

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

RESMED LIMITED, RESMED INC., and     ) Case No.  
RESMED CORP.,     ) IPR2016-01719  
   )  
                  Petitioners,     ) U.S. Patent  
   ) No. 6,398,197  
   )  
                  v.     )  
   )  
   )  
FISHER & PAYKEL HEALTHCARE LIMITED,) )  
   )  
                  Patent Owner.     )  
-----) )

Deposition of HARTMUT SCHNEIDER, M.D., PH.D.,  
taken at the offices of Knobbe Martens, 1717 Pennsylvania  
Avenue NW, Suite 900, Washington, D.C., beginning at  
9:03 a.m., on Wednesday, August 30, 2017 before Nancy J.  
Martin, a Registered Merit Reporter, Certified Shorthand  
Reporter.

Job No. 2655269

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1     A P P E A R A N C E S :

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I N D E X

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E X H I B I T S

PREVIOUSLY MARKED

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WASHINGTON, D.C., WEDNESDAY, AUGUST 30, 2017;

9:03 A.M.

- - -

HARTMUT SCHNEIDER, M.D., PH.D.,  
having been first duly sworn/affirmed,  
was examined and testified as follows:

EXAMINATION

BY MR. KANE:

Q. Good morning, Mr. Schneider.

A. Good morning.

Q. Could you please state your name and spell  
your name for the record, please.

A. My name is Hartmut Schneider, H-a-r-t-m-u-t,  
last name Schneider, S-c-h-n-e-i-d-e-r.

Q. And what's your current business address?

A. The business address is -- primary address is  
Johns Hopkins, 5501 Bayview Boulevard in Baltimore.  
That's the asthma and allergy center of the department  
of pulmonary critical care medicine of Johns Hopkins  
University.

Q. Dr. Schneider, have you ever been deposed  
before?

A. No.

Q. So I'll go over a few of the ground rules. I

1     imagine your counsel has done the same.

2             You understand this deposition is being taken  
3     in connection with a series of IPRs between ResMed and  
4     Fisher & Paykel?

5             A.   Yes.

6             Q.   And you understand that you're under oath  
7     today?

8             A.   Yes.

9             Q.   And that your testimony today is just as if  
10    you were giving it in a court of law in front of a  
11    judge?

12            A.   Yes.

13            Q.   And the court reporter will be taking down  
14    the questions and answers today.   So it's important  
15    that we try to make it easier on her.   One thing is I  
16    will try to make sure that I let you finish an answer  
17    before I start talking and ask a question, and  
18    likewise, if you can let me finish my questions before  
19    you start answering, that would be helpful.   All  
20    right?

21            A.   All right.

22            Q.   The other thing that's hard to do is you have  
23    to answer audibly, a "yes" or "no," not a nod of the  
24    head or a shaking of the head or an "uh-huh" or an  
25    "uh-uh" because those are hard for the court reporter,

1 obviously. All right?

2 A. All right.

3 Q. If you don't ever understand a question  
4 today, please let us know, and I will try to clarify  
5 and make it more understandable for you. Okay?

6 A. Okay.

7 Q. If you ever need to -- somewhere along the  
8 way you want to modify an answer, you have some  
9 additional thoughts in your head that come to mind  
10 that you want to add to your testimony, please let me  
11 know and we'll take care of that. All right?

12 A. All right.

13 Q. Your attorney may object from time to time,  
14 but in general, you will answer the questions unless  
15 the attorney instructs you otherwise. Okay?

16 A. Okay.

17 Q. And we will try to take breaks approximately  
18 once an hour or so, but if you ever need a break, just  
19 let me know and we will break. Just sort of a caveat  
20 will be that we ask that we not take a break when  
21 there's a question pending. We'll let you give an  
22 answer audibly, and then we can take our break. All  
23 right?

24 A. Yes. All right.

25 Q. Is there any reason why you cannot give

1 accurate and truthful testimony today?

2 A. No, there's no reason.

3 Q. Okay. Dr. Schneider, what did you do to  
4 prepare for your depositions today?

5 A. I got a substantial amount of documents that  
6 is related to the patent and the claim and the case,  
7 and over the last six months I was reading and  
8 preparing my declaration, and that was tens of hours.

9 Q. Okay. Specifically, say, in the last few  
10 weeks since you've learned of your deposition, what  
11 have you done to prepare for today?

12 A. Just reading and the -- the materials again  
13 and again, over and over again.

14 Q. Did you meet with anyone to prepare for your  
15 deposition?

16 A. I did not meet with anyone from any company,  
17 from any of this. ResMed or Fisher Paykel. And the  
18 only meeting we have had was with my attorneys this  
19 morning and occasionally there was a meeting.

20 Q. Occasionally -- I'm sorry?

21 A. Occasionally, if I have questions in the case  
22 of the declaration, how to put this in wording, there  
23 was phone calls too.

24 Q. Okay. So in terms of preparing for today,  
25 you reviewed the materials again?

1 A. Yes.

2 Q. And you had a meeting with your lawyers --

3 A. Yes.

4 Q. -- this morning?

5 A. Yes.

6 Q. And other than that, did you have any other  
7 preparation?

8 A. We have had general meetings with my  
9 attorneys about what the deposition is. What is the  
10 form. Exactly what you have written -- what you said  
11 before, that I have to swear, the form of how a  
12 deposition goes, speak to the end, all of what you  
13 mentioned before, I was instructed by my attorneys.

14 MR. BELLINGER: You shouldn't get into the  
15 content of the communications.

16 THE WITNESS: Yes.

17 BY MR. KANE:

18 Q. Okay. Have you ever spoken to anyone at  
19 Fisher & Paykel regarding this dispute, or these  
20 disputes?

21 A. No.

22 Q. Have you spoken to any person other than your  
23 lawyers in connection with these disputes?

24 A. I've been talking to my colleagues that I  
25 need to spend time on the case, yes. Not telling

1 about the contents of the case.

2 Q. Certainly.

3 (Previously marked Exhibit 2004 was handed  
4 to the witness.)

5 BY MR. KANE:

6 Q. I'm going to hand you one of your  
7 declarations. And this was a declaration that you  
8 filed in connection with the IPRs relating to the  
9 7,111,624, the 8,091,547, and the 8,550,072 patents.  
10 It's been previously marked as FPH Exhibit 2004 and  
11 IPR2016-01716.

12 Are you familiar with this document?

13 A. Yes, I am.

14 Q. And just could you turn to Page 96 for me at  
15 the end of the document. That's your signature?

16 A. That is my signature.

17 Q. All right. You mentioned earlier that you  
18 had been working on this dispute for approximately six  
19 months. Do you recall when you first started working?

20 A. No, I don't remember exactly. It could be  
21 April, May, end of March. More in the April range.

22 Q. Okay. Do you recall when you began working  
23 on the actual physical document for the declarations?

24 A. The documents may have been sent maybe four  
25 weeks later than after signing all the contractual

1 work and NDAs and all of that.

2 Q. Okay. Without getting into any specific  
3 communications, can you describe the process by which  
4 the documents were drafted?

5 MR. BELLINGER: I'm going to instruct you,  
6 consistent with the question, to not reveal  
7 contents --

8 THE WITNESS: Yes. Yes.

9 MR. BELLINGER: -- of communications with  
10 your attorneys.

11 THE WITNESS: You mean this document  
12 (indicating)?

13 BY MR. KANE:

14 Q. Yes.

15 A. It's the same method than what I do usually  
16 when I write scientific papers. You might have seen  
17 I've done lot of scientific papers. I'm drafting the  
18 paper first. The method is drafting the first  
19 proposal and then going over and over this again,  
20 dictating, getting this written out, and then in the  
21 end, in such a document as it is in a scientific  
22 paper, 50 versions of it.

23 Q. Okay. When the drafting began, did you start  
24 the drafting process or did your counsel send the  
25 draft to you?

1           A. No. It's the other way around. I'm drafting  
2 and then, of course, with the counsel needs to be  
3 worded specific legal words. You see, I'm writing  
4 very well in medical terminology, but when it comes up  
5 to legal terminology, and of course, also, my counsel  
6 informed me of what is obviousness, what is the legal  
7 definition of specific things that I needed to know in  
8 order to draft some response to it.

9           Q. Okay. Very good. Thank you.

10           So with that, let's turn to the declaration,  
11 and I believe Paragraph 3 on Page 1 you describe your  
12 education. I see that you have a medical degree from  
13 Phillips University in Marburg, Germany. Is that  
14 true?

15           A. Yes, that's true.

16           Q. Okay. And then you received a Ph.D. from  
17 that same institution in 1999?

18           A. Yes.

19           Q. What was the Ph.D. in?

20           A. The Ph.D. was in studying the blood pressure,  
21 cardiac function in dogs, and in these dogs we  
22 implanted several probes along the heart into the  
23 vessels. Also invented a few new methods to do these  
24 studies in a sleeping dog so that we could study the  
25 effects of sleep apnea and the heart.

1           There had been actually four publications of  
2     it. There have been good publications from the Ph.D.  
3     study.

4           Q. Okay. Thank you. When did you first begin  
5     working in the field of sleep disorder?

6           A. 1987.

7           Q. Okay.

8           A. March 1987.

9           Q. And how did you enter into that field?

10          A. That is a very good question. In the end, I  
11     was fascinated that there's a novel area that I  
12     haven't learned anything about in my medical school.  
13     I was one of the best students, yet I did not know  
14     anything about how my patients coped with the disease  
15     when they are asleep. One of the first patients that  
16     was admitted to my ward, I thought he would either die  
17     or would be on the ICU the next morning, yet, the next  
18     morning when I came, he was so markedly better, and I  
19     needed to find out why. And he was actually admitted  
20     to the sleep center, and that, of course, awoken my  
21     curiosity in that field. That's why I stayed there.  
22     That's why I stayed in that field.

23          Q. When you say that patient was in poor  
24     condition, you thought he was going to die, was that  
25     the result of his sleep apnea?

1           A. Yes. Yes. It was a Pickwickian Syndrome.  
2       That means you have sleep apnea for long years that  
3       has affected your lung -- the blood pressure in your  
4       lungs. So there's pulmonary hypertension. And  
5       because of the changes in the lungs, the gas exchanges  
6       also alter. So they have low oxygen levels. That's  
7       the third symptom. And because of sleep apnea, they  
8       are so sleepy they can't stay awake. And the  
9       hemodynamic consequences of that first patient in 1987  
10      was not well known.

11           That's why that led to my Ph.D. thesis  
12      10 years ago, but it also was the index case for me to  
13      stay in the sleep medicine area.

14           Q. In Paragraph 4 of your declaration you  
15      mention several manufacturers that you have worked  
16      with over the years. The first is a company referred  
17      to as "SEFAM" based in France. Do you see that?

18           A. Yes.

19           Q. And what type of work have you done with  
20      SAFAM? Is that how you say it?

21           A. Yes. In 1987 the devices to treat sleep  
22      apnea came from that French company, and at that time  
23      I even not aware that ResMed even existed at the time.  
24      It was founded in 1987. We were only aware of  
25      Respironics and SEFAM, a French company. And these

1 CPAP machines, the first CPAP machines, they were as  
2 big as a nightstand, and, actually, you had to replace  
3 your nightstand for a CPAP machine that were almost  
4 built like that, that you put your night lamp on the  
5 CPAP machine.

6 All the mechanical parts, like a valve and  
7 pressure portion of a valve were mechanical devices  
8 that were attached at the end of the SEFAM device.  
9 The SEFAM device was a simple, big drawer hidden in a  
10 nightstand.

11 Q. So what kind of work or consulting have you  
12 done with SEFAM over the years?

13 A. SEFAM was then actually the company Matals  
14 Electronics, which was later named to MAP. They had  
15 the sublicense for selling SEFAM devices in Germany,  
16 and Matals Electronics is the name that applies,  
17 improved the devices from the French company, SEFAM to  
18 smaller devices, and they were an integral part with  
19 that development.

20 And, of course, in 1987 the sleep center  
21 where I was working for was the only academic sleep  
22 center in Germany. Actually, there was only nine  
23 sleep centers at that time in Germany, and because of  
24 that engineers and people in both electronic and  
25 mechanical engineers in that field consulted us, what

1 is the need and what should be the specifications for  
2 a treatment device. And that is the start of my  
3 consulting in '88 already for medical companies.

4 Q. And was that consulting in '88 for SEFAM or  
5 for MAP or both?

6 A. It was for in between. There was first  
7 Matals Electronics. They did other electronics than  
8 also just sleep apnea devices. Later, as the sleep  
9 field closed, in the beginning of the '90's, the  
10 company was then separated, sleep field, and it was  
11 founded as MAP which means medicine for arts with  
12 physician and patients. In Germany we don't call it  
13 MAP. We call it M-A-P. And that was located in  
14 Munich. They moved from Freiburg to Munich.

15 Q. And how long did you consult with SEFAM?

16 A. SEFAM was -- as I said through this Matals  
17 Electronics. So there was no direct contact between  
18 SEFAM and me. It was through Matals Electronics. It  
19 might have been one year, two years. I don't recall  
20 exactly the transition.

21 I know the people who were involved in Matals  
22 Electronics, and I know there was that transition. It  
23 has to be somewhere in the '87, '88, '89, even into  
24 the '90's. I don't recall when the exact transition  
25 time was between Matals Electronics and the foundation

1 of MAP.

2 Q. How long did you -- and then do I understand  
3 correctly you moved from that relationship to a  
4 consulting relationship for MAP?

5 A. Yes.

6 Q. And how long did your relationship with MAP  
7 last?

8 A. That lasted from -- again, from the beginning  
9 of the '90's until the purchase of MAP by ResMed.

10 Q. Do you have a recollection of ResMed  
11 purchased MAP?

12 A. That must be somewhere in 2003 to 2004 range  
13 because I developed an AutoCPAP device with MAP and my  
14 colleagues at Johns Hopkins, and we have had -- it was  
15 during my fellowship and beyond. 2001 there was a  
16 meeting in Dresden and in Munich. So the purchase of  
17 MAP must be somewhere in 2002, 2003.

18 Q. Okay. And looking again at Paragraph 4, it  
19 says that you were a consultant medical advisor for  
20 MAP during that time; correct?

21 A. Yes.

22 Q. And you worked, I think you said earlier,  
23 with MAP's device engineers and software designers to  
24 develop CPAP machines?

25 A. Yes.

1 Q. When you say, "device engineers," I think you  
2 mentioned earlier mechanical and electrical engineers.  
3 Is that what you're talking about?

4 A. Both mechanical engineers and electrical  
5 engineers and also software engineers. Not -- and we  
6 have had -- particularly when I was a fellow at Johns  
7 Hopkins, I brought over the consulting contract from  
8 Germany to the U.S., and during that period we've had  
9 engineers staying with me for weeks and weeks and  
10 weeks. So MAP actually sent an engineer to Baltimore  
11 in order to facilitate all the necessary development  
12 needed for creating -- we created three CPAP devices  
13 for MAP.

14 Q. Okay. Let me walk through those. Can we  
15 start with the first device and what your involvement  
16 was in that first device?

17 A. You see, in 1996 -- no, 1995 I visited MAP in  
18 New York because of a very basic concept, and that was  
19 how to -- at that time CPAP machines did not measure  
20 air flow inside the machines. It was simple blowers,  
21 and there was no closed loop, no measurement of flow.  
22 There was a measurement of pressure, but not air flow.  
23 And that is actually still true for most CPAP devices  
24 nowadays.

25 Now, the concept if you were to measure air

1 flow in your CPAP machine, then we can actually  
2 measure not only the breathing pattern of a patient,  
3 but we can also measure how much the disturbance of  
4 the pharynx is. We can quantify that. At that time  
5 we called this the blood pressure measurement of the  
6 upper airway.

7 Q. Are you saying "blood"?

8 A. Blood. You'll see it's the same -- when you  
9 have hypertension you might have symptoms like light  
10 head or headaches. That was the state of sleep apnea  
11 medicine in the past. We counted how many events  
12 someone has, but we did not quantify the disturbance  
13 that causes the headaches in this case -- right? -- or  
14 the apneas.

15 So the basic concept was if we integrated a  
16 quantitative flow measurement and with some fancy  
17 algorithms, we can then determine the cause, quantify  
18 the cause for sleep apnea, and that would put -- now  
19 let's say in other words, they were so intrigued by  
20 that because it would put them on an advantage against  
21 competitors. So the first machine we built was a  
22 so-called critical closing pressure machine, PCRIT  
23 machine, that uses a CPAP machine and the algorithms  
24 to measure the critical closing pressure, as I said,  
25 which is similar to blood pressure measurement.

1           And if you look up in my applications, I'm  
2 well known in the area of pathophysiology of the upper  
3 airway, and I use these machines for years to come.

4           Q. And by "closing," you mean closing of the  
5 airways?

6           A. Closing of the airway, yes. And this machine  
7 was in production for the scientific community, and  
8 the scientific community around the world were using  
9 these machines. And when ResMed purchased MAP, they  
10 continued that production for scientists.

11          Q. Are those machines used in sleep centers?

12          A. Yes, in sleep centers who are doing  
13 scientific work only.

14          Q. Okay.

15          A. Second machine we built, that was in '98, the  
16 knowledge gained from that machine can be translated  
17 into an automated titration machine for being used in  
18 sleep centers so that we can titrate and adjust the  
19 pressure in an objective way rather than being -- you  
20 needing technicians, well-trained technicians in doing  
21 this one night this way and another night this way.

22                 This machine was called Autoset CPAP machine.  
23 This machine went onto the market in Germany,  
24 commercially available, but not outside Germany. And  
25 that machine was only meant to be a transition in

1 gaining experience in the lab by technicians, but it  
2 was meant to be an interim device, a transitional  
3 device to create a fully automated CPAP device.

4 And the difference between fully automated  
5 and this Autoset device is that the Autoset device was  
6 meant for in-lab use, but the design was not  
7 applicable for home use in a patient. So both the  
8 external design and the internal design needed to be  
9 made -- adopt to the needs in the home of a naive  
10 patient, to a layman person, not to a specialist.

11 And that AutoCPAP machine algorithm was then  
12 developed with mathematicians, statisticians who came  
13 also outside MAP, and it was developed within one and  
14 a half years period, and it was meant to compete, of  
15 course, with the market leader at that time. At that  
16 time it was ResMed Autoset device.

17 Q. What was your role in the development of that  
18 Autoset device?

19 A. That both the Autoset device and the AutoCPAP  
20 device, my role was developing and testing the  
21 algorithms that allows you to adjust the pressure. It  
22 was to create a report that clinicians can read and  
23 interpret. My role was testing it on a case-by-case  
24 basis, the validity of the algorithms, testing the  
25 hardware in terms of what if you attach a humidifier

1 to the device, how does that affect the algorithms.  
2 Helping to reduce the artifacts both on hardware --  
3 the artifacts so that an algorithm that's based on  
4 flow measurement and pressure -- that the algorithm is  
5 fail-safe but still measures flow and pressure and the  
6 conditions that CPAP is intended to be used.

7 I'll give you an example. If you were -- the  
8 initial humidification chambers for MAP devices, they  
9 were -- they showed me one where it created bubbles  
10 into the water chamber. That was a very common way to  
11 humidify the air. You see this in, for instance,  
12 oxygen treatment devices. Now you can consider that  
13 bubbles can create turbulence or fluctuations in the  
14 flow signal, and the signal-noise ratio was so  
15 disadvantageous, particularly when you have very low  
16 breathing flows.

17 But that's one example where I said to the  
18 engineer, "No, this type of Humidification will not  
19 work." Or if they have -- of course, at that time  
20 there was the transition between cold humidifiers and  
21 warm humidifiers already. So we looked at all  
22 different types of Humidifiers that were available and  
23 had to find one that has the best noise-signal ratio  
24 for our accurate measurements of flow and pressure.

25 But that's one example. There's multiple

1 other examples of my involvement, study, study design  
2 as a co-PI, PI, both studies in Germany and at  
3 Hopkins.

4 Q. Okay. And so you had the Autoset original  
5 device that was used for -- in the lab for the  
6 technicians, and then you had the Autoset CPAP device.  
7 Was your role any different with respect to the  
8 AutoCPAP device for home use?

9 A. It was not the Autoset. Autoset was reserved  
10 for the ResMed device. We call this "AutoCPAP." The  
11 role in the end was, you could say, more senior  
12 because of my experience with the Autoset and PCRT  
13 machine.

14 REPORTER MARTIN: The what?

15 THE WITNESS: PCRT, P-c-r-i-t. It was more  
16 focused than -- on the algorithms site and testing the  
17 algorithm site of the AutoCPAP and identifying and  
18 finding an algorithm that used the air flow signal and  
19 the pressure signal to differentiate between wake,  
20 non-REM, and REM sleep.

21 As you know, you only need to increase the  
22 pressure when you are asleep, and you have the problem  
23 of sleep apnea. Sleep apnea is the disease that only  
24 happens during sleep. When you are awake, you don't  
25 have that problem.

1           So in the ideal setting, you would like to  
2   identify sleep first and then open up all the  
3   algorithms that can accurately measure and be very  
4   specific and sensitive, but to turn off the algorithms  
5   when you are asleep -- when you are awake. That was  
6   the basic principle on that AutoCPAP device, to  
7   develop that algorithm, to monitor sleep or estimate  
8   sleep and wake based on air flow signal and blood  
9   pressure.

10           In order to do that, we needed collaboration  
11   with statisticians and mathematicians, and that was  
12   Michael Louk, who was trained at the MIT in Boston but  
13   has founded a consulting company in Freiburg. We both  
14   then worked together as a team for MAP for the  
15   AutoCPAP device.

16   BY MR. KANE:

17           Q. At some point did your -- were there any  
18   other devices that you worked on while you were with  
19   MAP? Or consulting with MAP. I'm sorry.

20           A. During that period I did not work on other  
21   devices than just for MAP. There was an abrupt end to  
22   the consulting both -- for two reasons. The lead  
23   engineer at MAP wanted to become independent, and he  
24   formed a new company with Michael Louk who was the  
25   partner for the development of AutoCPAP, and they

1 developed a so-called TNI high-flow device.

2 And that ended up in a dispute between MAP  
3 and these two engineers. The IP around that algorithm  
4 that was shared between me of the AutoCPAP, it was IP,  
5 me, the mathematician, Michael Louk, and MAP, and that  
6 departure from this lead engineer ended up in a legal  
7 fight.

8 MAP wanted to continue to work with me. So I  
9 was spared for that legal fight. In fact, I was more  
10 a witness between those engineers from MAP who were  
11 blamed by MAP to stole IP from MAP. So that was one.  
12 So I forgot about it when you -- does that count as  
13 deposition, or I was just a witness in Germany for  
14 explaining my position in the development compared to  
15 the other one.

16 So if that counts to the question whether I  
17 was already in court like this one, then I have to  
18 correct myself. It was just half an hour.

19 "Dr. Schneider, what is your role here in this  
20 development," and I don't even recall how long it was.  
21 I don't recall any of the questions anymore. The  
22 bottom line was I continued to work until the end,  
23 until the transition from MAP to ResMed as a  
24 consultant.

25 Q. And so that dispute, that was in a court case

1 in Germany?

2 A. That was in a court case in Germany, yes.

3 Q. And you testified live in front of a judge in  
4 Germany?

5 A. I believe it was, or was it -- yeah, I  
6 believe it was. It was a long table like this with a  
7 judge on the other side. I don't -- and it was in  
8 court, yes.

9 Q. Where was the location? Was it Munich?

10 A. Munich.

11 Q. And then if I understand correctly, you  
12 continued consulting with MAP until ResMed acquired  
13 MAP?

14 A. Yes.

15 Q. And is that when your consulting ended?

16 A. My official consulting ended there, as did  
17 all my contracts. Initially, I had contracts that  
18 included royalties of the device. I still received  
19 royalties in the first few years because that AutoCPAP  
20 was on the market in Germany, but, of course, it was  
21 phased out by ResMed, and then the royalties phased  
22 out.

23 I don't recall how long my consulting  
24 contract went on through the transition period. That  
25 has somewhere terminated as well. Maybe it was still

1 already under the ResMed umbrella because contractual  
2 work still continued. I don't recall that anymore.  
3 Somewhere in the 2003 or 2002 area. We have had also  
4 contractual work at Johns Hopkins with MAP, and I  
5 needed to be committed too as well under the MAP only  
6 or under the ResMed. I don't know.

7 Q. Did you have any discussions with ResMed  
8 about consulting after that transition?

9 A. No, I don't recall that I have any  
10 discussions to apply with consulting contract. What  
11 we have had during the transition, of course, was  
12 explaining our thought process. I was invited by  
13 ResMed, by Peter Farrell, to explain the concept of  
14 critical closing pressure. In fact, he said to me,  
15 "Hartmut, I don't know what you are up to," and he  
16 called this to me and my friend, Professor Schwartz.

17 And when we both said, "We are preparing  
18 ourselves for the post-CPAP era," he didn't like that  
19 answer because CPAP business is the core business.  
20 But that was an ad hoc invitation to talk to the  
21 ResMed foundation, and I don't know when that was.

22 And then, of course, continues over the years  
23 at meetings. Peter Farrell was always at meetings,  
24 very vocal to the medical community. There was always  
25 discussions about scientific meanings but not about

1 business.

2 Q. Was there any -- but there was no discussion  
3 about consulting for ResMed?

4 A. I don't know. I don't recall. I've never  
5 received a direct consulting contract from ResMed.  
6 Whether there was a discussion or not, then I refer  
7 this to John Hopkins office of conflict. All my  
8 consulting contracts are managed by that. Since one  
9 of my colleague, Jason Curtness, has had direct  
10 consulting contract with them, and our institution and  
11 Schwartz had a research contract with them. I had to  
12 recuse myself anyway.

13 Q. Why did you have to recuse yourself?

14 A. Because of the policies of John Hopkins.  
15 Conflict of interest have to recuse me to be active  
16 part of that work that ResMed was doing with my  
17 colleagues and with the institution. I had to recuse  
18 myself somewhere in the mid 2005 because I had a  
19 consulting contract from Fisher & Paykel.

20 Q. I see.

21 A. And before that I was part of the T&I Medical  
22 Company. So even though I was part of a team that did  
23 contract research by ResMed, I was quite limited in my  
24 role as research participant.

25 Q. You mentioned that Peter Farrell invited you

1 and I believe Dr. Schwartz to potentially talk to  
2 ResMed. Did that talk occur?

