "In  
20 fact, some time around 1998 but before 2001 in my role  
21 at Piper Medical I was asked to look into building a  
22 dose indicator for an inhaler product"?

23 Do you recall that counsel for the patent owner  
24 was asking you about that earlier?

25 A. I remember talking about this subject,

1 S. Piper

2 yes.

3 Q. And earlier this morning you had given  
4 some testimony that at one time you had some sketches of  
5 the dose counter device that you had contemplated as  
6 part of the sentence that we read, the dose counter you  
7 looked into between the 1998 and 2001 timeframe.

8 A. Right. Yeah. At one time I did have  
9 sketches.

10 Q. Do you still have those sketches today,  
11 to the best of your knowledge?

12 A. No, no. Those sketches are gone.

13 Q. I want to be clear. It's not that you  
14 had the sketches available but chose not to include them  
15 in your declarations; correct?

16 A. I don't physically have the sketches  
17 anymore. They've been gone for years. So I didn't have  
18 the option of including them as part of the declaration.

19 Q. To the best of your knowledge, do you  
20 still have any other documents related to the dose  
21 counter project discussed in Paragraph 74 of your 177  
22 declaration in your possession today?

23 A. No. I have any physical documents in  
24 relation to the work I did regarding feasibility of the  
25 dose counter, medical technology in 1998.



1 S. Piper

2 Q. To be clear, let's take a quick look at  
3 your Exhibit 1,002.2, which is your declaration in the  
4 '631 case, the IPR related to the '631 patent.

5 If you will take a look at Paragraph 135 in  
6 1,002.2, let me know when you've reviewed that.

7 A. (Witness complies with request.)  
8 Paragraph 135?

9 Q. Uh-huh, yes.

10 A. Okay, I've read that paragraph.

11 Q. In Paragraph 135 there's a sentence that  
12 says, "Sometime around 1998 but before 2001 in my role  
13 at Piper Medical I was asked to look into building a  
14 dose indicator for an inhaler."

15 Do you see that?

16 A. I do.

17 Q. That's referring to the same project we  
18 just discussed with respect to Exhibit 1,002.1,  
19 Paragraph 74 which we had just reviewed; correct?

20 A. Correct.

21 Q. I just want to make sure the record is  
22 clear, I'm going to ask you the same questions.

23 You gave testimony earlier today that at one  
24 time you had sketches of this dose counter device that's  
25 referred to in Paragraph 135 of Exhibit 1,002.2?

1 S. Piper

2 A. That's correct.

3 Q. And do you still have those sketches  
4 today, to the best of your knowledge?

5 A. No, I don't have those sketches anymore.

6 Q. And it's not that you had the sketches  
7 available but chose not to include them in your  
8 declarations, right?

9 A. Yeah, the sketches have been long gone.  
10 So I did not have the option of including them as part  
11 of that version.

12 Q. To the best of your knowledge, do you  
13 still have any and other documents related to the dose  
14 counter product discussed in Paragraph 135 of  
15 Exhibit 1,002.2 in your possession today?

16 A. I no longer have any documents in regards  
17 to the work I did regarding the dose counter with  
18 Vortran Medical Technology in 1998.

19 MR. SKLAR: No further questions.

20 MS. HARGRAVE: That will do it for me  
21 too.

22 (Proceedings adjourned at 3:54  
23 p.m.)  
24  
25

S. Piper

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EXHIBITS

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Exhibit 1,010	Patent owner's notice of deposition of S. David Piper	146

C E R T I F I C A T E

3M, et al., )  
 v. )  
 APTAR FRANCE, et al. )

I, BARBARA DeVICO, a Notary Public within and for  
 the District of Columbia , do hereby certify:

That SAMUEL DAVID PIPER, the witness whose  
 deposition is hereinbefore set forth, was duly sworn by  
 me and that such deposition is a true record of the  
 testimony by such witness.

I further certify that I am not related to any of  
 the parties to this action by blood or marriage; and  
 that I am in no way interested in the outcome of this  
 matter.

IN WITNESS WHEREOF, I have hereunto set my hand  
 this 1st of February, 2019.



