Date: April 16, 2019

Case: Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators

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UNITED STATES OF AMERICA

BEFORE THE

INTERNATIONAL TRADE COMMISSION

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IN THE MATTER OF: : Investigation Number

CERTAIN STRONTIUM-RUBIDIUM : 337-TA-1110

RADIOISOTOPE INFUSION SYSTEMS AND :

COMPONENTS THEREOF INCLUDING :

GENERATORS :

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HEARING - VOLUME IV

April 16, 2019

Courtroom C

U.S. International Trade

Commission

500 E Street, S.W.

Washington, D.C.

The Hearing commenced, pursuant to notice of the Judge, at 9:03 a.m., before the Honorable CLARK S. CHENEY, Administrative Law Judge for the United States International Trade Commission.

reporter. But I would like to move -- jointly move the admission of the exhibits that we are sending to the court reporter that were discussed -- discussed on the record from April 15th, 2019.

JUDGE CHENEY: I presume counsel for complainant and staff understand the list of exhibits that Mr. Hails has represented and is there any objection to the admission of those exhibits?

MR. DAVIS: No, Your Honor.

MR. KOO: No, Your Honor.

JUDGE CHENEY: The exhibits identified by Mr. Hails will be admitted to the record.

MR. HOFFMAN: Your Honor, Mr. Hails is sitting in front of me. I'm Mr. Hoffman.

JUDGE CHENEY: I'm sorry. Mr. Hoffman.

Any other housekeeping matters before we resume with Dr. Stone? Okay. Hearing none, we'll ask Dr. Stone to return to the stand. As you're coming to the stand, Dr. Stone, I'll remind you you're still under the same obligation to tell the truth under penalty of perjury.

Whereupon,

DR. ROBERT STONE,

was called as a witness by counsel for Respondents, and having been previously duly sworn, was examined and testified as follows:

THE WITNESS: Thank you, Your Honor.

JUDGE CHENEY: Mr. Hails, who has spent all evening talking slowly and clearly in the mirror so that today we'll just have a nice relaxed transcript.

MR. HAILS: We'll see. Yes, sir.

DIRECT EXAMINATION

BY MR. HAILS:

Q Dr. Stone, before we broke we were talking about shielding design. Do you recall that?

A Yes.

Q Let's pull up RX-357, page 10, if you can. Do you recognize this, Dr. Stone?

A Yes, I do.

Q Do you see any shielding compartments illustrated in this photograph?

A Yes, I do.

Q First of all, what does this picture illustrate?

A This is a picture of the interior of the cabinet of the CardioGen 82 or the Model 510 as it's called.

Q The Model 510. Okay. Do you see any shielding compartments in this design?

A I do.

Q Would you point them out for us?

A In the back is a shielding compartment. I believe that is for the waste container and here we have

the shielding compartment for the generator.

Q And Ricky, can we blow up that sticker in the middle center on that first.

All right. Do you see the sticker for the generator shield?

A I do.

Q Okay. You can back out of that. All right. So which way do the openings face on the shielding?

A They face vertically upward.

Q Let's switch over to RX-103 at page 4. Can we rotate that so the letters all line up. Thank you.

Do you recognize this as the Tate application that you've been discussing?

A I do.

Q Okay. Do you see any shielding containers -- sorry, shielding compartments in this -- illustrated in this figure?

A Yes, I do.

Q Can you point them out for us.

A Yes. Here we have, I believe it's a shielding compartment for the source. Here we have the shielding compartment for the onboard dose calibrator, and I believe this is a shielding compartment for the waste bottle.

Q And just for the record, Dr. Stone pointed to element 111 in this diagram, 121 in this diagram, and 127

in this diagram.

Dr. Stone, do you recognize this as a top view of the Tate cart?

A Yes, I do.

Q And which way do the openings of these shielding compartments face?

A They face vertically upward.

Q Can you explain why do people build shielding compartments with openings that face vertically upward?

A Yes. As one is approaching a device, the shielding can be complete and enclosed without access to the device if the shielding compartments face vertically upward. So the shielding is providing adequate protection for the thorax of a person unless -- and the only way they could get exposed to the thorax is if they leaned over that source of radioactive material. So they don't have to expose themselves to radiation as they approach the devices because it's fully enclosed with openings facing vertically upward and radiation only going upward even if the lid were open.

Q Can we return to the PowerPoint.

Okay. Before we broke, we were talking about this element shown here on slide 128 at the bottom, the first door element. Do you see that?

A I do.

Q Okay. And this claim element says that the first door is configured to provide access to the shielding compartment and to close over that first opening.

Do you see that?

A I do.

Q Did you see any teachings of this subject matter in the prior art?

A Yes. In Klein, the generator was placed in the cart and surrounded by lead rings to provide maximum radiation shielding. The opening faced vertically upward in that configuration. Similarly in Tate, the radioactive source was inserted into a well and had an opening which faced vertically upward.

Q Can you show us the door in the Tate design?

A In Tate, we have a door which closes over the source of radioisotope.

Q For the record, we're looking at figure 4A from Tate. And did you point to element 684 in that drawing?

A I did.

Q Are doors conventional structures for shielding design in the mid 2000?

A Doors are conventional structures for shielding in my entire history of looking at radioisotopes and radioactive sources. They are very common.

Q If someone applied a door to a shielding

structure, for example, in the Klein design, would it be accessible via the opening through the exterior shell of the compartment?

A Yes, it would.

Q Move forward, please.

JUDGE CHENEY: Mr. Hails, you tend to be doing this with microphone. I need you to be doing this with your microphone. There you go.

BY MR. HAILS:

Q Okay. We are at slide 129 in the presentation. Talking about claim 1. And claim 1 refers to a second shielding compartment. Do you see that in the slide?

A I do.

Q On the third line it talks about that the second shielding compartment is for the waste bottle.

Do you see that in claim 1?

A Yes.

Q Does the prior art claim teach a second shielding compartment for a waste bottle?

A Yes, it does.

Q Please explain.

A Klein had a waste bottle on the top shelf that was in a shielded container and it had an opening facing vertically upward.

Q And that opening, does Klein teach that that

opening is one through which a waste bottle can be inserted into or removed from the shielding compartment?

A Yes, he does.

Q All right. Let's move forward, please. I should note for the record that slide 129 has an excerpt from figure 2-3 of the Klein thesis.

The second door -- I'm sorry, the next element is a second door that is configured to provide access to the second shielding compartment and to close over the second opening. Did you see teachings of this subject matter in the prior art?

A Yes.

Q Please explain.

A As Klein describes, a waste container was mounted on the top shelf inside a lead container with a lid. That lid door sliding whatever, those are very common in the art.

Q Okay. The claim talks about that the second door is accessible by the opening through the top surface of the exterior shell of the cart. Did you see that subject matter talked about in the prior art?

A Yes, I did.

Q Please explain.

A I'm sorry. We previously showed that there was a door here that opened over this area and that's

accessible via the top shelf of the -- the top surface of the cart.

Q Okay. All right. So the slide 129 also lists a wherein clause from claim 1 saying that the first opening, which is the one corresponding to the generator shield, is located at a lower elevation than the second opening, which is the one corresponding to the waste bottle.

Will you please remind the Court how does the prior art teach that subject matter?

A The prior art teaches that subject in that, first of all, it would be obvious to relocate the generator and the shielding to a lower elevation for ergonomic purposes as we've discussed as taught by Chaffin, which would be well-known to a person who is designing medical devices and designing any industrial device.

Q And Chaffin, for the record, is RX-96. Let's move forward, please.

We are at slide 130 and the claim is talking about a radioactivity detector. Does the prior art teach a radioactivity detector?

A Yes, it does.

Q Please explain.

A We have a radioactivity connector at the activity counter in the Klein thesis as well as in other sources.

Q For the record, slide 130 shows an excerpt from Klein figure 2-2 on page 29. Is the radioactivity detector that's taught by the prior art, is it positioned to measure radioactivity of a rubidium radioactive eluant that flows through an eluant tubing line?

A Yes, it does. The tubing is positioned to go under the radioactivity detector and it counts it while the tubing -- the fluid is flowing through.

Q Is the eluate tubing line in fluid communication with an outlet tubing port of the strontium-rubidium radioisotope generator?

A Yes, it is. It's shown here this is the outlet and it's in fluid communication.

Q Let's move forward, please. We are on slide 131 of the presentation.

Claim 1 talks about a shielded well on board the cart configured to receive an eluate reservoir. Please explain how does the prior art teach this subject matter?

A Well, the Klein thesis has indeed a shielded well in the dose calibrator and it has the eluate reservoir in the shielded well while a dose is pumped into it. He doesn't have it on board the cart, but as we stated previously, it is obvious to relocate the dose calibrator. It was done by Tate. It's done by Medrad. There is nothing inventive in that step.

Q Again for the record, slide 131 shows a split screen, I guess, with both figure 2-3 and figure 2-2 from the Klein thesis. Next part of this shielded well element says that the eluate reservoir is configured to receive a test sample. Do you see that?

A Yes.

Q Does the prior art teach that subject matter?

A Yes, it does. The computer configures the flow path. So it goes out to the patient line, which itself is now inserted into the eluate reservoir so that the eluate reservoir can receive a test sample.

Q Let's move forward, please. Claim 1 also refers to the computer of the system and lists a variety of features. One is to provide a stop button on the touchscreen display. Did you see a stop button taught by the prior art?

A As we've seen before, the stop button is there for all elutions.

Q For the record, slide 132 shows a screenshot taken from page 64 of the Klein thesis.

Does the prior art teach that that stop button aborts a function of the infusion system in response to a user input that activates the stop button?

A That's correct.

Q Let's move forward, please. Claim 1 says that

the computer is configured to pump saline from a saline reservoir. Does the prior art teach this subject matter?

A Yes, it does.

Q Please explain.

A A computer controls a peristaltic pump, which takes saline from the saline reservoir.

Q All right. Please continue.

A It then pumps it through the generator valve into the inlet port of the generator and the eluate is pumped out of the outlet point -- sorry, through the outlet tubing port of the generator.

Q Okay. So this -- for the record, slide 133 again shows an excerpt from figure 2-2 of the Klein thesis and Dr. Stone was referring to the peristaltic pump that's illustrated in that diagram.

Okay. The claim says that the saline reservoir has to be positioned outside the interior space of the cabinet structure. Does the prior art teach that subject matter?

A Yes, it does.

Q Please show us.

A The peristaltic pump -- sorry, the saline reservoir is here outside the cart.

Q You're pointing to our own screen. Why don't we do it on the screen up here.

A Thank you. I'm sorry. Here we have the saline reservoir outside the cart.

Q And for the record, Dr. Stone was pointing to figure 2-3 from the Klein cart and the annotation that we provided on slide 133 for the saline bag.

Okay. Does the pump -- sorry, does the computer pump saline into the strontium-rubidium radioisotope generator through an inlet tubing port?

A Yes, it does. Here is the inlet tubing port we discussed previously.

Q And does that process generate the rubidium radioactive eluate that is discharged through the outlet tubing port?

A Yes, it does.

Q Please go back. Go back, please, one more. Just show us the outlet tubing port on slide 133.

A I'm sorry. Here we have the outlet tubing port.

Q Very good. Let's move forward, please.

All right. We are on slide 134 and we have an excerpt from figure 2-2 from the Klein thesis. The claim says that the computer of the infusion system fills the eluate reservoir in the shielded well on board the cart with a test sample of the rubidium radioactive eluate.

Please remind the Court, how does the prior art teach this subject matter?

A Again, this is a block diagram from the Klein thesis. We have the eluate reservoir in the shielded well with pumping and filling of that eluate reservoir is controlled by the computer configuring the valves and the pump in order to do that. And it doesn't to on board the cart, but as we say, it's obvious to relocate the cart for reasons we've discussed with regard to the weight of the cart and the movement.

Q Okay. And on this drawing here, figure 2-2 from the Klein thesis, you're pointing to the dose calibrator color coded in blue; is that correct?

A That is correct.

Q All right. Do you see that box with the little snowman-looking icon inside?

A Yes.

Q What is that?

A The box with the little snowman is the shielded well with the eluate reservoir inside.

Q Move forward, please. Claim 1 says that the computer is configured to determine a strontium breakthrough test result on the test sample. Please remind the Court, how does that process occur in the prior art?

A Well, we've discussed the Klein thesis that the strontium breakthrough test is termed by first measuring the activity when the sample is first placed in the well.

The computer then waits 30 minutes and takes another reading and computes the strontium breakthrough from the formula shown below.

Q And does that process operate on a test sample that is filled into an eluate reservoir in a shielded well?

A Yes, it does.

Q We've discussed here on board the cart, off-cart analysis already, correct?

A That's correct. All the system components were there in Klein. We are just talking about the rearrangement for a commercial product.

Q All right. Let's go through the while clause in this element. Does that process occur while the eluate reservoir remains in the shielded well?

A Yes, it does.

Q Let's move forward, please. Claim 1 further states that the computer is configured to not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

Please remind the Court, how does the prior art teach the subject matter?

A The Klein thesis states specifically that the computer disables patient elution -- sorry, that the computer does not enable patient elutions unless a calibration run and a successful breakthrough measurement

are completed. That's done daily. The amount is determined by the Health Canada guidelines for the strontium breakthrough level that's part of the daily protocol and the system software ensures that the protocol is followed; that is, each run is enabled only after the prerequisites have been completed successfully.

Q For the record, we are on slide 136 and the excerpts shown are from pages 39, 43 and 54 of the Klein thesis. Let's move forward, please.

Okay. Claim 1 talks about a shielding for a generator. Claim 2 says that the infusion system further comprises the strontium-rubidium radioisotope generator in the first two compartments. Did you see a strontium-rubidium radioisotope generator taught by the prior art?

A Yes.

Q Can you point it out to us?

A Here we have the strontium-rubidium generator in the interior space of the cabinet shown how we had proposed that it was obvious to move it, but it was in the interior previously.

Q All right. And so for the record, Dr. Stone is pointing, again, I think it's to figure 2-3 of the Klein thesis. So let's move forward, please. We are still on slide 37.

Claim 2 says that there is an eluate reservoir located in the shielded well on board the cart and in fluid communication with the eluate tubing line. Did you see that subject matter taught by the prior art?

A Yes.

Q Please explain.

A We've talked about the eluate reservoir in the shielded well previously. The on board the cart we've also talked about that it's obvious to relocate that as it's done in the prior art and it's in fluid communication with the eluate tubing line as shown in the hot pink tracing that we have here.

Q For the record, we are on slide 137 of this presentation and the hot pink he was referring to was taken from slide -- I'm sorry, from figure 2-2 of the Klein thesis.

All right. Let's move forward. So now we are at claim 3. We are on slide 138. Claim 3 says that the cabinet structure has a lowermost portion and the platform has a lower surface. Did you see that subject matter taught by the prior art?

A Yes.

Q Walk us through it, please.

A Well, we've talked about how it would be obvious to relocate the generator and the shielding compartment to

a lower elevation. Ergonomics is taught by Chaffin. If I look at this proposed concept here that would happen and compare it with a standard laboratory countertop, which is normally found at a height of 30 to 36 inches, so if I compare that to the opening that we have here in the first generator, that, by that comparison, my eye is easily determined to be nominally between one and two feet.

Q Let me stop you right there. Right now we are talking about part one of this claim and it says that the cabinet structure has a lowermost portion.

Let's talk about the cabinet structure just to make sure the record is clear. Do you see he a cabinet structure in this picture here on -- I think this is figure 2-3?

A Yes, we have a cabinet structure as shown here.

Q Does it have a lowermost portion?

A It does.

Q Did you see a platform in this figure 2-3?

A There is a platform here at the base of the cart.

Q And did that platform have a lower surface?

A Yes, it does.

Q All right. So now let's talk about the next elements. You were talking about the shielding and let's walk through the claim. The claim talks about the first

opening, which refers back to the shielding compartment of the generator and that must be at a first elevation.

So with the modifications that you've identified here using the Chaffin teachings, where is the -- what is the elevation of the first opening?

A Here is the first opening. That's where it's located.

Q Okay. So let's go to the next element. And that refers to a second opening, which refers back to the shielding compartment for the waste bottle. Applying these teachings, do you see that the second opening for the waste bottle would be at a second elevation?

A Yes. In the original location that's shown in Klein's thesis, we had the waste container located there at that second elevation.

Q All right. And then the next -- sorry, the next element says that the first elevation, which again refers to the shielding compartment, is between approximately one foot and approximately two feet with respect to the lowermost portion of the cabinet structure.

Okay. Please walk us through your analysis of this element.

A All right. Thank you. Again, using the standard height of a laboratory countertop positioned nominally between 30 and 36 inches for ergonomics for a

workspace, using that as a reference of nominally 36 inches, this first opening is halfway through. That would be between one and two feet.

Q And do you recall looking at the shielding generator this morning for the CardioGen 510?

A I do.

Q Would you agree with me that the shielding compartment of that structure also was at the bottom of that cart?

A Yes, it is.

Q Let's move forward please to the next element. So the next element says that the second elevation is between approximately two feet and approximately three feet with respect to the lower surface of the platform. Please explain your analysis of this element.

A The Klein thesis had the shielded waste container with its upwardly facing -- sorry, vertically upward facing opening was on that shelf. And as you can see in comparison with the countertop, that's between two and three feet with respect to the lower surface of the platform.

Q Let's move forward, please. We are at slide 139 and we are talking about claim 4 of the '869 patent.

Claim 4 says that the infusion system has a wherein clause, wherein the first shielding compartment

comprises two tubing passageways formed in a perimeter surface of the first opening.

Let's talk about tubing passageways first. In the Klein thesis, how many tubing passageways go in and out of the generator?

A Well, he has two tubing passageways because we have to have saline going in. I'm sorry. The system has saline going in and has the strontium-rubidium eluate coming out.

Q Did you see teachings of a shielding compartment with tubing passageways formed in a perimeter surface of an opening of the shielding compartment?

A We saw that in the -- the tubing passageways were formed in the perimeter surface on the Tate system.

Q We have an excerpt here from figure 6-E of Tate on page 119. Show me the tubing passageway.

A We have a tubing passageway here formed in the perimeter of the shielded well.

Q And the shielded well, is that element 111 in this drawing?

A Yes.

Q Okay. There is only one in the Tate system. But there are two tubing -- that's tubing in the Klein system. Why don't you explain why is that -- why is it obvious to put in two?

A Well, in the Tate system, using FDG, one merely needs a single tube in order to withdraw eluate -- or in order to withdraw the radioisotope source -- sample from the source. In the strontium-rubidium isotope generator, you need two tubes; one to go in with the saline and one to bring the eluate out.

Q Do you believe it's obvious to apply the teachings of Tate and to add a second tubing passageway, one for the other tube?

A One would have tubing passageways for each of the tubings. In order to do that, that would be obvious. It would be the standard thing to do.

Q On this slide 139, you color coded a tube 210 in pink; is that correct?

A Yes.

Q Okay. The opening in the perimeter surface of this shielded well, does it pinch that tube?

A No. It certainly would not be obvious to have anything that would pinch the tube if I need to have flow through that tube.

Q Does that opening crush the tube?

A No, it does not.

Q And you have this element 684 with the red halo around it on slide 139. Do you see that?

A I do.

Q And remind the Court, what is that?

A That is the source of rubidium-82 in a shielded container.

Q I'm sorry. So 684 --

A Actually, not rubidium-82. Of FDG.

Q We have a shielded well, right, at 111? Please look at the screen. And what is this guy?

A I'm sorry. That is a door over the -- over the vial of FDG.

Q All right. For the record, I was pointing to 684 as "this guy." So that door is closed in the shielded well. Would you agree?

A That's correct.

Q All right. Does Tate disclose that that door crushes or pinches that tube when that door is closed?

A No.

Q Let's move forward, please. All right. We are now on slide 140 and we are talking about claim 5 of the '869 patent.

Claim 5 says the opening through the exterior shell is configured to provide -- that is configured to provide access to the strontium-rubidium radioisotope generator within the interior space of the cabinet structure is through the front side of the exterior shell.

Did you see teachings of that subject matter in

the prior art?

A I do.

Q Show me the front side.

A Here is the front side.

Q And do you see an opening in the front side?

A There is indeed an opening in the front side.

Q And would that front side provide access to the generator?

A Yes, it does.

Q That was slide 140. Let's move to the next slide, please. So now we are at slide 141 still talking about the '869 patent. We are now at claim 8.

Claim 8 says wherein the infusion system is configured to determine the strontium breakthrough test result on the test sample at least once a day. Please explain how does this prior art teach this subject matter?

A Klein clearly describes that his system ensures compliance with the daily protocol prescribed in the previous chapter, a flush followed by a calibration run and successful breakthrough measurement must be completed in order to enable patient elutions for the remainder of the day. So at midnight, that daily protocol completed is cleared and the daily protocol chart has to be completed in order to enable patient elutions.

Q All right. The excerpt on this slide 141 is

taken from page 139 of the Klein thesis. We also have an excerpt showing figure 2-1 from the Klein thesis. Where in this daily protocol are the patient elution runs?

A Patient elution runs are here after the completion of the calibration run.

Q I was going to ask where in the daily protocol is the calibration run?

A It's after the daily flush.