3 A. The talk occurred in -- with me and my  
4 colleague in Munich, that was during the transition  
5 period where we were there for two or three days, but  
6 that was part of -- maybe it was part of the due  
7 diligence or it was part of the celebration. I don't  
8 know at what time of that transition it was.

9 After that meeting, of course, we talked to  
10 our engineers about critical closing pressure. The  
11 why and how of PCRIIT in San Diego. That was when I  
12 was invited on my own.

13 Q. So you went to San Diego and you had that  
14 meeting?

15 A. Yes. It was scientific. They invite at that  
16 meeting always a scientist to give a lecture that  
17 might be relevant to their field.

18 Q. And that was in San Diego, not Sydney?

19 A. That was in San Diego. I went to Sydney as  
20 well, you're right, but that was with a totally  
21 different topic.

22 Q. What was that topic?

23 A. I mentioned this somewhere in my declaration  
24 here, that I invented the new flow sensor, and this  
25 was a start-up company. On Page 7, Paragraph 12. So

1 what I have invented was a flow sensor that was quite  
2 unique that was a simple plastic tube without having a  
3 resistor inside.

4 Of course that was novel and that was  
5 supported by the NIH. We got 1.34 million to develop  
6 that sensor, and that started -- development started  
7 in 2005-ish at Hopkins. And both our technology  
8 transfer office and to our connections to everyone, to  
9 all the companies, we wanted to find someone, also  
10 ResMed, to license the technology. At that time the  
11 Johns Hopkins technology transfer office gave a  
12 proposal to ResMed that was outrageous for ResMed. We  
13 have had meetings with both in Baltimore with Glenn  
14 Richards. He said, "What's the meaning of a flow  
15 sensor, and does it have consequence."

16 Nevertheless, my colleague, Jason Curtness,  
17 who was part of the private contract with ResMed, he  
18 comes from Sydney, he said, "Let's talk over at the  
19 headquarters with Colin Sullivan," who is a good --  
20 he's another inventor of all the CPAP line at ResMed.  
21 So we introduced it to them as well at that point.

22 Never came out a contract out of that.  
23 That's why this -- attaching the flow sensor to the  
24 CPAP machine or integrating this into a CPAP machine  
25 failed as a business concept. We then approached

1 other companies, ventilator companies, such as  
2 Siemens, for home devices, the flow sensor is probably  
3 not applicable. I went even also to Phillips and  
4 introduced the flow sensor there. But at that time it  
5 was already transitioning with Respironics to  
6 Phillips, and the chief engineer, DeWitt, from  
7 Phillips was no longer able to negotiate to us.

8 I don't recall whether -- no, I did not  
9 introduce the flow sensor to Fisher & Paykel, nor to  
10 Breas, maybe to Breas. I don't know.

11 REPORTER MARTIN: To who? Breas?

12 THE WITNESS: Breas, B-r-e-a-s. It's a  
13 Swedish company.

14 It became evident that the integrating the  
15 flow sensor in CPAP machine is not of interest to CPAP  
16 companies. They have better ways and cheaper ways to  
17 do it. So that was the discussion, as I remember, in  
18 Sydney.

19 The other discussion in Sydney was the  
20 question, as I said, the PCRIT machines were now  
21 10 years after the first development with MAP. Our  
22 research came out, and ResMed was asked to deliver  
23 PCRIT machine or build PCRIT machines for the  
24 researchers in Australia and other researchers, and  
25 there was a discussion how can ResMed help to develop

1 PCRIT machines. This was my role as a John Hopkins  
2 researcher. Yes, there's a need. There's a research  
3 community. The PCRIT will be bringing the research  
4 forward, but that was not anything related private  
5 contract or private consulting.

6 BY MR. KANE:

7 Q. Okay. You mentioned in your declaration that  
8 you had done some consulting for Respironics; is that  
9 correct?

10 A. I talked consulting for Respironics,  
11 Phillips, yes. You see sometimes you get invited as  
12 an expert to do a -- it was a panel discussion about  
13 the future of respiratory medicine, and in that role I  
14 was invited as an ad hoc consultant for an afternoon  
15 meeting. There were several ad hoc -- that's my role  
16 when I give talks or other presentations.

17 Q. Did you do any product development work for  
18 Respironics or Phillips?

19 A. No.

20 Q. You mentioned in your declaration a  
21 distributor in Germany called Stimotron?

22 A. Yes.

23 Q. And what is Stimotron?

24 A. Stimotron was the distributor or the DME  
25 company that solely distributed Fisher -- Respironics

1 CPAP devices. So they introduced the Respironics  
2 device in '87 related to Germany.

3 Now, Stimotron also developed or had in their  
4 portfolio a bedside diagnostic unit in which I was  
5 heavily developed in helping the engineers to develop  
6 a bedside diagnostic unit for diagnosis purposes.

7 Q. That was a Stimotron device?

8 A. That was the Stimotron device. The name was  
9 Sidas, S-i-d-a-s. Stimotron, and I don't know what  
10 the abbreviation stands for. It was built in -- that  
11 was built in conjunction with Frank Stock. He was  
12 already 75 years old, but he was a genius engineer  
13 from Oxford. And we developed, as I said, a bedside  
14 diagnostic units in 198- -- let me see. Somewhere '88  
15 to '90, and I've written a book on that system. An  
16 entire how to do these bedside diagnostic studies.  
17 How to interpret that.

18 And that book is, as I said, end of the  
19 '80's. I don't recall now the name of it. Maybe  
20 Sidas something.

21 Q. What was your role in connection with that  
22 project?

23 A. My role was the link between the electrical  
24 engineer and translating, and the physiology and the  
25 medicine in how to translate the knowledge of medicine

1 into an electrical bedside diagnostic device. For  
2 instance, this device has had a new oximeter. At that  
3 time, in the late '80's, oximeter was not well  
4 facilitated in hospitals. It was only in the  
5 late '80's that oximeters became mandatory for the  
6 anesthesiology and the ICU department.

7 I still remember the first year when I was in  
8 the practice, that one person died in anesthesiology,  
9 a healthy person that hadn't had an oximeter  
10 monitoring. And that changed overnight that everyone  
11 needed to have an oximeter.

12 Now, at that time for sleep, it was the same  
13 problem. There was several oximeters out there. HP  
14 was the gold standard, and others. And everyone  
15 wanted to develop an oximeter which was cheaper,  
16 better, and we developed one too. So I had to be  
17 heavily involved in the design and the characteristics  
18 and the sampling rate and how to do moving average of  
19 new oximeter so that you can read it as a doctor.  
20 That was part of the involvement.

21 Q. When you say, "diagnostic machine," it was  
22 diagnosing sleep disorders?

23 A. Yes. All kinds of disorders, not just sleep  
24 apnea, but also problems with breathing, if you have  
25 muscular disorders, like muscle dystrophia. If you

1 have dysformation of the skelat.

2 So this was quite already well advanced  
3 bedside testing device. At that time you see we're at  
4 the beginning of computers. So it was quite not  
5 bedside diagnostic device which we have now. It was  
6 also a device that was made to wheel next to the  
7 patient, a PIC unit because of the big computers, not  
8 because of a single device.

9 Q. And then you mention in Paragraph 11, and you  
10 mentioned earlier, that around 2006 you became a  
11 consultant for Fisher & Paykel?

12 A. Yes. Around 2006, maybe 2005, around that  
13 period. The reason why I became consultant is also  
14 explained here, isn't it?

15 (The witness reviewed Exhibit 2004.)

16 THE WITNESS: Yes.

17 BY MR. KANE:

18 Q. Can you describe your involvement with Fisher  
19 & Paykel in your consulting role.

20 A. Yes. My research and from the mid, almost  
21 beginning of 2000, switched from how to use -- instead  
22 of determining the pathophysiology of the upper  
23 airway, rather than to say how can I find better  
24 treatments for actually sleep apnea or snoring, which  
25 is part of the spectrum of the disease. So for that I

1 developed a high-flow device, a nasal cannula, similar  
2 to an oxygen cannula. Instead of using low flows --  
3 and we call this TNI, transnasal insufflation, and I  
4 did a lot of research how to use that concept for  
5 sleep applications.

6 This concept of high flow was already out in  
7 the ICU and for horses, to protect them from pulmonary  
8 edema after horse racing. All these, the technology  
9 around that high flow was not suited for sleep because  
10 it was too noisy, too wet, too much. You could either  
11 breathe with it but not sleep. So I became an expert  
12 of using this device, high flow for applications  
13 during sleep. It was quite very challenging, both the  
14 technical, the hardware development, and the software  
15 development.

16 Nevertheless, we did a lot of publications,  
17 and Fisher Paykel at some point came, asked me would  
18 it be possible to modify one of the existing CPAP  
19 devices to a high-flow device. I said, "I don't know.  
20 That's something that your engineers have to find out"  
21 because, you see, delivering 20 liters through a small  
22 bore cannula is quite a challenge. You need to create  
23 a high driving pressure to create a high flow, not  
24 just 2 or 4 or 5 liters. Even 2 or 5 liters, oxygen  
25 is usually supplied by a compressor, not by a blower,

1 to provide 20 to 30 liters through a small bore  
2 cannula, and that was a challenge. So you need to  
3 have a compressor-based system.

4 Now, they said, "Here, we have a CPAP  
5 machine. Can we just attach a cannula," and maybe it  
6 is a small -- it's a mini high flow because I wanted  
7 to provide the head to high flow device for ICU Fisher  
8 Paykel, but not in the home care, catching the  
9 snoring. So I was invited to England. So they  
10 provided prototypes. It was presented to  
11 pulmonologists.

12 In the end nothing came out of it because the  
13 flow rate was too low to be effective. Doctors didn't  
14 adopt that for sleep apnea. And, nevertheless, I  
15 continued that involvement with ResMed on a high flow  
16 from then on, and still do.

17 Q. With Fisher & Paykel?

18 A. With Fisher & Paykel.

19 Q. Did you develop a high-flow device?

20 A. I developed a high-flow device with the  
21 German company, T&I Medical, yes.

22 Q. And what was your role in that?

23 A. I was the lead inventor, and I was involved  
24 in every design respect from the beginning to the end.

25 Q. What was the invention?

1           A. The invention was to deliver high humidified  
2           air through a small bore nasal cannula that would  
3           contrast to -- we needed to -- you'll know this from  
4           basic physics. Whenever there is fluid, humidified  
5           fluid goes from high pressure to low pressure and then  
6           it drains out. Right?

7           Q. Uh-huh.

8           A. So all competitors, including Fisher & Paykel  
9           at that time, they have had good humidification until  
10          the end of the cannula phase. That's where the  
11          problem starts to rain out, right at the nose and the  
12          nostrils. So we created a cannula that had a heating  
13          tube throughout the entire cannula. That was part of  
14          the invention. The concept of delivering tracks which  
15          is not just water. So there is a U.S. patent filed  
16          for that technology.

17          Q. And you were part of a team on that?

18          A. Yes. The team was -- consisted of the lead  
19          engineer, Howard Kinger, who was one of the previous  
20          head of MAP, the research, design development. It was  
21          Michael Louk and some of his engineers in Germany.  
22          Later the company was named Sillion, and -- yes.

23          Q. Have you been involved in consulting with any  
24          other CPAP manufacturers in your 20-plus years of your  
25          career?

1           A. I took consulting maybe -- Weinmann was a  
2       German CPAP company. I did -- no, I did not consult  
3       with them on the CPAP devices. We several times  
4       discussed just on conferences high flow versus CPAP.  
5       I maybe was in meeting with Prios, but maybe again,  
6       over dinner just discussing generic things.

7           At all these scientific meetings, like the  
8       American Thoracic Society, when we come together, you  
9       get invited by these companies for dinner and to just  
10      hang out with your colleagues around the work. The  
11      CPAP people would provide some of the infrastructure.  
12      And on these meetings you mingle both with your  
13      scientific community and with employees from those who  
14      invite you.

15           MR. KANE: All right. We've been going for a  
16      while, let's take our break. Thank you.

17           (A recess was taken from 10:13 a.m.  
18      to 10:24 a.m.)

19      BY MR. KANE:

20           Q. Dr. Schneider, I'd like to move on to Page 9  
21      of your declaration. Do you see there there's a  
22      section starting with the title "LEGAL STANDARD FOR  
23      OBVIOUSNESS"?

24           A. Page 9, yes.

25           Q. And you mentioned this earlier. Do I

1 understand correctly that these legal standards were  
2 provided to you by your counsel?

3 A. Yes. You can say that, yes.

4 Q. Okay. You don't consider yourself an expert  
5 in patent law, do you?

6 A. No, not in patent law. I've filed several  
7 patents, as you have seen in my CV, but all these  
8 patents have been going through, either through  
9 companies who have been experts in that field, like  
10 MAP, or through Hopkins, verified patents with patent  
11 attorneys who translated then the language and the  
12 meaning into specific wording.

13 You see, I never would write, "said device"  
14 this one, and the way how these patents are  
15 constructed is quite a different language, and that's  
16 why I can say I'm not a patent law expert.

17 Q. Prior to this engagement, had you done an  
18 obviousness analysis under 35 USC Section 103?

19 A. Not as rigorous as I did this here. When I  
20 filed a patent, then the last patent specifically took  
21 me seven years to get the patent through. We did, of  
22 course, comparisons of obviousness but more as a way  
23 of comparing the state of the art. The last patent  
24 was the flow sensor, which I talked to. Again, it  
25 took us seven years to show that this is not obvious.

1           And we succeeded in the end with the help of  
2     drafting the right words with the Hopkins attorneys in  
3     conjunction with an external attorney. So in general,  
4     yes, I was clear what "obvious" means. The specifics,  
5     what it does not mean, not.

6           Q. And that previous exposure was in connection  
7     with trying to obtain patents on your inventions  
8     through the patent office and the patent examiner;  
9     correct?

10          A. Yes.

11          Q. You've not offered any opinions or analysis  
12     previously that some third party's patents are invalid  
13     as obvious, have you?

14          A. No, I never did that.

15          Q. Have you ever analyzed a third party's  
16     patents for infringement issues?

17          A. No.

18          Q. Prior to this engagement, had you attempted  
19     to analyze a third party's patents in terms of scope  
20     of the claims in those patents?

21          A. I didn't catch your question exactly. The  
22     claims of this count?

23          Q. No. Prior to this work in these IPRs, had  
24     you done any analysis to determine the scope of patent  
25     claims in patents issued to third parties?

1           A. Issued to third parties. Yes. Of course, I  
2       studied the claims that was in the field of my  
3       invention. For instance, in that flow sensor, and a  
4       fair amount of these patents were filed by companies,  
5       Siemens, Toaka, they all developed expiratory flow  
6       sensors. So if that accounts for a third party, then  
7       I've done that, yes.

8           Q. So can you explain to me how you understand  
9       claims in issued patents are to be interpreted?

10           MR. BELLINGER: Object to form.

11           THE WITNESS: I didn't hear you.

12           MR. BELLINGER: I said object to form.

13       BY MR. KANE:

14           Q. You can answer.

15           A. Oh. Okay. The way how I looked in general  
16       with that claim was written in the patent has some  
17       similarity that what I want to claim or to my  
18       invention. And then when I looked at these claims, I  
19       notice mine is totally different or it falls under  
20       these claims. So that means that I cannot claim or  
21       find a way how it is different from the previous  
22       patents.

23           That was a very common procedure both in my  
24       scientific work. I have to do the same, demonstrate a  
25       novelty. And I look at it with the same eyes as a

1 scientist on the novelty of claims.

2 Q. You understand the rules that patent lawyers  
3 use to determine the scope of the claims?

4 MR. BELLINGER: Object to form.

5 THE WITNESS: I don't know exactly the rules  
6 of attorneys to do that, as I would not expect an  
7 attorney to understand my research in writing a paper.

8 BY MR. KANE:

9 Q. If we look at paragraph -- Page 24 of your  
10 declaration. There's a section there called "CLAIM  
11 CONSTRUCTION." Do you see that?

12 A. Yes. Yes.

13 Q. And you start there -- well, is this the  
14 understanding that you had in construing the claims of  
15 the patents in rendering your opinions?

16 A. Yes. This was -- in fact, this declaration  
17 was quite much more complicated and difficult than the  
18 other one because there was so many patents that was  
19 referred to in the past, and they were almost all  
20 somewhat similar. And because of that, I could not  
21 just simply use obviousness. I need to see what's the  
22 entire scope of the invention based on looking to  
23 see -- if you look here, there was several, as  
24 mentioned in the beginning, several patterns that  
25 needed to be considered.

1           And there was only tiny words sometimes  
2   between -- differences between one and the other  
3   patent. And because of that, it was more like the  
4   basic concepts. I asked, of course, my attorneys how  
5   to deal with this. It's a difference as to simply  
6   looking at one claim and say, "Oh, this is totally  
7   different. This claim is different, or this is not  
8   obvious." It was not as straightforward because of  
9   all the multi-layers. That's what I thought.

10          Q. Okay. So if you go back to Page 24 --

11          A. Yes.

12          Q. -- the second sentence there in Paragraph 47,  
13   you say, "I understand that the proper standard for  
14   claim construction is an IPR proceeding is the  
15   broadest reasonable interpretation in light of the  
16   specification to one having ordinary skill in the art  
17   at the time of the claimed inventions." Do you see  
18   that?

19          A. Yes.

20          Q. How do you apply that in rendering your  
21   opinions here?

22          A. You see. I interpret this as almost like as  
23   a basic principle that applies to a claim as to a  
24   research paper. We're not arguing whether it's a  
25   millimeter bigger or smaller or has a specific design.

1 It's a basic -- the broadest reasonable -- it's more  
2 like a concept rather than a clear design, and I have  
3 to find out if it is this way or this way. It still  
4 would apply.

5 Q. Okay. All right. Jumping back just a little  
6 bit to Page 13. Do you see there's a section called  
7 "PERSON OF ORDINARY SKILL IN THE ART"?

8 A. Yes, I see that.

9 Q. And how did you arrive at your opinion as to  
10 what a person of ordinary skill in this art was at the  
11 time of the filing of the patents in dispute?

12 A. At the time of the dispute, or the time of  
13 the patent, it was somewhere around 2000. And, again,  
14 I was given -- since then I've been involved heavily  
15 in discussing development of CPAP devices, as I  
16 mentioned before.

17 In fact, if you look at my CV, I was even two  
18 years out of clinical practice and was into working in  
19 the physiology department, primarily dealing with flow  
20 and pressure. So the training I got through that is  
21 intense. The formal training is only my medical  
22 doctor and thesis. The training I received there is  
23 just -- not "just." I think it's most valuable. It's  
24 the hands-on experience how to design this for  
25 patients, not an engineer for engineers. This is --

1 very often you'll see designs from young engineers to  
2 young people and even not consider that a patient that  
3 might shake still has to use something.

4 So in the end, even at that time I considered  
5 myself an expert, and that is highlighted by the fact  
6 that I was asked to consult or be a cofounder of  
7 companies, like T&I Medical or consulting for MIT.

8 Q. If we look at Paragraph 30 of your  
9 declaration --

10 A. Yes.

11 Q. -- you state there that a person of ordinary  
12 skill first would have a -- potentially have a  
13 bachelor's degree in mechanical engineering; right?

14 A. Yes.

15 Q. And you don't have a bachelor's degree in  
16 mechanical engineering?

17 A. No, I do not.

18 Q. Next is biomedical engineering, and my  
19 understanding you did not have a bachelor's degree in  
20 biomedical engineering either, do you?

21 A. I do not have that.

22 Q. Okay. And then you say, "or a related  
23 discipline." By that, do you mean -- well, what do  
24 you mean by that?

25 A. The related discipline is exactly. I am an

1 expert in exploratory physiology. That's well  
2 documented. And also in the related discipline is my  
3 medical expertise and a combination of both with the  
4 on-site experience of having worked with hundreds of  
5 hours with engineers. These are the -- these are my  
6 belief that I'm even more qualified than any bachelor  
7 in this area even in 2000, who had just came out of a  
8 school with a bachelor degree.

9 Q. I understand your thoughts on your  
10 qualifications, but just more generally, would you  
11 consider sleep medicine doctors, physicians in general  
12 to be persons of skill in this art?

13 A. No, not at all. The training -- the training  
14 of sleep medicine doctors is very frustrating.  
15 It's -- actually, the way how sleep medicine training  
16 has been developed is the same as it does in general  
17 medicine. It's just learning like robots and not the  
18 basic principles and laws of physics behind that. I'm  
19 teaching all over the years telling these doctors, "If  
20 you know the basic laws of fluid dynamics, of stalling  
21 resistors versus other resistors, they would learn the  
22 basics of this. Then they would not need to learn  
23 like robots.

24 I always said to my medical students it's  
25 easier to talk to an engineer than to a doctor.

1 Q. What is your understanding of who a person of  
2 skill in the art is in the view of the law?

3 MR. BELLINGER: Object to form.

4 THE WITNESS: I didn't get that.

5 MR. BELLINGER: Objection. Form.

6 THE WITNESS: Okay. Your question was under  
7 the law or under -- how I understand a person of  
8 ordinary skill.

9 BY MR. KANE:

10 Q. My question was what is your understanding of  
11 the -- how a person of ordinary skill in the art is  
12 defined under the law?

13 MR. BELLINGER: Objection. Form.

14 THE WITNESS: I believe that the law allows a  
15 specific -- or would define this in a specific way,  
16 for instance, such as a degree, like with that as an  
17 engineer or biomedical engineer, but it would also  
18 give room to an expert who has the acquired skills.  
19 I've not looked up -- as I said, I'm not a patent  
20 attorney or familiar with the law, but for me, it  
21 would be inconceivable that acquired knowledge through  
22 applications, maybe 10, 20 years or more, would not  
23 qualify. To be specific, I have to ask an attorney,  
24 but I see this inconceivable that this is not  
25 considered.

1 BY MR. KANE:

2 Q. Did you get an understanding of that concept  
3 of the law from the attorneys in connection with your  
4 work in this case?

5 A. No. The point was prior to my engagement and  
6 not only prior to my engagement that I received  
7 several calls. I don't even know whether this was  
8 headhunters or whether they were associated with this  
9 case. But when they interviewed me, whether I can say  
10 something about this technical development, whether I  
11 am an expert, I answer this usually with yes, I  
12 consider myself as an expert or a person of ordinary  
13 skills in the art, and that's why I put this as a  
14 skill in LinkedIn.

15 I don't know that, but I consider myself  
16 because other people consider this for me.

17 Q. Understood. I was asking again more  
18 generally, Dr. Schneider --

19 A. Yes.

20 Q. -- whether you had an understanding of the  
21 concept of a person of ordinary skill in the law prior  
22 to this engagement, or did that understanding result  
23 from discussions with the attorneys in this  
24 engagement?

25 A. No. You see, the point is when I said I

1 considered myself, I answer these questions. And when  
2 I received the call from the attorney, whether I can  
3 represent in the case, that I assumed that they would  
4 have tested it already, that it falls into the legal  
5 realm. Otherwise they would have said, "No, we cannot  
6 utilize Dr. Schneider's knowledge." But that was a  
7 simple assumption, not a way of higher -- how should I  
8 say. What's the right word? Predicament.  
9 Discussion, how can we do that.

10 It's just answering the phone calls and  
11 getting the question. I don't think that the attorney  
12 is stupid enough to ask me to do that if it doesn't  
13 fall into the legal laws.

14 Q. Again, I'm not talking about you personally.

15 A. Yes. Yes.

16 Q. I'm talking, for instance, in Paragraph 30  
17 you mentioned that your opinion is that a person with  
18 a bachelor's degree in mechanical engineering or  
19 biomedical engineering, for instance, it would be a  
20 person of skill --

21 A. Yes.

22 Q. -- and what I'm trying to understand is how  
23 you arrived at that conclusion.

24 A. Yeah. Engineers in a company -- you see,  
25 I've worked with engineers at MAP. They were

1 responsible in writing down all these things very  
2 detailed. So that's why I easily -- to assume, that's  
3 my experience of my own patents as co-inventor. As a  
4 primary inventor it was more difficult. There was  
5 almost no engineer involved. That's not true. There  
6 was also an engineer involved. That's why I  
7 automatically consider that as person of ordinary  
8 skill, as I would do, one who has an M.D. being a  
9 doctor or a treating patients.

10 MR. KANE: Okay. I'm going to hand you the  
11 '624 patent, which has previously been marked as  
12 Exhibit 10- -- RMD 1001.

13 A. Yes.

14 (Previously marked Exhibit 1001 was handed  
15 to the witness.)

16 BY MR. KANE:

17 Q. I'll then ask you to turn to Page 15 of your  
18 declaration. And you see there, there's a heading  
19 starting "OVERVIEW OF THE CHALLENGED PATENTS AND OTHER  
20 BACKGROUND"?

21 A. Yes, I see that.

22 Q. Then on top of Page 16 there's a figure,  
23 which is Figure 1 out of the '624 patent. Do you see  
24 that?

25 A. I see that, yes.

1           Q. And in Paragraph 35 you describe that "the  
2     respiratory apparatus has a main housing 3 adapted to  
3     receive the chamber 2 in a single slide-on motion." Do  
4     you see that?

5           A. I see that sentence, yes.

6           Q. So what do you determine "single slide-on  
7     motion" to mean?

8           A. I interpret this as the connection that you  
9     connect one unit with the other unit, in just one  
10    single action, and that everything is stands connected  
11    rather than having one unit and using the other hand  
12    to connect this one and this one, and all these things  
13    that is not single. It's two or three motions.

14          Q. Okay. So in connection with Figure 1, what  
15    are the connections that you're talking about that  
16    occur in that single slide-on motion?

17          A. The connection is to put the chamber in  
18    place, that it is functioning within the housing,  
19    meaning that it's a humidification chamber. So that  
20    means that once you have ended your single motion that  
21    it can humidify the air.

22          Q. Okay. And the next sentence talks about "The  
23    single slide-on motion makes connection to the gases  
24    inlet/outlet ports." Do you see that?

25          A. I see that.

1           Q. Is that one part of allowing the humidifier  
2 chamber to act as a humidifier with the flow  
3 generating unit that you mentioned previously?

4           A. You are right. The purpose of the things  
5 like motion is that the humidification chamber  
6 functions properly. In order to function properly,  
7 you need to be able to connect the humidifier with the  
8 inlet and outlets of the machine.

9           Q. Okay. And then in the next sentence you say,  
10 "In one alternative embodiment, the single slide-on  
11 motion may also urge a base of the chamber into  
12 contact with a heater plate on housing 3." Do you see  
13 that?