BARBARA DeVICO

## ERRATA SHEET

Case Name:

Deposition Date:

Deponent:

Pg.	No.	Now Reads	Should Read	Reason
6	_____	_____	_____	_____
7	_____	_____	_____	_____
8	_____	_____	_____	_____
9	_____	_____	_____	_____
10	_____	_____	_____	_____
11	_____	_____	_____	_____
12	_____	_____	_____	_____
13	_____	_____	_____	_____
14	_____	_____	_____	_____
15	_____	_____	_____	_____
16	_____	_____	_____	_____
17	_____	_____	_____	_____
18	_____	_____	_____	_____
19	_____	_____	_____	_____

\_\_\_\_\_  
Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

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

\_\_\_\_\_

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

## ERRATA SHEET

**Case Name:** 3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp. v.  
Aptar France S.A.S.

**Deposition Date:** January 25, 2019

**Deponent:** Samuel David Piper

<b>Pg. No.</b>	<b>Line No.</b>	<b>Now Reads</b>	<b>Should Read</b>	<b>Reason</b>
7	16	2003	1003	Typographical error
9	20	meter	metered	Transcription error
9	23	meter	metered	Transcription error
9	24	meter	metered	Transcription error
10	3	meter	metered	Transcription error
10	9	meter	metered	Transcription error
10	15	meter	metered	Transcription error
16	9	declaration	declarations	Transcription error
17	6	matters	hours	Transcription error
18	3	100	1000	Transcription error
21	6	meter	metered	Transcription error
22	4	May 92018.	May 9, 2018	Typographical error

<b>Pg. No.</b>	<b>Line No.</b>	<b>Now Reads</b>	<b>Should Read</b>	<b>Reason</b>
23	3	meter	metered	Transcription error
23	9-10	PMDI and is used for delivering meter dose	pMDI and is used for delivering metered doses	Transcription error
23	12	meter	metered	Transcription error
23	19	with	within	Transcription error
23	22	meter	metered	Transcription error
24	5	meter	metered	Transcription error
26	7	Vyzan 9	VISAN-9	Typographical error
26	9	worked powering	worked by powering	Transcription error
26	12	Burroughs Welcome	Burroughs Wellcome	Typographical error
26	19	Vyzan 9 as a meter dose inhaler	VISAN-9 as a metered dose inhaler	Transcription error
26	25	Burroughs Welcome	Burroughs Wellcome	Typographical error
27	7	Gentle Inhaler	GentleHaler	Typographical error
27	11	approving	improving	Transcription error
27	24-25	Gentle Inhaler	GentleHaler	Typographical error
28	16	meter	metered	Transcription error

<b>Pg. No.</b>	<b>Line No.</b>	<b>Now Reads</b>	<b>Should Read</b>	<b>Reason</b>
28	21	Gentle Inhaler	GentleHaler	Typographical error
28	24	Gentle Inhaler	GentleHaler	Typographical error
30	12	meter	metered	Transcription error
30	16	constructions	instructions	Transcription error
31	10	meter	metered	Transcription error
31	18	meter	metered	Transcription error
32	7	mold apart	molding a part	Transcription error
32	9	tapirs	tapers	Typographical error
32	21	pattern	powder	Transcription error
33	7-9	Nebulizers, just about all the nebulizers, not all the nebulizers I've developed have all been largely injection molded	Nebulizers, just about all the nebulizers, not all the nebulizers, I've developed have all been largely injection molded	Transcription error
34	25	Operation	Objection	Transcription error
35	21	meter	metered	Transcription error
35	22	meter	metered	Transcription error
36	11	meter	metered	Transcription error



<b>Pg. No.</b>	<b>Line No.</b>	<b>Now Reads</b>	<b>Should Read</b>	<b>Reason</b>
37	9	Gentle Inhaler	GentleHaler	Typographical error
37	12	Gentle Inhaler	GentleHaler	Typographical error
38	6	Gentle Inhaler	GentleHaler	Typographical error
39	23	meter	metered	Transcription error
41	5	meter	metered	Transcription error
41	24	I found the Piper Medical	I found Piper Medical	Transcription error
44	4	A. Most of the work I do regarding meter	A. Most of the work I do regarding metered	Typographical error
44	7	meter	metered	Transcription error
44	8	ventilation	Inhalation	Transcription error
44	10	meter	metered	Transcription error
45	3	meter	metered	Transcription error
45	11	meter	metered	Transcription error
46	4	meter dose inhalers	medication	Transcription error
46	18	meter	metered	Transcription error
46	20	able to breathe	not able to breathe	Transcription error