Q And you said that the calibration run must achieve a successful breakthrough measurement in order to enable the patient elutions; is that correct?

A That's correct.

Q Let's move forward, please. So we are at slide 142. And we'll talk about claim 14 of the '869 patent. Claim 14 talks about various functions of the computer of the infusion system. The first one is to track a volume of the saline remaining in the saline reservoir.

Please explain how does the prior art teach this subject matter?

A Well, saline is a consumable for the system. The international standard for user interfaces for medical devices calls for the user to be aware of the use of the correct consumable, the remaining amount of them, whether accessories might be used with the medical device, how to assemble them, how to check their correct functioning.

Saline is indeed a consumable. The user is made aware of that through the user interface as described and taught by this standard.

Q Okay. For the record, on this slide 141 we haven excerpt from RX-114 at page 63. All right. And do you see -- did you see a description of tracking saline in the Medrad documentation?

A Yes, we did.

Q We'll get to that in a moment. Did you see a description of tracking saline in the Tate patent application?

A Yes.

Q All right. Let's move forward. Claim 14 also talks about that the computer is configured to alert the user via the touchscreen display when the volume of the saline remaining in the saline reservoir is below a predetermined volume threshold. Why don't you walk us through the subject matter.

A Yes. As we stated previously, I believe that's covered by the international standard calling for the user to be made aware of the correct usage and how to assemble them, how to check their correct functioning. And it's also provided to Medrad where they provide an alert when the remaining saline is low.

Q We'll get to that in a moment. Let's move

forward, please. Can we move forward.

A Yes.

Q Okay. So now we are on slide 144. We were talking about claim 24. Claim 24 first recites a hanger configured to hold the saline reservoir at an elevation above the top surface of the exterior shell.

Does the prior art teach this subject matter?

A Well, the first portion of this element, the hanger that hangs the saline bag is taught both in Klein and in the Tate patent application; however, it's clearly disclosed in the CardioGen Model 510.

Q In your experience, is it common or is it an uncommon configuration to hang saline at high elevations on medical devices?

A It's hung at a high elevation. It makes it clearly visible from across the room.

Q Let's move forward, please. The next element is a handle that's configured for the user to grasp in order to move the infusion system. Did you see teachings of handles in the prior art?

A Yes. Handles for moving carts are quite a standard configuration. We have handles on the Tate cart -- I'm sorry, on the Klein cart, on the Tate cart, as well as on the CardioGen Model 510. And we also had it on Medrad.

Q All right. So for the record, we are on slide 145 and Dr. Stone was pointing out handles on page 34 of the Klein reference, page 2 of the Tate reference, page 13 of the CardioGen reference. Actually, let me read the exhibits in. 106 page 34, 103 page 2, RX-207 page 13.

Let's move forward. Next thing -- now we are at slide 146. The next thing you've got to have is four wheels mounted to an underside of the platform. Please explain, how does the prior art teach this subject?

A I believe this is a very standard and obvious feature. Klein had four wheels. The Tate disclosure had four wheels. The CardioGen 510 had four wheels.

Q All right. And again, for the record, we are pointing to pictures taken from page 34 of Klein RX-106, page 2 of Tate RX-103, page 13 of the CardioGen manual, RX-207.

A And just to be clear it was also on the Medrad though I neglected it.

Q All right. Let's move forward, please. Slide 147. Now we have to have a power inlet port for connecting the infusion system to a power source. Please explain, how does the prior art teach this subject matter?

A All the devices that we've talked about were powered by AC mains. Specifically, Klein states that the system is plugged into a wall socket at all times and only

needs several minutes of battery power while being moved.

Q For the record, this is slide 48 discussing claim 24 and the excerpt from which Dr. Stone read was page 46 of RX-106.

All right. And moving on. We have a printer that's configured to print a document concerning a patient infusion or a quality control test result generated by the infusion system.

Please explain. Does the prior art teach this subject matter?

A Yes, it does.

Q Can you walk us through it?

A Klein certainly has a printer as he displays here in the picture from his cart. Printer and power isolation transformers were mounted on the lower tray. When one is producing a medical device, it would be obvious to utilize that printer to print. What is done by Tate and Medrad, they disclosed printers for printing infusion data.

Q Okay. Just for the record, you were referring to an excerpt from Klein at page 35. You were referring to -- what are the portions of Tate that you relied on?

A We relied on the Tate. The RX-103 page 93.

Q Okay. And you said also that you saw evidence of that in Medrad; is that correct?

A Yes. That's RX-0200C page 91.

Q Let's move forward, please. Okay. We are at slide 149 and we are talking about tubing passageways again. The first shielding compartment comprising two tubing passageways formed in a perimeter surface of the first opening. Have we discussed this already earlier in your testimony?

A Yes, we have.

Q All right. You have an excerpt taken from Tate on page 119 figure 6E. Are you relying on the same disclosure in Tate as before in that prior claim element?

A Yes.

Q All right. You believe -- so just point out, please, where is the opening formed in the printer surface of the shielding compartment?

A We have the opening formed in the perimeter of the surface.

Q For the record, that's the opening through which the tube 210 proceeds. The next portion of this claim is that each of the two tubing passageways has a depth configured to prevent pinching or crushing of a corresponding tubing line routed there through when the first door is closed thereover. Is the tubing passageway, is it crushed or pinched in the Tate disclosure?

A No.

Q Is it crushed or pinched when that cap is closed

over the shielding well?

A No.

Q All right. Let's move to the next one. You also have to have a first door that's mounted by a hinge. How is this subject matter taught by the prior art?

A Well, we are showing the first door here and while it's still being mounted on a post, mounting a door on a hinge, a post, on rails, there is nothing inventive about how a door is mounted.

Q Have you seen in your experience shielding compartments with doors mounted by hinges before?

A Yes, indeed.

Q Let's move forward, please. Okay. Now we are on slide 150. We are still talking about claim 24. It says that access to an operation of the computer is regulated through a user login credential.

Did you see this subject matter taught by the prior art?

A Yes.

Q Please explain.

A In the Klein thesis, he states that the generator information screen is displayed first, which gives information as to the state of the generator activity and history. Following is a prompt for a user ID code, which is useful for avoiding tampering by unauthorized

personnel as well as enabling test runs, which were commonly used during a development cycle, but have no clinical application.

Q All right. And for the record, this excerpt is taken from page 63 of RX-106. Let's move forward, please. We are at slide 151 still talking about claim 24. It says the strontium breakthrough test result is for at least one of strontium-82 and strontium-85. How does the prior art teach this subject matter?

A Klein discloses the formulas which are used by the computer and he states the breakthrough of each isotope, strontium-82 and strontium-85, is calculated as a relative activity ratio of strontium activity to 82 rubidium activity delivered as demonstrated below.

Q For the record, this excerpt is taken from page 61 of Klein. Let's move forward, please. Slide 152. It says the exterior shell further includes a saline tubing opening configured for a saline tubing line to pass from the reservoir outside the exterior shell to the interior space of the cabinet structure.

Why don't you walk us through this subject matter.

A We have a saline bag on the exterior of the shell and it has a tubing line that passes through to the interior of the shell.

Q For the record, slide 152 has an excerpt taken from figure 2-4 of the Klein thesis. Dr. Stone was pointing to the tubing line that we've color coded in pink that terminates in the pointer for the generator.

A And to clarify, I said to the interior shell. It's to the interior space.

Q Thank you. Let's move forward, please. Slide 153. The computer is configured to determine the strontium breakthrough test result on the test sample at least once per day. I think we've discussed this, but please just refresh the Court, how does the prior art show this?

A This is a reminder at midnight the system is reset such that a daily protocol must be completed prior to enabling -- enabling patient run elutions for the remainder of the day.

Q And for the record, this slide has an excerpt from page 39 of the Klein thesis and also an excerpt showing figure 2-1. Let's move forward, please.

All right. So staying with claim 24, we are at slide 154, the computer is configured to pump saline through the strontium-rubidium radioisotope generator at a rate that's less than approximately 70 milliliters per minute. Please explain how the prior art teaches this subject matter.

A Well, Klein clearly states in his thesis that

the pump operates at less than 70 milliliters per minute. For example, during a flush run, flushing of all the lines in the system as well as 50 milliliters of flush of the generator at 15 milliliters per minute. That's certainly less than 70 milliliters per minute.

Q And for the record, that except is taken from page 53 of the Klein thesis. All righty. Let's keep going. Slide 155. The computer is configured to track a volume of the rubidium radioactive eluate discharged from the generator to the waste bottle.

Does the computer track a volume of eluate discharge from the generator to the waste bottle in the prior art?

A Yes, it does.

Q Please explain.

A During a flush run, he flushes all of the lines in the system as well as 50 milliliters of flush of the generator at 15 milliliters per minute. That flush of the generator goes to the waste bottles.

Q So what's the quantity that is tracked by the computer?

A 50 milliliters.

Q 5-0; is that correct?

A 5-0.

Q And that excerpt is taken from page 53?

A I'm sorry. I did not hear that.

Q Just for the record, that excerpt is taken from page 53. The claim also talks about the computer being configured to control the touch screen display to display a user screen guiding the user to empty the waste bottle.

How does the prior art teach this subject matter?

A Again, Klein provides guidance to replace some of the consumables to the generator, but he also provides direct guidance to present reminders to empty the waste bottle. If the level switch is tripped, the current elution continues to completion, but a new run is not permitted. If a new run is attempted without emptying the waste container, an error is produced and the elution does not proceed until the waste container is emptied and the elution is restarted.

Q And that excerpt is taken from page 45 of the Klein thesis. Let's move forward, please. Okay. Did you also see teachings of this subject matter in other references?

A Yes. As we read before, the user is -- has to be aware of the current use of the correct consumable, the remaining amount, whether accessories might be used with the device, how to assemble them and how to check the correct functioning.

Q And what about Medrad? Why do you have Medrad listed here?

A Medrad specifically has a reminder to empty the waste bag.

Q Let's move forward, please. The computer is also configured to track a volume of the saline remaining in the saline reservoir and to alert the user via the touchscreen display when the volume of the saline remaining in that reservoir is below a predetermined volume threshold. Again, walk us through your analysis of this subject matter, please.

A Again, the same international standard calls for the remaining amount of consumables to be made known and how the user is to use them. And Medrad tracks the volume of saline remaining in the saline reservoir and provides alerts to replace it.

Q And we don't have it here, but did you also see teachings of that subject matter in the Tate reference?

A Yes.

Q Let's move forward, please. All right. So we are done with claim 24 and now we are on to claim 27. We are on slide 158 of your presentation. This claim calls for a dose calibrator located in the shielded well on board the cart and in communication with the computer. Where is the dose calibrator in the Klein system?

A In the Klein system, the dose calibrator was off the cart, but it was in communication with the computer.

Q Does it have a dose calibrator located in the shielded well?

A Yes, it is.

Q The next part of this claim says wherein the dose calibrator is configured to determine the strontium breakthrough test result. Why don't you explain how does the dose calibrator participate in strontium breakthrough test results?

A The dose calibrator acts, as we've described previously, a sample of eluate is pumped into the reservoir. The radiation levels are taken by the computer. The computer waits, takes another radiation level and computes the strontium breakthrough level.

Q All right. For the record, Dr. Stone was pointing earlier to the dose calibrator shown on figure 2-2 on page 29 of the Klein thesis.

Let's move forward, please. Okay. We are at slide 159. We are still talking about claim 27. It says wherein the opening through the exterior shell configured to provide access to the strontium-rubidium radioisotope generator within the interior of the cabinet structure is through the front side of the exterior shell. Did you see this subject matter taught by the prior art?

A Yes.

Q Show me the front side opening, please.

A We have the front side opening of the cart in the Klein thesis.

Q And does it provide access to the generator?

A Yes, it does.

Q All right. And is that generator inside the interior space of the cabinet structure?

A Yes, it is.

Q All right. For the record, we were pointing to the picture from page 34 of the Klein thesis. Let's move forward, please.

So now we are at slide 160. We have an excerpt again, the block diagram taken from figure 2-2 of the Klein thesis on page 29. And we are talking about claim 8 of the '869 patent. All right. It says the infusion system comprises the generator with the inlet tubing port configured to receive saline. Did you see this subject matter taught by the prior art?

A Yes.

Q Show me.

A Here we have the generator configured to receive --

Q Does it receive saline?

A Yes. It receives saline.

Q All right. So that's the -- thank you. Just for the record, that's the hot pink coded stuff here on slide 160 that connects the saline IV through the pump to the generator.

The second part of this element says the generator also has the outlet tubing port configured to discharge the rubidium radioactive eluate. Why don't you point that out to the Court.

A Here we have a discharge -- sorry, an outlet tubing port that discharges the rubidium radioactive eluate.

Q And for the record, that's the pink color-coded extension from the generator to the input of the activity detector shown here on slide 160.

Let's move forward please. Claim 28 also says that the system comprises the eluate reservoir located in the shielded well on board the cart and in fluid communication with the eluate tubing line. Will you point out the eluate reservoir for us in this drawing?

A Once again, the eluate reservoir is here in blue in the shielded well off cart, but we've discussed how it's obvious to relocate the dose calibrator on the cart.

Q So for the record, Dr. Stone is pointing to the blue color-coded assembly that we have shown here on slide 161 and specifically to the inside of the box, let's say,

in the center top. We talked about on board the cart, off the cart. Why don't you explain, how is this eluate reservoir in fluid communication with the eluate tubing line?

A From the outlet port of the generator through the patient valve on to the eluate reservoir we have fluid communication.

Q And so for the record, that's the tubing extensions that we color coded between the generator that was shown in red and the dose calibrator that's coded in blue. The extension is hot -- coded in hot pink.

Okay. Let's move forward. We are at slide 162. We are still talking about claim 28. The next element says there is a waste tubing line in fluid communication with the eluate tubing line and the waste bottle. Why don't you point out where is the waste bottle in Klein?

A The waste bottle is here shown in green.

Q All right. And where is the waste tubing line that's in fluid communication with the eluate tubing line?

A We have the waste tubing line in fluid communication with the eluate tubing line.

Q Okay. And again, then for the record, that's the extension that is coded in pink from the generator, through the activity detector, through the patient valve and to the green coded waste container. Let's move

forward, please.

Claim 28 says you've got to have a valve configured to control fluid flow between the eluate tubing line and the waste bottle via the waste tubing line. Please show us how does the prior art teach this valve?

A Here we have the patient valve, which controls the fluid flow between the eluate tubing line and the waste bottle being in the waste line.

Q For the record, we are on slide 163. Dr. Stone was pointing to the patient valve assembly that we've color coded in orange. Let's move forward, please. Can we move forward.

Now we are at slide 164. And we've moved to claim 29 of the '869 patent. This claim says that the infusion system has a computer that's configured to measure an activity of the test sample filled into the eluate reservoir in the shielded well on board the cart. Which component in the Klein system measures activity of the test sample in the eluate reservoir?

A The computer measures the activity.

Q Okay. Where is the activity?

A The activity is in the sample vial that is in the dose calibrator.

Q Okay. Does the computer measure this activity while the eluate reservoir remains in the shielded well on

board the cart?

A Remains in the shielded well. He doesn't have it on board the cart. We've talked about how it's obvious to relocate it for ergonomic and utility reasons.

Q The wherein clause of this first element says that the activity is measured with the dose calibrator in the shielded well on board the cart. How does the prior art teach this subject matter?

A It's measured in the shielded well in the dose calibrator. It's not on board the cart, but it's obvious to relocate that on board the cart.

Q Let's move forward, please. Okay. This new element says that the computer calibrates the infusion system based on the activity measured by the dose calibrator. Will you walk us through the calibration operation?

A The Klein thesis he describes the calibration run as flushing of the generator at 15 milliliters per minute over 60 seconds into the dose calibrator. Obviously, that's into the sample vial in the dose calibrator.

Q And what is being calibrated?

A What is being calibrated in this case is the activity detector that's on board the cart.

Q Okay. And -- go ahead. I'm sorry.

A The integral activity is recorded from the dose calibrator and it's used to calibrate the activity counter and verify that the calibration constant is within tolerance from previous records.

Q And do you recall how we color coded the activity counter in prior drawings?

A I believe that was in purple.

Q All right. Let's move forward. Okay. So now we are at slide 166 and on claim 30 of the '869 patent. Have we seen this subject matter of claim 30 earlier in your testimony?

A Indeed we saw this in claim 3, and my analysis of these elements remain the same as it was in claim 3.

Q All right. So can we just walk through them. The cabinet structure element from claim 30, is it the same as claim 3?

A Yes.

Q Let's move forward, please. The first opening, are they recited the same in claim 30 and in claim 3?

A Yes.

Q Move forward, please. The second opening, are they recited the same in claim 30 and claim 3?

A Yes.

Q Next element, first elevation with one foot and two feet. Is the recitation the same between claim 30 and

claim 3?

A My analysis remains the same.

Q All right. And let's move forward. In the last element, is that the same between these two claims?

A Yes.

Q All right. So that was slide 166. Let's move forward, please. All right. So now we are at the '870 patent at slide 167. And if you would advance, now we are at slide 168.

We've got to start all over again. We've got claim 1, which is a method of using an infusion system on board a cart to deliver a rubidium radioactive eluate. Does Klein disclose an infusion system on board a cart to deliver a rubidium radioactive eluate?

A Yes, he does.

Q All right. The first element says you've got to install a saline reservoir on the infusion system. Does the prior art teach this subject matter?

A Yes.

Q Can you point out the saline reservoir?

A Here is the saline reservoir.

Q For the record, Dr. Stone was pointing to the illustration taken from page 34 of the Klein thesis, the markings we have on slide 168 for the saline bag. The wherein clause of this element says that the infusion

system comprises a platform and an exterior shell extending upwardly above the platform. Did you see this subject matter taught by the prior art?

A Yes, I did.

Q All right. Why don't you advance. I think it would be easier. Why don't you point out where is the platform and where is the exterior shell?

A As previously discussed, here is the platform. Here is an exterior shell.

Q So for the record, Dr. Stone was pointing to the annotations provided in yellow on the illustration taken from page 34. Why don't you advance.

Claim 1 says wherein the platform and the exterior shell collectively define an interior space of the cabinet structure. Did you see an interior space disclosed by the prior art?

A As we see here labelled an interior space in the Klein cart.

Q And again, for the record, Dr. Klein -- wow -- Dr. Stone was pointing to the yellow annotations for the interior space that are labelled here on slide 168.

All right. Let's keep going, please. Claim 1 says you've got to place the saline reservoir in fluid communication through a saline tubing line with an inlet tubing port of a strontium-rubidium radioisotope generator.

Does the prior art teach this subject matter?

A Yes. We still have the saline reservoir placed in communication with an inlet tubing line the inlet port of the strontium-rubidium generator.

Q So we are on slide 169. And for the record, Dr. Stone was pointing to figure 2-2, the block diagram, pointing out the saline IV in brown, the generator in red and the tubing lines in pink that extend between them.

All right. We are up to the generator. That generator, the claim says, must be located in a first shielding compartment in the interior space of the cabinet structure. How does the prior art teach that subject matter?

A We've already discussed the shielded rings that Klein utilized and it's in the interior space of the cabinet. When I say utilized, in order to place the shielded generator.

Q All right. Is the generator inside the cart?

A Yes, it is.

Q Move forward, please. We are at slide 170. There is a wherein clause. The strontium-rubidium radioisotope generator further comprises an outlet tubing port configured to discharge the rubidium radioactive eluate. Do you see an outlet tubing port?

A I do. Here it is located and it discharges the

rubidium radioactive eluate.

Q For the record, we are on slide 170. Dr. Stone pointed out the pink extension, let's say, on the far right-hand side of the excerpt from figure 2-2 of the Klein thesis on page 29. Let's move forward, please.

Claim 1 says the first shielding compartment has to have a first opening facing vertically upwardly. Do you see that subject matter taught by the prior art?

A Yes.

Q What's the structure?

A The structure was with Klein, the generator was placed in the cart surrounded by lead rings to provide maximum radiation shielding that still faces vertically upward. The shielded wells were also taught by Tate and Medrad with openings that faced vertically up.

Q So that's slide 171. Let's keep going. Woops. Let's not do that. And we move to the next slide. We are at slide 172. Talking about claim 1 of the '870 patent. The claim says inserting a waste bottle into a second shielding compartment on board the cart. Show us how the prior art teaches this subject matter, please.

A I indeed had a shielding compartment for a waste bottle that was on board the cart.

Q Okay. The second shielding compartment on board the cart has to have a second opening facing vertically

upwardly. How does the prior art teach this subject matter?

A Klein had a lead container for the waste bottle with a lid that faced vertically upward.

Q Okay. And then the last piece of this claim element says that the -- I think the waste bottle opening must be at a higher elevation than the first opening, which is the one corresponding to the generator. And remind the Court, how is this subject matter taught by the prior art?

A It would be obvious for ergonomic reasons to place the generator at the lower level of the cart.

Q Okay. Let's move forward, please. We are at slide 173. We have excerpts taken from both pages 34 and the block diagram on page 29 of the Klein thesis. We are talking about claim 1 and the claim element refers to placing the waste bottle in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator through an eluate tubing line. Please walk us through the subject matter.