14          A. I see that, yes.

15          Q. So you start that sentence with the words "In  
16 one alternative embodiment"; correct?

17          A. Correct.

18          Q. So there are multiple embodiments in the  
19 patent in your view?

20          A. In this patent there is multiple embodiments,  
21 yes, in some of the subclaims. That's why I'm  
22 referring this to one. The point here is that's why  
23 this one is an alternative of embodiment.

24          Q. Okay. Are there -- then the sentence  
25 continues and you highlighted the word "urge." Do you

1 see that?

2 A. Yes.

3 Q. Is this one alternative embodiment, in your  
4 view -- well, why did you highlight the word "urge" in  
5 that sentence?

6 A. Yeah. That's a very good question. When I  
7 write a paper -- as I said, sometimes people don't  
8 realize that the shorter you are writing, the more  
9 work. You'll see I already said that I didn't have  
10 time to write you a one-page letter. That's why it's  
11 three, because I didn't have time.

12 The point is when you write a paper on this  
13 one is where you carefully select your words. I  
14 assume that the inventor here did that too. I was  
15 intrigued by the word "urge," meaning it's not just  
16 placing one to the other. It's putting some force  
17 between one and the other.

18 And that's why I highlighted the word "urge."  
19 So I assume that they were as careful as anyone in the  
20 field to submit something important, that they  
21 carefully select their words. And initially I was  
22 puzzled why did they say "urge." Then I was thinking  
23 about the meaning of that, and they didn't say  
24 anything about the mechanism of "urge," but the  
25 meaning was clear.

1 Q. Okay. Are there embodiments where the single  
2 motion does not urge the base of the chamber into  
3 contact with the heater plate?

4 A. Yes. Several -- I don't know whether in this  
5 embodiment there is one without urging, but the  
6 competitors -- well, otherwise just if it's simple  
7 attachments without urging these two together; right?  
8 That's how I understood that, that it creates  
9 something that is just more than just attaching  
10 things.

11 Q. What's the difference between "urge" and  
12 "attach"?

13 A. You can attach it like this. This is an  
14 attachment; right? (Indicating)

15 Q. Like what? You have to say it out loud.

16 A. I'm sorry. I gently lightly touch one hand  
17 with the other hand. My hands are attached without  
18 using any extra force in my arms.

19 Now, if I do this one, then it's still  
20 attached. Nothing has changed with the attachment  
21 here in terms of from the outside, but I used a lot of  
22 muscle force, and just seeing how my fingers bent  
23 under the force, before that did not. So that's how I  
24 understand difference between "attachment" and  
25 "urging." (Indicating)

1 Q. And so your analysis and interpretation was  
2 based on your experience that the authors of an  
3 important paper like a patent choose their words  
4 carefully?

5 A. I assume that.

6 MR. BELLINGER: Objection. Form.

7 BY MR. KANE:

8 Q. Okay. So let's -- you point to a portion of  
9 the patent for that sentence. Do you see that?  
10 There's a 4:19 to 24 at the end of the sentence?

11 A. 4:19 to 24.

12 Q. Correct.

13 A. Yes.

14 Q. And that means Column 4, Lines 19 through 24  
15 of the patent?

16 A. Yes.

17 Q. Okay. So can you look at that for me, that  
18 section of the patent.

19 A. Okay. I see that.

20 Q. Why don't you read Column 4, 19 to 24 to  
21 yourself.

22 A. "The securing" --

23 Q. You can read it to yourself. You don't have  
24 to say it out loud.

25 A. Okay.

1 (The witness reviewed Exhibit 1001.)

2 THE WITNESS: Yes.

3 BY MR. KANE:

4 Q. Okay. You agree with me that the word "urge"  
5 does not appear in that section of the patent?

6 A. That's correct.

7 Q. Why did you site that portion of the patent  
8 in connection with the sentence where you were  
9 highlighting the word "urge"?

10 A. I don't remember that anymore, why I did this  
11 citation. They might have done a mistake here on the  
12 citation. Yeah, that's not related to the sentence  
13 before. It might be a mistake on my side.

14 Q. Okay. If you turn to Paragraph 36 for me.

15 A. Which paragraph? I'm sorry.

16 Q. Paragraph 36 of your declaration. I'm sorry.

17 A. 36, yeah.

18 Q. Why don't you read that to yourself.

19 (The witness reviewed the Exhibit 2004.)

20 THE WITNESS: Okay.

21 BY MR. KANE:

22 Q. I guess my question for you, Dr. Schneider,  
23 is if I'm understanding correctly in the example you  
24 gave us a few minutes ago, you used the example of  
25 putting your hands together sort of generally without

1 much force and then versus putting your hands together  
2 and pressing to establish a firm contact. Do I  
3 understand that right?

4 A. Uh-huh. Yes, you do.

5 Q. So that example -- well, does that example  
6 apply to this "establish a firm contact between the  
7 water chamber and the heater" that you're referring to  
8 in Paragraph 36?

9 A. Yes, it does.

10 Q. How does one go about determining whether or  
11 not there's firm contact between the water chamber and  
12 the heater versus something other than firm contact  
13 between the water chamber and the heater?

14 A. There's several ways I can consider that  
15 depending on the mechanism that creates the urge, the  
16 force. Now, in this patent there's nowhere that means  
17 how they do the urging. So the answer to your  
18 question might be different between the mechanisms  
19 that creates the urge or not.

20 Q. I'll just follow up on that. What types of  
21 mechanisms would you envision could create the urging  
22 and establish the firm contact between the water  
23 chamber and the heater?

24 MR. BELLINGER: Objection.

25 THE WITNESS: There is several mechanisms

1 possibly. Either you modify something on your heater  
2 plate or you modify something on your housing that  
3 creates force that might be beyond gravity, for  
4 instance. So there's several ways to do that,  
5 modifying the housing or modifying the base of the  
6 housing, of the chamber, or the heater plate. Yeah.  
7 These are the basic principles modifying.

8 BY MR. KANE:

9 Q. And do you have examples of modifications  
10 that you can envision?

11 A. I know that other devices put pressure from  
12 the top, beyond the filling of water. That is one way  
13 to do urging, to add pressure.

14 Q. So there's some sort of a lid or latch that  
15 pushes down on top of the water chamber?

16 A. Yes.

17 Q. Any others that you could envision?

18 A. I can envision there a gel, that when you put  
19 something on top of it, it creates something that  
20 forces the heater plate to go up. There's other ways  
21 to force the heater plate up. It could be several  
22 springs, for instance. There could be one spring.  
23 There could be -- the spring could be different forms.  
24 I have no idea how the engineers based on in that age,  
25 2000, have envisioned how to urge the content because

1 it's not displayed here. Spring-like system could be  
2 possible. Is it a spring like that that you move  
3 down, and it circles -- I don't know. There's several  
4 ways to do it.

5 Q. Okay. When you -- just to clarify, I think I  
6 understand what you were saying. You are saying a  
7 gel. I think you were referring to some sort of a  
8 polymer or material --

9 A. Yes.

10 Q. -- that has a spring-like reaction to it that  
11 you could press it and it has -- it would exert an  
12 upward force underneath the heater plate?

13 A. It is the nature of why -- because it sits in  
14 an encasement. If you push on one side you will  
15 create force. That's one way to do it. I don't think  
16 that you would do it if there's heat in it, but you  
17 never know what the -- you never know; right?

18 Q. I'm not sure we got that correctly. Sorry.

19 So when you say a "gel," you're talking about  
20 some sort of a material that has some sort of a  
21 spring-like characteristic to it?

22 A. If I see a spring-like or -- in the exact  
23 words in physics is the -- what is it? It's got a --  
24 nature of forces that retract and detract; right?  
25 That's a gel that would be a lot like spring-like, but

1 you could say could be spring-like, yes.

2 Q. Okay. All right. And how would you  
3 determine -- so let's assume there were -- either of  
4 those were occurring. There was a lid that pushed  
5 down or a spring that pushed up. Are those a couple  
6 of the modifications that we've just discussed?

7 A. That's -- yes. That's another way to do it  
8 but --

9 Q. What's another way?

10 A. You just can modify the heater plate to put  
11 pressure on top of the plate.

12 Q. And how would you modify the heater plate?

13 A. I'm not quite sure I disclose all my possible  
14 inventions here. If I would be asked to now solve the  
15 problem of urging, I don't know whether this is the  
16 scope of this work here because I can envision, as I  
17 said, several mechanisms to do this. But that's  
18 almost already disclosed in the invention here.

19 Q. Okay. How would you know whether or not you  
20 had established a firm contact such that you would be  
21 urging the water chamber into the heater plate?

22 A. I think I might have put this in some of the  
23 declaration here. I will answer your question. Can I  
24 just look at this? I can read this to you.

25 Q. Well, I guess you can. Feel free. But I

1 guess what I'm trying to understand, just to make sure  
2 my question is clear, Dr. Schneider, is is there some  
3 sort of -- you measure the force between the heater  
4 plate and the bottom of the humidifier, or is there  
5 some other type of measurement? I'm trying to  
6 understand if there's some sort of quantification that  
7 you would use to determine whether or not firm contact  
8 had been established.

9 A. Yes, there is. Can I just look through this  
10 because I spent some thought process behind your  
11 question.

12 Q. Certainly.

13 A. And I think I've dealt with that question.  
14 And I believe I put that in -- let me see.

15 (The witness reviewed Exhibit 2004.)

16 THE WITNESS: I remember the urging. Let me  
17 look at it.

18 (The witness further reviewed Exhibit 2004.)

19 THE WITNESS: 57 I'm starting already. Let  
20 me see here.

21 (The witness further reviewed Exhibit 2004.)

22 THE WITNESS: I'm pretty sure I put in one  
23 question with that.

24 (The witness further reviewed Exhibit 2004.)

25 THE WITNESS: So one way, for instance -- I

1 know that I've written it somewhere. I know that I've  
2 written it somewhere.

3 (The witness further reviewed Exhibit 2004.)

4 THE WITNESS: One way you can easily see and  
5 experience in clinical practice is following, when you  
6 slide two metals against each other on a daily basis,  
7 that's wear-and-tear, each day you slide metal over  
8 metal. And, in fact, the problem then is if these  
9 contacts are not pressed or urged against each other,  
10 they'll lose the contact over time. And that raise a  
11 problem because then patients tell you, "I don't get  
12 any more humidified air." That's one way you can  
13 decide that it is on a daily use over months, weeks  
14 and weeks that the characteristics of the humidifying  
15 unit changes through tear-and-wear of these two  
16 plates.

17 BY MR. KANE:

18 Q. If you had a brand new device in front of you  
19 and you were asked to decide whether or not the  
20 humidifier chamber was urged onto the heater plate,  
21 how would you determine that?

22 MR. BELLINGER: Objection. Form.

23 THE WITNESS: I would do the same approach --  
24 let's say as a doctor I don't have my measurement  
25 tools, and as a doctor, I would look over the course

1 of the night whether there's some changes in the  
2 characteristics of the humidification, meaning when  
3 it's half empty or empty or full of water, whether the  
4 characteristics of the humidification changes or not.

5 I would assume, if it was urged together it  
6 will not over time, over the course of a night.

7 BY MR. KANE:

8 Q. The characteristics would not change over the  
9 course of the night?

10 A. Yes.

11 Q. And you would assume if it was not urged  
12 together the characteristics would change over the  
13 course of the night?

14 A. I would assume that, yes. And, of course, I  
15 can go to my electrical engineer and say, "Prove this  
16 or not."

17 Q. Would that be a problem, if the  
18 characteristic changed over the course of the night?

19 A. Yes. If you have lost the contact, only  
20 parts of the contact between the blade and the base,  
21 that is a substantial problem, either overheating of  
22 the machine, of the blade, damage the machine in the  
23 middle of the night, or not providing the correct  
24 humidification to a patient. And I still think that  
25 I've written this here exactly like that.

1 Q. I do believe you wrote something like that.  
2 It's Paragraph 37, Dr. Schneider.

3 A. Yeah. You're right. Yeah. That's exactly  
4 the paragraph I was looking at.

5 Q. Okay.

6 A. Yes. I think the answer is I spent some time  
7 finding the right words and justification for that  
8 that's in here.

9 Q. But, you know, as we started back on  
10 Paragraph 35, we talked about the fact that there are  
11 embodiments in the patent interpretation that do not  
12 require urging; correct?

13 A. It doesn't say that the alternative  
14 embodiment was meant for the sliding mechanism, not  
15 for the urging of the pressure. The way how you put  
16 that sliding mechanism and in order to get -- there  
17 were several embodiments. So whether you do it in  
18 angle from top, so again, it depends on the others  
19 left to say there's several mechanisms of urging and  
20 several embodiments, how you can put these together so  
21 that it urges the two things together.

22 Q. So is it your understanding that all of the  
23 embodiments shown in the patent urge the heater plate  
24 and the bottom of the humidifier together?

25 A. Yes, that was my understanding because it was

1 a prior claim, and the other embodiments was later, I  
2 think, in Claims 7, 8 or so, yes.

3 Q. Okay. If you turn to Paragraph 60 for me,  
4 please, Dr. Schneider.

5 A. Yes.

6 Q. When I read that last sentence there it says,  
7 "Thus, a skilled artisan would understand that 'urges'  
8 or 'urging' means more than simply disposing or  
9 positioning the base of the water chamber adjacent  
10 and/or in contact with the chamber heater." Do you  
11 see that?

12 A. Yes, that's correct.

13 Q. So what is the difference -- well, what does  
14 urging require in addition to disposing or positioning  
15 the base of the water chamber adjacent and/or in  
16 contact with the heater -- chamber heater?

17 A. I explained this earlier already by using the  
18 example with my hands. You can just pose one hand to  
19 the other instead of -- an hour ago I said attach one  
20 hand to the other. Now I say I dispose one hand  
21 against the other.

22 REPORTER MARTIN: Dispose?

23 THE WITNESS: Yes, dispose. Expose, dispose.  
24 One hand held against the other, and that's still  
25 expose and dispose. Of course, this can be done with

1 and without urging, and that's the difference. So  
2 anything is disposed or exposed. The question is  
3 what's the nature of that. You can do it with force  
4 and without force.

5 BY MR. KANE:

6 Q. Could the attachment between the humidifier  
7 and the housing be at a horizontal angle and still  
8 urge the heater plate onto the bottom of the  
9 humidifier?

10 MR. BELLINGER: Objection. Form.

11 THE WITNESS: Yes. It depends on the  
12 mechanism of -- or the method of how they urge these  
13 things together. It can be done in an angle. It can  
14 be done in a horizontal plane or any deviation from  
15 the horizontal plane, depending on how -- what they  
16 have envisioned as a method to urge these together.

17 BY MR. KANE:

18 Q. Dr. Schneider, we looked at the sentence in  
19 Paragraph 35 earlier, and I directed you to Column 4,  
20 Lines 19 through 24. Do you recall that?

21 A. Yes.

22 Q. We looked at that and saw that the word  
23 "urge" did not appear in that section of the patent.  
24 Are you aware of any section in the patent where it  
25 describes that the single slide-on motion urges the

1 base of the water chamber into contact with the heater  
2 plate?

3 A. They're both in Claim No. 2 and 3.

4 And Claim 6 of the '542. Let me go back to  
5 the claims here.

6 Claim 3 here.

7 Q. Okay.

8 A. It would have been correct to put it on the  
9 citation in here in Claim 3. Yeah, it is in Line 17  
10 of -- it's Paragraph 10 --

11 Q. Okay.

12 REPORTER MARTIN: Of what?

13 THE WITNESS: Column 10, Lines 17 through --  
14 yes, 18, 19, it says, "and said single motion of  
15 engagement urges the base of said water chamber  
16 adjacent and in contact with said chamber heater."  
17 That is Line 17 and 18.

18 BY MR. KANE:

19 Q. Okay. If you look at Claim 2, Dr. Schneider.

20 A. Yes.

21 Q. Do you see there starting at about Line 7, I  
22 guess.

23 A. Yes.

24 Q. It says, "a chamber heater connected to said  
25 housing, and "said housing" includes a humidifier

1 engagement locating a said humidifier adjacent said  
2 chamber heater, said chamber heater adapted to  
3 vaporize liquid in said water chamber in order to  
4 provide water vapor to said gases flow passing through  
5 said water chamber." Do you see that?

6 A. I see that, yes.

7 Q. Now, that clause in Claim 2 uses the word  
8 "adjacent." It does not use the word "urge"; correct?

9 A. That is correct, yes.

10 Q. So is there a difference between Claim 2 and  
11 Claim 3?

12 A. Yes. One is just -- as I understand this one  
13 is just the fact that you say you have -- that you  
14 make a chamber that is not far away from the CPAP  
15 machine, that is close or adjacent to this CPAP unit,  
16 but it's not detached. It's adjacent. It could be  
17 detached maybe as well, but it is adjacent. That's  
18 clear, close, nearby rather than any characteristics  
19 of the -- how the heater and the heater plate are  
20 connected, and the figure speaks for it, the  
21 reference, the figure here. But it is obvious when we  
22 look at Figure 1 and 2.

23 Q. What's obvious when we look at Figures 1 and  
24 2?

25 A. That the housing of the humidifier is

1 adjacent to this entire embodiment of the CPAP  
2 machine. Figure 2 shows how it is in place. Now you  
3 could say Figure 2 of the patent shows how it is  
4 adjacent, closeby the entire housing of the CPAP  
5 machine, and Figure 1, how to put it there.

6 Q. So when you interpret Claim 2 and you see the  
7 word "adjacent" there, you're not talking about the  
8 interaction between the humidifier chamber and the  
9 heater plate?

10 A. It just says -- here it says it is "adjacent  
11 said chamber heater." So the humidifier engagement  
12 locating a said humidifier adjacent said chamber  
13 heater. Said chamber heater adapted to vapor. So it  
14 says "humidifier adjacent chamber heater." Yes. So  
15 it is in close proximity, as it says. I don't know --  
16 in this sentence it doesn't say anything about the --  
17 how adjacent it is, how close.

18 I'm waiting for more specification than was  
19 provided in Claim 3. So it is a very step-wise  
20 approach of saying what is the entire apparatus,  
21 Claim 1 and what's some of the characteristics in  
22 Claim 2, and it gets more and more specified.

23 In scientific words, I would say, "The  
24 general purpose is this. Specific aim is this. More  
25 specific is this."

1           Q. Claim 2 talks about -- it goes on to say that  
2       "said chamber heater is adapted to vaporize liquid  
3       water in said water chamber in order to provide water  
4       vapour to said gases flow passing through said water  
5       chamber." Do you see that?

6           A. I see that.

7           Q. So is it your understanding that in Claim 2  
8       as well, the heater plate and the bottom of the water  
9       chamber are in -- have been urged together in order to  
10      allow the vaporization of the water?

11          A. I cannot say anything about the nature of  
12      that connection based on Claim 2. I can only say  
13      there is some mechanism that vaporizes the liquid  
14      water. So the way how they have created that -- you  
15      see, there could be a simple way of -- there could be  
16      several ways how to heat and vaporize the water. It  
17      doesn't specify this in this paragraph.

18          Q. What ways would you envision that you could  
19      heat and vaporize the water?

20          A. If you want to find a new way to circumvent  
21      specific patents, you could have done a circular ring  
22      on the base of the house, on the side wall rather than  
23      below, and heat it right at the bottom from the side  
24      wall. It's still adjacent to -- it will meet the  
25      criteria here taken to a heater, but it's rather a

1 circular ring at the base rather than a place where it  
2 sits on top. I can see that that is one embodiment if  
3 someone wants to circumvent the, say, heater plate  
4 with top and below. That you put something, the  
5 housing on top of the plate.

6 Q. In Claim 2, what are you interpreting  
7 "chamber heater" to be?

8 A. You see, it's also possible -- and I've seen  
9 these designs too -- that you have like in a water  
10 heater in a kitchen, you have a spiral inside the  
11 water. So now let's say if you have a chamber and you  
12 have some mechanism that allows you to connect the  
13 heater inside and like the boiling water; right? As I  
14 said, there is -- I don't know what -- let's say when  
15 I stop at paragraph -- or Claim 2, I will be still  
16 left very uncertain how are they heating.

17 Of course it has to be right, in close  
18 proximity, but there's so many ways. It could be  
19 inductive, like they have in stoves now and whatever;  
20 right? Maybe in the future it is no longer with  
21 heating plates because they consume too much energy.  
22 Maybe it is a totally different mechanism in the  
23 future.

24 In 2002 you still could envision that there's  
25 other ways to heat, just by heating it conventionally.

1 Like microwave technology, inductive, like it heats  
2 stuff. The ideas and technology was there. So that's  
3 why I said when I stop here at 3, I would be curious  
4 to where did that go to.

5 MR. KANE: Okay. We've been going a little  
6 over an hour now. Let's take a break.

7 (A recess was taken from 11:39 a.m.  
8 to 11:56 a.m.)

9 BY MR. KANE:

10 Q. Welcome back, Dr. Schneider. I just want to  
11 follow up where we were and make sure I understand  
12 what you're saying. I think I do.

13 Claim 2 of the '624 patent that we're looking  
14 at uses the word "adjacent"; correct?

15 A. Correct.

16 Q. And if I understand correctly, you're saying  
17 that means proximity?

18 A. Yes.

19 Q. And then Claim 3 you use the word "urges,"  
20 and that's the -- this idea of pushing the base of the  
21 water chamber in contact with the chamber heater;  
22 correct?

23 A. Correct.

24 Q. With force?

25 A. With force.

1 Q. Yes. Okay. And you can envision -- and  
2 we've talked about some of those. You can envision  
3 multiple ways that that urging could be accomplished?

4 A. I can envision that, yes.

5 Q. Okay. And the patent doesn't describe any  
6 specific way of causing that. Is that true?

7 A. I have not seen that, yes.

8 Q. Let's look back to your -- we'll walk through  
9 your declaration then. We'll shift gears.

10 I was going to focus or start with the Netzer  
11 prior art.

12 A. Yes.

13 Q. You can look at starting on Paragraph 69.

14 A. Yes.

15 Q. And then if you look at -- well, it's your  
16 opinion that there's nothing in Netzer that describes  
17 the urging?

18 A. That's my opinion, yes.

19 Q. Nothing that describes the urging of the base  
20 of the water chamber into a heater plate; correct?

21 A. Correct. I would even go further that this  
22 design is very faulty over time.

23 Q. Why do you say that?

24 A. Because it has grooves on the side.

25 Q. It has what?

1           A.   Grooves on the side.

2           Q.   Grooves, yes.

3           A.   But that keeps the chamber at one place, and  
4   it cannot move upward, downward with gravity because  
5   it's fixed in the grooves. As I said before, if you  
6   slide metal over metal time over time, day by day, you  
7   will have wear-and-tear and then you will have no room  
8   to -- if there's a little bit of a disconnection, that  
9   will be faulty. As an engineer, I would not design it  
10   that way because eventually, after a matter of time,  
11   that this will be dysfunctional.

12          Q.   Okay. What if there was a spring underneath  
13   that heater plate. Would that resolve the problem?

14          A.   If -- there's no mention from him to even  
15   consider anything that pushes one against the other.  
16   It was not the purpose of his patent. So the patent  
17   is primarily meant for -- you see at that time in the  
18   late '90's we were not even clear -- or let's say it  
19   in other words.

20                The patients were put on CPAP without  
21   humidifiers. That was the first way to put a patient  
22   on treatment. Now, as more patients got CPAP, I was  
23   aware that some patients complained about dryness of  
24   the mouth. In that case, you need to justify the  
25   necessity first to prescribe the humidifier because

1 the humidifier, external commercially available  
2 humidifier were expensive.

3 And they were all detached from the CPAP  
4 devices, and Netzer's patent primarily deals with the  
5 fact "Hey, we can actually use a mechanism that turns  
6 on and off the bypass of air in an automated way," and  
7 it did not spend any thoughts about quality,  
8 characteristics of a humidifier. It's more like a  
9 release system turning on and off the air passage  
10 through a humidifier. And that's why I think he did  
11 not spend time on it, and that's why I think this is a  
12 very faulty design.

13 Q. Do you know Dr. Netzer, who like you comes  
14 from Germany?

15 A. Yes, I know him very well.

16 Q. You do?

17 A. And he's a very smart guy, but when I saw  
18 this one, initially I thought there must be a second  
19 or third patent following that elaborates a little bit  
20 better on his design. In the end, of course, this was  
21 never gone into production.

22 Q. Are you familiar with a device in Germany  
23 that's sold by the name Bivent?

24 A. Bivent, no, I'm not.

25 Q. Do you know a company called Primedic?

1 A. Primedic?

2 Q. P-r-i-m-e-d-i-c.

3 A. No. But I lost contact in '96 when I did my  
4 fellowship. So I lost contact with him. It might be  
5 that afterwards he has done something commercially.  
6 But it has never been coming to my attention either in  
7 my lab in Germany now, which started 2009 or before  
8 because I've been here most of the time.

9 Q. When did you start spending most of your time  
10 in the U.S.?

11 A. That was 2001. I got a faculty position  
12 2001. 2006 to 2009 I did my fellowship here, but  
13 during that time I was frequently traveling, at least  
14 once a week, which I still do, to Germany. One week a  
15 month. And, actually, I continue to do that. That  
16 was the last week in Germany, that's why I need my  
17 coffee break in the afternoon, for private and for  
18 business reasons.

19 Q. In Paragraph 72 you talk about a Levine  
20 reference.

21 A. Yes.

22 Q. It's your opinion that that does not disclose  
23 urging of the base of the humidifier chamber into the  
24 heater plate?

25 A. Yeah. That's exactly the same problem that I

1 alluded to first. This humidifier was actually used  
2 and still used as the humidifier on patients in the  
3 ICU where you have patients on a ventilator, hopefully  
4 only for three days and not longer. After that they  
5 go on a big ventilator, so a trache. You needed to  
6 justify the medical necessity for using this one in  
7 conjunction with the CPAP device (indicating). And  
8 insurance companies eventually said no, or declined  
9 that humidifier very often for patients on CPAP  
10 because it was still a debate, do people need  
11 humidifiers or not.

12           The question came up -- because this is a  
13 full-blown, very good humidifier. Now, at the end of  
14 the '90's people thought the air and the environment  
15 is also not that humid. Why do you need a humidifier  
16 in the home. But then, nevertheless, the industry  
17 came up with saying, "Oh, we can meet the demand and  
18 create it cold to pass over humidifiers." So those  
19 cold air and water, and it was just air passing over  
20 the surface.