<b>Pg. No.</b>	<b>Line No.</b>	<b>Now Reads</b>	<b>Should Read</b>	<b>Reason</b>
47	2	meter	metered	Transcription error
47	3	meter	metered	Transcription error
47	8	meter	metered	Transcription error
47	12	meter	metered	Transcription error
48	18	Is in that nature of your	Is that the nature of your	Transcription error
49	17	meter	metered	Transcription error
50	3	meter	metered	Transcription error
50	14	meter	metered	Transcription error
51	10	meter	metered	Transcription error
54	9-10	Gentle Inhaler	GentleHaler	Typographical error
54	14	resulted	resulting	Typographical error
56	11	include	includes	Typographical error
61	2	not anticipation	not an anticipation	Transcription error
67	13	numbers	members	Transcription error
67	14	figures	fingers	Transcription error

<b>Pg. No.</b>	<b>Line No.</b>	<b>Now Reads</b>	<b>Should Read</b>	<b>Reason</b>
72	10	wouldn't	would	Transcription error
77	13	useful and indicating a number of doses of a meter dose	useful in indicating a number of doses of a metered dose	Transcription error
77	22	meter	metered	Transcription error
77	23	meter	metered	Transcription error
77	25	meter	metered	Transcription error
78	4	would	wouldn't	Transcription error
81	4-6	MR. SKLAR: Objection. This is the last claim element of Claim 1. Before you go on	MR. SKLAR: Objection.  A. This is the last claim element of claim 1.  MR. SKLAR: Before you go on	Transcription error
84	14	of	that	Transcription error
90	5	meter	metered	Transcription error
97	10	Rhoades, which specifically	Rhoades, specifically	Transcription error
100	19	MR. SKLAR: Objection, nonresponsive.	MS. HARGRAVE: Objection, nonresponsive.	Transcription error
109	25	100,000s	100/1,000	Transcription error
111	15	meter	metered	Transcription error

<b>Pg. No.</b>	<b>Line No.</b>	<b>Now Reads</b>	<b>Should Read</b>	<b>Reason</b>
112	15	meter	metered	Transcription error
113	16	24	1-4	Transcription error
115	9	shade, dotted.	shaded, dotted.	Transcription error
126	23	counter	housing	Transcription error
131	2	of the Bason	of Bason	Transcription error
133	15	meter	a metered	Transcription error
133	22-23	I'm not sure what that's meant by the word "sophisticated." So in relative to something	I'm not sure what is meant by the word "sophisticated." So it's relative to something	Transcription error
134	6	meter	metered	Transcription error
134	19	meter	metered	Transcription error
135	7	meter	metered	Transcription error
135	13	meter	metered	Transcription error
135	21	meter	metered	Transcription error
136	2	meter	metered	Transcription error
137	3	100,000s	100/1,000	Transcription error

<b>Pg. No.</b>	<b>Line No.</b>	<b>Now Reads</b>	<b>Should Read</b>	<b>Reason</b>
137	10	125,000s	125/1,000	Transcription error
137	20	300,000s	300/1,000	Transcription error
137	24	125,000s	125/1,000	Transcription error
138	2	125,000s	125/1,000	Transcription error
138	17	meter	metered	Transcription error
139	3	of	in	Transcription error
139	6	medications	medication	Typographical error
139	13	meter	metered	Transcription error
139	25	meter	metered	Transcription error
140	8	meter	metered	Transcription error
140	10	meter	metered	Transcription error
145	5	meter	metered	Transcription error
145	9	meter	metered	Transcription error
147	8	him	them	Transcription error
147	24	Drohme	3M	Transcription error

<b>Pg. No.</b>	<b>Line No.</b>	<b>Now Reads</b>	<b>Should Read</b>	<b>Reason</b>
148	16	information	of information	Transcription error
153	15	that a person with skills	that to a person of skill	Transcription error
153	17	the '177 patent specification, a specification	the '177 patent specification,	Transcription error
154	25	as explicit	as an explicit	Transcription error
155	5-6	construed a term or how I thought somebody of person of skill in the art would have interpreted a term	construed a term or how I thought somebody, a person of skill in the art, would have interpreted a term	Transcription error
155	10	meter	metered	Transcription error
160	23	No. I have any	No. I don't have any	Transcription error



**Signature of Deponent**