A We have the outlet tubing port in hot pink here from the strontium generator through the patient valve directed to the waste container in fluid communication.

Q And for the record, we are on slide 173. Dr. Stone was pointing to the pink coded tubing lines on the slide and also to the waste container coded in pink --

sorry, in green. Let's move forward, please.

Still on slide 173. Wherein a computer on board the cart is configured to control the fluid communication between the waste bottle and the outlet tubing port. First of all, why don't you call out the computer for us.

A The computer is shown here in light green.

Q All right. So that's the green-coded computer on figure 2-2. Please explain how does that computer control the fluid communication between the waste bottle and the outlet tubing port of the generator?

A Klein's thesis discloses an interface board that is utilized to control the patient valve, which in turn controls the communication between the generator and the waste bottle.

Q All right. And for the record, Dr. Stone was pointing to the patient valve that is coded in orange on slide 173. All right. Let's move forward, please. A wherein clause. Wherein the computer has a touchscreen display. Does Klein disclose a computer with a touchscreen display?

A He does over here.

Q That's -- for the record, Dr. Stone is pointing to the photograph on slide 173 taken from page 34. Is that computer mounted on a vertical post with a top end extending above the cabinet structure?

A It is. Here is the top of the cabinet structure and here is the vertical post.

Q All right. And again, for the record, we are pointing to the excerpt taken from page 34 of RX-106. Let's move forward please.

Claim 1 says we are inserting an eluate reservoir in a shielded well on board the cart. Please explain, how does the prior art teach that subject matter?

A Klein has the eluate reservoir in the shielded well of the dose calibrator and we've talked about how that would be obvious to relocate the dose calibrator and the eluate reservoir on board the cart as disclosed and taught by Tate and Medrad.

Q So that's slide 174. Let's keep going. We are still on slide 174. The next element is placing the eluate reservoir in fluid communication with the eluate tubing line. Please explain, how does that eluate reservoir get put in communication with the eluate tubing line?

A In this case, the computer in green once again controls the patient valve to direct the fluid to the patient line which now is connected to the eluate reservoir and as we've said, that would be obvious to place it on board the cart.

Q And just to knock this out, the computer is configured to control the fluid communication between the

eluate reservoir and the eluate tubing line. Remind us how does the computer control this?

A The computer controls it with software through this computer control -- through this interface port to the valve.

Q All right. And for the record, Dr. Stone is pointing to the patient valve color coded in orange on slide 174.

Okay. Let's move forward. We are on to slide 175. Claim 1 says you're pumping a -- sorry, you're pumping a sample of the rubidium radioactive eluate into the eluate reservoir in the shielded well on board the cart. Why don't you show us the pumping.

A So here we have the computer controlling the peristaltic pump which in turn pumps saline into the generator. The generator has now the rubidium radioactive eluate coming out going through the patient valve into the reservoir, and we've discussed the on board the cart fairly extensively.

Q Okay. For the record, we are -- Dr. Stone is referring to color codings on slide 175 extending from the pump through to the dose calibrator. Let's move forward, please.

Claim 1 says there is measuring a radioactivity of the sample of the rubidium radioactive eluate flowing

through the eluate tubing line with a radioactivity detector on board the cart. Did you see the subject matter in the prior art?

A Yes.

Q Would you point out the radioactivity detector?

A Here we have the radioactivity detector, which is measuring the activity while the eluate is flowing through tubing on its way to the reservoir.

Q For the record, we are on slide 176 and Dr. Stone has called out the activity counter color coded in purple and also the tubing line color coded in pink that extends from the generator to the dose calibrator. All right. Is that radioactivity detector on board the cart?

A Yes, it is.

Q All right. And does that radioactivity detector do its job while the sample of the rubidium radioactive eluate is flowing through the eluate tubing line?

A Yes, it does.

Q Let's move forward, please. All right. We are on slide 177 still talking about claim 1 of the '870 patent. This claim element says that we are measuring a calibration radioactivity of the sample pumped into the eluate reservoir, and let's stop there.

How does this -- how does the prior art teach measuring a calibration radioactivity of the sample?

A Klein teaches measuring the radioactivity of that sample when it is first pumped into the eluate reservoir.

Q All right. So that sample is pumped into the eluate reservoir; is that right?

A That's correct.

Q Is it in the shielded well?

A It is.

Q All right. It's not on board the cart, but we've discussed that, right?

A No.

Q Does that measuring occur while the eluate reservoir remains in the shielded well?

A Yes. That's the way the system works.

Q All right. Let's move forward, please. All right. We are on slide 178. We've got a comparison step. This one is kind of wordy. All right. Let's look four lines from the bottom. Do you see this?

A Yes.

Q All right. I'm going to try to walk you through you this claim element. First, we are comparing, one, the radioactivity of the sample of the rubidium radioactive eluate flowing through the eluate tubing line measured by the radioactivity detector on board the cart while the sample of the rubidium radioactive eluate is flowing

through the eluate tubing line. That's one thing that we are -- we've taken.

And then second, the claim says we are comparing that with the calibration radioactivity of the sample pumped into the eluate reservoir in the shielded well on board the cart. Why don't you explain this to the Court. How does the prior art teach this subject matter?

A Well, Klein discloses that flushing of the generator into the dose calibrator and the integral activity recorded from the dose calibrator while that is done as the integral activity while it's flowing through this line is used to calibrate the activity counter -- sorry, the integral activity and then the dose calibrator's reading here is used to calibrate that activity counter and verify the calibration constant is within tolerance from previous readings.

Q All right. For the record, this slide 178 refers to an activity counter color coded in purple and a dose calibrator color coded in blue taken from this block diagram on page 29 of the Klein thesis. So am I correct that the activity countermeasures one radioactivity?

A Yes.

Q And the dose calibrator measures a second radioactivity?

A That's correct.

Q And are they for the same sample of rubidium eluate?

A Yes, they are.

Q All right. And who does the comparison of those readings taken from those two components?

A The computer.

Q All right. Let's move forward, please. We are at slide 179 still talking about claim 1, and this element refers to determining a strontium breakthrough test result. You've got to determine the strontium breakthrough test result on the sample pumped into the eluate reservoir in the shielded well on board the cart.

Again, walk us through, how does the prior art show this subject matter?

A Well, again, Klein has the sample pumped into the reservoir and radioactivity readings taken at the appropriate times does the computation. It doesn't do it on board the cart, but we've shown that it's obvious to place it on board the cart.

Q All right. This claim element says that that process occurs while the eluate reservoir remains in the shielded well on board the cart. We've talked about the on board the cart piece. But the rest of it, does this process occur while the eluate reservoir remains in the shielded well?

A Radioactivity readings are taken while the eluate reservoir is in the shielded well of the dose calibrator.

Q All right. Claim 1 has -- this element has a wherein clause. The computer of the infusion system is further configured to not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit. Again, please walk us through this subject matter.

A Enablement of patient elutions is reset to not being enabled each night at midnight and a daily protocol must be completed in order to -- with a successful breakthrough run measurement as it states here -- must be completed in order to enable patient elutions for the remainder of the day. This is done by the system. The amount is utilized compared to strict Health Canada guidelines and the data protocol computes that strontium breakthrough in accordance with the formulas as we've discussed previously.

Q Okay. Thank you. So for the record, we are on page 179 of the presentation. And the excerpts from which Dr. Stone was referring are pages 39, 43 and, in this case, 28 of the Klein thesis. Let's move forward, please.

All right. We are at slide 180. And now we get to talk about claim 2 of the '870 patent. You have to

place the eluate tubing line in fluid communication with a patient. Does that happen in the prior art?

A Yes, it does.

Q Where does the patient go?

A The patient line is here at the imaging system. The patient line is placed in eluate -- I'm sorry, the eluate tubing line is placed in fluid communication with the patient by the patient valve of the system and that's done -- controlled by the computer through the interface board.

Q For the record, we have an excerpt here on slide 180 from page 29 of the Klein thesis. When Dr. Stone was referring to the patient, he was referring to the thing color coded in yellow. What did you call it? It's not a person. What is that?

A I'm sorry.

Q What is the thing color coded in yellow?

A In yellow, that's the imaging system with the patient lying on the tray there.

Q And Dr. Stone also referred to the tubing that connects the generator that's coded in pink to that imaging system. All right. And then I'm not sure the record is clear, so let's go back through this piece. There's a wherein clause here in claim 2 that says the computer is further configured to control the fluid communication

between the eluate tubing line and the patient. Again, walk us through how -- what are we seeing here on slide 180 showing?

A The first portion here is the eluate tubing line and the valve -- the patient valve controlled by the computer controls the flow to the patient.

Q All right. So for the record, Dr. Stone is pointing to the patient valve that's color coded in orange on slide 180.

A And I should have said the fluid communication rather than the flow.

Q Let's keep going. All right. We are at slide 181 still talking about claim 2. The method includes pumping a dose of the rubidium radioactive eluate to the patient. Does that occur in the prior art?

A Yes, it does.

Q Tell us.

A We'll start with the computer which controls the peristaltic pump taking saline from the bag in hot pink line that goes on through the generator valve to the inlet port of the generator eluating now rubidium chloride through the outlet port of the generator through the -- or sorry, through the activity detector through the patient valve to the patient and that's the pumping action all controlled by the computer.

Q All right. And for the record, slide 181 has the same excerpt taken from page 29 of the client thesis, and Dr. Stone was walking us through those components. Let's go forward.

All right. Claim 2 says there is flushing of the rubidium radioactive eluate remaining in at least a portion of the eluate tubing line into the patient. So how does Klein teach flushing eluate that remains in a tubing line into the patient?

A As shown here in the diagram, when the appropriate dose has been measured here at the activity counter, this valve is -- sorry, this valve shifts now to pump saline from this location on and flushes any remaining radioactive eluate into the patient.

Q Okay. All right. So the system decides that the patient has had enough. Is that really where we are at?

A That's where we are at.

Q All right. And when that decision is made, where is the remaining radioactivity that's relevant under this claim?

A The radioactivity here, which hasn't been measured yet, but measured activity is from this point on to the patient.

Q All right. For the record, Dr. Stone is

pointing to the activity counter on the slide 182, which probably is the only component not color coded for us.

Okay. So that's where the radioactivity occurs. How does the system push that radioactivity into the patient?

A By switching the inlet -- sorry, the saline that's being pumped from the generator input inlet through the bypass line and forcing any fluid remaining from this point on on into the patient.

Q All right. So let's walk through the rest of this claim to make sure that we've got it captured. That flushing must occur by pumping saline from the saline reservoir to the eluate tubing line through a bypass line. Show us the bypass line, please.

A Bypass line is shown here.

Q All right. So for the record, Dr. Stone is pointing to a pink color coded line that extends through the orange generator valve. It is the top of the two lines extending into the generator valve let's say.

All right. That bypass line has to bypass the strontium-rubidium radioisotope generator. Does that occur in the prior art?

A It does. Here is the generator. There is no longer flow in this line. Instead, it bypasses the generator and goes to the junction point just before the

activity counter.

Q And then the claim also says that the computer is configured to control fluid communication via the bypass line. Just remind the Court, how does the computer control all this?

A The computer controls that by controlling this valve through the interface board that's shown in orange.

Q All right. Thank you. So let's move forward, please. So now we are on slide 183. We get to talk about claim 8 of the '870 patent. Claim 8 says that the computer of the infusion system is configured to present on the touchscreen display a screen for starting the patient infusion by touching a button on the touchscreen display.

Does the prior art teach this subject matter?

A Yes. Klein displays a screen with a button to start the patient infusion. They are asked if they want to start the constant activity elution here in this sample screen and the patient must push on the button outlined in yellow here the yes button in order to start that constant activity elution.

Q All right. So for the record, there is a screenshot illustrated here on slide 183 that's taken from page 64 of the Klein thesis. And Murphy's Law, there's probably like eight of those screenshots, but this one is the one that's entitled "Start constant activity elution"

question mark on the green gray screen.

Let's move forward, please. All right. So claim 8 also says that the computer is configured to present on the touchscreen display a screen reminding the user to insert the eluate reservoir in the shielded well on board the cart. Please explain your analysis of this element.

A Well, here we have one of the differences between a prototype and a device that's configured for operations. The system provides reminders in Klein to operating personnel, but not for an eluate reservoir. But we have pointed out that the -- that he does have warnings and he has -- and we have other evidence that shows that that would be obvious to do.

Q Let's go on to slide 184. Why don't you advance, please, and now we get to go to slide 185. You have an excerpt from this international standard. Is that the subject matter that you're referring to?

A Yes. This is where the international standard teaches that the user has to be aware of the correct consumable, how to assemble them and how to check the correct functioning. That vial is a consumable and its use must be made known to the user.

Q I don't think we've shown the Court this picture shown here on the lower left-hand side of slide 185. What

is that?

A That's a diagram from the Klein thesis that shows the vial in the dose calibrator, which is itself a shielded well, but it's also had additional shielding surrounding it, though he's not showing the additional shielding. He's showing that ion chamber that is a shielded well for measurements.

Q Okay. So we've been using the word "eluate reservoir." What's the eluate reservoir in Klein's system?

A Klein calls it a vial.

Q Let's move forward, please. We are at slide 186. Claim 8 further refers to a computer that is configured to present on the touchscreen display a screen indicating that the patient infusion is in process. Does the prior art teach this subject matter?

A It does.

Q Why don't you walk us through it, please.

A So Klein's thesis states that the realtime graphics display must include a system diagram with updated information about the state of the system. This includes the current activity rate reading, the flow rate, the valve status, expected accumulated activity at the patient outlet. In addition, progress bars must be included for each stage of the elution so as to facilitate monitoring of the system. And an emergency stop button must be enabled

throughout the elution and take immediate effect to bring the system to the safe mode.

Q Okay. So do you think this disclosure teaches a display screen that indicates a patient infusion is in process?

A Yes.

Q All right. And then the wherein clause of this element says that the screen indicating that the patient infusion is in process displays a stop button to abort the patient infusion. How does the prior art teach this subject matter?

A Indeed, Klein shows a stop button for one of the steps that's taking place as shown here on the diagram in yellow.

Q All right. For the record, Dr. Stone is pointing to the screenshot excerpted from page 64, the stop button that is coded in yellow on slide 186 of the presentation. All right. Let's move forward, please.

Claim 8 says that the computer of the infusion system is configured to present on the touchscreen display the strontium breakthrough test result. Do you see this subject matter taught by the prior art?

A Yes.

Q Why don't you explain it to us.

A First of all, he says that a record is kept of

all the completed elutions for analysis and filing. But he also states at the end of an elution, reports must be generated based on the type of elution and its mode of completion. In addition, a separate window must list a comprehensive display of all statistics in addition to activity curves relating to the activity rate and the integrated activity at the patient outlet.

Q Okay.

A I believe it's obvious that strontium breakthrough test results are a statistic that is related to the elution.

Q So you think a person of skill would think that strontium breakthrough test results are a relevant statistic to the calibration run?

A Yes.

Q All right. Let's move forward. All right. So we are on slide 188 and we are talking about claim 9 and there are four elements listed here. The first one says that there is logging into the computer by entering a user login credential on the touchscreen display.

Please explain how the prior art teaches this subject matter.

A As we've seen before, that the generator information screen is displayed first and following there's a prompt for number one, a user ID code, which is useful

for avoiding tampering by unauthorized personnel as well as enabling test runs.

Q All right. So that excerpt is taken from page 63 of RX-106. The next element of claim 9 is entering a patient ID on the touchscreen display. How does prior art teach this subject matter?

A Again, from the Klein thesis, depending on the chosen run type, the user is prompted for additional information such as the patient ID number, number two.

Q All right. And that excerpt is from page 65 of the Klein thesis. Sub-element 3 of claim 9 is entering a patient dose on the touchscreen display. Is a patient dose taught by the prior art?

A Continuing from that same location in Klein, it also displays that a person can enter the dose activity, number three.

Q All right. And the fourth element here in claim 9 is entering a flow rate on the touchscreen display. Does the prior art teach this subject matter?

A Again, continuing from the same location, that flow rate and priming of the patient line, etc., number four as in the Klein thesis.

Q All right. So again, for the record, Dr. Stone is referring to an excerpt taken from page 64 of the Klein thesis.

All right. Let's move forward, please. We are at slide 192 and we are talking about claim 10 of the '870 patent. Claim 10 refers to tracking a volume of saline remaining in the saline reservoir. Have we seen this element before?

A We have. The '869 patent claim 24 and my analysis remains the same.

Q All right. Let's cycle forward. Claim 10 refers to providing an alert via the touchscreen display when the volume of saline remaining in the saline reservoir is below a predetermined volume threshold.

And actually let's move forward, please. Claim 10 also refers to presenting on the touchscreen display a screen reminding the user to empty the waste bottle. These three elements that are shown here on slide 192 for claim 10, where have we seen these elements described?

A Those are in the '869 patent claim 4 and my analysis remains identical.

Q All right. Let's move forward, please. We are at slide 193 and we're talking about claim 11. It says that the method further comprises initiating a generator column wash through the touchscreen display. Please explain what does -- how does Klein describe a generator column wash?

A Klein refers to that as a flush run that's

initiated from the user interface, and we see on the screen a sample screen from the Klein thesis that shows how a flush run is initiated.

Q All right. For the record, Dr. Stone is referring to page 64, another one of these screenshots taken from the client thesis. All right. So the flush run, is it initiated from the user interface?

A Yes.

Q All right. Let's move forward. Claim 11 says that a predetermined amount of saline is pumped through the strontium-rubidium radioisotope generator and directed to the waste bottle during the generator column wash. How does Klein describe operation of the generator column wash?

A From the Klein thesis, we have that the flush run flushes all the lines in the system as well as a 50 milliliter flush of the generator at 15 milliliters per minute.

Q All right. And this excerpt that you're referring to is taken from page 53 of the Klein thesis; is that correct?

A That's correct.

Q Let's move forward, please. All right. We are at slide 194 and we are still talking about claim 11 from the '870 patent. And this new element refers to initiating a purging process through the touchscreen display to purge

a patient tubing line of air. How does Klein describe purging patient tubing lines of air?

A Well, once again, the same citation from Klein that the flush run flushing all of the lines in the system as well as 50 milliliter flush of the generator at 15 milliliters per minute, which ensures flushing of air bubbles in the saline and strontium breakthrough from the generator.

Q And the claim also refers to the patient tubing line being in fluid communication with the eluate tubing line. Did you see that subject matter taught by the prior art?

A Yes.

Q All right. Let's move forward. We are at claim 12 of the '870 patent on slide 196 of the presentation. The first element says that the saline tubing line and the eluate tubing line are routed through tubing passageways.

Let's move forward, please. Claim 12 also says that the tubing passageways have depths configured to prevent pinching or crushing of the tubing lines routed there through. Have we seen this subject matter before in your analysis?

A Yes. We saw those elements in claim 4 of the '869 patent and my analysis remains the same.

Q Let's move forward, please. We are at slide 198

and we are talking about claim 13 of the '870 patent which refers to a handle and also to four wheels. Have we seen this subject matter in your analysis already?

A My analysis of handles and wheels remains the same as in the '869 patent claim 4.

Q Claim?

A 24.

Q Claim 24. Thank you. Let's move forward, please. We are at slide 200. Talking about claim 16 of the '870 patent. The infusion system further comprises a dose calibrator in the shielded well on board the cart and in communication with the computer to determine the strontium breakthrough test result. Have we seen this subject matter before in your analysis?

A Yes, we have.

Q Where?

A It's in the '869 patent claim 27. My analysis remains the same.

Q Your analysis at claim 16 is the same as claim 27; is that correct?

A That's correct.

Q Let's move forward, please. All right. Now we are at slide 202. We are talking about claim 17 of the '870 patent and you have a comparison here between claim 17 and claim 3 of the '869 patent. Have we seen the elements

of claim 17 already in your analysis?

A We have. These were in the '869 patent claim 3.

Q All right. So let's just move forward. Would you cycle through this to show the Court how they correspond.

All right. And how does your analysis of claim 17 of the '870 patent correspond to your analysis of claim 3 from the '869 patent?

A My analysis of the '869 patent claim 3 remains the same and it's the same analysis for claim 17.

Q Let's move forward, please. All right. We are at slide 203 talking about claim 27 of the '870 patent. I'm not sure we've seen this before. This one says the computer of the infusion system is configured to track time passed from the completion of pumping the sample of rubidium radioactive eluate into the eluate reservoir to determining the strontium breakthrough test result.

Please explain, how does the prior art teach this subject matter?

A In Klein, we see here that the activity of the dose calibrator is registered 30 minutes after the end of the elution to compute the strontium-82 and strontium-85 breakthrough activity.

Q All right. So this excerpt is taken from page 28 of the RX-106. How much time does the computer track?

A The computer tracks 30 minutes. The computer does the measurements. It does the tracking of time.

Q All right. Let's move forward, please. All right. So we are at slide 204 and we get to shift to the '826 patent. All right. And we are at slide 205. Thank you.

All right. So let's talk about claim 1. Claim 1 talks about a method of building an infusion system to deliver a rubidium radioactive eluate. Does Klein teach how to build an infusion system to develop rubidium radioactive eluate?

A He does.