21           In the end it was a placebo humidifier. It  
22 did a little bit of the job, but you could sell it  
23 well. And there was a lot of cold pass-over  
24 humidifiers. That also spurred -- was a disfavor to  
25 the patients because some patients said, "Oh, it

1 solves my problem," and the others said, "No, it did  
2 not." So there was -- whether a humidifier is helpful  
3 in the home for patients on CPAP and whether that will  
4 improve outcomes was actually invented both by either  
5 using suction machine or by the cold pass-over  
6 humidifier. We might come to that later.

7           This one here has a similar sliding mechanism  
8 as the Netzer one. Now, the difference between the  
9 Netzer and this one is this is not intended for  
10 long-term use. This is the ICU-type device. As you  
11 can see from the picture, it's very complicated,  
12 expensive, and the tear-and-wear, the sliding  
13 mechanism that happens on a daily basis when you  
14 remove in the morning, put it back in the evening, and  
15 on a day by day, that doesn't happen here because most  
16 of these chambers were single-use chambers and you use  
17 it from one patient to the other patient.

18 (Indicating)

19           So under this condition I don't see that as  
20 even a need to put an urging mechanism between the  
21 housing of the heater chamber and the plate because  
22 the intended use is not that as used with CPAP. Even  
23 at that time in '99, or even particular in these times  
24 when people did not think that people need a  
25 sophisticated humidifier outside or in the home

1 outside the hospital.

2 Q. So the device, such as shown in Levine prior  
3 art, do I understand you to be saying that with a new  
4 humidifier chamber there was sufficient contact  
5 between the heater plate and the humidifier chamber to  
6 heat the water?

7 A. There was contact between the heater plate  
8 and the housing, yes, there was, but just sliding it  
9 on top of it, but how firm the contact was was  
10 dependent on how much water was in it. And as you can  
11 see on this mechanism, they have actually an automated  
12 refill of water. So they knew on that mechanism that  
13 the contact was not firm when there was less water  
14 onto it. Do you see the Spout 26 (indicating)?

15 Q. Yes.

16 A. This was meant here to have one of the water  
17 reservoirs attached to it so it automatically filled  
18 the water. And so it was clear that this device is  
19 not firm contact between the heater and the heater  
20 plate and the conditions of changing water.

21 Q. So it's your understanding that the auto fill  
22 feature of this device was to maintain contact between  
23 the heater and the base of the water chamber and --

24 A. The gravity --

25 Q. -- the heat plate?

1           A. Yes. As I said, there's several ways to  
2       create firm contact. You can use a lid. You can use  
3       the gravity. As I explained this in Paragraph 37, if  
4       you don't maintain things constant without a firm  
5       urging contact, you will have to find other  
6       mechanisms.

7           Q. So it's your understanding that this design  
8       uses an auto fill feature to maintain the water level  
9       in order to maintain gravity to maintain contact --

10          A. No. No. Excuse me. The water automatic  
11       refill is to guarantee that there's always water in it  
12       for the patients in the ICU, but such a small  
13       reservoir, patients in the ICU can fill three or four  
14       times as much when they have respiratory distress, and  
15       it's prone that this water chamber might empty, and  
16       then you have overheating and all of these things. So  
17       that the primary purpose of filling water into it is  
18       to guarantee that you have vaporization over your  
19       night or period of night or at the time of treatment.  
20       That's the primary purpose.

21          Now, this design has no -- it's just a  
22       sliding mechanism, as is for Netzer, and this is not  
23       prone to tear-and-wear because you use new chambers  
24       all the time when you change it from one patient to  
25       the other patient. It's likely to be used more than

1 6, 7, 8, or 10 sliding mechanisms over one life cycle  
2 of the chamber. So it's unlikely that you'll lose  
3 contact. So there was no need to think about an  
4 urging -- a mechanism.

5 Q. And there was no need to have the urging  
6 mechanism because of the limited number of uses?

7 A. Yes.

8 Q. Or because of the gravity of the water? The  
9 weight of the water?

10 A. I cannot tell anything about the gravity and  
11 the weight. If I look into this, it has some grooves  
12 here in the end as well, horizontal grooves. I don't  
13 know whether the -- whether this similar design is  
14 that of Netzer, that it sits in grooves. And by that,  
15 in a constant position. Again, if it does by that,  
16 then we have to look it up.

17 Is it labeled here 96? Maybe. I don't know.  
18 But, again, it is not an urging. It's just attaching,  
19 exposing, disposing the word as we used in the first  
20 hour here, and the problem that comes up when you do  
21 slide on and off on a daily basis doesn't appear here.  
22 So if I would look into this one, say, "Can I improve  
23 this one" as an engineer, this would not come up as a  
24 substantial problem.

25 Q. What about the wear-and-tear on the face of

1 the heater plate?

2 MR. BELLINGER: Objection. Form.

3 THE WITNESS: That could be a problem. When  
4 you use it and see it doesn't work anymore, then you  
5 purchase a new one. If you have a new patient, that's  
6 not a big issue. Or you repair the surface -- I don't  
7 know. You repair it if you see that. You give it to  
8 your repair person and you say, "I need a smooth  
9 surface" if it was being used a year or so. Or the  
10 engineer will -- anyway, the inspections, all this  
11 device can be inspected on a regular basis. They  
12 would request that.

13 BY MR. KANE:

14 Q. You're not saying that a device that uses  
15 grooves to hold the humidifier chamber could not also  
16 urge the humidifier chamber into the heater plate?

17 MR. BELLINGER: Objection. Form.

18 THE WITNESS: It's hard to see how that you  
19 could do that. The question was whether grooves can  
20 create an urging force. Is that the right question?

21 BY MR. KANE:

22 Q. Well, whether a device that uses grooves  
23 could create an urging force.

24 MR. BELLINGER: Objection. Form.

25 THE WITNESS: That question depends on

1 whether -- where and how the urge is created. If the  
2 urge is created in the heater plate, then of course, a  
3 groove wouldn't be a problem. If you keep the blade  
4 and the groove, the housing fixed in place, as it  
5 would be here, it's not movable, and if you have on  
6 top a fixed housing that cannot vertically move, then  
7 you can't. Then you cannot make it in an angle  
8 either. Then you have to make the other one in an  
9 angle as well. I think it's a catch 22 somehow.

10 BY MR. KANE:

11 Q. If you look at Paragraph 85 of your  
12 declaration.

13 A. Yes.

14 Q. Paragraph 85.

15 A. Oh. 85, yes.

16 Q. You did say something about an angle. So I  
17 see you wrote here that "Levine does not teach or  
18 suggest that the water chamber is inserted into the  
19 heater base at an angle such that inserting the water  
20 chamber presses the base from the water chamber  
21 against the heater plate." Do you see that?

22 A. Yes, I see that.

23 Q. We talked about earlier that Levine has  
24 grooves; right?

25 A. Yes. It appears that it has. I really have

1 not used that device, how the sliding mechanism is  
2 made.

3 Q. Your understanding is it has some sort of --  
4 has grooves?

5 A. Yes. Must be anchored in the grooves in the  
6 end. Maybe that's a clicking mechanism.

7 Q. And if it has grooves, is there a way --  
8 again, assuming the device has grooves, is there --  
9 well, is there some way to insert it at an angle that  
10 would create the urging force?

11 MR. BELLINGER: Objection. Form.

12 THE WITNESS: I could envision to move it  
13 onto the heater plate in an angle, but then if you do  
14 that one, then it might sit at the end of the device,  
15 but then you have to put it on vertically because the  
16 heater plate is horizontal. So you can -- of course  
17 you can attach -- you can put it initially into an  
18 angle, and then you just let it go so that it sits  
19 horizontal on top of each other.

20 But, again, that is just sitting on top of  
21 each other, and that we defined already is not urging.  
22 It is just attaching or exposing or disposing.

23 BY MR. KANE:

24 Q. Okay. So looking at the figures on Page 51  
25 here, I want to make sure I understood what you were

1 just explaining to us.

2 In words, again, so we can get it -- the  
3 court reporter can get it down --

4 A. Yes.

5 Q. If I understood what you were saying, you can  
6 see that in Levine, the channel, and there's a  
7 structure there, 95. Do you see that? It looks like  
8 the --

9 A. Yes.

10 Q. And that only extends partially around the  
11 circumference of the circular plate?

12 A. Yes, I see that.

13 Q. All right. If I understood what you were  
14 saying was that you could take the humidifier chamber  
15 and bring it at an angle to touch the surface of the  
16 heater plate, which is 94.

17 A. Or touch the 95, 94, touch 95, the groove.

18 Q. I see. Touch 95, the groove. But then as  
19 you inserted the humidifier chamber into the groove,  
20 it necessarily would become horizontal?

21 A. Necessarily has to come horizontal, yes.

22 Q. And then it would just be adjacent or  
23 exposed. It wouldn't be urged?

24 A. Exactly.

25 Q. Okay. Thank you.

1           A. It doesn't teach in the -- it doesn't teach  
2 anything about, in this patent, as I recall when I  
3 read that, it doesn't tell anything about urging. If  
4 it would have been an urging mechanism, that they  
5 would have talked about that because that's the basic  
6 concept. If you come up with this one already that  
7 you urge something on it, they would have told us in  
8 the patent.

9           Q. And even -- but you understand that, even  
10 though there's no urging, that this humidifier  
11 actually does heat the water and allow water vapor to  
12 get into the air stream to deliver to the patient?

13          A. Yes.

14          Q. Then if we look at Paragraph 64.

15          A. Yes.

16          Q. Do you see there's a discussion of the HC200  
17 manual?

18          A. Yes.

19          Q. And do you know who manufactured HC200?

20          A. Yes.

21          Q. Who is that?

22          A. Fisher Paykel.

23          Q. Your opinion is that the HC200 manual  
24 likewise does not disclose urging of the base of the  
25 humidifier chamber into the heater plate; correct?

1           A.   Correct.   There's several missing pieces in  
2   the manual, but that is, of course, not needed because  
3   it's made as a manual for the user.   As you can see,  
4   there's no -- the heater chamber don't show anything  
5   of the inside of the chamber, and they don't show  
6   anything of the inside of the (inaudible) either.  
7   It's not needed in the manual.

8           THE REPORTER:   I'm sorry.   Please repeat.  
9   "Inside of the..."?

10          THE WITNESS:   It's not needed in the manual  
11   for technician and patients.   You don't need to show  
12   the inside out of any electrics in the manual that's  
13   meant for patients and technicians.

14          Q.   You understand that to be a commercial  
15   product?

16          A.   Yes.

17          Q.   And you understand that that humidifier  
18   chamber in the HC200 vaporized the water?

19          A.   Yes.

20          Q.   Do you have any understanding as to whether  
21   or not the humidifier chamber was urged against the  
22   heater plate?

23          MR. BELLINGER:   Objection to form.

24          THE WITNESS:   There's nothing mentioned in  
25   the manual that is an urging mechanism.   This is a

1 device that has been used in the past. I understand  
2 it's no longer in use. So it might be possible that  
3 the experience with patients have shown that the  
4 humidification was suboptimal or also faulty. Maybe  
5 they have not done good, firm contact, that was one,  
6 or that the chamber was too noisy or something else  
7 was -- led to the fact that they had to phase it out.

8 It was the first generation of the CPAP with  
9 a humidifier. And in any first generation you gain  
10 experience in your first generation and in your second  
11 and your third generation.

12 BY MR. KANE:

13 Q. Have you used the HC200 with any of your  
14 patients?

15 A. I have not used this HC200 for CPAP use in my  
16 patients because at that time I was already in the  
17 U.S., and in the U.S. we prefer to use Phillips, U.S.  
18 devices 50 percent and 50 percent ResMed.

19 Q. If you look at -- if you can compare for me,  
20 say, Figure 2 of the '624 patent.

21 A. Yes.

22 Q. With the Figure --

23 A. 54. Yes.

24 Q. With the drawing of the HC, the HC200 manual?

25 MR. BELLINGER: Do you have a copy for me?

1 I'm sorry. I don't mean to interrupt.

2 (Pause in proceedings.)

3 BY MR. KANE:

4 Q. So we're looking now at the HC200 manual,  
5 which is RMD 1017, Dr. Schneider. We're on Page 7.

6 A. Yes. I've opened Page 7 here, yes.

7 Q. So comparing that figure in the HC200 manual  
8 to Figure 2 of the '624 patent, do you notice any  
9 similarities as to how the water chamber and the  
10 heater plate are oriented?

11 A. I see substantial differences in one versus  
12 the other. There is similarities and differences.  
13 The similarities in general, the form of the housing  
14 of the machine. The similarity is of both systems we  
15 have not low profile chamber but a high profile  
16 chamber. So these are the similarities.

17 The inside outs differ. So now, this is  
18 similar. When you say, "Do you see similarities  
19 between a Volkswagen and Porsche," I would say, "Yes.  
20 All have four wheels. They all sit four people, and  
21 you can drive in all of them." But no one would say a  
22 Porsche is similar to a Volkswagen beetle.

23 Q. I was trying to focus specifically on the  
24 orientation of the humidifier chamber base and the  
25 heater plate in the two devices, and, likewise, the

1 chamber guard.

2 A. Yes.

3 Q. Do you see any similarities in that?

4 A. There is some similarities in that there's a  
5 guard, a chamber guard, yes. And there is a heater  
6 plate, and that is similar in both devices.

7 Q. And do you see the chamber has a chamber base  
8 with a flange or a lip around the base?

9 A. Yes.

10 Q. Is it possible that HC200 urges the  
11 humidifier chamber onto the heater plate?

12 MR. BELLINGER: Objection.

13 THE WITNESS: When you ask the question is it  
14 possible, everything is possible. I don't know at  
15 this time -- and it doesn't specify this here --  
16 whether they have had already in this device an urging  
17 mechanism. It's clear that they do not have a single  
18 motion mechanism because you still have to attach on  
19 the outlet here. That's a different design. It  
20 doesn't tell anything about that.

21 So again, as I said, this is the first --  
22 maybe there's a prototype, but for the first, it's the  
23 first generation of the humidification system. We  
24 actually made jokes and fun out of it when it came out  
25 on the market because we said, "This is a humidifier

1 with CPAP and not a CPAP with a humidifier." Now,  
2 this is the first generation, and they gained  
3 experience, and they might have a lot of faulty  
4 designs.

5 As I said, I don't know anything about their  
6 mechanism of attaching, as I don't know anything about  
7 the mechanism on this patent of urging, and I consider  
8 myself as an expert back in 2000.

9 BY MR. KANE:

10 Q. Okay. I'd ask you to turn to Paragraph 66 of  
11 your declaration, Page 36.

12 A. Yes. Yes, I have that here.

13 Q. And you understand that the Wickham device,  
14 they have a removable portion of the flow path so that  
15 that that portion can be cleaned?

16 A. Yes.

17 Q. And why is it important to be able to clean  
18 components that are in the flow path of a respiratory  
19 device?

20 A. You see, again, mid '90's, even until maybe  
21 2005 CPAP machines were -- CPAP machines were very  
22 expensive. The cost very often exceeded \$2,000,  
23 \$3,000, and when patients were using a CPAP either in  
24 the hospital or in the home and returned the CPAP  
25 device, because these devices were bought by the

1 insurance company and then returned, people wanted to  
2 reuse and refurbish the CPAP machines to give it to  
3 another patient.

4 In order to do that, you needed to clean such  
5 a device from the inside out. I cannot tell you how  
6 often I've seen CPAP patients putting a CPAP machine  
7 on my table and cockroaches crawl out of it.

8 So the point here was that was also, if you  
9 want to reuse a CPAP machine, you needed to find --  
10 either develop a new CPAP machine that allows you to  
11 easily clean the air passage, even inside a CPAP  
12 machine, and the Wickham is actually one of the first  
13 designs that attempted to do that.

14 There was another reason for this invention.  
15 And, in fact, a lot of sleep centers use so-called  
16 inlet titration machines so that one machine was used  
17 one night for one patient and another night for the  
18 next patient. And it was a debate whether you can  
19 even do that because of the cross-contamination.

20 Now, in the hospital setting in regulated  
21 space, you need to protect yourself against such  
22 incidents for legal reasons and, of course, for  
23 ethical reasons. This is no longer needed if you put  
24 it in the home of a patient because there is no risk  
25 of cross-contamination even. If the spouse wanted to

1 use it, they have the same bacteria anyway. So this  
2 is meant for these conditions where you change it from  
3 one patient to the other, to be protected.

4 That has totally changed with lowering prices  
5 of the CPAP machine. Now the CPAP machines are so  
6 inexpensive, you don't care about cleaning anymore.  
7 It's like the printer cartridge. Same principle. In  
8 the past the CPAP machines were expensive. The masks  
9 were less expensive. Now it's just totally upside  
10 down. The CPAP machine costs \$150 to put to use. No  
11 one cares about cleaning these devices.

12 Q. So you understand -- correct me if I'm  
13 wrong -- that a cleaning occurs still in CPAP devices  
14 in the home; correct?

15 A. Yes.

16 Q. And what is cleaned in the home use?

17 A. What is cleaned is the mask, the tubing that  
18 connects to the humidifier, and the humidification  
19 chamber on a daily basis.

20 Q. And why are those components cleaned on a  
21 daily basis?

22 A. Because depending on the design of the CPAP  
23 machine, you can have in the next morning, and on use  
24 of the CPAP machine, you can have standing water in  
25 the tubing. If the patient sleeps and the tube bends

1 like that, that can then cause bacteria over a day if  
2 you don't remove the fluid inside and if you don't  
3 clean it well and hang it out in a specific way, let  
4 it dry out. These are all the conditions that also  
5 ensures longevity of the mask, the tubing, and the  
6 humidification chamber. (Indicating)

7 But you don't change nowadays, don't do  
8 any -- like this one here (indicating). These  
9 machines are no longer in use for the home.

10 Q. When you say, "this one here," you're  
11 referring to Wickham?

12 A. To Wickham, yes.

13 Q. So just to make sure it's clear, the masks  
14 are cleaned on a daily basis?

15 A. Yes.

16 Q. Recommended?

17 A. Recommended, yes.

18 Q. And is that because of water can congregate  
19 inside the mask?

20 A. Water and sweating. Once you have -- most  
21 patients don't use the mask after four or five hours  
22 because it's getting way too hot. So they start  
23 having sweating effects. Combined with  
24 humidification, it's quite inconvenient after that.

25 Q. And that water or sweat that forms inside the

1 mask could lead to the growth of bacteria?

2 A. Depending on the salt content, yes. If  
3 there's low salt content, it can.

4 Q. Is there other reasons to clean the mask?

5 A. Yeah, for longevity. I'll give you an  
6 example. Here in the U.S. we have a healthcare system  
7 that allows a patient to order masks -- new masks once  
8 in a quarter. In Germany you can order only once in a  
9 year. So that's why you need to be more careful in  
10 cleaning and taking good care of your mask. And the  
11 cost, that's because of the general healthcare system.  
12 Here a lot of patients get one or two masks each  
13 quarter adding to the overall cost of the treatment.

14 Q. And then you mentioned earlier the tube that  
15 runs from the CPAP device to the mask might have water  
16 collect overnight; correct?

17 A. Correct.

18 Q. You call that rainout, I believe, yes.

19 A. It could be rainout, or it could be in the  
20 morning -- as I said before, when the patient turns  
21 off the mask, you now have high pressure -- before,  
22 when the mask is attached to the patient, you have a  
23 pressure of, let's say, 10 centimeters in the entire  
24 system from the CPAP device to the humidifier to the  
25 tubing to the mask.

1           The patient removes that. Now you change  
2       from high to low pressure inside the tubing, and then  
3       it rains out after he disconnects. So at what time --  
4       if the patient doesn't turn off the device right  
5       away -- and most patients don't -- then it accumulate  
6       water in the tubing, yes.

7           Q. So then you said that's why the tubing is  
8       recommended to be washed every day and hung so that  
9       the water can drain out and dry inside the tube?

10          A. That's one, yes. That's what you recommend  
11       to do, yes.

12          Q. Okay. And then finally we have the  
13       humidifier water chamber itself; correct?

14          A. Yes.

15          Q. That obviously has water in it --

16          A. Yes.

17          Q. -- during the night; correct?

18          A. Correct.

19          Q. And so that's recommended be washed out as  
20       well?

21          A. Yes. Primarily, for two reasons. One is  
22       when water vaporizes and you do not use distilled  
23       water, then you have, of course, residuals from  
24       calcium and other minerals on your plate, and that  
25       changes your characteristics of the plate. And a lot

1 of people do not use distilled water. And then you  
2 have to do that. Otherwise, in three, four days  
3 you'll lose all the characteristics of the heating.  
4 Then you'll have a salt layer on top of your metal.

5 Q. What's the other reason?

6 A. For cleaning?

7 Q. For cleaning. You said -- I asked why you  
8 clean out the humidifier chamber. You said,  
9 "Primarily for two reasons."

10 A. Oh. Okay. Of course the other reason is  
11 that once you have then residual water in it, it's  
12 still water and it's still warm. There is a minimal  
13 risk that gives rise to grow something -- right? -- if  
14 you don't empty it from the water.

15 Q. I don't think I asked you this, but what are  
16 the reasons for cleaning out the tubing?

17 MR. BELLINGER: Objection. Form.

18 THE WITNESS: The tubing, as I said, again,  
19 the same thing. If you keep the tubing -- let's say  
20 you step out of your bed. Your machine stands on the  
21 side. The tubing bends, nice U-shaped curve on the  
22 side of your bed. Maybe the mask is under your  
23 pillow, and you leave it like that. I can tell you  
24 right away the next day, next evening you will come in  
25 and it smells like that you don't want to use the CPAP

1 mask because the manual here shows it fairly well.

2 The HC200 manual on Page 8 shows that there  
3 is the risk of condensation and still water in the  
4 tubing when you have a U shape. We now discussed when  
5 a patient puts the mask off, that the accumulation of  
6 that water is not while the patient is breathing with  
7 the device. It's simply the fact that he has  
8 disconnected himself.

9 Now, if you leave this bent there as is, then  
10 you'll have not prevented any cause of bacteria inside  
11 the tubing if it is not done inside the housing.

12 So --

13 BY MR. KANE:

14 Q. And you mentioned some sort of smell would  
15 occur?

16 A. Yeah. If it grows something, if bacteria  
17 grows, then it can smell.

18 Q. Can it make the patient sick as well?

19 A. It is his own bacteria. Now, whether the  
20 load is high enough to make him sick, he needs then to  
21 actually -- in order to get that, he needs to get it  
22 in the lungs. So he needs to aspirate. So he needs  
23 to get the fluid into the lungs by way of coughing  
24 reflex. It's unlikely, but it's uncomfortable and  
25 longevity of both mask and everything.

1 MR. KANE: Okay. I think it's been about 45  
2 minutes. I think it's a good time to break.

3 MR. BELLINGER: Sure.

4 (A recess was taken from 12:48 p.m.  
5 to 1:35 p.m.)

6 BY MR. KANE:

7 Q. Welcome back, Dr. Schneider.

8 A. Thank you.

9 Q. I hope you enjoyed your lunch.

10 One question I hadn't asked you previously  
11 was at any point today during the breaks, have you  
12 been -- have you talked or discussed the substance of  
13 your testimony with your counsel?

14 A. No.

15 Q. Let's shift gears a little bit and look at  
16 Paragraph 49, which is on Page 24 of your declaration.  
17 And you can see there there's a Section A that's  
18 relating to "'at least one auxiliary electrical  
19 connection plug or socket pneumatic connection plug or  
20 port.'" Do you see that?

21 A. Yes, I see that.

22 Q. And if we then turn over to the next several  
23 paragraphs, and you can review that if you need to.  
24 End of Paragraph 53 you state that the connection --  
25 or maybe 52, "that the claimed auxiliary connections

1 are separate and distinct from the connection formed  
2 between the patient outlet and the breathing hose."  
3 Do you see that?

4 A. The last sentence?

5 Q. Let me read it. At the end of Paragraph 52  
6 it says, "These terms require distinct structures that  
7 are not merely points of contact between the patient  
8 outlet and the breathing hose, and the use of those  
9 terms in the claims further shows that the claimed  
10 auxiliary connections are separate and distinct from  
11 the connection formed between the patient outlet and  
12 the breathing hose"; right?

13 A. Right.

14 Q. And so is that how you interpret the claim  
15 limitation that is shown at Roman -- Roman A on  
16 Paragraph 24?

17 A. Yes.

18 Q. Okay. All right. So if we look -- where is  
19 it? If we look at the patent, go to the patent. '64  
20 patent.

21 A. Yes.

22 Q. And if you look at Figure 1.

23 A. Yes.

24 Q. Okay. And you can see there that there's  
25 something identified as -- by Figure No. 9. Do you

1 see that, Element No. 9?

2 A. Yes, I see it.

3 Q. And what is that?

4 A. That's an elbow that connects the patient's  
5 tube, the hose to the connector, to the humidification  
6 chamber.

7 Q. Okay. And then there's another structure  
8 identified as 54. Do you see that?

9 A. Yes, I see that.

10 Q. And what is that?

11 A. That's an extra port somewhere adjacent to  
12 the outlet.

13 Q. Okay. How do you understand the patient hose  
14 to connect to the flow generator, and specifically  
15 with Structure 9 and Structure 54?

16 A. From that angle I cannot say how much space  
17 is between the plug and the Outlet 9. So I -- under  
18 these pictures I cannot depict whether there is  
19 separate connectors for each or whether there's a twin  
20 connector that is -- still separates one versus the  
21 other like a twin plug. You have two separate  
22 connectors. So the housing is in one, or whether -- I  
23 need to go here to Figure No. 4 where another view of  
24 the device because that puts it more from the above  
25 perspective, this figure. Figure 4.

1           So Figure 2, and one is more from upward,  
2   above perspective, and Figure 4 is more close up.  
3   Here, I can clearly see that there is space between  
4   the Elbow 51 and 54 on Figure 4, showing that in fact  
5   it can be -- it is a separate port.   A known  
6   extending auxiliary port, and that's the way I  
7   understood that.   It's not an integral part of the  
8   tubing.   And it is possible to have either separate  
9   connector for the tubing and a separate connection to  
10  the port.

11           Q.   And so when you offer your opinion in the  
12  declaration that the auxiliary connections must be  
13  separate and distinct, are you saying that there has  
14  to be that space between the auxiliary port and the  
15  flow path connection so that there could be two  
16  separate connectors?

17           MR. BELLINGER:   Objection.   Form.

18           THE WITNESS:   Let me see how I explain this  
19  here first and then I will answer your question in  
20  my -- if it is not well said here already.

21           MR. KANE:   Okay.

22           THE WITNESS:   Let me read Paragraph 50.

23           (The witness reviewed Exhibit 2004.)

24           THE WITNESS:   Okay.   I think it's already  
25  well said in Paragraph 50 and 51 in my declaration,

1 and I would refer -- do you want me to read the  
2 explanation to answer your question, or do you have  
3 additional questions?

4 BY MR. KANE:

5 Q. Well, what I was trying to understand, given  
6 what you just testified to, you've talked about the  
7 fact that Figure 4 showed that there was some  
8 distance -- I'm not sure what word -- between the 54  
9 and 51, for instance, in Figure 4. Is that  
10 distance -- how does that distance or gap, whatever  
11 you want to call it, play into your analysis?

12 A. As I said in my Paragraph 51, for example, if  
13 you go to the last sentence, "Figure 4, shown below,  
14 (as well as Figure 1-3 and 11) of the Challenged  
15 Patents show an auxiliary connection socket or plug,"  
16 that's No. 54, "is distinct from the connection  
17 between the" electrical and the pneumatic connection  
18 54 for the conduit may be used.

19 This portion of the specification further  
20 illustrates that the claimed auxiliary electric  
21 connection of plug or socket or connection plug or  
22 port is separate and distinct, connection between the  
23 patient outlet and the breathing hose.

24 And now, definition of "distinct" here is  
25 that you can remove one and the other one stays put.

1 Q. Okay.

2 A. It has nothing to do with the distance  
3 between one and the other. That's illustrated here  
4 very well in Figure 4.

5 Q. All right. If we look at Figure 1 --

6 A. Yes.

7 Q. -- do you think that is shown as being  
8 separate and distinct?

9 A. As I said, this is on the first view, on the  
10 first distance drawing from -- I would say if I put  
11 the device in here, it's from the direction pointing  
12 to maybe 45 degrees or even 70 degrees upwards. So  
13 the perspective of that drawing cannot tell you  
14 whether is there a separation or not. It's just  
15 simply a matter of perspection. It's exactly when you  
16 go here and look at the monument here -- right? -- it  
17 looks as if this is directly attached to this  
18 neighbor's house.

19 It's just a matter of perspection. You  
20 cannot draw any conclusion out of that. For that you  
21 will need to turn the device or show it in another  
22 perspection or another side view.

23 Q. And is the same then true for Figure 2?

24 A. Same is true for Figure 2. Figure 2 is  
25 almost the same, direct point of view, yes.

1 Q. How about Figure 3?

2 A. A little bit -- actually, Figure 4 --  
3 Figure 2 appears to be a little bit rotated, but only  
4 slight, slight one.

5 Q. Okay. But so Figure 2, though, you're saying  
6 that Figure 2, like Figure 1, the perspective doesn't  
7 allow you to determine whether or not there's a  
8 separation?

9 A. Because one is standing in front of the  
10 other. I can't see it.

11 Q. Uh-huh. And then what about Figure 3?

12 A. Figure 3, the elbow is extending in front of  
13 54. It's the same problem here.

14 Q. Okay.

15 A. That always you have one standing in front of  
16 the other rather than like in Figure 4 where you can  
17 say, "No, remove one," and then you can see. There's  
18 separation.

19 Q. And then what about Figure 11?

20 A. Yes. Again, same thing. And we need to  
21 rotate the device to see whether -- how much space is  
22 between one and the other.

23 Q. Okay. And if there's no space, would it be  
24 separate and distinct?

25 A. The definition of separate and distinct is

1 not created by the distance of these two. It could be  
2 simply defined by the fact that if you remove one,  
3 that the other one still stays.

4 Q. Okay.

5 A. But if you remove the tubing, as we have seen  
6 in Figure 4, it's still -- and the other one still  
7 remains in place. So that means one is not an  
8 integral part of the other.

9 Q. Let's see. So if I look through this portion  
10 of your declaration -- well, I see in Paragraph 52  
11 there's a reference to Column 5, Lines 1 to 6. Do you  
12 see that --

13 A. Yes.

14 Q. -- in quotations on that portion of the  
15 patent; correct?

16 A. Yes, I see that quotation.

17 Q. And does that quotation say anything about  
18 you can remove one but not the other?

19 A. It simply states here that "'an additional  
20 electrical and/or pneumatic connection 54 for the  
21 conduit may be used."

22 Q. I'm actually looking at, I think the  
23 paragraph before on the previous page, Dr. Schneider.

24 A. Which one, 52? This one (indicating)?

25 Q. Yes. And can you read that, and then at the

1 bottom of the last line of that page there's a  
2 reference to Column 5, Lines 1 to 6.

3 A. Yeah. Let me look at Column 5, Lines 1  
4 through 6 first.

5 (The witness reviewed Exhibit 1001.)

6 THE WITNESS: So I've read this one, and it's  
7 all in line with what I said in my declaration. So I  
8 don't understand your question. Can you phrase your  
9 question, please.

10 BY MR. KANE:

11 Q. Sure. If I understand what you're saying is  
12 that "separate and distinct" means that one of the  
13 connections can be removed and the other connection  
14 can stay intact; is that right?

15 MR. BELLINGER: Objection.

16 THE WITNESS: Yes. It says in Paragraph --  
17 it's cited here in Exhibits 1001, Column 5, 1 through  
18 6, it says that the connector may -- it says it very  
19 well here. One moment.

20 (The witness further reviewed Exhibit 1001.)

21 THE WITNESS: The connector is actually  
22 integral with the CPAP housing, and not -- that's what  
23 it says. That's why I add Citation 5, Line 1 through  
24 6. It says, "In the present invention the connector,  
25 which includes the electrical and the pneumatic

1 connection 54 for the conduit, is integral to the  
2 connection manifold of the CPAP machine." It doesn't  
3 say integral to the tubing or the patient outlet form.

4 So in conjunction with Figure 4, it's clear  
5 that these are two separate connections -- not  
6 connections. Two separate -- not connections. Two  
7 separate things. One is connected integral to the  
8 CPAP machine. That's why I'm citing this one. And  
9 the other one is integral to the tubing and the  
10 humidification and mask system.

11 BY MR. KANE:

12 Q. It's referring to the electrical wiring in  
13 the heated tube there, isn't it, at Column 5?

14 A. Column 5?

15 Q. Look at Column 5 of the patent.

16 A. Yes.

17 Q. You see there it says, "The use of a heated  
18 conduits required electrical wiring connectors between  
19 the conduit and the humidified air source," and then  
20 it continues a little bit at the top.

21 A. The humidified air source of the CPAP  
22 machine.

23 Q. Correct. I agree.

24 So there has to be -- so you're saying that  
25 the auxiliary connector that you're talking about is

1 part of the flow generator; correct?

2 A. Yes.

3 Q. That has to mate and connect somehow to a  
4 wire on the heated wire; correct?

5 A. It has to somehow do that, yes.

6 Q. Okay. And I thought -- so how do I know  
7 whether or not that connection is separate and  
8 distinct?

9 MR. BELLINGER: Objection. Form.

10 THE WITNESS: How do you know?

11 BY MR. KANE:

12 Q. How do I know if the connector is separate  
13 and distinct? I thought earlier you said you could  
14 make one connection separate from the other  
15 connection.

16 MR. BELLINGER: Objection. Form.

17 THE WITNESS: First of all, you see on the  
18 drawings it is separate because when you remove one  
19 from the other, you can -- one still stays put. So  
20 that's clearly shows that it's separate. There is  
21 even a distance between one and the other.

22 BY MR. KANE:

23 Q. Can we stop right there.

24 A. Yes.

25 Q. When you say you can take one and remove it

1 but not the other, what are you talking about?

2 A. If I remove Elbow 51 and 53 in Figure 4 --

3 Q. Right.

4 A. -- the auxiliary connection plug or socket  
5 stays at the same location unaffected by removing that  
6 plug.

7 Q. Okay. So you're not analyzing -- you're not  
8 looking at all the -- at the heated tube portion of  
9 this -- that would mate to that connection?

10 A. No. That is not the scope of this invention,  
11 how it would create the heated tube. That's totally  
12 separate. Of course, there's several ways how to  
13 create this. You can have a stand-up tube. You can  
14 have something circled around to make cheap. You can  
15 have it integrated. You see, that's all a matter of  
16 manufacturing a tube with portions of whatever you  
17 want.

18 There might be -- some tube you'll want to  
19 have maybe a pneumatic connection. Some tubes you  
20 might not want any electrical or pneumatic components  
21 in it. Some tube you might have oil. So how the tube  
22 is actually connected is not part of that. It's out  
23 of scope of this patent. I'm pretty sure that Fisher  
24 Paykel has another patent on that, or a separate one.

25 Q. So if you'd look at Column 5. It says in the

1 present -- starting at Line 6. "In the present  
2 invention the connector which includes an additional  
3 electrical or pneumatic connection is integral to the  
4 connection manifold of the CPAP machine and therefore  
5 allows the disposable water chamber to remain as  
6 simple as possible." Do you see that?

7 A. Yes.

8 Q. So when it says, "In the present invention  
9 the connector," what is the connector? How do you  
10 interpret what the connector is?

11 A. The auxiliary connection plug. That's how I  
12 interpret it.

13 Q. If you read the sentence with me,  
14 Dr. Schneider, it says, "the connector which includes  
15 an additional electrical or pneumatic connection," are  
16 you saying that it's only 54?

17 (The witness reviewed Exhibit 1001.)

18 THE WITNESS: Yes. That's exactly the way I  
19 understand that because it says, "In the present  
20 invention the connector which includes an additional  
21 electrical and/or pneumatic" connector "54," that's  
22 why that's labeled with the number, "for the conduit  
23 is integral to the connection manifold of the CPAP  
24 machine." Exactly as you said that.

25 If it would not be integral to the CPAP

1 machine, then when you remove the elbow, it would not  
2 stay put in the CPAP machine. So it is not integral  
3 to the humidification portion of the device. It's  
4 integral to the CPAP machine, and as we see here in  
5 Figure 4, we can remove the humidification portion,  
6 including the tube and the elbow, and it still stays  
7 put. So that's why I interpret the connector as the  
8 auxiliary plug.

9 BY MR. KANE:

10 Q. What does the word "additional" refer to in  
11 that sentence?

12 A. That -- you see this connector or this plug  
13 has --

14 Q. What are you referring to?

15 A. Oh, sorry. The question was "additional."  
16 What "additional" means.

17 Q. Correct. I just want to clarify. You said,  
18 "this connector." I want to make sure you said --  
19 because you were pointing. I just want to make sure.

20 A. Yes. So the connector described in Figure 4  
21 as 54 AS, of course, must have as any connector  
22 plastic housing and electrical wires inside or a  
23 pneumatic tube inside, and that's how I understand an  
24 additional electrical pneumatic connection.

25 So you have your connector. That is like, in

1     this form, a male connector, and it has inside several  
2     electrical wires and/or small pneumatic conduit for  
3     pressure sensing.

4           Q.   Okay.  Does the fact that the word -- No. 54  
5     does not appear after that first reference to the  
6     connector influence how you interpret that sentence?

7           A.   Which sentence?

8           Q.   It says, "In the present invention the  
9     connector."  There's no 54 there; right?

10          A.   Yes.

11          Q.   Okay.  "...which includes an additional  
12     electrical and pneumatic connection 54."  Why is the  
13     54 -- my question is why is the 54 after that  
14     reference to the additional connection rather than  
15     after the connector?

16          A.   For that you have to ask that question to the  
17     one who has written this.  The 54, I can easily see  
18     the 54 referring to the entire sentence before from  
19     starting the present -- the connect from the  
20     connector, which includes this one, this one, this  
21     one --

22                 REPORTER MARTIN:  I'm sorry.  The connection  
23     which includes...

24                 THE WITNESS:  "includes an additional  
25     electrical and/or pneumatic connection 54."  That is

1 almost a citation or an explanation that 54 can refer  
2 to the entire sentence -- entire words that stands  
3 before that.

4 BY MR. KANE:

5 Q. You're thinking, at least in your  
6 interpretation, that that sentence, this refers to the  
7 structure labeled as 54?

8 A. I refer this to the entire sentence before,  
9 not just to the additional electric pneumatic, yes.

10 Q. Okay. So then if you go back to Paragraph 52  
11 of your declaration.

12 A. Yes.

13 Q. Okay. Again, that last sentence I'm trying  
14 to have you explain to me. You say, "the use of those  
15 terms in the claims further shows that the claimed  
16 auxiliary connections are separate and distinct from  
17 the connection formed between the patient outlet and  
18 the breathing hose." Do you see that?

19 A. Yeah. But you use some words that were  
20 different from my writing here.

21 Q. I didn't mean to.

22 A. Oh. Okay. Yes.

23 Q. So where in the Column 5 that we just looked  
24 at does it say anything about the auxiliary  
25 connections being separate and distinct from the

1 connection formed between the patient outlet and the  
2 breathing hose?

3 A. As we outlined this, and I've cited this one  
4 here now again, and you can combine the entire  
5 citation Column 5, 1 through 6 and 6 to 10. These are  
6 the lines which we just have for it; right? The first  
7 10 lines of Column 5. What I did here in my  
8 declaration, I first explained Line 1 through 6. And  
9 then in the second portion I explained 6 to 10.

10 Now, taken together, what we just discussed  
11 on this paragraph that one is integral to the CPAP  
12 machine and the other not, so the connectors integral  
13 to the CPAP machine, the hose and the humidification  
14 unit can be removed without affecting the connector  
15 clearly illustrates what I've just said here in the  
16 declaration.

17 "Further" -- and I'll read this out again --  
18 "these portions of specifications" -- and I mean with  
19 these portions of specification, I mean Line 1 through  
20 10 of Column 5 -- "further illustrate that the claimed  
21 auxiliary electrical connection plug or socket or  
22 pneumatic connection plug or port is separate and  
23 distinct from the connection made between the patient  
24 outlet and the breathing hose.

25 And I see no other way to interpret this.

1 Q. Okay. So where's -- I'm trying to break it  
2 down, and we'll get to -- you also cite -- and I  
3 agree -- you cite Column 6 that we'll come back to.

4 A. Yes.

5 Q. But my question was in that last sentence of  
6 52 there's -- you're drawing -- you're saying that the  
7 claimed auxiliary connections are separate and  
8 distinct from the connection formed between the  
9 patient outlet and the breathing hose; right?

10 A. I state that, yes.

11 Q. Okay. Where in Column 5 -- and we'll go to  
12 Column 6 later, but where in Column 5, 1 through 10,  
13 is there any reference to the "patient outlet"?

14 A. This first paragraph simply refers to the  
15 specifications of the connector and where and how it  
16 is integral to the CPAP machine. I have to add there  
17 is another description -- and I should have maybe  
18 cited that -- that, in fact, the humidification unit  
19 is flexible and can be disconnected, and I now will  
20 have to read through the entire claim again because I  
21 didn't cite that one. To answer your question where  
22 is it written --

23 Q. Well, can we look at Column 6 --

24 A. Yes.

25 Q. -- 13 to 21.

1 A. Yes.

2 Q. Is there a reference there to the patient  
3 outlet as you use that term in Paragraph 52?

4 A. There is indirect in both, in 5 as well it  
5 says, as you'll remember last line, Line 9 and 10 of  
6 Column 5, and 20 and 21 on Column 6 are similar. They  
7 say, "...therefore allow the disposable water chamber  
8 to remain as simple as possible." "Disposable," I  
9 mean I interpret this as removable. And that's the  
10 way I might have put here exactly, "formed between the  
11 patient outlet and the breathing hose." That's still  
12 disposable, removable component of the unit.

13 Q. Let's look at Column 6, 47 to 52.

14 (The witness further reviewed Exhibit 1001.)

15 BY MR. KANE:

16 Q. Have you read that?

17 A. Yes.

18 Q. Is there any reference there that the patient  
19 outlet is separate and distinct from the auxiliary  
20 connection?

21 A. So in these Lines 44 to 50 they describe an  
22 alternative embodiment, and that starts here, "An  
23 advantage of this alternative embodiment is that all  
24 parts in contact with condensation are removable for  
25 cleaning or sterilization And here that's the way how

1 the sentence started that you were referring to.

2 I continue to read, "This embodiment also  
3 retains the advantage of engagable/disengagable water  
4 chamber in a single slide-off motion. This embodiment  
5 may also include additional electric or pneumatic  
6 connections for making a connection between the CPAP  
7 machine and a conduit." So when I read this, I  
8 started with the cleaning and sterile of the removable  
9 part. Cleaning and sterilization. And that is  
10 separate from the "removable."

11 These are removable, and the other one is not  
12 removable. But had to be the same concept as before.  
13 It's in line with if you remove one, the other one  
14 stays. That's the definition of being separate.

15 Q. Okay. And if you'll see if we look up at  
16 Column 6, about Line 27 --

17 A. Yes.

18 Q. -- it says, "This alternative embodiment is  
19 shown in Figure 4."

20 A. Yes.

21 Q. Yes. And if we go to Figure 4, that's the  
22 figure that shows the removable elbow?

23 A. Yes.

24 Q. Let's look at, say, Figure 11.

25 A. Yes.

1           Q. If the elbow is not removable in Figure 11,  
2           is it separate and distinct? Is there -- is the  
3           patient outlet separate and distinct from the  
4           auxiliary connection?

5           MR. BELLINGER: Objection. Form.

6           THE WITNESS: In Figure 11, this elbow is  
7           integral to the housing of the CPAP machine, yes.

8           BY MR. KANE:

9           Q. And so what does that mean?

10          MR. BELLINGER: Objection. Form.

11          THE WITNESS: That means this elbow is  
12          separate as the other one. You see on the left-hand  
13          side, you'll see inlet and an outlet.

14          BY MR. KANE:

15          A. Correct.

16          Q. The inlet is also separate from the outlet,  
17          and the outlet is separate from the connector. So  
18          just the fact that one is closer in proximity to the  
19          other doesn't mean that they are now no longer  
20          separate. That's just -- you see if I take three  
21          glasses here; right? One is close to this one, and  
22          this is farther way. They're still separate from each  
23          other. (Indicating)

24                 If I look from this side, I cannot see that  
25          because one stands in front of the other. I have to

1 move my head around and say, "Oh, yes, they are  
2 separate."

3 Q. Okay. So whether or not the elbow in  
4 Figure 11 comes out or not, it's still separate?

5 A. Yes.

6 Q. Okay. So then it's now part of the housing;  
7 correct?

8 A. It's part of the housing, as is the  
9 electrical manual is part of the housing.

10 Q. Okay. So then how do I know whether the  
11 connector -- the auxiliary connector in Figure 11 is  
12 separate and distinct from the elbow in Figure 11?

13 A. Because it says so in the description.

14 MR. BELLINGER: Objection.

15 BY MR. KANE:

16 Q. Where does it say that?

17 A. As we said here before -- I can read this  
18 again in Paragraph 6.

19 Q. Well, Paragraph 6 is talking about Figure 4.  
20 We've already established that.

21 A. No. It says here -- one moment, please.  
22 There's an alternative.

23 (The witness reviewed the document.)

24 THE WITNESS: If you look at Page 52,  
25 Column 6, Line 53 to 57. Why Figure 4 shows this

1 alternative preferred embodiment of the present  
2 invention applied to a CPAP machine, it is envisioned  
3 that this embodiment may also be applied in an  
4 analogous manner. So in the same way, meaning in the  
5 separation to an in-line humidifier as described in  
6 the second embodiment of the present invention and  
7 pictured in Figure 3. If you look at that, Figure 3  
8 is almost the same than Figure 11 because -- the elbow  
9 is integrated into -- if you've referred Figure 6 as  
10 you can see here -- Figure 3, the difference between  
11 Figure 3 and Figure 4 is there is two different  
12 alternatives how to create this invention.

13 One is that in Figure 4, as we discussed, an  
14 easy to remove elbow.

15 BY MR. KANE:

16 Q. Okay.

17 A. Figure 3, that elbow cannot be removed. It's  
18 integral to the CPAP machine, and as this line what I  
19 just read explains, everything is analogous, meaning  
20 everything else is the same as in Figure 4 in an  
21 analogous manner.

22 Q. Well, okay. If you look at figure --  
23 Line 53, it says, "While Figure 4 shows this  
24 alternative preferred embodiment of the present  
25 invention applied to a CPAP machine" -- that's

1 Figure 4; right?

2 A. Yes.

3 Q. -- it is envisaged that this embodiment may  
4 also be applied in an analogous manner to an in-line  
5 humidifier such as that described in the second  
6 embodiment of the second invention and pictured in  
7 Figure 3"; right?

8 A. Yes.

9 Q. And I think what you said was in Figure 3 --

10 A. Yes.

11 Q. -- the elbow is not easily removable?

12 A. Yes.

13 Q. Okay. And so my question, then, is is that  
14 elbow that's not easily removable in Figure 3 separate  
15 and distinct from the auxiliary connection 54 shown in  
16 Figure 3?

17 MR. BELLINGER: Objection. Form. Asked and  
18 answered.

19 THE WITNESS: Yes.

20 BY MR. KANE:

21 Q. Okay. Why?

22 A. Yes, because it says it is in an analogous  
23 manner.

24 Q. It says it could be applied in an analogous  
25 manner?

1           A. No, it says "also be applied" not "could be."  
2       It says, "also be applied in an analogous manner."

3           Q. May.

4           A. No, it's not "may." It says it is applied.

5           Q. No, Doctor. Let's read it together.

6           A. Okay.

7           Q. "It is envisaged that this embodiment may  
8       also be applied in an analogous manner." It's "may."

9           A. "...may also be applied in an analogous  
10       manner."

11          Q. In fact, if it was being applied in an  
12       analogous manner, you wouldn't need to say -- you  
13       could say it's Figure 3 and it's in Figure 4. What  
14       this is saying is here's Figure 4. You may apply that  
15       same concept to the device shown in Figure 3.

16               MR. BELLINGER: Objection. Form.

17               THE WITNESS: It's semantics. It says it may  
18       apply in an analogous manner. That means that the one  
19       who has written this envisioned it should be applied  
20       or may be applied or is applied. And you see I cannot  
21       speak for the non-"mays," what alternative he has  
22       envisioned rather than doing it in an analogous  
23       manner.

24       BY MR. KANE:

25           Q. Okay. So you told me a couple times that the

1 elbow in Figure 3 is not easily removable; right?

2 A. Yes, that's exactly the case. Yes.

3 Q. And the elbow in Figure 4 is removable?

4 A. Yes.

5 Q. Okay. So you can make a device where the  
6 elbow is not easily removable?

7 A. Absolutely, yes.

8 Q. Will that device -- let's assume that's what  
9 we've got.

10 A. Yes.

11 Q. So we're at Figure 3. The elbow is not  
12 easily removable. Okay?

13 A. (Nods head.)

14 Q. Is the auxiliary port 54 separate and  
15 distinct from the patient outlet?

16 MR. BELLINGER: Objection. Form. Asked and  
17 answered.

18 THE WITNESS: In order -- you see the  
19 previous definition, what I took was when I removed  
20 one, then the other stays put for being separate.  
21 Now, you are right in assuming that now you cannot  
22 remove one easily. So you cannot easily find out  
23 whether you are going to remove this, then the other  
24 one still stays put.

25 Now, of course I could then take my

1 screwdrivers and can open up the machine and can open  
2 the elbow in order to make that -- to see whether my  
3 definition is still met or not. But let's assume I  
4 don't have a screwdriver, and I cannot easily remove,  
5 or not even with difficulty remove one port and decide  
6 whether the other one stays put. I still can take a  
7 ruler and see whether there is a distance between one  
8 and the other because that also meets the criteria of  
9 being separate.

10 BY MR. KANE:

11 Q. Okay. So there does -- that's a separate way  
12 of showing that it's separate if there's a distance  
13 between the two?

14 A. Yes. And for that, again, I need to turn to  
15 the -- either inspect the machine fairly closely and  
16 turn it around, see it from different angles. The  
17 fact that the elbow here in Figure 4 -- if you look  
18 closely, there is a distance between the enclosure 52  
19 and the electrical port assumes -- for that, it's  
20 clear that there's a distance between the elbow 51 and  
21 port 54.

22 Now, on Figure 3 I have now a side view of  
23 the CPAP unit, and everything is in the back. I  
24 cannot see this from this perspective is the distance.  
25 I have to assume that it's the same distance than what

1 I see in Figure 4. Let's go back to Figure 11. Maybe  
2 they have another perspective here. Now even in  
3 Figure 11, we need to turn around the machine in order  
4 to make that differentiation.

5 So all what I've left here is Figure 4 to  
6 see, yes, there is a distance, and that distance  
7 might -- is the same or might be the same in all the  
8 other ones. Just not able to show this because of the  
9 way how they have chosen to draw the figures.

10 Q. Okay. Can you look at Claim 7 for me,  
11 Doctor.

12 A. Yes.

13 Q. Why don't you read that to yourself.

14 (The witness reviewed Exhibit 1001.)

15 THE WITNESS: Yes.

16 BY MR. KANE:

17 Q. Okay. So you see there that it says that the  
18 patient outlet includes a connector for receiving the  
19 breathing hose; right?

20 A. Yes.

21 Q. Okay. Let's look in Figure 3.

22 A. Yes.

23 Q. You'll see what's been marked as 14 is the  
24 outlet for receiving the breathing hose?

25 A. Yes.

1 Q. Okay. And that patient outlet includes a  
2 connector -- well, so the patient outlet -- actually,  
3 I misspoke, I think.

4 What do you understand -- what would you  
5 define in Figure 3 as the patient outlet?

6 A. The patient outlet, that's the outlet that  
7 the elbow -- 51, or the Tube 14 in Figure 3 and in 11.

8 Q. Let's just stick to Figure 3.

9 A. Yes. Figure 3. That's 14.

10 Q. Okay. It says, "Patient outlet includes a  
11 connector for receiving a breathing hose." What's the  
12 connector for receiving a breathing hose?

13 A. That's different connectors. You can have --  
14 usually there are either rubber connectors that you  
15 put on top of it. You can have a twist-down  
16 connector. So but in most cases it's a rubber portion  
17 that connects plastic piece with the flexible hose.