Q All right. So let's move into the elements. The first thing you've got to do is install a first shielding compartment, a second shielding compartment, and a shielded well on a platform of a cart. Walk us through where are the first, second shielding compartments and where is the shielded well that's relevant to this element?

A Klein has first shield -- Klein has a first shielding compartment, a second shielding compartment. We talked about the obviousness of placing this shielded well for the dose calibrator on board the cart.

Q And for the record, Dr. Stone is pointing to, again, this photograph taken from page 34 of the Klein thesis and to the red, green and blue annotation provided

on slide 205.

Okay. So claim 1 has a couple of wherein clauses. The first wherein clause is that the first shielding compartment has a first opening facing vertically upwardly. Have we encountered this before?

A We have. And we've explained that Klein has his shielding compartments with openings facing vertically up.

Q And we've also discussed that with respect to CardioGen and Tate; is that correct?

A That is correct.

Q The next part of the wherein clause is that the first opening is configured for a strontium-rubidium radioisotope generator to be inserted into and removed from the first shielding compartment. How does the prior art teach this subject matter?

A As we spoke previously, the generator was placed in the cart surrounded by lead rings to provide maximum radiation shielding. They had an opening facing vertically upward through which the strontium-rubidium generator could be inserted into and removed from that compartment.

Q All right. And the other prior art references that we've discussed, the Tate, the Medrad and CardioGen, did they have radiopharmaceuticals placed?

A They had radiopharmaceuticals. The source was placed in shielded wells with vertically opening -- with

vertical openings facing upward.

Q All right. Let's move forward, please. We are at slide 206. We are talking about the second shielding compartment which is color coded and was color coded in green in the prior slide. This one says also that that shielding compartment must have a second opening facing vertically upwardly. Have we discussed this in your analysis already?

A We have.

Q All right. Again, explain how does the prior art show this subject matter?

A We had a waste container mounted on the top shelf inside a lead container with a lid.

Q All right. Claim 1 also refers to the second opening being configured for a waste bottle this time to be inserted into and removed from the second shielding compartment. How does the prior art teach this?

A Well, again, we spoke of the waste container shielding compartment that Klein has.

Q And then, I guess, the last part of this wherein clause is that the first opening, that's the one for the generator shield, is located at a lower elevation than the second opening, which is the one for the waste bottle shield. Why is this subject matter obvious over the prior art?

A As we've spoken before, it would be obvious to take the heavier objects that have to be handled by the user and place them at the lower elevation than that second opening that we dealt with.

Q Let's move forward, please. Now we are at slide 207 still talking about claim 1. This one says that the shielded well is configured to receive an eluate reservoir that is configured to receive a sample of the rubidium radioactive eluate. Again, walk us through your analysis of this piece.

A Again, we have the calibrator chamber that's a shielded chamber located in a shielded well and inside is the vial, the eluate reservoir that is configured to receive a sample of the radioactive rubidium.

Q So for the record, Dr. Stone is pointing to the excerpt at page 57 that we have here on slide 207 and to the vial coded in blue and to -- would you call it a doughnut assembly, the doughnut cylinder illustrated as the calibrator chamber. All right. Let's move forward, please.

All right. We are on slide 208. We are talking about claim 1. And claim 1 starts -- this excerpt starts off with configuring a computer with a touchscreen display for the infusion system to do a bunch of stuff. Again, remind the Court, does the prior art teach a computer with

a touchscreen display?

A Yes. Klein's thesis described a computer with a touchscreen display.

Q All right. The first thing that the computer must configure the system to do is to fill the eluate reservoir in the shielded well on board the cart with the sample of rubidium radioactive eluate. Remind the Court, how does this happen?

A We've discussed this previously. The computer controls -- the computer controls the peristaltic pump which pumps saline through the generator to the eluate reservoir. The only difference here is that it's not on board the cart. And we talked about how it's obvious to relocate the dose calibrator and the eluate reservoir on board the cart that is taught by Tate and Medrad.

Q So for the benefit of the record, Dr. Stone is referring to the color-coded elements here in this excerpt from page 29 of the Klein thesis.

All right. You've got to fill the eluate reservoir by pumping saline from the saline reservoir into the strontium-rubidium radioisotope generator via a saline tubing line. So just to be absolutely clear, where is the saline tubing line?

A We have saline tubing lines going from here through the generator.

Q Dr. Stone is referring to the pink color-coded lines extending from the saline IV to the generator.

A That's correct. And that's controlled by the computer.

Q It's got to thereby generate the rubidium radioactive eluate that is discharged through an eluate tubing line. So where is the rubidium radioactive eluate discharged from?

A It's discharged from the discharge port through the eluate tubing line.

Q All right. So for the record, Dr. Stone is pointing to the red generator and to the pink line that exits that generator and goes into the activity counter.

All right. Let's move forward, please. Configuring the computer for the infusion system to determine a strontium breakthrough test result on the sample of the rubidium radioactive eluate built into the eluate reservoir in the shielded well on board the cart. Remind us, how did that occur in the prior art?

A The only missing element here is on board the cart. We have -- in Tate, we have readings from the dose calibrator taken by the computer, which also computes the time and ultimately calculates the strontium breakthrough test result while the sample remains in the eluate reservoir in the shielded well.

Q All right. So you stole a little bit of my thunder. But I want to make sure we've knocked out this while clause at the bottom. So it must occur while the eluate reservoir remains in the shielded well on board the cart. And again, tell me the while.

A The while is the sample readings are taken by a dose calibrator while it's in the shielded well.

Q Okay. And again, for the benefit of the record, we are on slide 209 and Dr. Stone is testifying about the blue color coded dose calibrator and the green color coded computer and the communication between them.

Let's move forward, please. All right. So now we are at slide 210. Claim 1 says you've got to configure the computer for the infusion system to not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit. Again, remind us how does this occur?

A The system ensures compliance with the daily protocol, which includes a calibration run and successful breakthrough in order to enable patient elution runs. The amount is based on the strontium breakthrough activity limited to the Health Canada guidelines, and only after a calibration run with low strontium breakthrough has been successfully completed can patient elutions be carried out.

Q All right. Let's move forward, please. That

was slide 210. And now we are on slide 211 and we have claim 2 of the '826 patent. So claim 2 says we are configuring the computer to measure a radioactivity of the sample of the rubidium radioactive eluate while the sample is flowing through the eluate tubing line to the eluate tubing -- to the eluate reservoir. Excuse me. How does the computer measure this radioactivity?

A The computer measures it by being in communication with the activity counter which measures the activity while the eluate is flowing through the tubing line to the eluate reservoir.

Q All right. So we are on slide 211. And for the record, Dr. Stone is referring to the purple coded activity counter and the pink coded tubing lines.

Let's move forward, please. We are at slide 212. This refers to configuring the computer to measure a calibration radioactivity of the sample while the sample remains in the eluate reservoir in the shielded well on board the cart. How does the computer measure a calibrator radioactivity?

A When the sample is in the eluate reservoir where it's first pumped in, the computer measures the activity, receives that activity from the dose calibrator. The only thing missing is on board the cart and we've shown how that's obvious to place that on board the cart.

Q Let's move forward, please. All right. Claim 2 further refers to configuring the computer to compare the radioactivity of the sample measured while flowing through the eluate tubing line and compare that value with the calibration radioactivity of the sample measured in the eluate reservoir in the shielded well on board the cart.

So please explain how does this comparison occur in the prior art?

A As we've discussed before, the integral activity is used to calibrate the activity counter and verify the calibration constant is within tolerance from the previous records. Those activities are taken while the sample is flowing through the dose -- the activity counter and the activity that's read when the sample vial is filled.

Q So that's slide 213 and the excerpt that you're referring to is taken from page 53 of RX-106. Let's move forward, please.

JUDGE CHENEY: That's probably a good place to take our morning break. We'll take 15 minutes. We are off the record.

(Recess.)

JUDGE CHENEY: Let's go back on the record. We are on the record in the 1110 investigation. Before the break we were in the direct examination of Dr. Stone the respondents' expert on the issues of patent validity.

Please continue when you're ready Mr. Hails.

MR. HAILS: Thank you, Your Honor.

BY MR. HAILS:

Q Before we broke we were on slide 215 of your presentation. This shows claim three of the '826 patent and the claim element refers to installing a dose calibrator in the shielded well on board the cart with the dose calibrator in communication with the computer to measure the strontium breakthrough test result. Have we seen this part of this claim earlier in your analysis?

A Yes. We saw that in the '869 patent claim 27.

Q And has your analysis of claim three of the '862 patent correspond with claim 27 of the '869 patent?

A It remains the same.

Q There is a second piece of this claim that says the dose calibrator is not only to measure the strontium-rubidium test result. It is also to measure the calibration radioactivity of the sample pumped into the eluate reservoir. Please explain how does this process occur in the prior art?

A As we've disclosed previously, the calibration radioactivity at the sample pump into the eluate reservoir is measure by the dose calibrator as soon as the saline has been pumped into the dose reservoir and is used for that calibration factor.

Q And, again, what is the system calibrating?

A It's calibrating the activity counter on board the cart.

Q Let the record reflect Dr. Stone is pointing, has pointed to the blue dose calibrator color coded on slide 215 and the communication connectivity between that element and the computer shown in green. All right. Let's move forward please all right. We just talked about a dose calibration radioactivity, so why don't we move on from slide 216. All right. Now we are at slide 218. Talking about claim five of the '826 patent. This claim says configuring the computer to allow a user to initiate a purging process through the touch screen display to purge a patient tubing line of air and that the tubing line is in fluid communication with the eluate tubing line. Have we seen this subject matter before in your analysis?

A Yes. We described our coverage of that in claim 11 of the '870 patent. My analysis remains the same.

Q So your analysis of claim five is the same as your analysis of claim 11 of the '870, is that correct?

A That's correct.

Q Let's move forward, please. All right. Now we are on slide 225 and we are talking about claim nine of the '826 patent and you have a comparison here between claim nine and claim eight of the '870 patent. This is the one

that talks about starting the patient infusion by touching a button on the touch screen display --

And why don't you cycle through these elements.

How do the --

Keep going, please. And one more.

So how do the elements of claim nine from the '826 patent compare to the elements of claim eight from the '870 patent?

A Those are the same elements and my analysis of claim eight, or sorry, of claim nine of the '826 is identical to my analysis of claim nine of the '870.

Q You said claim nine of the '870 but just for the record...

A Sorry. Claim eight of the '870.

Q That's all right. This is a toughy for us both. Let's keep going. We are on slide 227 talking about claim 10 from the '826 patent. Have we seen the subject matter of claim 10 already in your analysis?

A We have. Cycling through each of these elements, these elements are identical to the elements of claim nine of the '870 patent so my analysis of claim 10 of the '826 patent is identical to my analysis of claim nine of the '870 patent.

Q Thank you. That was slide 227 of your presentation.

Can we move forward, please. All right. We are at claim 11 of the '826 patent on slide 228.

This says configuring the computer to track time passed from completion of pumping the sample of the rubidium radioactive eluate into the eluate reservoir to measuring the strontium breakthrough test result. Remind the court, how does the computer track time between these events?

A Indeed, as Klein states, the activity in the dose calibrator is registered 30 minutes after the end of the elution to compute the breakthrough of strontium-82 and strontium-85 activity. Those measurements are done by the computer and the tracking of the time is done by the computer.

Q Okay. And so this excerpt on slide 228 is taken from page 28 of RX-106. Again, how much time is tracked by the computer?

A 30 minutes is tracked by the computer.

Q Let's move forward, please.

Claim 11 also says you got to track a volume of saline remaining in the saline reservoir --

And will you advance, please.

You also have to provide an alert via the touch screen display when the volume of saline in the saline reservoir is below a predetermined volume threshold. Have

we seen this subject matter before in your analysis?

A We have in the '869 patent at claim 14. Those elements are identical. And so my analysis of claim 11 of the '826 is identical to my analysis of those elements in claim 14 of the '869 patent.

Q Or at least with respect to these two newly added elements, correct?

A With those elements, yes.

Q Let's move forward.

All right. So that was slide 232 and now we are at slide 233 talking about the final two elements of claim 11 tracking a volume of the rubidium radioactive eluate discharge from the generator to the waste bottle. Thank you. And presenting the touch screen, on the touch screen display a screen reminding the user to empty the waste bottle. Have we seen this subject matter before in your analysis?

A Yes. My analysis of those elements in claim 24 of the '869 patent are identical to these elements in claim 11 of the '826 patent.

Q All right. So let's move forward, please.

All right. So now we are at slide 237. We are talking about claim 12 from the '826 patent. Let's cycle through the elements of claim 12. Have we seen the elements of claim 12 already in your analysis?

A Yes. Those elements were present in claim 11 of the '870 patent.

Q Okay. And how does your analysis of claim 12 for the '826 compare to your analysis from claim 11 of the '870?

A My analysis of claim 12 of the '826 remain identical to the analysis of those elements in claim 11 of the '870 patent.

Q So that's slide 237. Let's move forward, please.

Claim 13 of the '826. I think we are talking about tubing passageways again and perimeter surfaces of openings and pinching and crushing of tubing lines. Have we seen this subject matter of claim 13 before in your analysis?

A Yes. We saw those elements in claim 4 of the '869 patent. My analysis of these elements in claim 13 of the '826 remains identical to my analysis of those elements in claim four of the '869 patent.

Q Okay. So that's slide 240. Why don't we move forward. So now we are at slide 241 and we are going to talk about claim 14 of the '826. The first element is an exterior shell extending upwardly above the platform wherein the platform and the exterior shell collectively define an interior space of a cabinet structure. Why don't

you just walk us through this. Have we seen this subject matter before?

A We have indeed. Here we have the Klein -- here we have the Klein thesis with a platform and exterior shell on the platform.

Q And an anterior space, do we have an anterior space?

A We have an anterior space.

Q All right.

A Similarly we have those elements in the Tate disclosure, as well as in the CardioGen Model 510.

Q Let the record reflect that with respect to his analysis of Klein he was pointing to the structures illustrated in this picture taken from page 34 of the Klein reference. All right. Let's move forward.

Handles and wheels. Have we seen this subject matter before in your analysis?

A We covered this subject matter in the '870 patent claim 13 and my analysis of claim 14 of the '826 where those elements remains identical.

Q All right. So that's slide 244. Let's move forward, please.

So now we are at slide 246. Talking about claim 17 of the '826 patent which refers to a dose calibrator in the shielded well on board the cart. That's in

communication with the computer to measure the strontium breakthrough test result. Have we seen this subject matter before in your analysis?

A We have indeed. We've analyzed that as claim 27 of the '869 patent and that element, my analysis remains the same for that element of claim 17 of the '826 patent.

Q All right. You said of claim -- which -- your analysis of claim 17 is identical to your analysis of which claim for the '869 patent?

A Claim 27.

Q All right. Let's move forward, please.

That was slide 246 and now we are up to 248. Claim 18. Have we seen the subject matter of claim 18 before in your analysis?

A Yes. Each of these elements we saw previously in claim three of the '869 patent. Those elements in claim 18 are analyzed in my analysis remains identical to my analysis of the claim three of the '869 patent.

Q So just to be clear, your analysis of claim 18 for the '826 is identical to the analysis of claim three of the '869. Is that what you meant?

A That is correct.

Q Let's move forward, please.

All right. Now we are at slide 249. This claim is claim 19 from the '826 patent. It requires configuring

the computer to do a bunch of things. The first thing is to control a fluid communication between the strontium-rubidium radioisotope generator and the saline reservoir. Please walk us through how does the prior art teach this subject matter?

A The computer on the Klein thesis controls the peristaltic pump which controls fluid communication between the saline reservoir. It also controls the generator valve to control fluid communication to the inlet of the strontium-rubidium generator.

Q All right. For the record, Dr. Stone is pointing to this excerpt taken from page 29 of Klein referring to the blue color-coded peristaltic pump, the orange color-coded generator valve and the connections between the saline IV and the strontium-rubidium radioisotope in red. Let's move forward.

Claim 19 says you got to configure the computer to control a fluid communication between the eluate tubing line and the eluate reservoir. How does the computer do this?

A Well, the hot pink eluate tubing line is configured to the fluid communication with the eluate reservoir by the patient valve which is controlled by the computer.

Q And just for the record, Dr. Stone is pointing

to the picture taken from page 29, the orange color-coded patient valve. All right. Let's move forward, please.

The next piece of claim 29 is the computer is configured to control a fluid communication between the eluate tubing line and the waste bottle. Let's talk about how this occurs.

A The eluate tubing line shown in pink is in fluid communication with the waste bottle by the positioning of the patient valve controlled by the computer.

Q All right. Let's move forward, please.

All right. There is two elements in claim 29 that are compared to '870, placing the eluate tubing line in fluid communication with a patient, pumping a dose of the rubidium radioactive eluate to the patient. Have we seen this subject matter before?

A We have. In the '870 patent claim two we saw those two elements and my analysis for claim 19 of -- those two elements of claim 19 of the '826 is identical to my analysis of the -- those two elements in the '870 patent, claim two.

Q All right. And then let's move forward, please.

Claim 19 also says you got to flush the rubidium radioactive eluate remaining in a portion of the eluate tubing line to the patient using this bypass line. Have we seen this subject matter before?

A Yes. We saw that element in claim two of the '870 patent and so my analysis of this element for claim 19 of the '826 is identical to my analysis for claim two of that element. That element of claim two in the '870 patent.

Q Let's move forward, please.

All right. We are at slide 258 and we are talking about claim 28 from the '826 patent. Talks about initiating a column wash through the touch screen display. Also talks about a predetermined amount of saline being pumped through the generator and directed to the waste bottle during the generator column wash. Have we seen this subject matter before?

A We have. We covered those two elements in the '870 patent claim 11 so my analysis of these two elements in claim 28 of the '826 is identical to my analysis of those elements in claim 11 of the '870 patent.

Q All right. Let's move forward, please.

All right, Your Honor, I'd like to run through the Medrad documents, please.

JUDGE CHENEY: Okay. So there has been some discussion about what is public about the Medrad prior art, including dates of sale and things like that. What exactly are you going to be getting into now that has a third-party assertion of confidentiality?

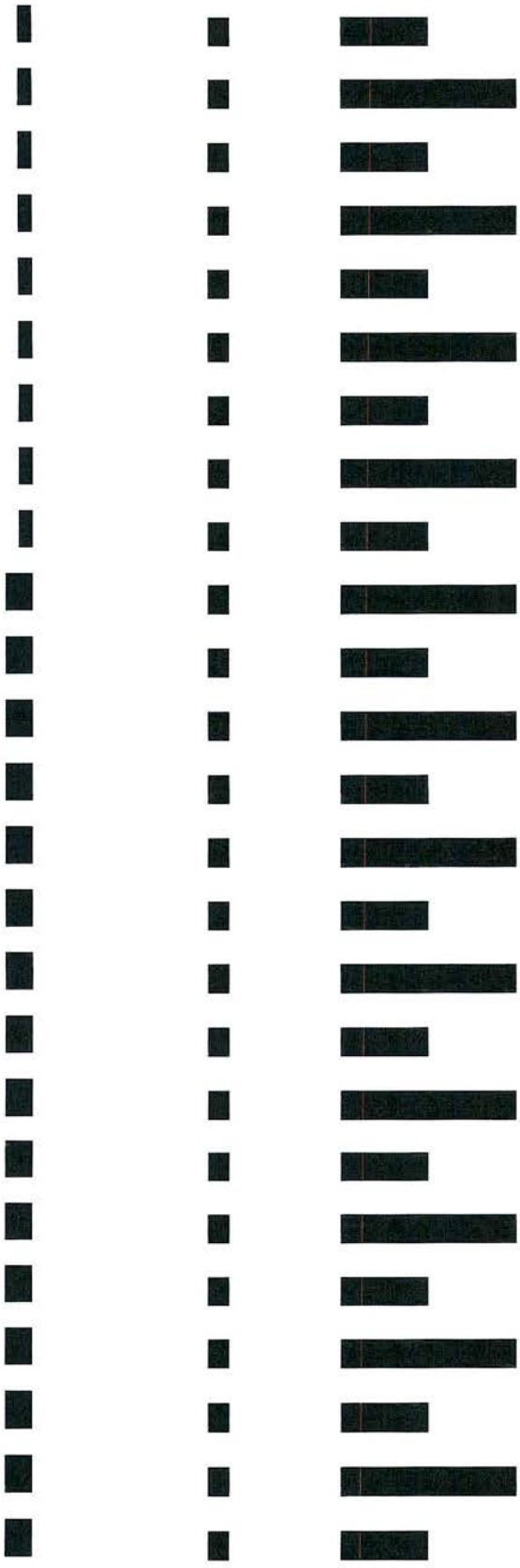
MR. HAILS: So to my understanding, all of these documents have third-party claims of confidentiality and I recognize they are untested. We are going to go through the sales documents and documents showing dates of installation and location of installation and we are going to go through user manuals to essentially confirm the analysis that Dr. Stone has provided earlier, those yellow redaction bubbles.