18 Q. So you think the connector is something  
19 different than what's shown as 14 in Figure 3?

20 A. Yes. That's a connector for receiving a  
21 breathing hose. That's a simple connector for the  
22 breathing hose.

23 Q. What is 14 in Figure 3?

24 A. That's the plastic piece, similar to the  
25 plastic piece on 51.

1 Q. Okay. Is that a connector for receiving a  
2 breathing hose?

3 A. Yes.

4 Q. Okay. So what's the patient outlet?

5 A. That's the patient outlet (indicating).

6 Q. Well, it says, "The patient outlet includes a  
7 connector." Do you see that?

8 A. Yes.

9 Q. So is the patient outlet something more than  
10 the connector? 14.

11 A. It says that in the following sentence what  
12 it is. "A patient outlet includes a connector for  
13 receiving a breathing hose and at least one auxiliary  
14 plug," electrical connection plug, "or a pneumatic  
15 connection plug or port for simultaneously connection  
16 when connecting a breathing circuit having  
17 complimentary electric pneumatic connection."

18 So as you can see this one, there is two  
19 components of this as it is described here.

20 Q. What are the two components?

21 A. One is the breathing hose, and one is the  
22 electrical socket. The plug.

23 Q. Okay.

24 A. Which we already stated is separate from each  
25 other. They are separate with -- if you have the plus

1 and the minus on your electrical plug. When you  
2 connect these together, there would be a shortcut.  
3 Still, there's only one twin plug that has the plus  
4 and the minus or the neutral and the power line, and  
5 the neutral and the power line are always separated.  
6 But still you have only one plug, one connector that  
7 goes into your electrical outlet. Still, the neutral  
8 and the power is separated.

9 Q. Okay.

10 A. And that's the way how I understand that.  
11 You have one connector for receiving a breathing  
12 hose -- that's your neutral -- and at least one  
13 auxiliary electrical connection that's your power  
14 line, but still, that's separate from each other. But  
15 they need to be connected. Here we're talking about a  
16 plug that might fit over this. It doesn't tell you  
17 anything about whether one or the other one is  
18 connected or separated.

19 Q. Okay. So let's -- can we apply that to  
20 Figure 3?

21 MR. BELLINGER: Objection. Form.

22 THE WITNESS: We can apply this to Figure 3.  
23 As I said before, you cannot see whether 14 and 54 are  
24 in this picture separated or not because of the  
25 perspective.

1 BY MR. KANE:

2 Q. And does that -- so what is the connector for  
3 receiving the breathing hose in Figure --

4 A. 14.

5 Q. What is at least one auxiliary connection  
6 plug or port or pneumatic connection plug or port?

7 A. That's 54.

8 Q. Okay. And those two together make up the  
9 patient outlet?

10 MR. BELLINGER: Objection. Form.  
11 Foundation.

12 THE WITNESS: No. 14 makes the outlet to the  
13 air. 54 receives information from the tubing and like  
14 or feeding electrical power into the tubing. So the  
15 definition of patient outlet was always that it's the  
16 outlet of air and not the outlet of power.

17 BY MR. KANE:

18 Q. Okay. If you look at Claim 7, though,  
19 remember it says, "patient outlet includes a connector  
20 for receiving a breathing hose," which I think you  
21 identified as 14, "and at least one auxiliary  
22 connection." I won't read it all.

23 MR. BELLINGER: Objection. Form.  
24 Foundation.

25 THE WITNESS: But it says the connector that

1 includes -- you could say either one and the other.  
2 So it doesn't say that it's integral. It says it  
3 includes a connector for receiving the breathing hose  
4 and one auxiliary electrical. It doesn't say anything  
5 about whether they are -- that's separate or not.  
6 It's two components. You can have two plugs or one  
7 plug. One connector.

8 It includes a connector for receiving the  
9 breathing hose and at least one auxiliary connection  
10 plug or socket.

11 BY MR. KANE:

12 Q. Okay. And, again, I'm just trying to read  
13 the words, Dr. Schneider. It says the "patient  
14 outlet." We're talking about a patient outlet; right?

15 A. Yes.

16 Q. It "includes a connector for receiving a  
17 breathing hose"; correct?

18 A. Correct.

19 Q. And then it says, "and."

20 A. Yes.

21 Q. And then it says, "at least one auxiliary  
22 connector"; correct?

23 A. Yes. That's how it reads that, yes.

24 Q. So it has to have two things. It has to have  
25 a connector for receiving a breathing hose and at

1 least one auxiliary connection; correct?

2 MR. BELLINGER: Objection. Form.

3 THE WITNESS: Yes. It's connector for  
4 receiving a breathing hose and at least one auxiliary  
5 electrical connection plug. At least one. It could  
6 be also two or three. And the only thing is "for  
7 simultaneous connection when connecting a breathing  
8 circuit having complimentary electrical pneumatic  
9 connectors."

10 BY MR. KANE:

11 Q. Okay. And so that last portion about the  
12 simultaneous connection, when connecting a breathing  
13 circuit having complimentary electrical or pneumatic  
14 connectors, how do you interpret that in conjunction  
15 with, say, Figure 3 of the patent?

16 A. I interpret this the same way as connecting  
17 in one simultaneous movement the inlet and the outlet  
18 of the humidifier. There are two distinct, separate  
19 ports. One goes in the chamber. One goes out of the  
20 chamber within one single motion. That means because  
21 I'm connecting this all in one single motion, it  
22 doesn't mean that they are now connected together --  
23 right? -- the inlet and the outlet?

24 They connect in the same way that you have to  
25 connect two separate plugs at the same time,

1 simultaneously.

2 Q. And so how would that apply on Figure 3?

3 A. In Figure 3, I don't know. In Figure 3 we  
4 don't have the connector depicted. So I can only --

5 Q. We don't have the breathing hose depicted,  
6 you mean?

7 A. No, I don't have the female part or the male  
8 part, whatever they envisioned, how to connect 14 and  
9 54. I don't see that in Figure 3. As I said, in  
10 Figure 3 we cannot see the dimensions between 14 and  
11 54.

12 Q. Okay. In Figure 3 what the claim says is  
13 that there has to be simultaneous connection when  
14 connecting the breathing circuit; right?

15 A. (Nods head.)

16 Q. You understand the breathing circuit to be  
17 the hose that goes to the patient?

18 A. Yes.

19 Q. Okay. So there has to be a simultaneous  
20 connection of 14 and 54 --

21 A. Yes.

22 Q. -- when connecting the breathing circuit?

23 A. There has to be some sort of a connector that  
24 can separately -- that can connect two separate  
25 connectors, an electrical and an air conduit, both of

1 which are separate in one single motion. And I don't  
2 see that connector here. So that's why I cannot say  
3 if they envision -- let's say a male connector for 14  
4 and a female for 54 or vice versa. I cannot see  
5 that.

6 Q. Sure. Are you saying that the air connection  
7 is always separate from the electrical connection?

8 MR. BELLINGER: Objection. Form.

9 THE WITNESS: No, of course not, because  
10 there's other embodiments that accompanies, and one  
11 predicate we have from, I think it was Drago, Siemens,  
12 they have integrated electrical wiring into the  
13 breathing conduit. So your question, is it always the  
14 case? I have to say no. Is it in this embodiment the  
15 case, I would say no, I don't see that.

16 BY MR. KANE:

17 Q. You don't see what?

18 A. That this is an integral part of the air flow  
19 connector.

20 Q. Okay. In your -- if 54 -- if there's no  
21 space between 54 and 14 -- okay?

22 A. Yes.

23 Q. Let's assume that there's no space. Is that  
24 separate and distinct connections?

25 MR. BELLINGER: Objection. Form.

1 THE WITNESS: Yes, if I can remove one and  
2 the other one stays.

3 BY MR. KANE:

4 Q. Excuse me. Remove what?

5 A. If you remove either the -- so let's say if I  
6 would then remove either the housing and leave the  
7 humidifier with the 14 and Chamber 10, 13, 14, 10, 11  
8 and 15 in place but just remove the housing, then the  
9 plug would either move with the housing. Then it  
10 would be separate. Or if I do the other way, I leave  
11 the housing and just remove somehow the tubing 14 with  
12 a wrench, with some force, and the plug would still  
13 stay even if they would be so close together that you  
14 might think -- you see if I touch these now, you might  
15 think they are together.

16 But now I remove this one, and this stays the  
17 same. So they are separate.

18 Q. What if it's a common wall between 54 and 14  
19 so you cannot take 14 out separately from 54 even with  
20 a wrench or screwdriver or any other tool? It's  
21 molded together into one solid piece of plastic.

22 MR. BELLINGER: Objection. Form.

23 THE WITNESS: If it is molded together, then  
24 it might meet your definition of -- there's no  
25 distance if they are molded together, and if I remove

1 one, I have to remove the other. I will effectively  
2 move the other as well. So in that way they are --  
3 it's only the electrical -- the electrical line is  
4 separated and the pressure port, as it is in the plug,  
5 the neutral and the power. The plastic housing are  
6 connected together.

7 Now, if you read again the 7 where it says an  
8 "auxiliary electrical connection plug," that's a plug  
9 or the socket. Yeah. Again, this, the figures do not  
10 indicate that they are molded together; otherwise, 54  
11 would not be possible. It also says in the patent,  
12 fairly well in 6, that one end in Column 8, one is  
13 removable and the other not. You have a removable  
14 component. And so in the end -- let's see. We talked  
15 about this already; right?

16 BY MR. KANE:

17 Q. Yes.

18 A. That one is removable, disposable, and the  
19 other not. So the fact that they talk about a  
20 disposable unit and a socket is -- clearly indicates  
21 that they're not molded together.

22 Q. Well, in that embodiment, they're not?

23 A. In that embodiment, yes.

24 MR. KANE: I think we've been going a little  
25 over an hour. Let's take a break.

1 (A recess was taken from 2:47 p.m.  
2 to 3:10 p.m.)

3 BY MR. KANE:

4 Q. All right. So let's look at -- I just want  
5 to clarify. I think I'm getting some clarity here,  
6 but I want to make sure I understand.

7 So if you go back to the '64 patent,  
8 Column 5. You pointed me earlier to the sentence that  
9 begins at Line 6. "In the present invention the  
10 connector, which includes an additional electrical and  
11 pneumatic connection 54 for the conduit, is integral  
12 to the connection manifold of the CPAP machine and  
13 therefore allows the disposable water chamber to  
14 remain as simple as possible." Do you see that?

15 A. Yes.

16 Q. But then if you look at Figure 4 where the  
17 elbow is removable --

18 A. Yes.

19 Q. -- and the connector 54 is not, that, in your  
20 interpretation, shows that it's separate and distinct,  
21 that those two components are separate and distinct?

22 A. Yes, in Figure 4. Yes.

23 Q. Okay. Is it possible for the connector, 54,  
24 to also be removable from the housing?

25 A. Everything is possible. It appears that the

1 claim doesn't construct that claim as a screw top.  
2 Like to screw this on, you might remove it, whatever.  
3 It appears it's an integral part of the CPAP housing.  
4 What are the way how they made it integral, there's no  
5 specific mention of that.

6 Q. Okay. For your analysis you assumed it was  
7 integral however that was achieved?

8 A. However it was achieved. It might be a screw  
9 below. It might be molded with the housing. It might  
10 be screwed on the housing from the inside. I have no  
11 clue how they made it.

12 Q. Okay. And then the other -- another  
13 potential configuration that we discussed was that the  
14 connector for the breathing conduit and the auxiliary  
15 connector were molded together into one piece. Do you  
16 recall that?

17 A. No, we did not establish the fact that they  
18 were molded together. You had had a hypothetical  
19 question what if they were molded together. As in  
20 Claim 7 -- Claim 7 is the last claim. It clearly  
21 states what has been established in Claim 1 through 6.  
22 It says -- starts Claim 7, "An apparatus for use in  
23 humidified gases delivery treatment as claimed in any  
24 of claim 1-6." That's how this Claim 7 starts.

25 And in Claim 1 through 6 it is well

1 established that the auxiliary port is separate from  
2 the breathing and humidification circuit, as we  
3 outlined this before.

4 Q. Well, I wasn't -- maybe I was unclear. What  
5 I was saying is I agree it was a hypothetical that I  
6 had proposed, but the hypothetical I proposed that if  
7 they were molded -- if the breathing connector and the  
8 auxiliary connector were molded into one piece --  
9 okay, that's a hypothetical?

10 A. Yes.

11 Q. And in that hypothetical, if I understood  
12 your testimony earlier, was that those would not be  
13 separate and distinct?

14 MR. BELLINGER: Objection. Form.

15 THE WITNESS: I don't want to talk about  
16 speculation. I heard hypothetical things. But the  
17 fact here is that in Claim 1 through 6 clearly  
18 established they were separate, and they established  
19 this at several levels. And now in the last claim  
20 they construct a method how to simultaneously connect  
21 two components, namely the auxiliary port and the  
22 breathing circuit in a simultaneous manner.

23 BY MR. KANE:

24 Q. Okay. So where in Claim 1 does it establish  
25 that the auxiliary connector is separate and distinct?

1 In Claim 1 --

2 A. It was --

3 Q. In Claim 1 --

4 A. No, it doesn't say -- one moment.

5 (The witness reviewed the document.)

6 THE WITNESS: No, I was mistaken. In the  
7 description of the invention, it was clearly said in  
8 Column 5, as we did this before, and in Column 6 where  
9 you're talking about the fact that one can be removed  
10 and the other one cannot be removed. So that we have  
11 both clearly demonstrated that these are separate  
12 components, including Exhibit 4.

13 BY MR. KANE:

14 Q. And we don't need to revisit all of that. I  
15 understand that your interpretation of Columns 5 and 6  
16 are that they are separate and distinct components;  
17 correct?

18 A. Yes. Correct.

19 Q. So my hypothetical is I've got two components  
20 molded together into a single plastic piece. All  
21 right?

22 A. But why do I need to talk about hypothetical  
23 when they are not?

24 Q. Because I want to understand what "separate  
25 and distinct" means. That's why. And my question is

1 whether that component, those connectors are separate  
2 and distinct under your definition.

3 MR. BELLINGER: Objection. Form.

4 THE WITNESS: As I said before, if you remove  
5 one and the other one stays put, then they are  
6 separate. Or if there is a distance between -- a  
7 measurable distance, that can be a fraction of a  
8 millimeter against the other, then they are separate.  
9 It also or -- I give you another.

10 They have to be separated because one is  
11 electrical and one is an air line. The regulations,  
12 you cannot have an electrical conduit somehow feeding  
13 into the air outlet. There has to be a separation for  
14 safety and security.

15 If there were no separation between one and  
16 the other, it will not pass regulation.

17 BY MR. KANE:

18 Q. Okay. So I'm just trying to understand. So  
19 if they are molded into one piece, would you agree  
20 with me that under your definition they would not be  
21 separate and distinct?

22 MR. BELLINGER: Objection. Form. Asked and  
23 answered.

24 THE WITNESS: If they're molded in one piece,  
25 I must still see a separation between one and the

1 other. So to answer your question, if they are molded  
2 together does not mean that they are no longer  
3 separated. They can be still molded, that there is a  
4 space between one and the other. The fact is that  
5 that depends on how you create that mold. There can  
6 be still separated by space, still have one mold but  
7 still two separate portions that are separated by  
8 distance, still one mold.

9 But it could be one mold and you can create  
10 another mold where there are 2 millimeters in  
11 distance, 1 millimeter in distance, an inch in  
12 distance. It could still be one mold. So to answer  
13 your question correctly, I would have to say whether  
14 they are separate or not separate depends on how they  
15 created the mold.

16 BY MR. KANE:

17 Q. What if they share a common wall?

18 MR. BELLINGER: Objection. Form.

19 THE WITNESS: If it is one single mold, you  
20 can create a single molding or two-phase molding,  
21 two-component molding apparatus that can be still  
22 separated. It has a common wall but can be still  
23 separated by distance. Can have an outer wall, like  
24 let's say you have a house with an outer wall, but you  
25 have two separate rooms inside the house.

1           You would not make a living room into your  
2   bedroom saying, "Oh, because they share a base and the  
3   roof, say this is the same room." They might be  
4   separated by floor in between. Still they share the  
5   same roof and the same perhaps floor.

6   BY MR. KANE:

7           Q. So then what does it mean to be not separated  
8   in that example?

9           A. If -- for instance, if you have opened up the  
10  walls between your living room and the bedroom and  
11  make it one room. But that's not possible because one  
12  is an air conduit here in this case, and the other one  
13  is electrical conduit.

14          Q. So is the way to determine whether or not  
15  it's separate is whether the humidified air is able to  
16  contact the electrical contacts?

17           MR. BELLINGER: Objection. Form.

18           THE WITNESS: That's not possible. You  
19  cannot have humidified air connecting to electrical  
20  wire. They have to be separate. You know what  
21  happens when you put water onto your electrical lines.  
22  You create shortcuts and danger.

23   BY MR. KANE:

24          Q. Okay. So they can be molded together into  
25  one piece so long as the electrical contacts do not --

1 are not exposed to the humidified air?

2 MR. BELLINGER: Objection. Form.

3 THE WITNESS: Whether they can be molded in  
4 one piece in that way, that's a matter of the molding  
5 people who create the molds. I cannot answer your  
6 question in that aspect, whether they can be molded  
7 that way or not. For that, I'd need to go to the  
8 molding specialists.

9 BY MR. KANE:

10 Q. Well, let's assume that it can be.

11 A. Why should I assume that?

12 Q. Because you're being deposed, Dr. Schneider.  
13 I'm trying to understand.

14 A. As I said --

15 Q. Here's my hypothetical. I have a  
16 hypothetical. I have gone to the molding people.  
17 They have made me a molded part. It's one piece. It  
18 has electrical contacts, and it has a portion for the  
19 breathing conduit.

20 A. Yes.

21 Q. Is that -- are those two connections separate  
22 so long as the humidified air is not able to reach the  
23 electrical contacts?

24 MR. BELLINGER: Objection. Form.

25 THE WITNESS: You see, when I am exposed to

1 these engineers, my first question would be "How did  
2 you separate these two things?" That would be my  
3 first question, to ensure safety.

4 BY MR. KANE:

5 Q. Okay. Assuming that it's safe.

6 A. That they come up with a good explanation on  
7 how well it is separated.

8 Q. Okay.

9 A. The second thing what I would do is look in  
10 the regulatory and see what are the requirements of  
11 the law to define good separation and whether it would  
12 meet that definition. As soon as I see that it is not  
13 well separated, I would say, "Don't do this mold" when  
14 there is a risk that it doesn't go through regulatory  
15 affairs.

16 So the better the separator, the likelier it  
17 is it will go through regulatory affairs. And as a  
18 designer of this one, I would not risk failing the  
19 regulation, FDA regulations and all of that. So I  
20 would make it as best separated as possible, and that  
21 is either by distance or by having something --  
22 insulation between one and the other, that it is well  
23 separated by materials. Not the same material between  
24 one and the other. But separated.

25 And it appears that they have -- that we

1 talked this over in Figure 4 and we talked -- it is  
2 explained a couple of times in the explanation that  
3 one is removable and can be -- this can be disposed  
4 and the other one not. It appears that I have done  
5 that intention exactly to be able to meet the  
6 regulatory requirements.

7 Q. And the -- well, and the separation that they  
8 achieved in the figures in the patent, then, is that  
9 the regulatory folks will be satisfied that the  
10 humidified air will not be exposed to the electrical  
11 contacts causing a short or some other problem?

12 A. Yeah. You have to be really careful.

13 MR. BELLINGER: Objection. Form.

14 THE WITNESS: There's two way that a  
15 nonseparation can be a danger. If you not well  
16 separate electrical conduit from your air, even from  
17 humidified air, if you have oxygen running through  
18 this, if you enrich the entire air with oxygen, which  
19 usually is possible and could stand -- people not only  
20 use pressure but oxygen -- then an electrical spark  
21 can lead to an explosion of the oxygen.

22 The other one is that the humidified air can  
23 corrode your electrical components. So you have to  
24 have a good separation between one and the other.

25 BY MR. KANE:

1 Q. And when you're saying, "separation" there,  
2 are you using that term in the sense of a barrier?

3 A. The separation creates in effect an  
4 impermeable barrier, whether that is by distance or  
5 whether it is by any other material. The distance  
6 creates just a gap between one and the other, which we  
7 seen in 4, that there is a gap in one or the other.  
8 So we see this in Figure 4.

9 Q. Okay. If you look at Paragraph 98 of your  
10 declaration, Dr. Schneider, for me, please.

11 A. Yes.

12 Q. Okay. And then it's talking about the Bahr  
13 prior art. Do you see that?

14 A. Yes.

15 Q. And I believe you say elsewhere that your  
16 understanding is that Bahr is used or can be used with  
17 a ventilator?

18 A. Yes.

19 Q. And you say in that second sentence there  
20 that "Bahr does not teach the disclosed device can be  
21 used in connection with a humidifier."

22 A. That's true.

23 Q. Okay.

24 MR. BELLINGER: Do you have a copy of Bahr?

25 MR. KANE: I'm handing what's been previously

1 marked as RMD 1011, which is the Bahr prior art.

2 (Previously marked Exhibit 1011 was handed  
3 to the witness.)

4 BY MR. KANE:

5 Q. Okay?

6 A. Yes.

7 Q. So if we look back to Paragraph 98 --

8 A. Yes.

9 Q. -- the third sentence says of Bahr you say,  
10 "If the electrical contacts described in Bahr were  
11 used on the gas outlet port of the CPAP device,  
12 including the devices described in the HC200 Manual,  
13 Kenyon, and Netzer, these mating surfaces could be  
14 exposed to water, including condensation form in at  
15 least the breathing conduit." Do you see that?

16 A. Yes, I see that.

17 Q. And so that is consistent with the discussion  
18 we just had that you had to have separation to avoid  
19 the condensation or water from getting to the  
20 electrical contacts; correct?

21 A. Correct.

22 Q. Okay. And it's your opinion a person of  
23 skill would not want to use the contacts in Bahr -- or  
24 a configuration such as shown in Bahr because of that  
25 problem?

1 A. Yes.

2 Q. Okay.

3 A. That's how I stated. After Paragraph 98, in  
4 99 I would say, "A skilled artisan would not have used  
5 electrical contacts placed on the mating surfaces of  
6 the breathing hose connector (like Bahr's) in a CPAP  
7 machine such as shown in Netzer, the HC200 Manual, or  
8 Kenyon because the interaction of water and the  
9 electrical components would cause serious problems."  
10 First, "Water ingress onto the connector, which is  
11 possible due to the location of the connectors as  
12 shown in Bahr, could cause short circuits that would  
13 cause inaccurate readings in" the "sensor measurements  
14 of the CPAP device. The inaccurate readings could  
15 cause the temperature of a heater wire of the  
16 breathing hose to be driven too high or too low,  
17 thereby causing harm to the patient. If the patient  
18 reconnected the breathing hose after cleaning without  
19 drying the electrical contacts, it could cause the  
20 device to malfunction from a similar electrical short.  
21 Connecting wet electrical connection could also shock  
22 and cause injury to the patient."

23 Now, I can tell you now a little bit what  
24 patients do in the home with CPAPs.

25 Q. Okay.

1           A. What can go wrong, goes wrong. It's just a  
2 matter of how many patients you put on CPAP. I have  
3 seen patients who put the mask upside down.  
4 Connecting two mates together even if it was not  
5 supposed to do. They're not cleaning it accurately.  
6 Again, they know they have to clean it. Rather, than  
7 clean it in the morning, they're cleaning it in the  
8 evening before they go to bed. The thing stays wet.  
9 You have to be very, very careful designing a CPAP  
10 machine for the home otherwise it will get litigation,  
11 and it's just a matter of time when you do a flawed  
12 design that bears the risk of that.

13           The Bahr invention is quite an interesting  
14 patent, and even I'm not aware, but that it has come  
15 into production. Maybe it was integrated into a  
16 production that was done by Siemens, 2001 whether this  
17 was part of the ventilators. I'm not aware of that.

18           If so, the ventilators were managed by  
19 skilled technicians and not used in the home as home  
20 ventilators. So there might be a totally different  
21 application. As you know, in the ICU, when you set up  
22 a ventilator in a separate room to be ready for a  
23 patient that comes in with the emergency unit, and  
24 that is usually a highly skilled intensive risk  
25 technician that they use both sterilized clothes and

1 cloth and connecting everything, ready for use on the  
2 patient.

3 Under that circumstance, such an invention  
4 might work. If you were an engineer in designing home  
5 ventilators or CPAP in the home and would come up with  
6 such a design, any project leader, project manager  
7 would say, "This solution is a no-go for home use for  
8 patients."

9 As I said, what can go wrong, goes wrong in  
10 the home, just a matter of you do 1,000 patients,  
11 10,000 patients, 100,000. We have several millions  
12 now on CPAP. So that is poor design and poor risk  
13 management.

14 Q. In Paragraph 101 of your declaration you  
15 refer to an "electrostatic discharge." Why don't you  
16 read that to yourself.

17 A. Okay. I read Paragraph 101.

18 (The witness reviewed Exhibit 2004.)

19 BY MR. KANE:

20 Q. So can you describe for me how the  
21 circumstance of electrostatic discharge through  
22 contact with the patient could occur.

23 A. We create now a new electrical component to  
24 the tubing of patients that's almost nowadays quite  
25 common that you could have a tube with electrical

1 wires. Still, you have movement of the mask that can  
2 create some electrostatic discharges. If there's  
3 tear-and-wear either on the tubing, and in particular  
4 the tubes, any tube that -- like here in the Bahr one,  
5 I can show this better on the patent application. And  
6 I refer to on the Bahr invention you'll see several  
7 transitions from, let's say, a hard plastic or even a  
8 metal that is coming out of the machine, let's say 46,  
9 44 that meets with a female connector.

10 Also there's a plastic piece, and then you  
11 have a flexible tube with spirals that goes then over  
12 a longer distance to the patient.

13 Now, very often there's kinking occurring  
14 right at the transitions from the hard piece to the  
15 soft piece, and that is so common that's why patients  
16 request new tubes all the time. Just pull this a  
17 little bit, and you can easily envision that when you  
18 have right at this edge there is tear-and-wear, and  
19 that tear-and-wear, when that is dependent on the  
20 electrical circuit, again you have to protect it  
21 somehow.

22 So the way how they currently do these tubes,  
23 they try to mold this in one piece so that you don't  
24 have these transitions. Again, this is the basis for  
25 that paragraph that any -- so there's a risk of

1 damage -- one moment.