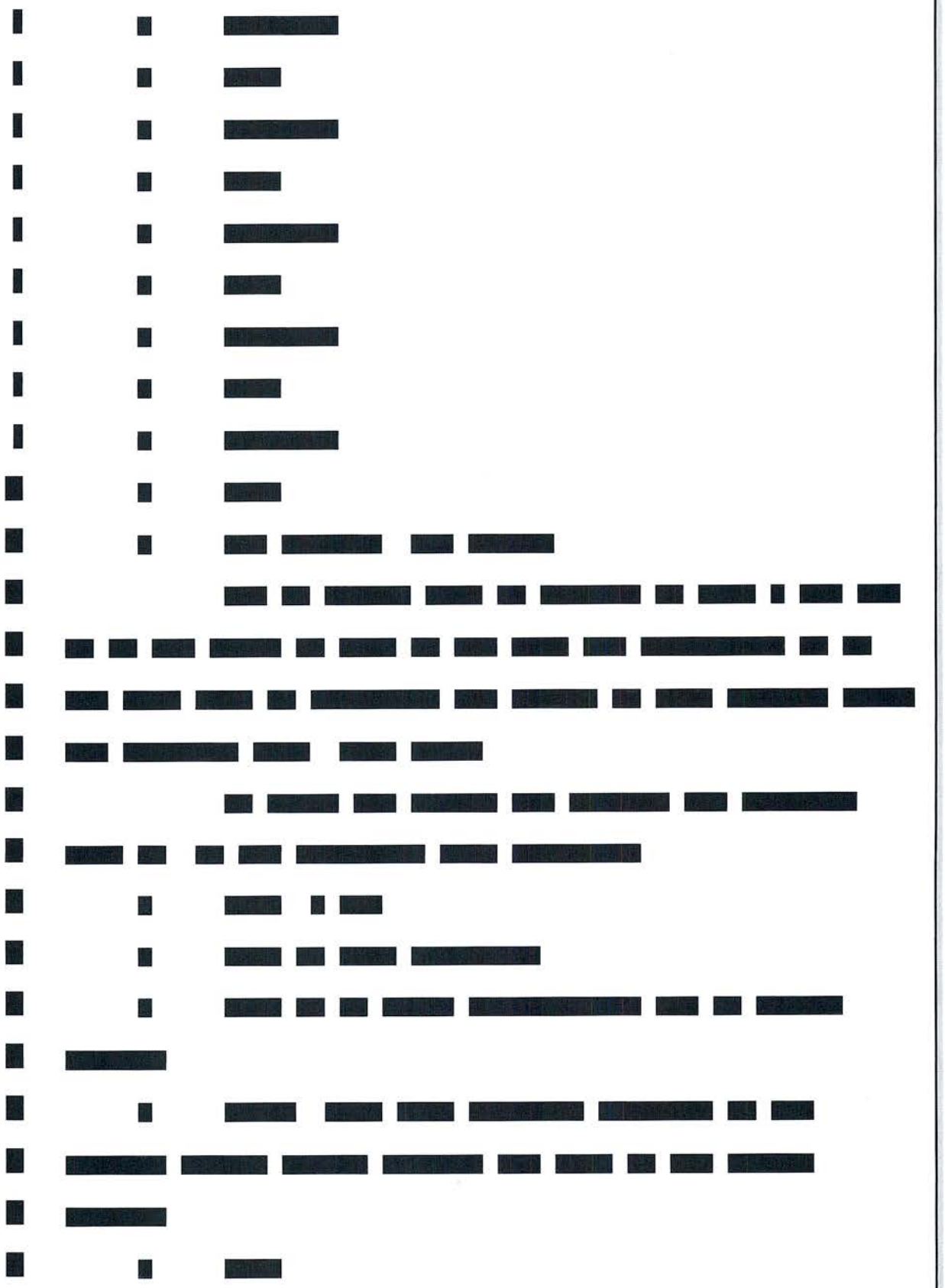
JUDGE CHENEY: Are you going to call any witnesses about these documents?

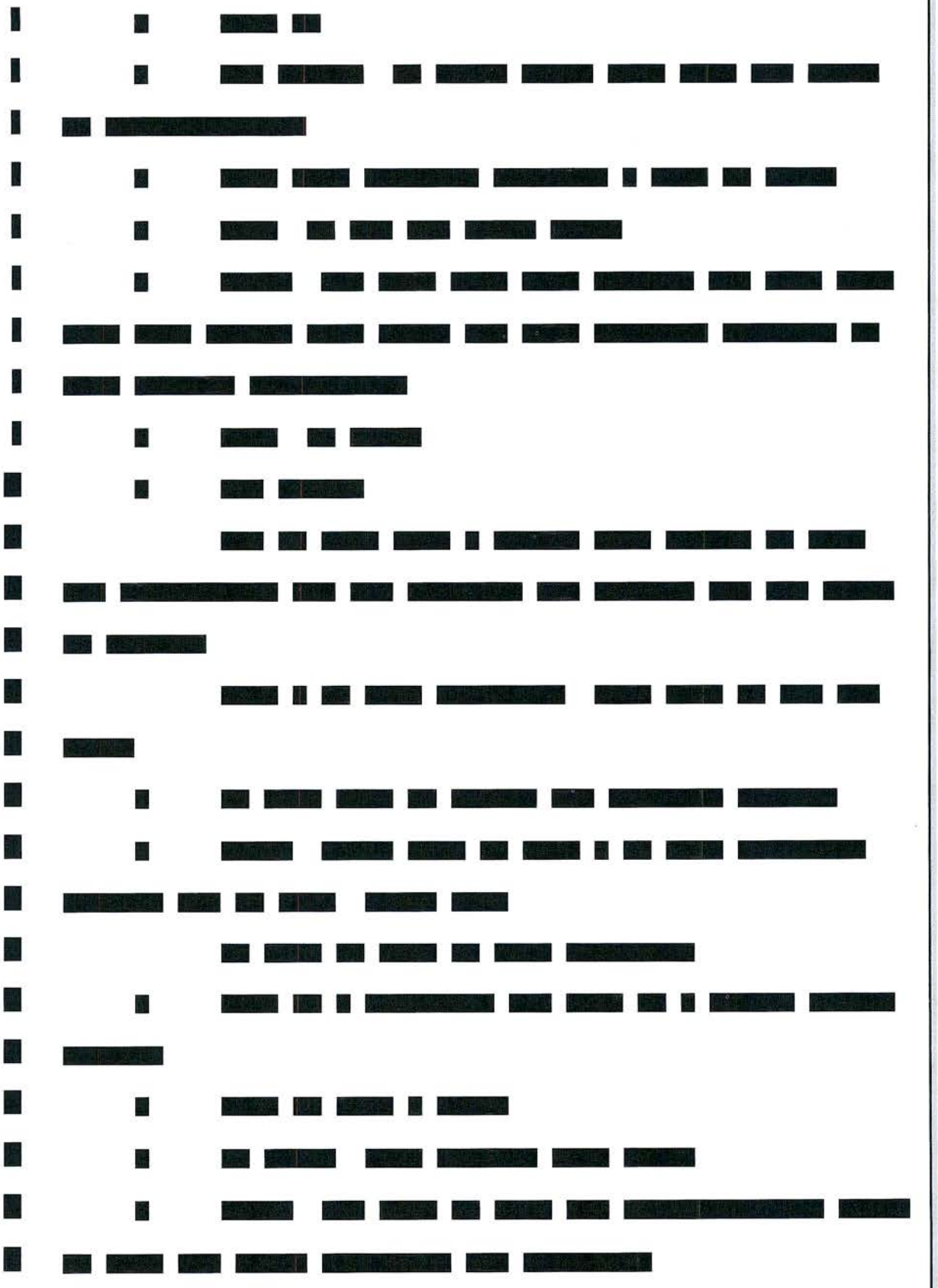
MR. HAILS: We have a declaration from a Medrad, I guess a Bayer person, attesting to these documents that's included.

[redacted]

CONFIDENTIAL SESSION







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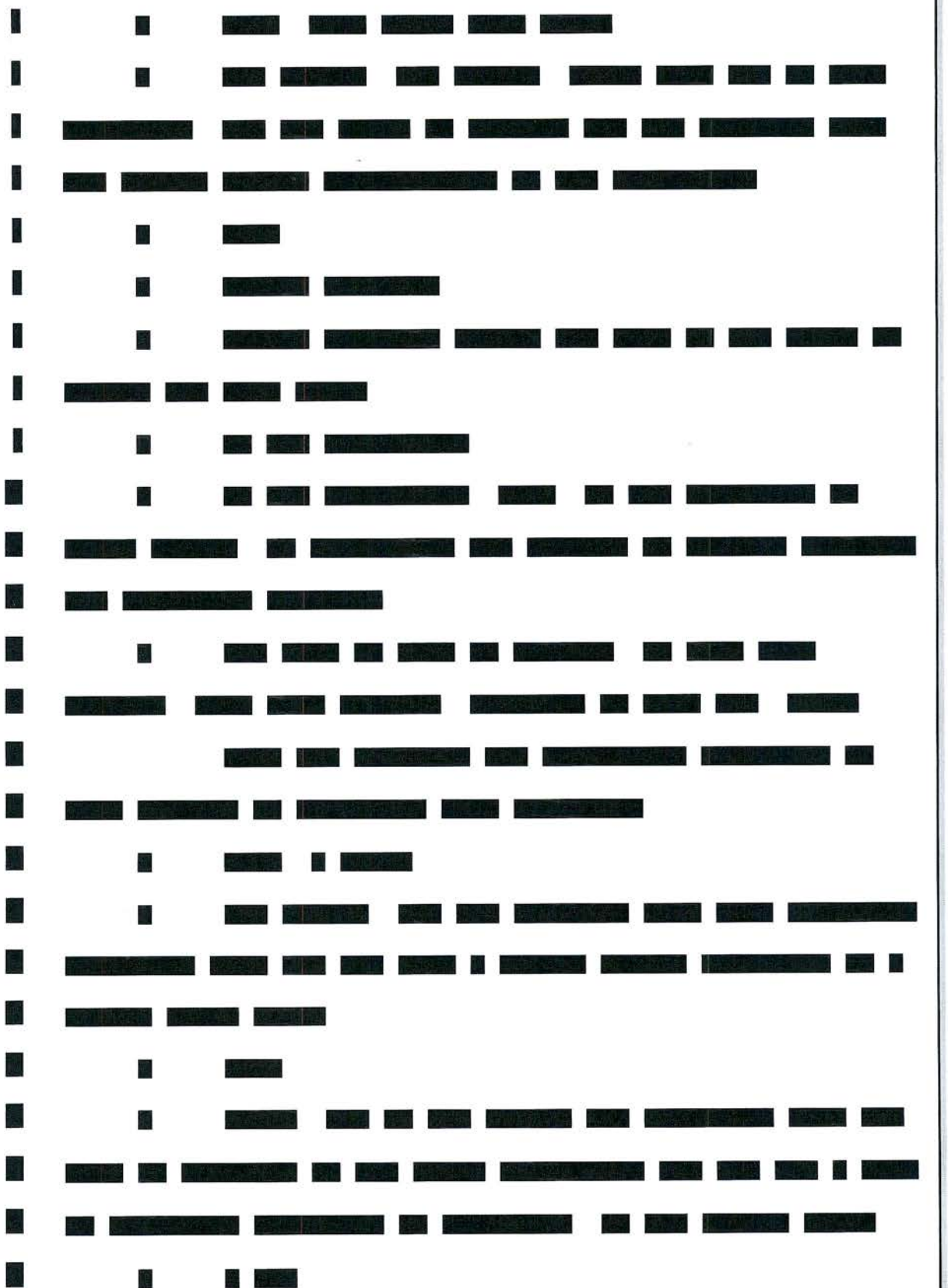
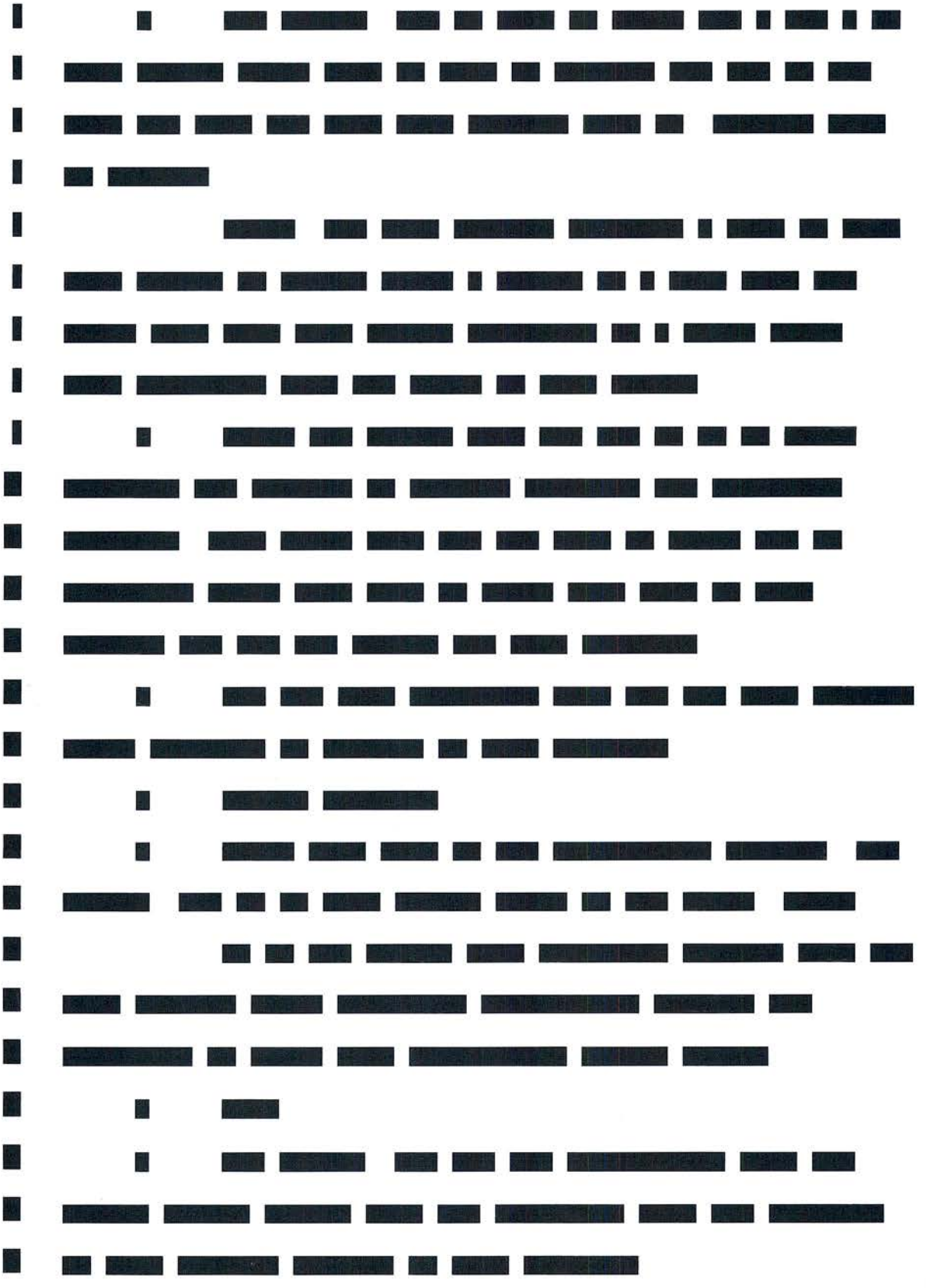
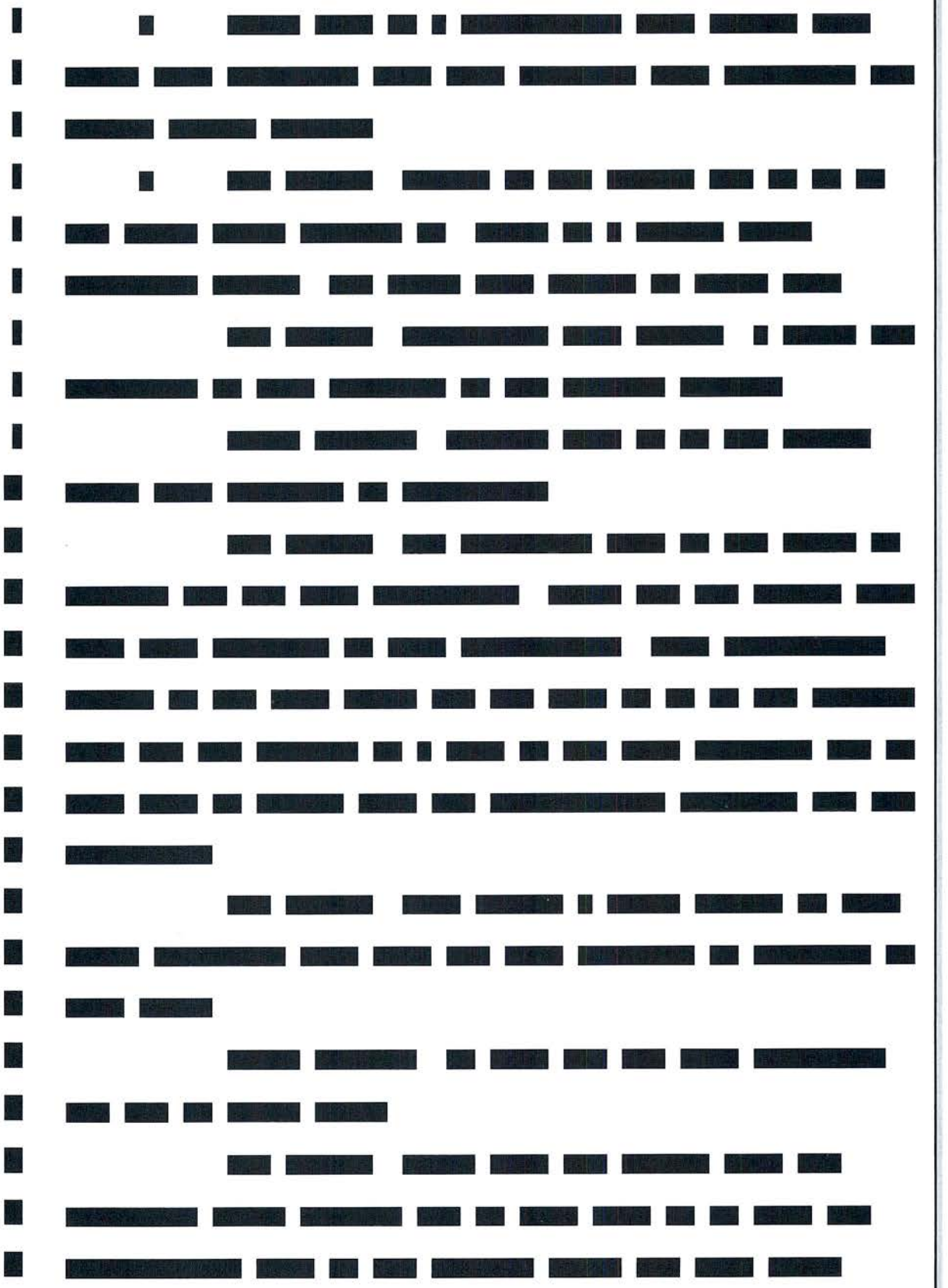
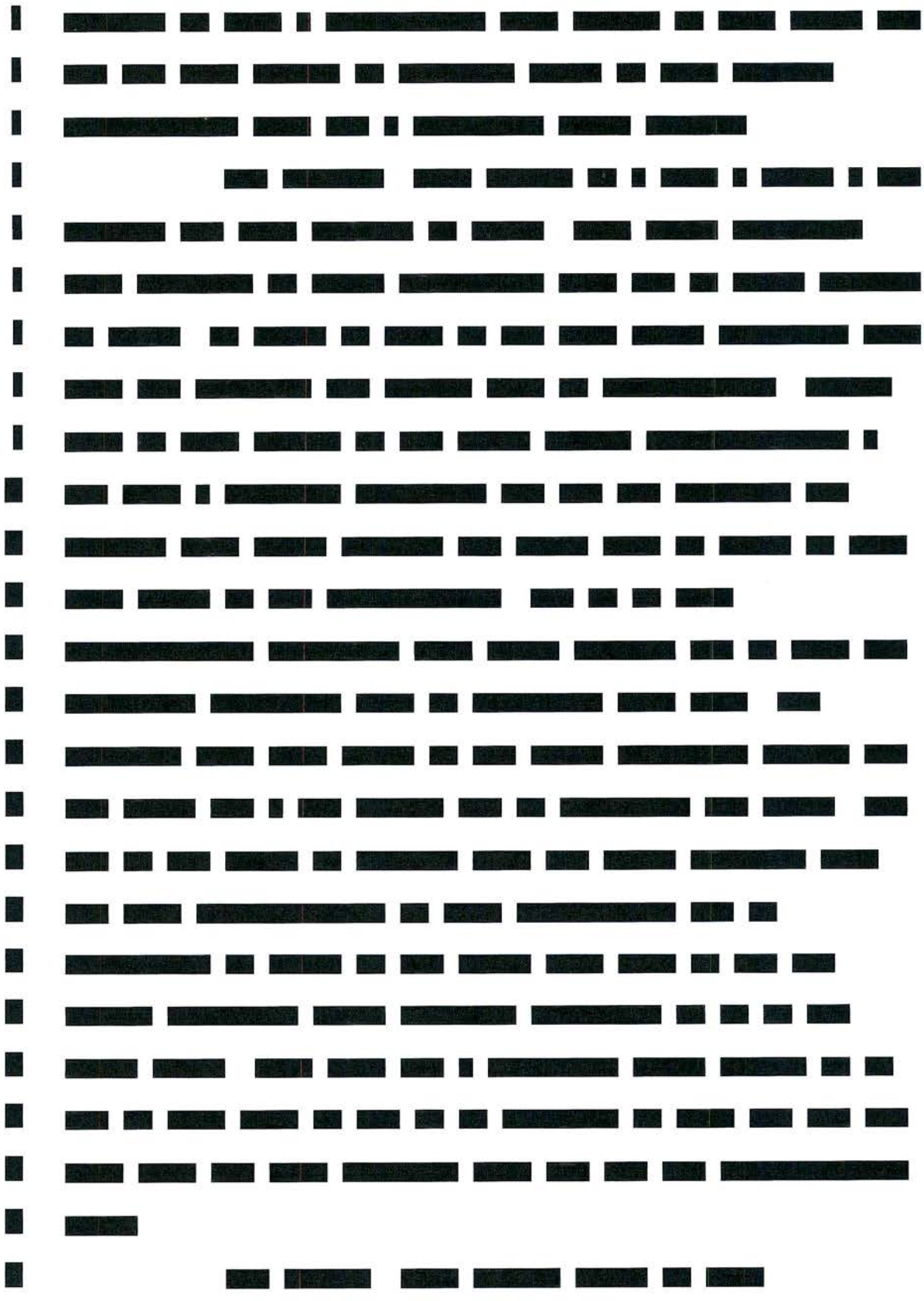
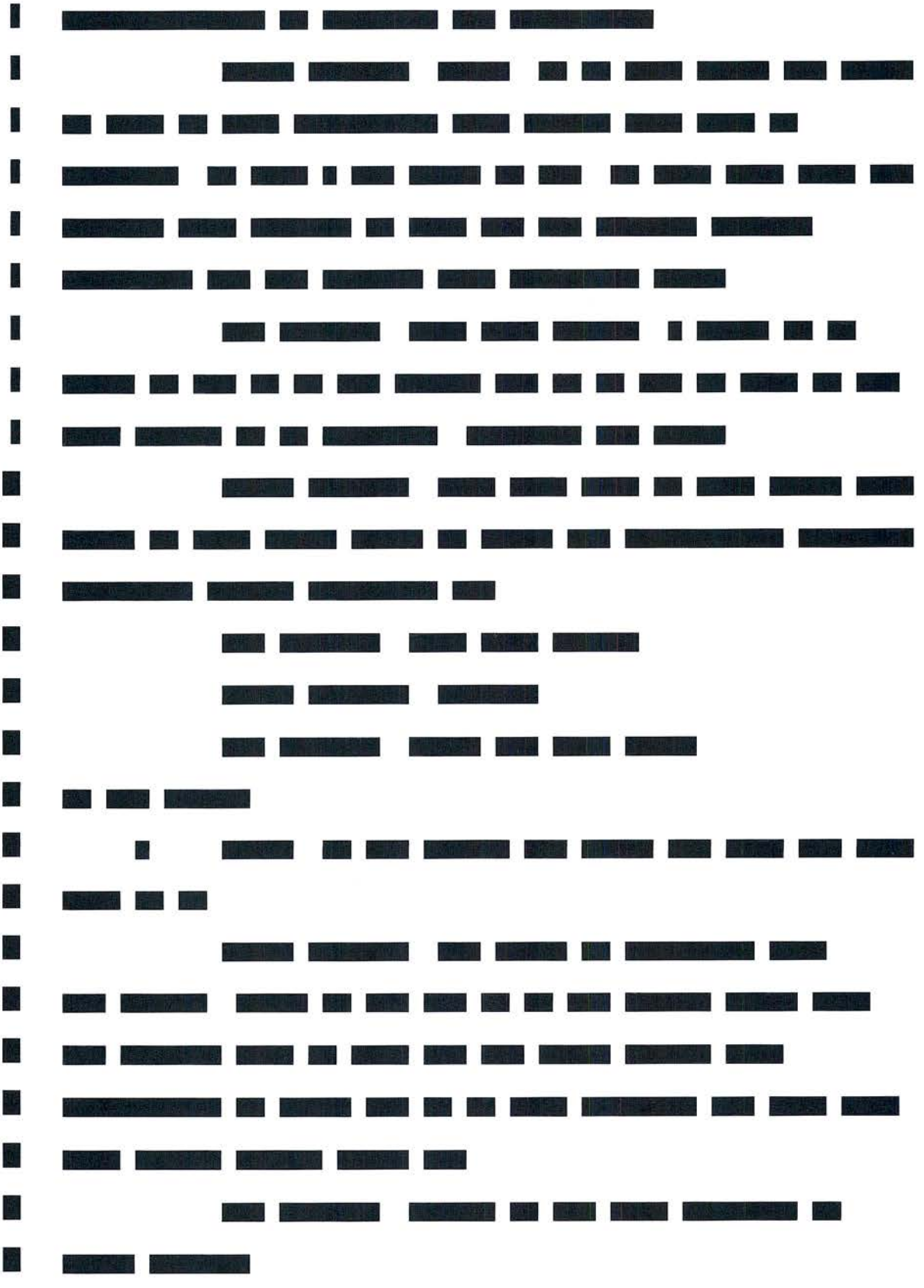
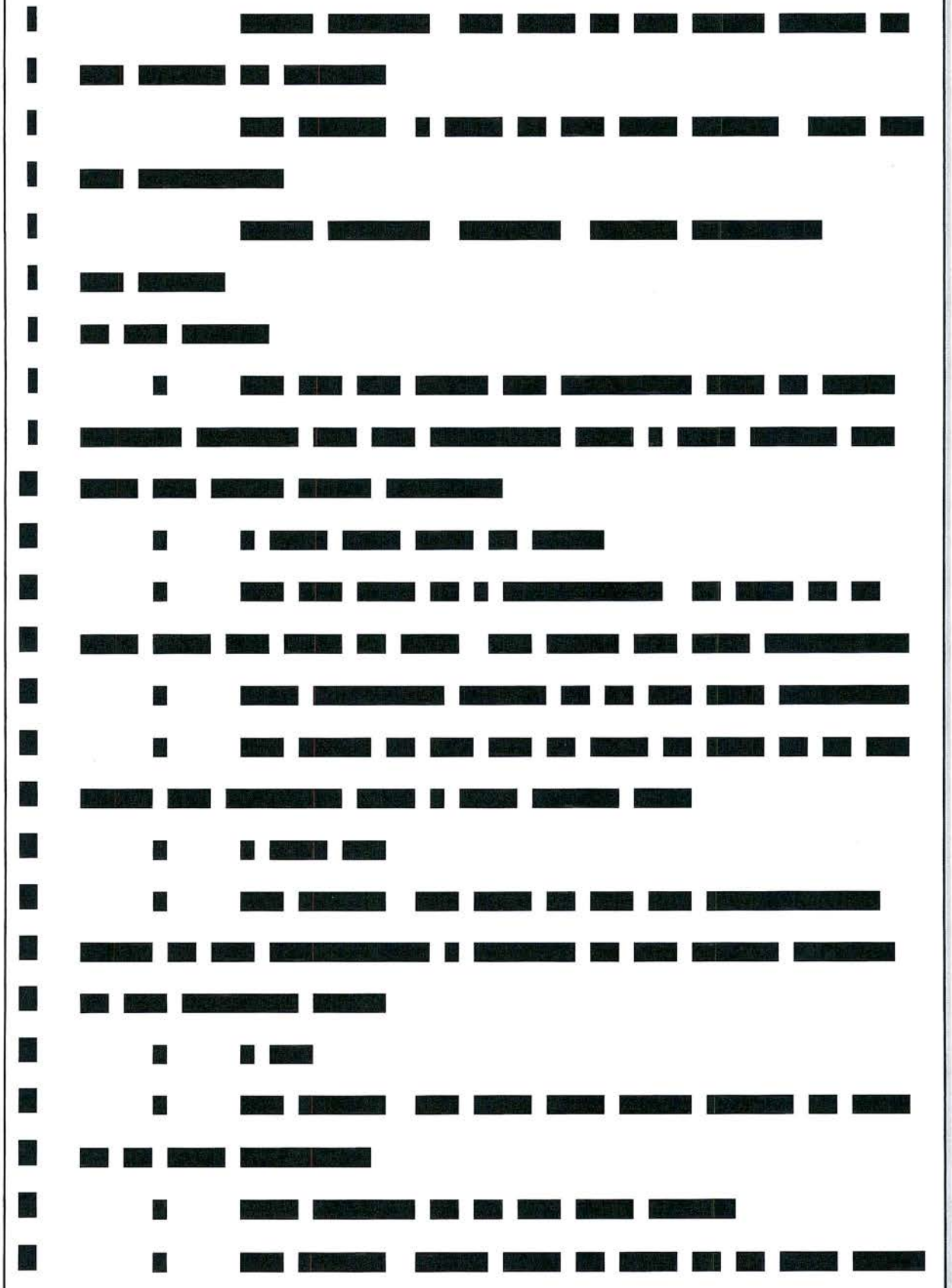