2 (The witness further reviewed Exhibit 2004.)

3 THE WITNESS: Yeah. It's poorly written by  
4 discharge through contact with the patients. It's  
5 more like that there is electrostatic discharge that  
6 then, of course, when you have a circuit to either  
7 breaking, the circuit in the tubing, that when you  
8 create a shortcut that, of course, it fits back into  
9 the machine and you need to have surge protections and  
10 all of these things in order to not damage your CPAP  
11 machine.

12 BY MR. KANE:

13 Q. And how do the contacts in Bahr increase that  
14 risk?

15 A. As I said before, one is that the patient is  
16 not accurately connecting the tubes, male and female.

17 Second is that he has not really waited to  
18 have these -- each of these components, specifically  
19 the connectors completely dried out when he's cleaning  
20 this. Maybe even an alcohol tissue to make it really  
21 clean. Have not turned off the machine at the same  
22 time. So these are -- there's some risks associated  
23 with this.

24 As I said, this design might be possible to  
25 use in a very controlled setting, but I would be -- I

1 would not sleep comfortable having this put out to  
2 millions of patients.

3 Q. Can you identify the portion or the  
4 difference -- yeah. Let me re-ask that question.  
5 Sorry.

6 What about the Bahr context increases those  
7 risks? For example, no matter what -- how the  
8 contacts are configured, the patient could wash the  
9 tube and not wait a sufficient amount of time for the  
10 tubing and the contacts and the tubing to be  
11 completely dry; correct?

12 MR. BELLINGER: Objection. Form.

13 THE WITNESS: Yes.

14 BY MR. KANE:

15 Q. So how do the contacts at Bahr make that a  
16 worse situation?

17 A. Because the -- you see here, as we said  
18 before, it is almost a daily routine cleaning the  
19 air -- cleaning the tubes.

20 Q. And whether the Bahr contacts or some other  
21 kind of contacts, you're supposed to clean the tubes;  
22 right?

23 A. Absolutely.

24 Q. So why does the Bahr make it worse?

25 A. Because the electrical connections are part

1 of the tube. As you can see here easily, when you  
2 disassembled it, now you have to disassemble that than  
3 to clean the tube. And then even if you have couplets  
4 on the inside and then you reconnect everything, how  
5 can you make sure that a person is cleaning -- making  
6 the inside of a tube dry, make sure that it is dry  
7 before they connect it. It's impossible.

8 Q. Okay. But you understand that the claims  
9 require a simultaneous connection between the  
10 breathing tube and the auxiliary connector; right?

11 MR. BELLINGER: Objection. Form.

12 THE WITNESS: That's true. That's why you  
13 create a separate, one separate plug with the other  
14 one, to make sure that even if there is residual fluid  
15 in the tube, that this does not affect the electrical  
16 component.

17 BY MR. KANE:

18 Q. Okay. Work with me on this, Dr. Schneider.  
19 We're talking about a breathing tube; correct?

20 A. Yes.

21 Q. And the patient takes the breathing tube off  
22 and cleans it; correct?

23 A. Yes.

24 Q. And at the end of that breathing tube, it has  
25 some sort of a connector where it can create a gases

1 passageway and an electrical connection?

2 A. Yes.

3 Q. So the patient could take that tube with the  
4 electrical connections and dump it into a sink of  
5 water; correct?

6 MR. BELLINGER: Objection. Form.

7 THE WITNESS: In theory, the patient can do  
8 that too. As I said before, the patient can do  
9 whatever he wants to. I cannot refer to the connector  
10 of the tube and the tube itself because it is not  
11 shown in that patent. It just vaguely says there is a  
12 connector that can be simultaneously connected to both  
13 separate ports.

14 Now, how the engineer has created a solution  
15 for that to prevent the risk which we just discussed,  
16 I don't know because it's not shown here. Maybe it's  
17 a valve mechanism that as soon as it disconnects that  
18 connector, that shuts off automatically the electrical  
19 component. Whether there is a separation between one  
20 and the other is so far in distance that even spilling  
21 out of the tube would not prevent any contamination of  
22 fluid to the electrical component.

23 Maybe there's a vertical difference, meaning  
24 that one is much -- it's not on the same horizontal  
25 line in the connector. There's multiple ways how

1 engineers might follow the safety and security to  
2 prevent the problems which we discussed with Bahr.

3 BY MR. KANE:

4 Q. Are you familiar with heating tubes that are  
5 being used in CPAP machines today?

6 A. Yes.

7 Q. Are you familiar with the ResMed heated tube?

8 A. I think the ResMed heated tube of both of the  
9 S9 and the S10.

10 Q. Is there anything that would prevent the  
11 electrical contacts in that tube from being wetted by  
12 a patient?

13 A. They have the screw in the end. They have a  
14 screw-in mechanism. So I don't know how they've done  
15 the solution to prevent that risk. There's no power  
16 supply for that. I have to go further into detail on  
17 that. But I'm pretty sure they have done a good job  
18 in eliminating that risk that we described fairly  
19 well, as well.

20 Q. Okay. But you don't know, sitting here  
21 today, how that risk has been eliminated?

22 A. No. How they have done that. I know that  
23 this is fairly separated as well from one of the other  
24 because it has a mechanism that you have to slide over  
25 the other, the electrical components. This is the

1 tube, and then there's electrical components that's  
2 also on top, and you have to screw it into place  
3 (indicating).

4 Q. Do you know if you took a ResMed heated tube  
5 and put it into a sink of water and then stuck it into  
6 the flow generator whether the contacts would be wet?

7 A. If you take -- no, I have not done that. As  
8 I said, I would do the cleaning and everything, do it  
9 the correct way. At least teach the patients to do it  
10 the correct way. But when one thing is sure, as  
11 Einstein already said, one thing is infinite. That's  
12 the universe and human stupidity.

13 Q. Some patient somewhere is going to do  
14 something, as you said, that doesn't follow the  
15 instructions?

16 A. Yes. Because you cannot protect any  
17 incident, but you need to make it as unlikely as  
18 possible.

19 Q. And have you ever had a patient knock the  
20 CPAP off the nightstand?

21 A. That's a very good question. That problem  
22 actually occurred only recently with the -- recently  
23 as maybe in the last 10 years with the effort to make  
24 CPAP machines smaller and smaller and integrated  
25 everything. As I said, in 2000 the CPAP machines was

1 much heavier as the laptops. You see now we have here  
2 everywhere iPads, various light-weighted laptops. The  
3 same development happen on CPAP. They were quite  
4 heavy at that time, either flat. So there was no way  
5 that you could pull these off the nightstand. Or as I  
6 said at the beginning, they were even nightstands.

7 So the fact that you pull off or pull on a  
8 CPAP machine with your hose when you turn your body  
9 became a problem more and more in the recent years  
10 rather than past years in 2002 because of the light  
11 weight of the CPAP machines.

12 Q. Okay. If you'd look at, for instance, the  
13 HC200 --

14 A. Yes.

15 Q. -- is that a machine that a patient might  
16 pull off of their nightstand?

17 A. Absolutely, yes. Yes.

18 Q. Okay. And if -- so in that case, is there a  
19 possibility of the water flowing back into the flow  
20 generator?

21 A. Yes. In this design that was very well  
22 possible that under two conditions. First, you see  
23 the design of this device is that the outlet hose  
24 leaves the humidification chamber on top. And there  
25 was a good reason for that. As we discussed already,

1 we could have accumulation of fluid when there was  
2 particular U shape in the tubing. And the easiest  
3 part here was to just put your hose on top of your  
4 humidifier, and the fluid went back where it came from  
5 in the humidification chamber. There was no problem  
6 with that. That was the purpose on the top, to catch  
7 excess fluid back in there.

8 Now, the chamber here, I don't know the  
9 internal of the chamber. It's not given here. But  
10 let's just assume it's just an empty -- an empty  
11 house; right? There's no interior design. Of course,  
12 the lightness of the machine would easily bring back  
13 the fluid into the machine. That happened quite often  
14 with this machine.

15 Q. The fluid would go back into the machine if  
16 the patient knocked it off the nightstand and --

17 A. Yes. Yes. Or just -- yes. But knocked it  
18 off, really meaning knocked it off. Or just put it  
19 this way -- right? -- from horizontal to vertical.

20 Q. Okay. When you say the water would go back  
21 into the machine, you're saying the water would go  
22 back into the flow generator portion of the machine?

23 A. I don't know the interiors of this machine,  
24 but it has to go -- it came out at the end of the  
25 machine. So it went through the machine and came out

1 here. So what damage and where it went through this,  
2 I don't know. (Indicating).

3 Q. And you were just gesturing there. Why don't  
4 we figure out what page that was you were just  
5 pointing to.

6 A. It was the description of Page 7. I was  
7 depicting the portion of the CPAP machine at the back  
8 end where the air filter and filter hoses sit, and the  
9 air, the water came out here at this portion  
10 (indicating).

11 Q. Where the filter holder is?

12 A. Where the filter holder is. The electrical  
13 supply was well insulated probably. Otherwise, it  
14 would have been shocked. That's a requirement anyway.  
15 But, again, to prevent this water flowing back into  
16 the machine, that was not an issue when there was just  
17 tilting of 45, 70 or maybe up to 90 degrees. You  
18 might discuss this later. It was more a fact, as you  
19 just said, when you totally turned the machine into an  
20 upside down, vertical to horizontal. Maybe not, but  
21 you need to have a major accident. It's a way of the  
22 machine really changing the position from horizontal  
23 to vertical.

24 Q. And that problem would occur even with the  
25 humidifier chamber attached and staying in the same

1 relative position to the flow generator?

2 A. Now, remember, this is -- rather than a  
3 low-profile, it's a high-profile chamber. So as you  
4 can see here, the water level is quite low. So in  
5 order to get spillage from movement, you'll have to  
6 really create movements, shaking or -- and then in  
7 effect, then you look at the insides of that chamber,  
8 there's other mechanisms that prevented water flowing  
9 back by even greater movements, much greater  
10 movements.

11 So, again, anything can happen when you put  
12 things on a patient. Of course you can do the machine  
13 upside down or if you have something else, violence  
14 going on in the family; right? But these are not  
15 conditions of regular use.

16 Q. All right. But I guess, again, I'm just  
17 trying to clarify, again for the record,  
18 Dr. Schneider. The situation that we're talking about  
19 where these major accidents would occur would be a  
20 situation where -- looking at the HC200, Page 7, the  
21 humidifier chamber has water?

22 A. Yes.

23 Q. The humidifier chamber has been attached to  
24 the flow generator, and the chamber guard is holding  
25 it in place; correct?

1           A.   Yes.

2           Q.   And then there is some sort of an upset or  
3   accident that causes the combined unit, the flow  
4   generator and the humidifier chamber to not be  
5   horizontal, be it 90 degrees or upside down or  
6   whatever the condition is; correct?

7           A.   Correct.

8           Q.   And then in that circumstance you have seen  
9   water flow back through the humidifier chamber and  
10   exit from the portion of the flow generator we talked  
11   about earlier near the filter holder?

12          A.   Yeah.  I can only say I've seen patients  
13   coming back or telling that the water came back, and  
14   the only report is "Did the machine fall from your  
15   table or something like that," and they said yes.  So  
16   I don't know whether it was 90 degrees, whether it was  
17   180 degrees with a flip, turn, all of these things.  
18   We usually advise the patient to actually extend the  
19   tube from 6 feet to 12 feet and creating a Klen  
20   (phonetic) on -- somewhere between the machine and the  
21   blanket so that when they move, that there is no  
22   traction or pulling on the machine.

23                But we don't do this in everyone because  
24   that's a rare instance.  It's much more common that  
25   patients place this machine on, let's say, not really

1 on a plane, horizontal surface that there's a book or  
2 a newspaper underneath so it's not totally plane and,  
3 again, that would be a problem for -- not for this  
4 device, because it's a high-profile chamber, not a low  
5 profile chamber. And the air is coming out of the  
6 top. So this was no risk that through the tilting  
7 that air goes into the tubing.

8 Q. You said the air goes into the tubing?

9 A. No. Even if you tilt this 45 degrees, that's  
10 already a lot. If you adhere to the instructions  
11 having the water level only half full, since the  
12 outlet is on top, there is little likelihood that this  
13 leads to spillage of water into the outlet tube.

14 Now, as we can see later, the inlet port has  
15 almost a mechanism involved -- it's not shown in the  
16 HC200 -- that creates a protection from tilting,  
17 drawing water into the machine under regular use, and  
18 the regular use, I mean it still can have variations  
19 of about 45, maybe 70 degrees of your device in any  
20 direction without risking spillage of water.

21 Q. Are you -- is it also desirable to prevent  
22 the water from coming out of the patient -- or getting  
23 into the patient conduit to the tube, as you said?

24 A. Yeah. That is very desirable. If you  
25 breathe in one droplet in the night in your nose, you

1 wake up instantly like having had mosquitoes in your  
2 nose.

3 Q. I didn't quite catch that. You said if you  
4 breathe in what?

5 A. If you breathe -- if you inspire through the  
6 mask, and then in a sudden you get water into your  
7 nose, you'll wake up instantly. It's like water  
8 boarding or like having a mosquito biting you in your  
9 nose. You get startled. That's unbelievable.

10 Q. Have you ever seen that in a patient or heard  
11 about that in a patient?

12 A. I've heard this in patients, and I have  
13 experienced this myself. I do a lot of CPAP on myself  
14 on experimental basis when we test out new things.

15 Q. And under what circumstances did that happen  
16 where -- let's start with you personally, that you  
17 ended up with water in your nose?

18 A. Because you see when you have a poor  
19 humidification system, meaning, for instance, that you  
20 have rainout in the tubing, as we said, for several  
21 reasons, just disconnecting and connecting it again,  
22 and not making sure you have emptied the hose. It is  
23 not the fault system. It's just by nature, as we  
24 talked high pressure versus low pressure. If you put  
25 it on again, then you got the air droplets in your

1 nose with the next breathing because you have water in  
2 the tube.

3 Q. Okay.

4 A. When you take a deep breath, then you get  
5 half water, half air.

6 Q. I see. And what about any patient --

7 A. The patients, sometimes you have to tell them  
8 how to place that tubing that the CPAP machine is  
9 always lower than the bed unit and the patient so that  
10 when water flows back, it can flow back into the  
11 humidification unit rather than into the patient.

12 If you put the patient on -- a CPAP machine  
13 on top of your nightstand, that's where the risk is.

14 Q. And the risk being that water gets into the  
15 patient tube and the patient inspires?

16 A. Yes. That's why you want to prevent both  
17 spillage for the outlet and spillage for the inlet,  
18 and now engineers are pretty sure that they can  
19 prevent damage to the CPAP machine by internal  
20 configuration, but you cannot prevent damage to the  
21 patient. You might lose your patient to the  
22 treatment, "No way. I don't want to do this anymore."

23 Q. That doesn't want to put that machine back on  
24 after that experience?

25 A. Absolutely.

1 MR. KANE: Why don't we take a break.

2 (A recess was taken from 4:06 p.m.

3 to 4:28 p.m.)

4  
5 EXAMINATION

6 BY MR. HOFF:

7 Q. We're going to switch gears and talk about  
8 the '197 patent now.

9 A. What was your name again?

10 Q. Chris Hoff.

11 A. Thank you.

12 Q. So it's IPR2016-01719.

13 A. Yes.

14 Q. And here I'm handing you your declaration.

15 A. Yes.

16 Q. We were talking about U.S. Patent 6,398,197.

17 A. Yes.

18 Q. Do you recognize this document?

19 A. Yes, I do.

20 Q. What is it?

21 A. It is a patent humidification chamber.

22 Q. The document I just handed you.

23 A. Oh, yes. It's my declaration.

24 Q. Can you turn to the last page, Page 67.

25 A. I have that here.

1 Q. Is that your signature on the back?

2 A. That's my signature.

3 Q. So I want to kind of go back to some of the  
4 discussion about the HC200. You had mentioned when  
5 the HC200 came out, people laughed at it. Why did  
6 people laugh at it?

7 A. Because the portion of the high-profile  
8 chamber was much bigger than -- almost as big as the  
9 CPAP machine. At that time the Sullivan CPAP machine,  
10 the European CPAP machine from SEFAM, they were all  
11 quite big machines, and the humidifier was either  
12 attached -- most of the times below, as a small  
13 add-on. Now, this appears to be a chamber with an  
14 added CPAP machine.

15 Q. So you thought that the form factor looked  
16 odd?

17 A. No. It was a change in paradigms. That's  
18 now a company who has paid more attention on  
19 humidification rather than -- it didn't look right.  
20 Everybody was, "We have better machine. We have quiet  
21 housing," this one and that one. It was a change in  
22 paradigm, and it might be the right change in  
23 paradigm.

24 Q. Okay. Were there any problems with the  
25 HC200? I think before you mentioned that it could --

1 frequently water would go back through the blower  
2 outlet?

3 MR. BELLINGER: Objection. Form.  
4 Foundation.

5 THE WITNESS: No. No, that's not true. I  
6 said in the rare cases where a patient was really  
7 flipping the device, then it was -- there was CPAP --  
8 there was water running out of either the outlet or  
9 the inlet. But that -- again, that was either due to  
10 the fact that you have had an additional nightmare or  
11 where you just suddenly jump out of the bed -- so  
12 there was a disease behind that -- or that patient --  
13 for some other reasons, getting started.

14 But, again, these are rare instances as an  
15 accident in your car when you drive too fast or do  
16 something else that is extraordinary.

17 MR. HOFF: I'm going to hand you what's  
18 marked as Exhibit RMD 1015.

19 (Previously marked Exhibit 1015 was handed  
20 to the witness.)

21 BY MR. HOFF:

22 Q. I'd like you to turn to Page 9.

23 A. Yes.

24 Q. Well, first off, what is this?

25 A. This is the HC200 manual of the -- yes. Of

1 the early years.

2 Q. All right. So if you could turn to Page 9.

3 A. Yes.

4 Q. It's a little confusing on the bottom. It's  
5 Exhibit Page 9, but it's actually marked as Page 8 in  
6 the manual?

7 A. Yes.

8 Q. So on the right-hand side, kind of towards  
9 the top of the document there's an underlined all bold  
10 statement "CAUTION."

11 A. Yes.

12 Q. Do you see that?

13 A. Yes, I see that.

14 Q. Do you see below that it says, "CAUTION:  
15 "Avoid moving or tilting the HC200 when the  
16 humidification chamber is full of water"?

17 A. Yes, I see that.

18 Q. Does that warning address the spillage issue  
19 you just mentioned?

20 A. No.

21 Q. What does this warning pertain to?

22 A. First of all, it's in the manual that you  
23 create for patients. It not only serves for teaching  
24 a patient proper use, but also to give you some sort  
25 of protection for any potential litigation. The fact

1 is that you now have on the coffeepot, "Be careful not  
2 drinking too hot" after that case of burned, that one  
3 woman. There is cautionary notes everywhere where you  
4 think it shouldn't be there. It is self-evident.

5 THE REPORTER: As you see here on Page 6 --  
6 no, on the same manual, there's warning of electrical  
7 danger. Now, why is that warning of electrical  
8 danger? It's not because the plug of the HC200 is  
9 faulty. It is just that you can't control the  
10 conditions of the plug in the house of a patient. You  
11 need to give a cautionary note.

12 This one, I see the same thing with this one.  
13 If a patient would follow the instructions here, there  
14 was no danger of tilting, getting water into the  
15 machine except that he did not. Let's say if he turns  
16 it 90 percent; right? But then he's not following the  
17 instructions.

18 Q. So you're saying if the instructions are  
19 followed, this warning doesn't matter?

20 A. Doesn't matter.

21 Q. But it's possible that someone wouldn't  
22 follow the instructions?

23 A. It's possible that patients lie, and they  
24 say, "I did follow the instructions," but in  
25 actuality, they did not.

1           Q. So if a patient didn't follow the  
2 instructions and tilted HC200 while the humidification  
3 chamber was full --

4           A. Let's say if the patient would come back and  
5 say, "I did follow the instructions and the tilting  
6 was not more than 70 or 50 degrees. I was carrying  
7 the machine -- let's say I was filling the machine and  
8 I was carrying it from the bathroom to my bed" --

9           Q. With it assembled?

10          A. With it assembled and everything. Then  
11 tilting is water falling back was not an issue. If he  
12 said by that motion water was falling back, then you  
13 could easily demonstrate it is not possible, that he  
14 has underestimated the movement of his -- that you  
15 might have really put it upside down or whatever.

16          Q. I'm sorry. What was not possible?

17          A. It was not possible, the way, because we  
18 mentioned that before, and it is well displayed on  
19 Figure 2 here. It is a high-profile chamber, not a  
20 low-profile water chamber. And if they probably  
21 filled the water level to half of the height of the  
22 chamber, that water would flow back by just carrying  
23 it from the bedroom to the bath -- from the bathroom  
24 to the bedroom, it is -- it was unlikely that water  
25 came either out of the inlet or the outlet because the

1 outlet is on top. So it's a far distance between the  
2 water level and between both the inlet and the outlet.

3 Now, in case that it was still water in the  
4 machine, now there's cautionary notice there to  
5 protect your company. Under regular conditions it  
6 doesn't happen, and under the unregular use, excessive  
7 force to the machine, it might happen, and then you  
8 insert a cautionary note in there.

9 Q. So I believe before you said what -- let me  
10 back up.

11 So the HC200 is designed for in-home use;  
12 correct?

13 A. Yes.

14 Q. And I believe before you said what can go  
15 wrong will go wrong in an in-home use setting;  
16 correct?

17 A. Correct.

18 Q. And so is it fair to assume that some  
19 patients are not going to follow the water level line  
20 and might overflow?

21 A. Everything is possible, yes.

22 Q. And in the event that someone overfills and  
23 they carry the device around, it's more likely then  
24 that water would go either through the patient outlet  
25 or through the blower outlet; is that right?

1           A. If you overfill it to the top, then of course  
2 it's possible, yes.

3           Q. Okay. What are ways that you could minimize  
4 the risk of water going back through the blower  
5 outlet?

6           MR. BELLINGER: Objection. Form.

7           THE WITNESS: Creating a smart design inside.  
8 Either a valve that prevents water coming back, to  
9 preventing tubes, tubulars, all kinds you can envision  
10 to prevent it.

11 BY MR. HOFF:

12          Q. Let's go back to the valve first. Where  
13 would the valve be placed?

14          A. If you were to -- let's say if your CPAP  
15 machine really breaks with water flowing back into the  
16 machine, that's a serious problem. Even if the CPAP  
17 machine -- it's a serious problem when you no longer  
18 can use the machine. That means when you can no  
19 longer can use the machine, you put the patient in  
20 danger or you have to have an emergency system in  
21 place that immediately, within hours, can replace the  
22 device.

23          Q. So the valve -- would the valve be located in  
24 the blower unit itself?

25          A. No. You can do this in the humidification

1 chamber if you decide to go for valves in one way that  
2 just closes. That could be one solution.

3 Q. Okay. Did you -- were there humidification  
4 chambers that had valves?

5 A. I'm not aware of that. I'm aware that we  
6 have had valves at the mask, and in the past we have  
7 had valves at the outlet of the CPAP machine, one-way  
8 valves.

9 Q. And then I believe you also said another way  
10 to minimize the potential risk would be through a  
11 tube; is that correct?

12 MR. BELLINGER: Objection. Form.  
13 Foundation.

14 THE WITNESS: Tube or tubulars, however you  
15 create that, yes, the inside.

16 BY MR. HOFF:

17 Q. And where would the tube be placed?

18 A. Far away from the surface of the water. So  
19 it would be somewhere in the distance and in a way  
20 that you can tilt without risking the water that goes  
21 into that.

22 Q. So the tube would be connected to the inlet  
23 of the water chamber; is that correct?

24 A. Yes. It would create -- in order to prevent  
25 the flowing back into the machine, you would create a

1 tube at the inlet, yes.

2 Q. And so what sort of situations would the tube  
3 help to mitigate -- let me start over.

4 What sort of risks associated with water  
5 going back into the blower would the tube help  
6 mitigate?

7 MR. BELLINGER: Objection. Form.

8 THE WITNESS: The primary risk is, here  
9 again, when the patient wants to use the CPAP in the  
10 night, when the patient is actually in danger of sleep  
11 apnea, people can die from sleep apnea if it's severe  
12 sleep apnea. If the patient believes he can no longer  
13 use the CPAP machine because he is seeing water coming  
14 out of the machine. Now, this is not the primary  
15 responsibility of the manufacturer. It is the  
16 intermediary provider which, usually a DME company,  
17 durable medical equipment device company, that stands  
18 between the manufacturer and the insurer and the  
19 patient, and the insurer is paying the DME company.

20 And the contract of the payer is also that  
21 the DME company who provides the care for the patient,  
22 like a pharmacy, makes sure that the patient gets  
23 replacement if there's something wrong with the  
24 machine, replacement of the mask and the tubing.  
25 That's what they're getting paid for, that service, to

1 make sure there's continuity in the service in case  
2 that something happens or in case that the need for a  
3 new machine.

4 BY MR. HOFF:

5 Q. So just so I understand. So the DME company  
6 would be the one who would be looking to place a tube  
7 on the --

8 A. The DME --

9 MR. BELLINGER: Objection.

10 THE WITNESS: No. The DME company is  
11 responsible for ensuring the training and the  
12 education of the patient. Now, and the reason here is  
13 also responsible for making sure that the patient is  
14 using CPAP by calling the patient or by monitoring the  
15 patient. The DME is not responsible for any design of  
16 the manufacturer or of the humidification chamber,  
17 whether there's tubes inside or whatever. That's not  
18 what -- the DME is just taking the machine that is  
19 prescribed and teaching the patient how to use it in a  
20 proper way.

21 BY MR. HOFF:

22 Q. Okay.

23 A. And in that way the DME company would hand  
24 out that user's manual to the patient. They will  
25 explain that, the use of it, and that's why this

1 manual has been in plain and simple language, as it  
2 is, with symbols, precautionary notes of how to put  
3 even an electrical plug into the outlet, and it has a  
4 danger if you connect a plug into an outlet even  
5 though everyone does it on a daily basis.

6 There is a picture on Page 6 where you see  
7 all the components that can be detached or attached in  
8 a simple way, and then there's some risks to how to  
9 set it up, how to operate that. And then, again, of  
10 course, you have some caution on each page, Page 7.  
11 There's cautionary notes of excessive condensation.  
12 We talked about that, how that might happen.