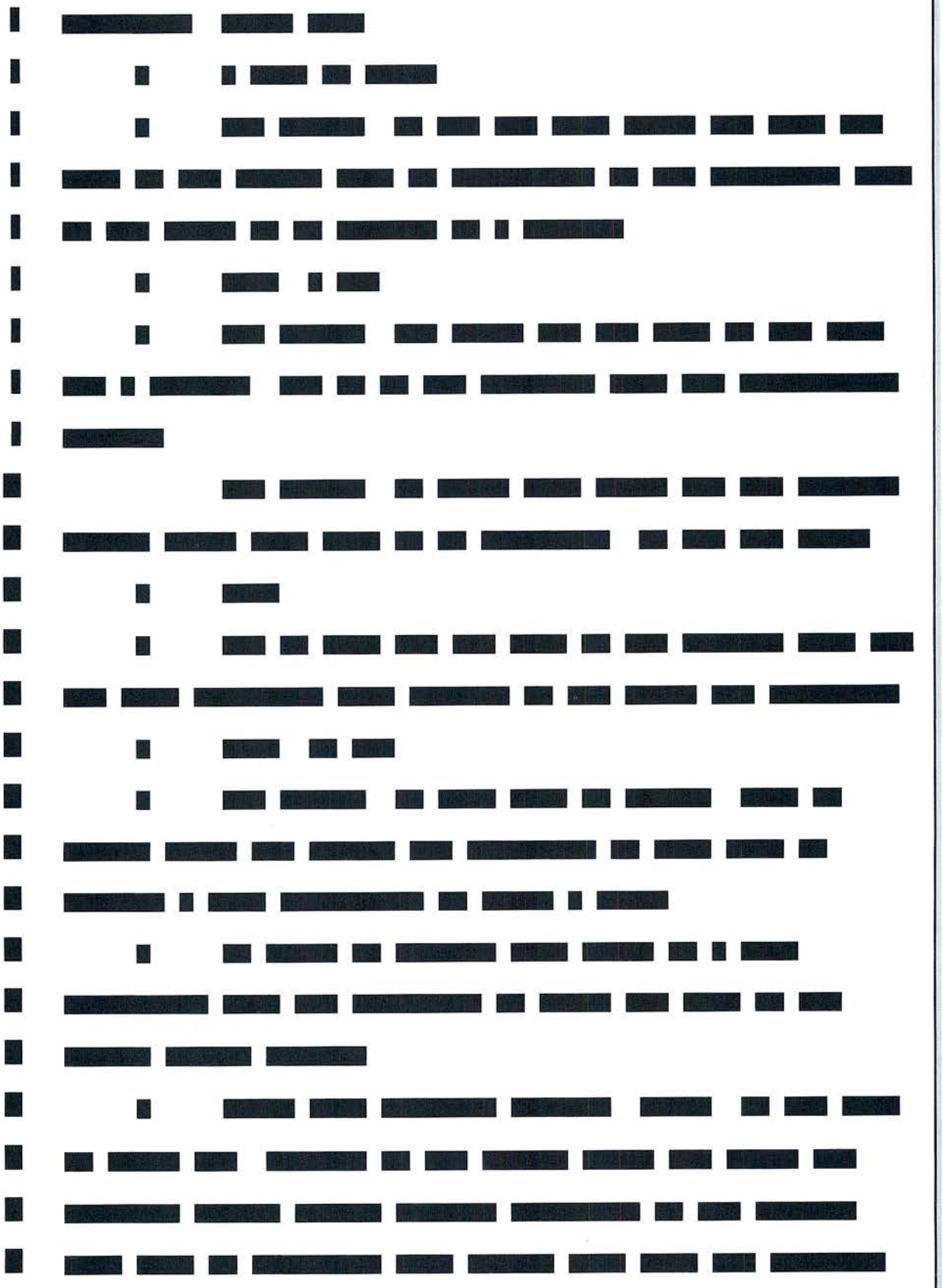


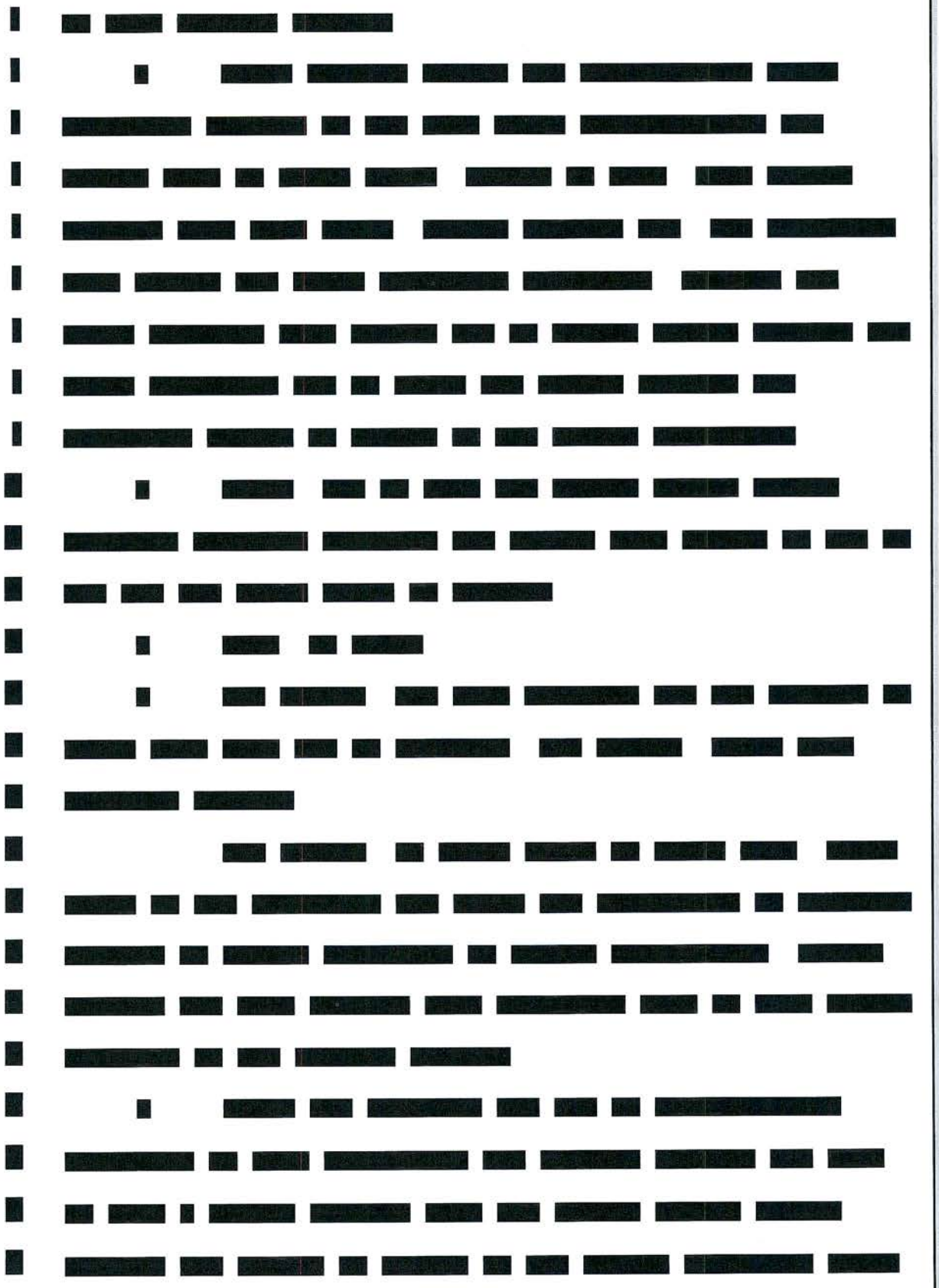


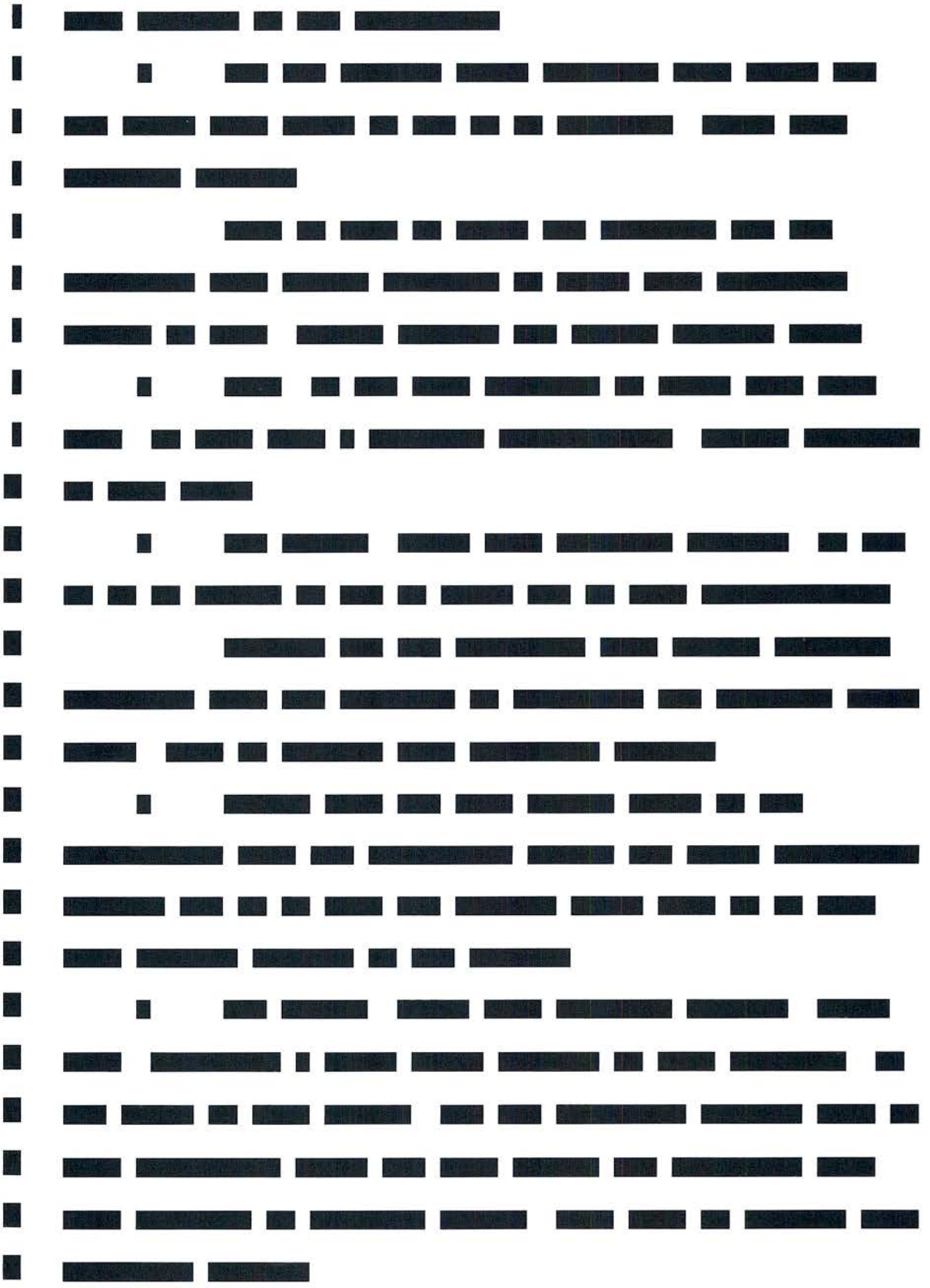












[redacted] Your Honor, we can go back to the public record. Thank you.

JUDGE CHENEY: We are back on the public record.

(End of confidential session.)

OPEN SESSION CONTINUED

BY MR. HAILS:

Q Okay. Now let's talk about your anticipation opinions. Can we move forward, please. And let's start with slide 69. So earlier, I had asked you if you believed that the June 2009 date that you had used for priority for your obvious analysis, whether that was the proper priority date. Do you remember that?

A I do.

Q Okay. And what was your answer?