13 And there's, of course, cautionary note on  
14 Page 8 that if you don't use it adequately, then you  
15 might have the risk that water comes back into the  
16 machine, that what happens with low CPAP pressure.  
17 There's on each page a cautionary note or one. And  
18 that is part of any manual.

19 Q. Okay. So just to clarify, so there is,  
20 although the manual provides instructions to a user on  
21 how to operate the device, there is a risk that they  
22 could operate the device in a way that would permit  
23 water to flow back into the blower; correct?

24 A. There's always the possibility and the risk  
25 that that can happen, yes. Even though it is very

1 rare.

2 Q. And even if the user followed all the  
3 directions, there's always a risk of an accident. For  
4 example, the device tipping; correct?

5 A. "Tipping," meaning putting it upside down.  
6 You are just tipping or changing the horizontal level  
7 to, let's say, a plus/minus 45 degrees, which is  
8 substantial, under these conditions. It would not  
9 happen. It would happen when, as I said, we have an  
10 accident that you throw the machine out from your side  
11 stand.

12 Q. For example, the machine falls off your  
13 bedside table?

14 A. Yes, and twists and turns. Yes.

15 Q. Okay. Are there any other potential problems  
16 that the HC200 presented in terms of providing therapy  
17 to a user?

18 MR. BELLINGER: Objection. Form.

19 THE WITNESS: As I said, I've not used the  
20 HC200 in too many patients. It was -- no, I have not  
21 seen any other -- the CPAP pressure was not as  
22 optimal as in other devices. There was much more --  
23 it was not less constant as in other devices.

24 BY MR. HOFF:

25 Q. So why was that?

1           A. That depends on the speed of the -- power of  
2 the blower.

3           Q. Okay.

4           A. That is the Respironics one was very poor.  
5 In the end of the '90's almost all CPAP machines were  
6 not as meant to be constant, positive airway pressure  
7 to an inspiration and expiration. It was actually  
8 when the patient takes a deep breath that the blower  
9 could not respond fast enough in the '90's to keep up  
10 with the pressure, just accelerate the speed so that  
11 the pressure remained constant to inspiration and to  
12 an expiration. You need to lower the speed of the  
13 blower, keep it constant.

14           And the reason why the technology was not  
15 ready is because it was just switched from a valve  
16 system to a nonvalve system. The valve clicked with  
17 each inspiration, expiration, and then someone came up  
18 and said, "We don't need a valve there on the mask.  
19 We can regulate the speed of the engine to provide  
20 enough flow and consistency."

21           Q. So one thing you mentioned earlier was that  
22 one of the paradigm shifts of the HC200 was that it  
23 had a tall water chamber; right?

24           A. Yes.

25           Q. And previous water chambers before the HC200,

1 they were wider and they were flatter, or not as tall?

2 A. Yes. The first generation of humidifiers was  
3 simply cold pass-over principle, meaning you had just  
4 a small -- a large base where water is as a large  
5 surface area, and then you pass air over this. Again,  
6 it was not heated, and for that, in order to get  
7 enough humidification you needed to have a large  
8 surface area. But it was never really very  
9 sufficient.

10 Q. Okay. So by moving to a taller chamber, did  
11 the outlet and the inlet to the chamber become closer  
12 together in the HC200?

13 A. Not necessarily. They might appear for the  
14 dimensions. There was several cold passovers. See,  
15 the difference within these two, between the inlet and  
16 outlet as depicted on Page 6 of that might be the same  
17 difference. In the cold pass-over, for instance,  
18 there was one from Rose, I believe, cold pass-over  
19 with an inlet and an outlet. They were also close  
20 together. This is not the same.

21 Q. What did Rose do to avoid short circuiting?

22 MR. BELLINGER: Objection. Form.

23 THE WITNESS: That's a totally different  
24 design because the CPAP machine was on top, and you  
25 connected tubes from the CPAP to the inlet and then

1 another small tube, it was about a foot long, maybe 20  
2 to 30 centimeters, and that connected you to the CPAP  
3 machine which was on top of the humidifier. So you  
4 would have had the air coming from the CPAP outlet to  
5 the inlet of the humidifier, and then from the  
6 humidifier you have the outlet to the patient.

7 And since the CPAP machine, as we said  
8 before, was quite heavy, this was as -- cold pass-over  
9 usually were either on the side stand, and then the  
10 CPAP machine was on top of it. So it was plain and  
11 horizontal. That's why it could be a low profile CPAP  
12 device. We didn't want to have a high-profile CPAP  
13 with your chamber that big and then on top another  
14 CPAP device; right?

15 BY MR. HOFF:

16 Q. How did the structures inside the water  
17 chamber impact humidification?

18 A. That affects -- again, the basic principle of  
19 this cold pass-over humidification was if you wanted  
20 to direct air flow and expose the air flow to as much  
21 surface area as you can, you created a surface area.  
22 The crater would be the humidification.

23 Now, that passing air flow over this cold  
24 pass-over humidifiers worked quite okay when you have  
25 low speed, low pressure, 6, 7, 8 centimeters, maybe up

1 to 10 centimeters. But as soon as you started to use  
2 high pressure and high air flows, that created some  
3 problems, splashing to the outlet of the humidifier.  
4 There was almost -- in particular, a problem in eye  
5 level CPAP. It's called eye-level PAP. So that means  
6 the pressure during inspiration is much higher than  
7 during expiration, and then you have pulse waves  
8 coming and forcing on the water surface, and these  
9 pulse -- because to an inspiration the pressure was  
10 5 centimeters or 10 centimeters higher than during  
11 expiration. Then you are always (indicating).

12 That pressure goes into a cold pass-over, and  
13 usually that created wave forms that either you  
14 couldn't use eye PAP, or you couldn't use eye-level  
15 CPAP pressures or you couldn't use the humidifiers.

16 Q. So in terms of max -- it sounds like one of  
17 the things impacting humidification is the surface  
18 area of the water; correct?

19 A. Uh-huh.

20 Q. And so in a device like the HC200 that is  
21 taller and has a smaller diameter than water chambers  
22 before, how would you go about maximizing the air flow  
23 over the surface area of the water?

24 MR. BELLINGER: Objection. Form.

25 THE WITNESS: On a heated humidifier it's no

1 longer that much an issue because that's the purpose  
2 of the heated. The warmer the water, the easier is it  
3 to expel molecules into the air. So what we said the  
4 principle said before is very important and true for  
5 cold pass-over humidifiers. As soon as you have  
6 heated humidifiers, you can reduce the surface area  
7 because you can increase the temperature, and by that  
8 you can create air and humidification, vaporizing  
9 molecules. That's what the purpose is of  
10 humidification.

11 BY MR. HOFF:

12 Q. Are there other factors that would impact the  
13 level of humidification?

14 A. So temperature of water is one. If you  
15 create -- if you go to create and there is other  
16 humidifiers, like in nebulizers, where you have high  
17 frequency motions on a humidifier, that doesn't create  
18 waves but it creates a little bit of frequency that  
19 allows to expel more molecules in the water. That's  
20 the principle of the nebulizers.

21 So temperature, surface area, turbulences  
22 that you might -- if you have laminar air flow, the  
23 flow is less likely to carry the molecules away that  
24 sits on the surface of water. If you have turbulence  
25 air flow --

1 Q. So turbulence, if there's more turbulence,  
2 that improves humidification?

3 A. Yes.

4 Q. And so to achieve turbulence, you need the  
5 air to be flowing onto the water?

6 A. No. You need to change the direction of air  
7 flow. You need to create -- so a laminar is one  
8 constant air flow in one direction.

9 As soon as it change directions of the air  
10 flow, or if you direct this air flow into -- by other  
11 means, changing directions, that's turbulence. The  
12 more turbulence you have, the higher you can vaporize  
13 the air with water.

14 Now, the problem with turbulence is that it  
15 creates noise. So you have to balance then. You have  
16 to really measure and you have to protect to see  
17 whether you are going to create turbulence to increase  
18 the humidification with that method, whether then you  
19 create another side effect.

20 Q. And how do you go about breaking up the  
21 laminar flow to create turbulence in a humidifier?

22 MR. BELLINGER: Objection. Form.

23 THE WITNESS: There are several ways to do  
24 that. There are multiple ways to do this. One is you  
25 create a narrow entrance, change in the diameter in

1 the entrance so it speeds up. You create a specific  
2 way how to direct the air flow by creating chambers  
3 inside the humidifier, like honey bee chambers.

4 Then again, you can create -- there's all  
5 different ways. We have to make the air flow from  
6 laminar to nonlaminar by trying to change directions  
7 of the air flow, both in a horizontal or in the  
8 vertical axis.

9 Now, if you have a low-profile device, any  
10 change in the vertical direction might create waves.  
11 That's why you need to be careful, not changing the  
12 shape of the height. If you have a high profile, you  
13 can change direction in both directions, horizontal  
14 and vertical.

15 BY MR. HOFF:

16 Q. And how would you go about accomplishing a  
17 change in direction?

18 MR. BELLINGER: Objection.

19 THE WITNESS: The air goes into -- hits  
20 something, either that one hits a wall or then it has  
21 to be directed in another way according to what comes  
22 here about a CPAP device. Flow follows like water the  
23 pressure gradient. At the end of your humidification  
24 chamber, you have lower pressure of inlet and the air  
25 finds its way. Whether you have multiple chambers, it

1 always finds a way from high to low pressure.

2 BY MR. HOFF:

3 Q. So looking at the HC200 device that's  
4 depicted, for example --

5 A. Yes.

6 Q. -- looking at Page 1 here (indicating).

7 A. Yes.

8 Q. It looks like there would be a pretty clear  
9 laminar flow from the lower outlet to the patient  
10 outlet there.

11 A. From the inlet to the patient outlet, yes.

12 Q. Yeah.

13 A. So on this first figure, I can only see that  
14 there is a groove as you cannot see on the outlet;  
15 right? It goes inlet. And then you have some of  
16 these flanges here on the outlet. Can you see that?  
17 (Indicating)

18 Q. Yes.

19 A. Now, that can create turbulence, and maybe  
20 that was the solution of the engineers for the HD200  
21 because if you wouldn't have that, the air flow that  
22 comes directly out of the machine would create a  
23 laminar flow, as you correctly pointed out, from  
24 the -- in this time inlet to the humidification to the  
25 outlet and not passing a lot of air molecules because

1     it has not passed the surface.

2           Q.   So just to summarize, what you identified on  
3   Page 1 on the HC200 manual is a structure that would  
4   lock laminar flow at least partially to the out -- to  
5   the patient outlet; is that correct?

6           A.   No.   This start to create some turbulence.   I  
7   did not say locked laminar flow.   I said it is likely  
8   that these structures create some turbulence.   It  
9   might be still what you can see is some laminar flow,  
10   but it's just the edges that creates some turbulence.

11          Q.   To increase the turbulence in the HC200 water  
12   chamber, are there some things that you could do?

13               MR. BELLINGER:   Objection.   Form.  
14   Foundation.

15               THE WITNESS:   You would create -- as I said,  
16   any turbulence flow has the danger to create noise,  
17   very unsatisfactory noise.   When I look at this one  
18   here, I would expect some noise if this were the  
19   design of the chamber.   Now, I don't know whether this  
20   is simply -- is not picture.   It may be simply a  
21   drawing and hiding something.   (Indicating)

22               The basic principle is we want to create  
23   smooth and laminar flow where we reduce turbulence as  
24   best as possible by not creating sharp edges.   Here  
25   you look at this picture again.   The three edges you

1 see are sharp edges. You want to reduce sharp edges.  
2 You want to increase the laminar flow as much as you  
3 can.

4 BY MR. HOFF:

5 Q. It sounds to me like there's a tension  
6 between noise and turbulence.

7 A. Oh, absolutely.

8 Q. The more sharp edges, the more turbulence,  
9 but also the more noise. Is that fair to say?

10 A. Yes, that's clear to say.

11 Q. So what would be more effective for patient  
12 therapy? More turbulence and better humidification,  
13 or more noise -- sorry. Let me start over.

14 What would be better for a patient? More  
15 turbulence and more noise to create more  
16 humidification or less turbulence and less noise and  
17 less humidification?

18 MR. BELLINGER: Objection. Form.

19 THE WITNESS: The noise -- if the noise  
20 prevents you from using it, the humidification doesn't  
21 matter. Even if it's the best humidification, the  
22 patient will not use it. So the noise is the major  
23 obstacle of a patient to use it. If it makes a  
24 humming noise, a noise like a mosquito, if it's a  
25 high-pitched noise, the patient will accept this.

1 BY MR. HOFF:

2 Q. What are some ways to create turbulence and  
3 minimize noise?

4 MR. BELLINGER: Objection. Form.

5 THE WITNESS: As I said, you would choose  
6 sharp edges and make them soft edges or smooth edges,  
7 curvature, anything that creates a sudden change in  
8 the direction. You try to make sure that when air  
9 enters from a tube into a large -- from a small bore  
10 tube to a larger bore tube, for instance, then that  
11 you have according -- you'll have change in speed  
12 because of change in diameter.

13 Then the flow has not -- the wall somewhere,  
14 such as when there's a shutter effect. These are all  
15 kinds of change, things that you want to prevent.  
16 Sudden changes -- large changes in a small or short  
17 unit, time unit or distance.

18 BY MR. HOFF:

19 Q. Let's go back to talking about spillage and  
20 tubes. Is there a relationship between how much  
21 spillage could be prevented and the length of a tube?

22 MR. BELLINGER: Objection. Form.

23 THE WITNESS: You see, no, it's not clear  
24 relationship. A little spillage can do a lot of harm  
25 already, as we said before. Little spillage in the

1 outlet to the patient. It all depends on -- let's say  
2 if you have bended your CPAP tubing in a U shape like  
3 that, then you still have accumulate a lot of water,  
4 but there's still air that passes by over the surface  
5 in the tube.

6 If your tube is like a narrow U, then it  
7 might plug the entire tube, or a little bit it might  
8 block the entire tube from air passage. You got the  
9 concept?

10 BY MR. HOFF:

11 Q. Yeah, I think I do.

12 A. Yes.

13 Q. So just to summarize what you said is that  
14 the length of the tube doesn't necessarily impact  
15 spill prevention?

16 A. No, I didn't say that. I talked about the  
17 CPAP tubing.

18 Q. Oh. I'm talking -- sorry. Let me back up.

19 So I was talking about -- we talked earlier  
20 about a tube being placed on, for example, the inlet  
21 to the water chamber as a way to prevent a sudden  
22 horizontal to vertical.

23 A. That tube inside of an extension tube, inside  
24 on the inlet. The longer the tube, the more it will  
25 prevent spillage.

1 Q. Okay.

2 A. And here, as I said, I don't see any inside  
3 tube on the HC200 manual. That's why I was talking  
4 only to the outside tubing.

5 Q. Okay. Got it.

6 A. Okay.

7 (Previously marked Exhibit 1012 was handed  
8 to the witness.)

9 BY MR. HOFF:

10 Q. I'm going to hand you what's marked as  
11 Exhibit RMD 1012.

12 Are you familiar with this reference,  
13 Dr. Schneider?

14 A. It looks similar to this one. I'm not quite  
15 clear whether this is the same or not. Let me have a  
16 look at that. Or whether this is a later version of  
17 that. (Indicating)

18 Q. It was included with the petition.

19 (The witness reviewed Exhibit 1012.)

20 THE WITNESS: I might have seen it, but I  
21 might have also overlooked a couple things because I  
22 might have thought it was the same manual as this one.  
23 I cannot directly answer whether I'm familiar with  
24 the -- this document, but I'm familiar with most of  
25 the pictures. (Indicating)

1 BY MR. HOFF:

2 Q. Okay. It's fair to say you're familiar with  
3 the HC200 device --

4 A. Yes.

5 Q. -- right?

6 A. Yes.

7 Q. And is it also fair to say that this manual  
8 appears to describe the HC200 device as you understand  
9 it?

10 A. I see it says it in the title, "HC200 Series  
11 Humidified CPAP System."

12 Q. I just want to check on the first page of the  
13 manual, it's actually Page 12 there.

14 A. Yes. Yes.

15 Q. So on the next entitled "Troubleshooting" --

16 A. Yes.

17 Q. -- it says, "In the unlikely event that you  
18 tip water into the blower outlet," and then it  
19 provides instructions, "remove air filter and chamber.  
20 Shake excess water out of the back of the unit. Turn  
21 unit on. Apply pressure for five minutes, then  
22 reassemble and use as directed." Do you see that  
23 portion?

24 A. I see that, yes.

25 Q. This recitation is also describing the

1 possibility of water going back through the blower  
2 outlet in the HC200 device?

3 A. Again, in the unlikely -- as it says, in the  
4 unlikely event, it might happen. As we said, things  
5 can go wrong, like you can get in an accident when you  
6 drive with your car. It's an unlikely event that you  
7 run into an accident. Now, what is remarkable on this  
8 one is that they have actually a mechanism and that it  
9 did not damage the machine. So that's quite a good  
10 engineering that you can just say, "Shake the excess  
11 water out. Then turn the unit on again and then  
12 reassemble." So that was quite unique that you didn't  
13 damage the CPAP machine. So...

14 Q. But it's fair to say, reading this, that it  
15 was understood that that was a risk with the HC200  
16 device?

17 A. Of course it's a risk with any integrated  
18 humidification device.

19 MR. HOFF: Why don't we take a break.

20 (A recess was taken from 5:15 p.m.  
21 to 5:29 p.m.)

22 THE WITNESS: Can I correct my last sentence?

23 BY MR. HOFF:

24 Q. Sure.

25 A. When I said there is the unlikely risk that

1 water spills back in the HC200. I said in any CPAP  
2 device. I was referring in any HC200 device.

3 Q. Okay. As a follow-up to that, was spillback  
4 a problem more broadly in CPAP devices?

5 MR. BELLINGER: Objection. Form.

6 THE WITNESS: That depends on the  
7 configuration between the humidifier and the CPAP  
8 device in 2000. At that time there was -- the MAP  
9 also could have had a similar configuration with a  
10 humidification chamber attached to the CPAP machine,  
11 integrated into the CPAP machine. Here it was a  
12 problem too.

13 BY MR. HOFF:

14 Q. I think I've seen that.

15 A. Yeah.

16 Q. Is it fair to say that, with any smaller CPAP  
17 device, that spillback would be a problem?

18 MR. BELLINGER: Objection. Form.

19 THE WITNESS: That's hard to say. As we  
20 said, movement of patients can occur when they have  
21 nightmares, sudden night terrors. They have the mask  
22 on, stand up. There's even one disease that's called  
23 Shanks Syndrome, meaning there is people act out what  
24 they dream. So they dream standing up doing  
25 something. When they have the mask on they can --

1 anyone can pull off a CPAP machine regardless of the  
2 weight under these conditions from the side table and  
3 then can -- regardless how heavy it is, it can flip  
4 down and then it spills back.

5 Now, how big the problem is for it depends on  
6 how well the CPAP machine is manufactured and  
7 isolated. As I said, it appears remarkable that in  
8 this HC200 water can fall back and still doesn't  
9 destroy the machine. I'm not aware that other CPAP  
10 machines would function in the same way.

11 Again, this is unlikely event. If that event  
12 was more likely if it was one device than the other,  
13 there would have definitely been a recall of such  
14 devices. I'm not aware of any recall of the HC200.  
15 So meaning the spillage in that device was not more or  
16 less than another, any other device.

17 BY MR. HOFF:

18 Q. Okay. I just want to switch back to talking  
19 about the inlet tube --

20 A. Yes.

21 Q. -- in the water chamber.

22 A. Yes.

23 Q. And --

24 A. But that's not depicted in the HC200.

25 Q. Not specifically with regard to the HC200.

1           A.    Okay.

2           Q.    The inlet tube in a humidification device,  
3           how would that impact noise if you had it in a  
4           humidification chamber?

5                   MR. BELLINGER:  Objection.  Form.  Vague.

6                   THE WITNESS:  Can you refer to a document to  
7           the inlet because there's several designs on the inlet  
8           tube?  Can you show me a document of the inlet tube?

9           BY MR. HOFF:

10          Q.    Let's refer to your declaration.  So looking  
11          at, for example, Page 16 of your declaration, which  
12          depicts the Figure 2 of the '197 patent.

13          A.    Yes.

14          Q.    How would adding an inlet tube impact noise?

15                   MR. BELLINGER:  Objection.  Form.  Vague.

16                   THE WITNESS:  The inlet tube itself would  
17          first -- as you see on Page 16, you'll see the  
18          Figure 2.  The inlet marking No. 2 and the inlet  
19          marking No. 2.  And you see the horizontal arrows  
20          through the green area depicting laminar flow for that  
21          portion would reduce the noise.  Then you see bended.  
22          So the extension tube would actually help to reduce  
23          noise.

24                   And then, of course, you see some arrows of  
25          air flow that are curved.  That's marked here with 21.

1 That is where noise will be created. Now it's just a  
2 balance between reducing and increasing noise, whether  
3 the net effect is less or more noise.

4 BY MR. HOFF:

5 Q. And how would an inlet tube impact  
6 humidification?

7 MR. BELLINGER: Objection. Form. Vague.

8 THE WITNESS: That's exactly also depicted  
9 here. As we said before, on a high-profile chamber  
10 you can create turbulences in the vertical direction,  
11 and in this one the tube would not affect  
12 humidification, but when you are able to create  
13 turbulences after the tube, the air exits the tube.  
14 Then it will create the turbulence desired to create  
15 humidification.

16 MR. HOFF: So it's -- I think that's it for  
17 questions from us.

18 MR. BELLINGER: Okay. Why don't we take a  
19 break so I can look at my notes.

20 MR. KANE: All right.

21 MR. HOFF: Okay. Thanks.

22 MR. BELLINGER: Thank you.

23 (A recess was taken from 5:36 p.m.  
24 to 5:52 p.m.)

25 MR. BELLINGER: All right. I just have a few

1 questions.

2 EXAMINATION

3 BY MR. BELLINGER:

4 Q. Dr. Schneider, let me put in front of you  
5 what's previously been marked as FPH Exhibit 2004,  
6 which is a copy of your declaration in connection with  
7 U.S. Patent Nos. 7,111,624, 8,091,547, and 8,550,072.

8 Now, Dr. Schneider, do you recall you were  
9 asked some questions this morning about the meaning of  
10 the claim term "urges" or "urging" as it appears on  
11 the claims of these patents?

12 A. Yes, I remember this.

13 Q. Okay. If you could turn to Paragraph 35 of  
14 your declaration, which is on Page 16. Do you have  
15 that in front of you?

16 A. Yes, I see it. Yes.

17 Q. At the beginning of the third sentence of  
18 that paragraph it reads, "In one alternative  
19 embodiment, the single slide-on motion may also urge a  
20 base of the chamber into contact with the heater plate  
21 on the housing. The patent explains that the slide-on  
22 direction may be 'at an angle from the horizontal or  
23 vertical.' By orienting the slide-on direction at an  
24 offset from the horizontal, the motion used to connect  
25 the water chamber to the housing would also urge the

1 water chamber against the chamber heater." Do you see  
2 that?

3 A. I see that, yes.

4 Q. Could you also turn to Paragraph 56 of your  
5 declaration, which appears on Page 29. This paragraph  
6 reads, "The challenged patents explain that this can  
7 be performed by providing a 'slide-on direction  
8 employed to fit the water chamber [that] is not  
9 horizontal but at an angle on the horizontal or  
10 vertical.' By orienting the slide-on direction at an  
11 offset on the horizontal and the chamber heater, the  
12 motion used to connect the water chamber to the  
13 housing would also urge or press the base of the water  
14 chamber against the chamber heater." Do you see that?

15 A. Yes.

16 Q. Do reading these portions of your declaration  
17 refresh your memory as to whether the Fisher Paykel  
18 patents explain away that the motion used to connect  
19 the water chamber to the housing would also urge the  
20 water chamber against the heater?

21 A. Yes, I remember. In the next paragraph it  
22 says, "'urging' requires more than just simply  
23 maneuver two components to touch each other." That's  
24 what we discussed this morning.

25 Q. And is one of the ways that the Fisher Paykel

1 patent explains that the water chamber could be urged  
2 against the heater is by making the slide-on direction  
3 at an angle from the horizontal and vertical?

4 MR. KANE: Object to the form.

5 THE WITNESS: Yes.

6 MR. BELLINGER: All right. No further  
7 questions.

8  
9 FURTHER EXAMINATION

10 BY MR. KANE:

11 Q. Just one follow up, or a couple of follow-up  
12 questions, Dr. Schneider. Do you have the '264 patent  
13 in front of you?

14 A. '264 patent, yes.

15 Q. Yeah. Can you turn to Column 7 of the  
16 patent.

17 A. Yes.

18 Q. Line 57. Read the paragraph to yourself  
19 starting at Line 57.

20 (The witness reviewed the document.)

21 THE WITNESS: Yes, I've got that.

22 BY MR. KANE:

23 Q. Do you see anything in that paragraph that  
24 refers to the heater plate?

25 A. The last paragraph starting in 5, let me have

1 a look at Figure 5 between. Yes, in Figure 5. So  
2 this refers to the heater -- the chamber, the plastic  
3 container, but it has a heat conductive base. And  
4 it's not talking about the heater plate.

5 MR. KANE: No further questions.

6 MR. BELLINGER: Nothing further.

7 Very good. We're done.

8 (Witness excused.)

9 (Deposition concluded at 5:58 p.m.)

ACKNOWLEDGMENT OF DEPONENT

I, HARTMUT SCHNEIDER, M.D., PH.D., do hereby  
certify that I have read the foregoing pages, \_\_\_\_\_  
to \_\_\_\_\_, and that the same is a correct  
transcription of the answers given by me to the  
questions therein propounded, except for the  
corrections or changes in form or substance, if any,  
noted in the attached Errata Sheet.

DATE

SIGNATURE

Subscribed and sworn to before me this \_\_\_\_\_ day  
of \_\_\_\_\_, 20\_\_.

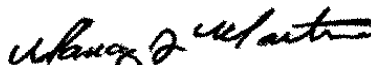
My commission expires: \_\_\_\_\_.

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C E R T I F I C A T E

I do hereby certify that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof.

Dated: September 8, 2017



Nancy J. Martin, RMR, CSR

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**[academic - answer]**

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**[cloth - connected]**

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**[device - distance]**

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**[distance - electric]**

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**[time - turn]**

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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