A I don't believe that that's the proper priority date.

Q Okay. And what priority date do you believe is proper under the circumstances of these patents?

A I believe no earlier than March of 2017 is the proper priority date to use for these patents.

Q Okay. Let's say it was March 2017. What does that mean for the status of the RUBY product, particularly the user manual as against these claims?

A It means that the RUBY product was priority, is prior art for those patents and invalidates them.

Q Okay. Why do you think that the priority date does not extend backwards to June 2009?

A Because there is no evidence that those inventors had possession of the claims that are in those

patents.

Q All right. Let's move forward, please.

We are jumping to slide 35 of your presentation. And here you have another timeline. Will you walk us through this material.

A All right. First of all, in 2008 we have four patents that were filed by Bracco and its contractor/employees. And in 2009 we have the June of 2009 we have the PCT application which enters the United States which for the first time claims an on board -- sorry, it doesn't claim, it discloses an on-board dose calibrator and then we have the U.S. patent for that in 2010.

Q Okay. And so those are not the asserted patents, is that correct?

A Those are not the asserted patents.

Q All right. So when were the asserted patents filed?

A In 2016 after Bracco obtained the user manual for the FDA approved RUBY-FILL product, the patents were -- the '869 was filed and then in 2017 the '826 and the '870 patents.

JUDGE CHENEY: I'm sorry to interrupt. Dr. Stone, is your microphone on?

THE WITNESS: I'm sorry. Yes, Your Honor.

JUDGE CHENEY: You can move it like this.

THE WITNESS: I have some water here that I spilled, Your Honor. I'm good. Thank you. Paper towels would be nice.

JUDGE CHENEY: Will someone please assist Dr. Stone. There is no need to suffer in silence. We have so many resources available to us.

THE WITNESS: Thank you. I'm prepared, Your Honor.

JUDGE CHENEY: Okay. Thanks.

BY MR. HAILS:

Q All right. So let's -- let's talk about foundation. Do you have a binder that contains the materials that form the foundation of your opinions on this priority issue?

A Yes.

Q All right. Can you pull it out for me. All right. Just administrative note, rather than provide the entireties of prosecution histories we have excerpts for certain exhibits but let me run through this list and see in my list is the same as yours.

Ready?

A Yes.

Q First of all, JX-1, 2 and 3, those are the asserted patents?

A Yes.

Q JX-4, pages 18 through 25?
A Yes.
Q JX-5 and JX-6?
A Yes.
Q All right. JX-26, pages 1535 through 1543?
A Yes.
Q JX-63, pages 2105 through 2110.
A Yes.
Q All right. And then a couple excerpts from JX-64, page 2347. Also page 2, 351 through 2538.
A Yes.
Q All right. Two excerpts from JX-65, the first one from 1498 through 1525.
A Yes.
Q The second one from pages 1738 through 1747.
A Yes.
Q I think this is three excerpts from CX-169. Pages 21 and 24.
A Yes.
Q 2940?
A Yes.
Q 2948 through 2958?
A Yes.
Q All right. And RX-373?
A Yes.

Q All right. So those documents form the foundation of your opinions, is that correct?

A Yes. They do.

Q All right. All right. So we've talked about the filing of the asserted patents. The asserted patents were filed in 2016 and 2017 respectively, is that right?

A That is correct.

Q All right. And what was the trigger event for the filing of these applications?

A The triggering event was when Bracco obtained the user manual for the RUBY-FILL Version 3.

Q All right. Let's move forward, please.

All right. And that is what you've shown here. Let's move forward, please. Okay. So let's start back in 2008. Why don't you walk us through what's the same and what's different about these 2008 filings.

A What's the same about these 2008 filings is the disclosure. What is different are two factors. There are different inventors for different claim elements that are asserted. The tubing circuits we have one set of inventors. The shielding assembly is still another set of inventors, at least, we add two more inventors there. The cabinet structure still a slightly different set of inventors and then finally we have computer controls which has a very different set of inventors.

Q Okay. So all of these patents were filed as applications on the same day, is that correct?

A That's my understanding.

Q Okay. And did you say that they all had the same disclosure?

A Yes.

Q Okay. But you said that the claims were different. Again, just walk us through how are the claims different among these four cases?

A The '534 relates to tubing circuits. The '674 relates to shielding assemblies. The '352 claims relate to cabinet structure and the '053 patent relates to computer controls of the process.

Q Okay. And the different patents have different sets of inventors, is that correct?

A That is correct.

Q All right. Let's move forward, please.

Okay. So now we are on slide 52 and you have the PCT application shown which was filed in 2009. Why don't you explain to the Court what is the claim and who are the named inventors on this?

A Well, this disclosure for the first time adds computer controls. It's very similar disclosure with a couple of lines added with regard to computer control and it has the same inventors, most of the same inventors that

were on the '053 but it adds a couple.

Q All right. Let's move forward, please.

So now we are at slide 59. Here you have comparison of the inventorship, is that correct?

A That's correct.

Q Why don't you just summarize for the Court when you're talking about claims to computer controls, what kind of subject matter do you see in these claims?

A Well, they claimed pumping an eluate through a generator could generate an eluate. They claimed providing indication that the elution is completed, providing indication of time lapse since completion, since the elution completion was completed. But there are no claim elements that are drawn to shielding structures or cabinet structures in either of those two patents.

Q All right. So just to make sure the record is clear, the '053 element doesn't have any claim elements drawn to shielding structures?

A No.

Q And does the '053 have any claims directed to the elements of the cabinet structure?

A No.

Q The PCT application, when it was filed did it have any claim elements drawn to shielding structures?

A No.

Q And did the PCT application when it was filed have any claims directed to elements of a cabinet structure?

A No. It did not.

Q All right. Let's move forward.

All right. Slide 53. You have the asserted claims and we've been through them. What kinds of claim elements do we see in the asserted claims?

A We see not only computer controls but now we see also claim elements directed towards shielding assemblies and to cart configurations.

Q All right. Let's move forward, please.

What do we see by way of inventorship for the asserted patents?

A We see inventors claimed who were the inventors for the PCT filing.

Q All right. Let's move forward, please.

So now we are at slide 54. And you have the '674 patent shown here on the left. Why don't you give us a sense of what kinds of claim elements do we see for the shielding assembly claims from the '674 patent?

A Well, a couple of key elements are that they talk about openings for a generator compartment and a waste bottle compartment that are being oriented upward, openings for a second waste bottle and a compartment at a second

elevation being greater than the first elevation of the opening.

Q Okay. Let's move forward.

Okay. So the '674 patent when it was filed in 2008 and it had these claim elements, did it identify any of the people who are identified as named inventors on the asserted claims as inventors for the '674 application?

A Now, the inventors of those elements in the asserted claims were -- the only ones that had those elements previously were from the '674 patent and that was Charles Quirico, Ernest Balestracii, Daniel Dorst, Eric Krause, Vishal Lokhande, Jacob Childs, Peter Madson, Daniel Clements. It does not include the -- none of those were included in the '674 patent that are on the later patent, Stephen Hidem, Aaron Fontaine, Janet Gelbach, Patrick McDonald, Kathryn Hunter, Rolf Swenson, or Jules Szoda.

Q Let's move forward, please.

So now we are at slide 57. Do we see claim elements that were filed in the patent in 2008 in the asserted claims that were filed in the 2016 -2017 time frame?

A Yes. We do. These new patents have some of the same claim elements. They have a shielding compartment that's opening facing vertically upwardly. Again, second shielding compartment with an opening facing vertically

upward and different locations. The first opening is located at a lower elevation than the second opening.

Q Okay. Let's move forward.

Again, any overlap between the inventorship between those sets of patent filings?

A Between those claim elements, no.

Q Okay. Let's move forward, please.

So now we are at slide 62 of your analysis. In this investigation was Bracco requested to provide information on contribution of the various inventors of these patent filings?

A Yes.

Q And what information do they provide on the inventive contributions of the people who are identified as inventors on the asserted patents?

A They had no information what these individuals may have contributed to the claimed invention.

Q Okay. So did Bracco have any information on what Mr. Hidem provided?

A No.

Q Did they have any information on what Mr. Fontaine provided?

A No.

Q Mr. McDonald?

A No.

Q Ms. Hunter?

A No.

Q Any information on what Mr. Swenson may have provided?

A No.

Q What about Dr. Zodda?

A None.

Q But you have an exception here for Janet Gelbach. What information did Bracco provide on her contributions?

A Mr. LaVanway thought she might have proposed the idea of an on-board dose calibrator.

Q What is Mr. LaVanway?

A Mr. LaVanway is the patent attorney who wrote these claims and filed the patent.

Q Let's move forward, please.

Okay. So now we are on slide 63. Was Bracco asked to provide information on inventive contributions that may have been made by the named inventors of the '674 patent?

A Yes. They were.

Q And what did they identify as the contributions made by these individuals?

A They had no information on what they may have contributed to the claimed invention.

Q So does Bracco have any information on what Mr. Quirico may have done, Mr. Balestracii may have done, Mr. Dorst may have done, what Mr. Krause may have done, what Mr. Lokhande may have done, what Mr. Childs may have done, what Mr. Madson may have done or what Mr. Clements may have done?

A No.

Q Okay. Earlier you said that Bracco had gotten a copy of JDI's product literature and drafted the asserted claims. Are you familiar with that?

A Yes.

Q Okay. Was Bracco asked if they targeted JDI specifically with those asserted claims?

A Yes.

Q And what did they say?

A Yes.

Q And who was the person who was testifying on such issues?

A Mr. LaVanway.

Q Who was the person who drafted the asserted claims for filing at the Patent Office?

A Mr. LaVanway.

Q Okay. And who actually filed them at the Patent Office?

A It's my understanding it was Mr. LaVanway.

Q And who testified he had no information regarding any inventive contributions made by the named inventors on the asserted patents?

A Mr. LaVanway.

Q Let's move forward, please.

We are at slide 68. So let's say you file a patent application and you claim priority back to a prior application and you have no idea what the named inventors on your new filing may have contributed to the subject matter that you've claimed. Do you have an understanding of what that affect is for priority date?

A It means you really can't claim that as a priority date.

Q Okay. And so is priority date, are priority date claims effective in that circumstance?

A No. They are not.

Q Okay. And if a priority date made by the asserted patents in this case were ineffective then what is the priority date that should be assigned to those patents?

A Priority date is when the claimed inventors actually sign a declaration that they were in possession of the invention.

Q Okay. The date that you've ascribed, does that predate or does that postdate Bracco's acquisition of the RUBY-FILL product materials that they removed?

A It postdates it.

Q And you're aware of the analysis that's been performed in this investigation already, the final determination that the asserted claims read on the RUBY products?

A Yes.

Q Okay. So are you aware that it's been decided already that there is element-for-element correspondence between the asserted claims and the RUBY product?

A I have.

Q And if RUBY is prior art to the asserted claims, what does that mean?

A It invalidates these patents.

Q Thank you. Let me --

MR. HAILS: Your Honor, thank you. We pass the witness.

JUDGE CHENEY: Is there any cross-examination of Dr. Stone?

MR. DAVIS: Yes, Your Honor. If we could take a minute to pass out the binders.

JUDGE CHENEY: While the binders are being passed out I'm concerned about completing this hearing on time. So it seems like time estimates are getting blown through.

MR. WALKER: Given where we are, I think I'd

probably go ahead and provide -- I think we are going to go ahead and probably drop Dr. Clark. Mr. Clark. Forgive me. So I just want to let the other side know that, given where we are right now.

JUDGE CHENEY: Okay.

MR. DAVIS: Your Honor, we believe we can still meet our time constraints.

JUDGE CHENEY: Okay. Please proceed when you're ready, Mr. Davis.

CROSS-EXAMINATION

BY MR. DAVIS:

Q Thank you, Your Honor. Good morning still. I'm Mark Davis. I'm one of the attorneys who represents the complainant Bracco.

A Good morning.

Q Now, in opining that the RUBY-FILL Version 3 anticipates the claims of the asserted patents, you rely on a priority date of no earlier than September 30th, 2016, correct?

A That is correct.

Q Okay. But you can see that the specification of the parent '031 application filed on June 11th, 2009, discloses, among other things, a dose calibrator, an eluate reservoir and shielded well, right?

A I concede that.

Q Okay. And the '031 application is a parent to the asserted patent, correct?

A I'm sorry. You'll have to show me which one the '031 is. I don't keep them all memorized.

Q Okay. So why don't we pull up JX-1 and the related U.S. application data, page 2 of the patent. So do you see here where it mentions the continuation of application 12/808,467 filed as application number PCT/US2009/047031 on June 11th, 2009, now patent number 9,607,722?

A Thank you. I recognize that now. Now what was your question.

Q Yes. So that's the parent application to the asserted patents, correct? That's a parent to not only JX-1, but JX-2 and JX-3?

A The '031 and the '722. Yes.

Q Okay. And the disclosure of the parent '031 application, that disclosures are repeated in the specification of the asserted patents, correct?

A Yes.

Q Okay. And you did not offer an opinion that any of the asserted claims failed to satisfy the written description requirement, correct?

A I did not offer such an opinion. That's correct.

Q Okay. And you didn't offer an opinion that any of the asserted claims are not enabled by the disclosure of the '031 application?

A I did not discuss any of them.

Q And now in your initial report, you have a section regarding the applicable law regarding written description and priority dates, correct?

A I believe that's correct.

Q So that's page 21 of your initial report. And at paragraph 51, you state I understand that all patent applications must contain a written description of the invention claimed by the application. The written description requirement has two primary elements, the specification must not only describe the subject matter claimed by the patent, it must, it also must describe the claimed subject matter in a manner that demonstrates the attorneys had possession of the claimed subject matter. Possession of the invention is demonstrated when the subject matter of the invention is described in a manner that conveys to the reader that the inventors recognized the claimed subject matter of their invention. So that's what you were instructed with regard to your written description, correct?

A I see that.

Q Okay. Now let's go to paragraph 52. Now, in

523 of your report, you state that I understand that, to benefit from priority of an earlier-filed application, a patent must claim priority to the earlier-claimed application and that earlier-filed application must satisfy the written description requirement. Correct?

A I see that.

Q Okay. Now, you agree, we just showed that the patents in suit all claim priority back to the '031 application, correct?

A I see that.

Q All right. And in your deposition, you admitted that if priority of the claims is based on what is disclosed in the specification then the priority date is no earlier than 2009, as opposed to 2016, correct?

A I didn't say it was as opposed to. I believe I said that it was no earlier than 2009.

Q Okay. So if you base priority on what's disclosed in the specification then you have a 2009 priority date?

A If I'm basing my analysis on obviousness, I used 2009.

Q Okay. Well let's look at your deposition. This is page 187, line 19 to 188, line 1. All right. And you say based on inventorship and when it was filed, it can be no earlier than 2007. Based on the disclosure when the

material was first added, it could be no earlier than 2009. Correct?

A That's what I said.

Q Okay. So the written description requirement and the priority -- I'm sorry. Let me restate that question. So you indicated that your understanding of priority law was that you needed to claim priority and you needed to disclose the subject matter in the specification, and you admit that the subject matter claimed in the asserted patents is disclosed in the specification, correct?

A Again, with regard to obviousness, I utilized the date of June 2009. That's not the only thing with regard to priority that I did an analysis on. I also did an analysis based on inventorship.

Q Okay. So my question was, was the subject matter of the claim disclosed in the specification?

A As we've acknowledged the subject matter, the idea of the -- the idea was disclosed but not claimed previously.

Q Okay. Let's turn to inventorship. You read the transcript of Janet Gelbach's deposition, correct?

A I did.

Q And she testified that she has no reason to believe the incorrect inventors are listed on the asserted

patents, correct?

A She may very well have.

Q Okay. Well, let's pull it up. It's JX-176 at page 85. Now, Exhibits 4, 5, 6 and 7 we are talking about the inventorship of various patents. Do you have any reason to believe that the incorrect inventors are listed on any of those?

A No.

Q So she didn't think there was a problem with inventorship for the asserted patents, correct?

A She did not.

Q And you read her testimony that she was one of the people who conceived of putting the dose calibrator on board the cart, correct?

A I believe she said that it was a joint decision, but she knew of a dose calibrator being on a cart at the time of this disclosure.

Q Okay. And she said that she was part of the team that contributed that idea and that contribution was back at the time when she was in Bracco working on the new design in this 2006 to 2009 time period, right?

A She indeed brought that idea to the design team but at the time they didn't claim it as a patent and I don't think they recognized it as such. I don't think they -- it was already in commerce at that time.

Q Okay. Well, let's look at your deposition. 140, line 23 to 141, 25. I think admitted a little bit more forcefully that Janet Gelbach contributed to the on-board dose calibrator. Do you see where the question is? So it seems as though we've established your opinion that Ms. Gelbach contributed to the on-board dose calibrator. She was named on the 2008 application, and then also all the way through to the asserted patents which claim the on-board dose calibrator, right? Answer. I believe that is correct that she is the only one. Was that your testimony?

A That was my testimony.

Q Do you still believe it to be true?

A She brought the idea. It was not recognized as an invention until after Jubilant had their product on the market. It was an idea. It was a part of a product, not a claimed invention.

Q Right. And it was disclosed in the specification in 2009, correct?

A The idea was indeed disclosed in the specification.

Q And again, she got this idea while working at Bracco before she went to JDI?

A She got this idea, as she stated, looking at and having seen an on-board dose calibrator in commerce, that's

correct, that was while she was working at JDI -- I'm sorry, Bracco.

Q Did you read her testimony also that the only reason that the design team not to -- decided not to incorporate the on-board dose calibrator was for cost-saving purposes?

A I saw that.

Q Now, in forming your opinion regarding inventorship, you did not make a determination of what each inventor contributed, correct?

A No. I did not.

Q All right. And beyond the fact that Janet Gelbach contributed the idea of the on-board dose calibrator, you had no information that links various claim elements to various inventors, correct?

A No. The only thing we could look at was what had been disclosed and who were the claimed inventors of those elements in the previous patents and those were not the claimed inventors of the patents that are in suit now.

Q And just to be clear, in your deposition you stated that your opinion was not that the named inventors should not have been named, but rather you thought that additional people should have been added as inventors, correct?

A I think the correct inventors are not the ones

that were named.

Q Okay. But I just want to clarify for the record who you think is wrongly named. At your deposition you said you didn't think anybody listed on the patent should not have been listed on the patent, correct?

A That's correct.

Q All right. So we are talking about people named on other patents you think should have been added as additional inventors?

A We are talking about people who actually claimed that they invented certain claim elements that were left off the patent.

Q And you haven't identified any motivation by Bracco for purposely leaving any inventors off, correct?

A I would have to speculate with regard to any motivations.

Q Right. And indeed on the named -- on the asserted patents, there are named inventors who worked for third-party vendors such as North Pole Engineering, correct?

A That's correct.

Q Now, to your knowledge, did JDI depose any of the people that you thought should have been named as inventors to find out what they contributed?

A I have no knowledge of that.

Q Okay. Let's turn to prosecution laches. In your presentation as RDX-2, page 35, you failed to address multiple patent applications that relate to the patents in suit that were being prosecuted in the relevant time period, correct, and this continues on throughout your slides?

A I did.

Q Right. And -- and at your deposition you indicated that you purposely left off some of those applications, correct?

A I don't believe I said I purposely left them off.

Q Well, you knowingly left them off, correct?

A I don't think I tracked that through. I don't think it was relevant to the analysis we were doing.

Q Okay. So you left them off despite knowing the applications because you thought those other applications being prosecuted were not relevant to the issue of prosecution laches?

A I don't think they were relevant to these particular patents.

Q Okay. So it's not that you opine that Bracco wasn't actively prosecuting patent applications in this patent family during the relevant time frame, correct?

A That would be likely a valid statement.

Q Okay. So your opinion is based purely on the raw amount of time that passed between the priority filings and the time that claims were written that correspond to what are in the asserted patents?

A It's fundamentally based on the amount of time that went by from disclosure of an idea which seems to be germane to this topic before one files it and after one sees another product on the market so converting an idea into a claimed patent. I believe that's my analysis with regard to prosecution laches.

Q Okay. Let's talk about obviousness. So you don't have any experience working with elution infusion systems, correct?

A I do not work with it. I'm not a medical practitioner.

Q Okay. And your obviousness analysis is largely based on four references, correct?

A That's correct.

Q And the sole primary reference upon which you rely is the Klein thesis?

A I believe that the Klein thesis is a primary reference. I don't use that term as sole because there were other things that were brought in that are key to a couple of the components there.

Q Okay. But you didn't use any of the other art

that you relied on as the primary reference that would be modified by other references, correct?

A If you want to call that the sole reference or the primary reference that's your calling. I looked at all of those as being applicable in doing my analysis.

Q Okay. And the analysis you did was how would the Klein thesis be modified based on these other references, correct?

A I believe that most all the terms are addressed by Klein. Other terms are addressed by the other references that I utilized.

Q Okay. So for example, Tate. You didn't say it was obvious to modify Tate to match the claimed -- the claims in this case. You said it was, it would be obvious to modify Klein using Tate?

A That's a fair representation.

[redacted]

Q Okay. And so was Tate and the CardioGen, correct?

A Yes.

Q And you clarified at your deposition that you weren't relying on the Version 1 or the Version 0 or the Version 2 or the RUBY-FILL as prior art. You were relying on the Klein thesis, right?

A That is correct.

Q Now, so with Klein, CardioGen and Tate all of record before the Patent Office, the Patent Office still allowed the claims at issue in this case?

A I believe the Patent Office was looking mostly at whether they were anticipated and I saw him referring very often to deKemp and I saw very few references to Klein.

Q Okay. But they were all of record before the Patent Office?

A They were.

Q Okay. And yet the Patent Office still allowed the claims.

A They did.

Q Okay. Now, Tate is an FDG system, right?

A It is.

[redacted]

A Yes.

Q All right. As such, they don't use generators?

A They do not use a generator. They use a radioactive -- positron emission source.

Q Okay. And all of the asserted claims in this case go to a generator and the elution system for that generator, correct?

A I believe that's correct.

[redacted]

A During what time period are we referring to?

Q During the time that the patient treatment. When you're actually using the cart.

A No. It's not variable. When you say using the cart that's different.

Q Okay.

A When you are actually eluating to the patient it is a variable source. That's correct.

Q Not -- did you say invariable. I'm not sure. I wasn't sure what your answer was.

A I'm sorry.

JUDGE CHENEY: Why don't we start again so we can have a clear question and a clear answer.

BY MR. DAVIS:

Q Okay. FDG systems, the radioactive source is

not a variable source of background radiation, correct, when it's sitting on the cart?

A When it's sitting on the cart, that's correct.

Q Okay. And so the amount of background radiation that the dose calibrator is exposed to as a result is also not variable.

A That is a true statement.

[redacted]

A No. Those systems do not include the necessary plumbing for a rubidium generator.

Q And for the Tate and Medrad saline isn't used for the same purpose as it is in Klein, correct?

A That's a partially correct statement but it's not totally true.

Q Okay. So I mean you're certainly not using saline with a generator, correct, to create the radio -- radiopharmaceutical on board the cart?

A Saline is not used to generate a rubidium elution. It is instead used to push the sample of the radioactive material into the patient just as it is in the RUBY system.

Q Right, but in the claimed invention you use the saline and it actually travels through the generator to get the rubidium?

A It does indeed.

Q Okay. And that's not what's happening in Tate or Medrad?

A No. That particular feature doesn't happen.

Q Okay. So let's go through and see if we can get agreement on what the Klein thesis doesn't disclose. So the Klein thesis does not disclose a first opening in the first shielding compartment being at a lower elevation than the second opening of the second shielding compartment, correct?

A The Klein thesis does not disclose that.

Q Okay. And the Klein thesis also does not disclose a shielded well configured to fill the eluate reservoir in the shielded well on board the cart?

A No. As we stated, the on board the cart feature is not there.

Q Okay. Klein thesis does not disclose a computer configured to determine a strontium radioactive eluate filled on board the cart while the eluate reservoir remains in the shielded well on board the cart, correct?

A The on board the cart is missing from the Klein thesis.

Q Okay. And the Klein thesis also does not disclose a computer configured to measure a calibration radioactivity of the sample while the sample remains in the

eluate reservoir in the shielded well on board the cart?

A As we stated, the Klein thesis does not include the on board element.

Q Okay. And so, for example, the dose calibrator is not in a shielded cart on board the cart in Klein?

A The system has all those components but it does not do it on board the cart.

Q Okay. And Klein thesis does not disclose configuring a computer to present on a touch screen display a screen reminding the user to insert the eluate reservoir in the shielded well on board the cart?

A The Klein thesis prototype does not indeed have that particular reminder disclosed.

Q Okay. And the Klein thesis does not disclose a specific elevations of the openings of the first and second shielding compartments, correct?

A No. Those elevations -- as I've stated, those are obvious configuration choices that one would utilize in changing a prototype into a product.

Q Well, I think your testimony was that they are just irrelevant. Is that what you stated on direct?

A I believe these are standard things that a person would do when they are going from a prototype to a product so the relative heights I believe aren't relevant. That's correct.

Q Okay. And if they are irrelevant there is no motivation to change them?

A I don't think there is anything inventive about putting components at different heights.

Q Okay. But I mean, if people don't care about it, there is no motivation to change those features, right? Especially on a system as complicated as the RUBY?

A We spoke about putting heavy items where they would not have to be lifted great distances for ergonomic purposes which is what one would do going from a laboratory prototype to a production device that would be used in an occupational use.

Q Okay. Oh, I'm sorry. I thought you were done.

Klein thesis does not disclose tracking the volume of saline remaining in the saline reservoir, correct?

A The Klein thesis does not track what's remaining in the reservoir. That is correct.

Q Okay. And the Klein thesis does not disclose providing an alert on the touch screen display when the volume of saline remaining in the reservoir is below a predetermined volume?

A That's correct. That laboratory prototype did not disclose that.

Q All right. Similarly, Klein thesis did not

disclose a first door accessible via the opening through the exterior shell, the first door being configured to provide access to the first shielding compartment and to close over the first opening, correct?

A I'm sorry. If the first shielding compartment -- again.

Q Sure. I'll just repeat it. So Klein thesis does not disclose a first door accessible via the opening through the exterior shell, the first door being configured to provide access to the first shielding compartment and to close over the first opening.

A The Klein thesis had the first shielding compartment, which I believe was for the strontium-rubidium generator, is that correct? So I can answer this correctly.

Q So why don't we bring up your deposition at page 260, lines 6 through 21. So do you see the question? Okay. And just going by the claim element to make sure that we understand what your opinions are. All right. I'd like to talk to you about the '869 patent for a moment, specifically element 1.3, which is on page 413 that's of your report, correct?

A I see that.

Q In the images here from the Klein thesis you've not labelled the first door accessible via the opening

through the exterior shell, the first door being configured to provide access to the first shielding compartment and to close over the first opening. Right? And you answer, I have not?

A That's what I said.

Q And the follow-up question was, well, is it disclosed by Klein? And you said, no. Correct?

A That's what I said at this location. That's correct.

Q Okay. And you still maintain that testimony, correct? That was true then? It's true now?

A To the best of my memory.

Q Okay. And the Klein thesis does not disclose that the infusion system is configured for the saline tubing line and the eluate tubing line to be routed through two tubing passageways formed in a perimeter surface of the first opening wherein each of the two tubing passageways has a depth configured to prevent pinching or crushing of the corresponding tubing line, correct?

A No. We were not relying on the Klein thesis for anticipation. We were relying on how it would be modified for obviousness; and as I stated in my prior testimony, if one is going to route those tubing lines through the perimeter it would be obvious to anyone skilled in the art not to configure those so that they would not be pinched or

crushed by a door. That is the only thing that makes sense.

Q At this point I'm just trying to make sure we have agreement on what Klein discloses and doesn't disclose. We'll get to combinations a little bit later. So do you agree that Klein didn't disclose that claim element, correct?

A Klein did not disclose that claim element.

Q All right. And you didn't identify anything in the Klein thesis indicating that the system disclosed therein should be modified in any way, correct?

A I'm sorry.

Q Yeah. So in Klein itself you didn't point to a passage in Klein that said, you know, you may want to consider modifying this feature that I disclosed?

A No. I don't recall, although he does talk about improvements that could be made in his system before he closes things out.

Q Okay. But you haven't identified anything in your direct with regard to a motivation from the Klein thesis itself to make any of the modifications that you propose?

A I did not identify anything directly in the Klein thesis for those motivations. That's correct.

Q Okay. And so could you turn to page 417 of your

initial report. Or you can just read it on the screen if that's easier. I just want to ask you about element 1.5. So see here, a second door accessible via the opening through the top surface of the exterior shell, the second door being configured to provide access to the second shielding compartment and to close over the second opening.

A I see that.

Q Okay. Now, let's turn now to RDX-2.196 and talk about what you considered to be the door in Tate. So do you identify on the record what you consider to be the door shown here?

A I believe we've shown a door in Tate here. Or down below. Can we back up.

Q Yes. Why don't we go to the one down below the figure 4A.

A We talked about this door right here.

Q So this is the red highlight is what you considered to be the door disclosed by Tate?

A That is the door disclosed by Tate.

Q All right. Now, Tate doesn't actually call it a door, does it?

A I think he calls it a lid. Lids, door. Access hatches. These are all things you would find together, I believe, in any thesaurus.

Q Tate calls it a vial access system, correct?

A Vial access lid, I believe.

Q So why don't we pull up Tate RX-103, page 97, paragraph 139. You have the vial access system, right? So you've got it's a system. It's got the vertical support arm that goes to the housing. You've got a cap member and a handle member and they are all connected to an upper end of the vertical support arm, correct?

A Yes. I believe he calls it the cap member.

Q Okay. And then what you do is you grab the handle, you pull it up and you twist, correct?

A That's one of the things that you do. Yes.

Q All right. Let's go back to the RDX-2 at 196. All right. Now, in Tate, this is designed to be used on top of the cart, correct?

A It's designed to be accessed via the top of the cart. That's correct.

Q Okay. And that access system is mounted via that sliding arm, correct?

A That's correct.

Q Now, the claimed door that you're equating the system in Tate to, that's the door for access to the generator, correct, and that's why you colored it red?

A That's correct.

Q Okay. Now, let's look at RDX-2 at 166. So if we can blow up the RX-106 at 34 portion. So here in your

modification of Klein the generator is on the bottom, correct?

A That's correct.

Q And you've got the dose calibrator and the lead shielding right above it?

A That's how it's shown configured. Yes.

Q Okay. So you couldn't actually use what you describe as the door in Tate to obtain access to the generator in this configuration, could you?

A No.

Q All right. So one wouldn't be motivated to use the door in Tate to access the generator if the door in Tate wouldn't work in the design?

A That particular configuration would not work. It would be obvious to a person of skill in the art to configure his door such that one could have access to the generator as described in Klein.

Q Okay. But so the door in Tate as it's shown is not used?

A I disagree. He has a door. He has it where it provides access. The manner in which it provides access, how it's attached, those are obvious design choices that a person would make as one configures a commercial system.

Q So Tate, the door in Tate as shown -- well, the vial access system -- when you -- to pull out the rod you

would just, your hand would just run into the dose calibrator and lead shielding above before you could gain access to the generator, correct?

A I'm sorry?

Q Sure. If you were using the vial access system actually disclosed in Tate that you showed with the -- that uses the slidable bar that you pull up on, if you were to try to use that as the door to the generator, your hand would just run into the dose calibrator and shielding or whatever supporting that before you actually gained access to the generator?

A I believe you were the one that said it was the dose access system. I said it was the cap that was the door and the attachment to the door I don't believe is an inventive process.

JUDGE CHENEY: And with that, we will take our lunch break. We'll see you in one hour.

MR. DAVIS: Thank you, Your Honor.

(Whereupon, at 12:33 p.m., the hearing in the above-entitled matter was recessed, to reconvene at 1:33 p.m.)

AFTERNOON SESSION

(1:33 p.m.)

JUDGE CHENEY: We are back on the record in the 1110 investigation. Before our lunch break we were listening to the cross-examination by complainants of Dr. Stone, who has been called by respondents as an expert on issues relating to patent validity. Mr. Davis, you may resume.

MR. DAVIS: Thank you, Your Honor.

BY MR. DAVIS:

Q Dr. Stone, could you turn to RX-106 and page 34, the Klein thesis, and that photo. 34 of RX-106. That's 34 of the document. Sorry. There we go. So could we blow up the top photo. All right. Now, could you explain to me again what, in your opinion, is the front side of the exterior shell?

A Certainly. Front slide of the exterior shell is determined by these four corners on the front of the device of the cabinet.

Q Okay. So in your opinion, the front side of the exterior shell includes this opening, correct?

A That's correct.

Q All right. What's your understanding of the word shell?

A A shell is something that tends to surround

something. It has a cover, for example, a turtle has a shell across its back and openings for its legs. A shell is an enclosure.

Q Okay. So it's something that encloses or protects. Is that fair?

A That's a fair assumption. Yes.

Q All right. Now, is there anything in the front side enclosing or protecting the various filament that's shown here?

A It doesn't say the front side has to do with the completion of the enclosing and protecting, just that the cabinet does that.

Q So but it is a four-sided exterior shell, correct?

A It is a four-sided cart.

Q It's a four-sided shell.

A It's a four-sided cart enclosed on three sides, top and bottom.

Q Okay. So, so your opinion that this meets the shell is based on your understanding that the claims don't call for a four-sided exterior shell?

A No. In fact the claims do call for two side walls. It does not call for a front wall.

Q So let's -- all right. Could we go to JX-2 at page 45, column 27, lines 47 to 50. So here we have a

limitation that the exterior shell further includes an opening, correct?

A That's correct.

Q Now, so is it your opinion that the front of the cart constitutes both the opening and part of the shell?

A The opening that it calls for here is for a saline tubing line.

Q Let's go to the picture, page 34 of 106 again. RX-106, page 34. All right. So where is the saline -- where is the opening in the exterior shell for the saline tube?

A The opening for that, as we disclosed earlier, is through the top surface here.

Q All right. So Ms. Gelbach considered FDG to be a whole different product that does not do the same type of study as a system like a CardioGen, correct?

A I believe she may have stated that. Yes.

Q Okay. And you have opined that it would have been obvious for a person of ordinary skill to take the on-board dose calibrator of Tate and incorporate it on board into the Klein thesis, correct?

A I have.

Q All right. And you agree that the on-board dose calibrator of Tate measures radioactivity that will be delivered to the patient, right?

A That is correct.

Q All right. And the Klein thesis that already disclosed a detector separate from the dose calibrator that measures the radioactivity that's delivered to the patient, right?

A Yes. After it's been calibrated by dose calibrator.

Q Okay. So the Klein thesis doesn't need Tate's dose calibrator to measure the radioactivity delivered to the patient?

A No. Only to calibrate the detector that is measuring that.

Q Now, Klein conducts breakthrough testing, correct?

A He does.

Q And it does that with the off-board dose calibrator, correct?

A He does.

Q And you've pointed to nothing in the Klein thesis that indicates that Klein thought that the breakthrough testing with an off-board dose calibrator should be changed, correct?

A Klein includes an off-board calibrator as part of his system. He doesn't say whether -- he doesn't teach any changing in the Klein thesis.

Q All right. Let's go to 247 of RDX-2. All right. So this shows your proposed placement of the dose calibrator, the generator and the shielded waste container, correct?

A That's correct.

Q All right. Now --

A Excuse me. That's what a person of the art might do. It's not necessarily I'm proposing that. But it would be obvious do that.

Q Okay. So this is, but this is the configuration that you testified regarding?

A That's correct.

Q All right. Now, first of all, the front opening is blacked out but there is pre-existing equipment on the shells not shown in this picture, correct?

A Yes. He used pre-existing off-the-shelf equipment to put together his laboratory prototype.

Q And to put the shielded waste container there and the shielded generator and the dose calibrator in shielding you'd have to move all that equipment that was previously there. You'd have to find a new home for it?

A As I'm configuring a product I would probably find new homes for that equipment. That's correct.

Q Okay. And you opine that one would have been motivated to put the generator down low for ergonomic

purposes, correct?

A I do.

Q All right. Now, the premise of your ergonomic analysis is that with a lower generator you're closer to the floor, correct?

A You're closer to the level of a cart that would be rolled up having the generator on it to transfer it into the device and you're also dropping the center of gravity making the cart more stable.

Q So I believe you're -- now, you did not actually do any analysis of how users of the system actually handle the generator, correct?

A I did not.

Q All right. And so if, for example, somebody was motivated not to bend over to pick something up from down low, but rather to keep it up high because it's heavy, the ergonomics would be to keep the generator up high so that you could move it to the shelf more easily, correct?

A If the device were there on the shelf. However, I note that the CardioGen-82, the so-called Model 510, already had the generator down low.

Q Okay. But I'm just asking about ergonomics.

JUDGE CHENEY: Mr. Davis, when you're away from the mic then the court reporter doesn't hear you through her headset.

MR. DAVIS: I apologize, Your Honor.

JUDGE CHENEY: Please stick close to the mic.

BY MR. DAVIS:

Q But you didn't do an ergonomic analysis of how people actually handle the generator?

A I did not.

Q And the University of Ottawa -- I'm sorry.

A I am aware of how heavy objects are transported and the types of carts that they are. It's very typical for that to be a low, near-floor cart so a person of skill in the art would know that.

Q You understand that as an expert you're supposed to disclose your opinions in your report, correct?

A To the best of my knowledge. Yes.

Q Okay. So I just want to ask you about the opinions you've already disclosed in your report and testified today. I'm not, I'm not asking you to form any new opinions.

A I'm sorry. You asked me about my analysis as to whether I had done that. I formed my opinion based on what I as a person of skill in the art knew already.

Q Are you an expert in ergonomics?

A I utilize ergonomics and have to review those when I'm doing a product definition.

Q So now, the University of Ottawa's request for

information included in RX-144 touts the ergonomic design of the existing design for the Version 1, correct?

A Yes.

Q All right. So that's the last bullet point on page 10?

A Yes.

Q All right. So, in this version the generator was up high, correct?

A What they are discussing is they are talking about how the device can easily be used without powering down minimizing the amount of motion that has to take place, the amount of time. They are not discussing here ergonomics with regard to the weight and the orientation of the materials.

Q They are talking about an overall ergonomic design, correct?

A No. They are talking about adding convenience through ergonomic design. They are not talking about necessarily what would be in a finished product.

Q So they are talking about this design being ergonomic, correct?

A They are talking about they have added convenience through some ergonomics.

Q All right. And that was with regard to the existing configuration?

A With the existing configuration which is a prototype ready to be productized.

Q All right. And there is also restrictions on the placement of the dose calibrator on the cart due to possible interference between the dose calibrator and the generator, correct?

A That's correct. That's a matter of how the shielding is set up and where the components are place.

Q So one of ordinary skill wouldn't want to place the dose calibrator right above the generator, you'd want some distance?

A Depending on the shielding, distance would be a factor that they would consider.

Q Okay. But if you kept it close you'd have to add additional shielding which would add to the weight of the cart?

A Actually, I believe they actually measured this. It's even reported, I believe, in one of our documents that we referenced that they measured it and didn't have a problem with the generator. They had a problem with something else.

Q But in your deposition, you stated that there are restrictions on the placement of the dose calibrator on the cart due to possible interference between the dose calibrator and the generator, correct?

A There could be possible interferences. That's correct.

Q Right. One of ordinary skill would know that and one of the ways to address that would be to separate the two?

A That's correct.

Q You're also aware that when the University of Ottawa met with JDI to discuss a possible modifications to the Version 2, they suggested that the tubing be changed so that the system could be used with a variety of existing dose calibrators, right?

A That was a suggestion. That's correct.

Q Right. So that was in the 2008 time frame?

A I believe 2007, 2008 time frame.

Q And according to Mr. Donnelly, as of 2004, the -- the Version 1 had already been used to perform procedures on 667 patients, right?

A That's correct.

Q Right. So that number would be even larger by the 2008 meeting?

A That's the assumption I would make. Yes.

Q Okay. So even after, and the first use by University of Ottawa of a Rubidium Elution System was 1997, right? The Version 0?

A The Version 0 -- by the University of Ottawa,

1997. I believe that's correct.

Q Right. So you remember --

A I'd have to refresh my memory on the document. I don't recall that.

Q Okay. So even after 11 years approximately from '97 to 2008, and somewhere, you know, somewhere north of 700 procedures, Dr. Klein and the University of Ottawa still thought the dose generator should remain off the cart, correct?

A I think you misstated that. Do you want to read back your own question?

Q I'll just restate the question. So, so the first -- Ottawa starts using the rubidium system '97 with Version 0. They are talking to JDI in 2008 time frame. We are talking about 11 years and we are talking about, you know, nearly 700 procedures just using the Version 1 alone by 2004. Even after all that experience and all that time, University of Ottawa was still thinking and Dr. Klein was still thinking when they are discussing options with JDI, that the dose calibrator should remain off the cart and that way the cart could be used with various existing dose calibrators that the facilities already had?

A I don't think they necessarily think it should, but it did.

Q But that was the, that was the design they were

proposing to JDI. They are saying, you know, a couple of things we need to update. One of them is to change the tubing so we can have it interchangeable with several different dose calibrators rather than just the one that we were using at Ottawa?

A I don't think the tubing is related to the dose calibrator, is it?

Q Well, they were talking about changing the tubing in order to make the cart compatible with multiple dose calibrators. Why don't we bring that up. So day two, page 340 and 41, Mr. Donnelly's testimony was that the technology transfer happened and you'll need to reprove -- one of the things was to change the tubing so that the cart would work with multiple types of dose calibrators because there were multiple types of dose calibrators on the market. Right. And Mr. Donnelly said correct. So --

A Okay. Sorry. Go ahead.

Q So as of this time period, Ottawa and Dr. Klein were suggesting to JDI that one of the changes they should make going forward is to make the cart compatible with multiple dose calibrators because various facilities had different dose calibrators?

A This seems to be discussing tubing and the tubing goes and is connected to the vial. The dose calibrator being off the cart. The only thing I can think

of that that might have to do with the length of the tubing. It's not discussed so it would be very unclear as to why that would be significant.

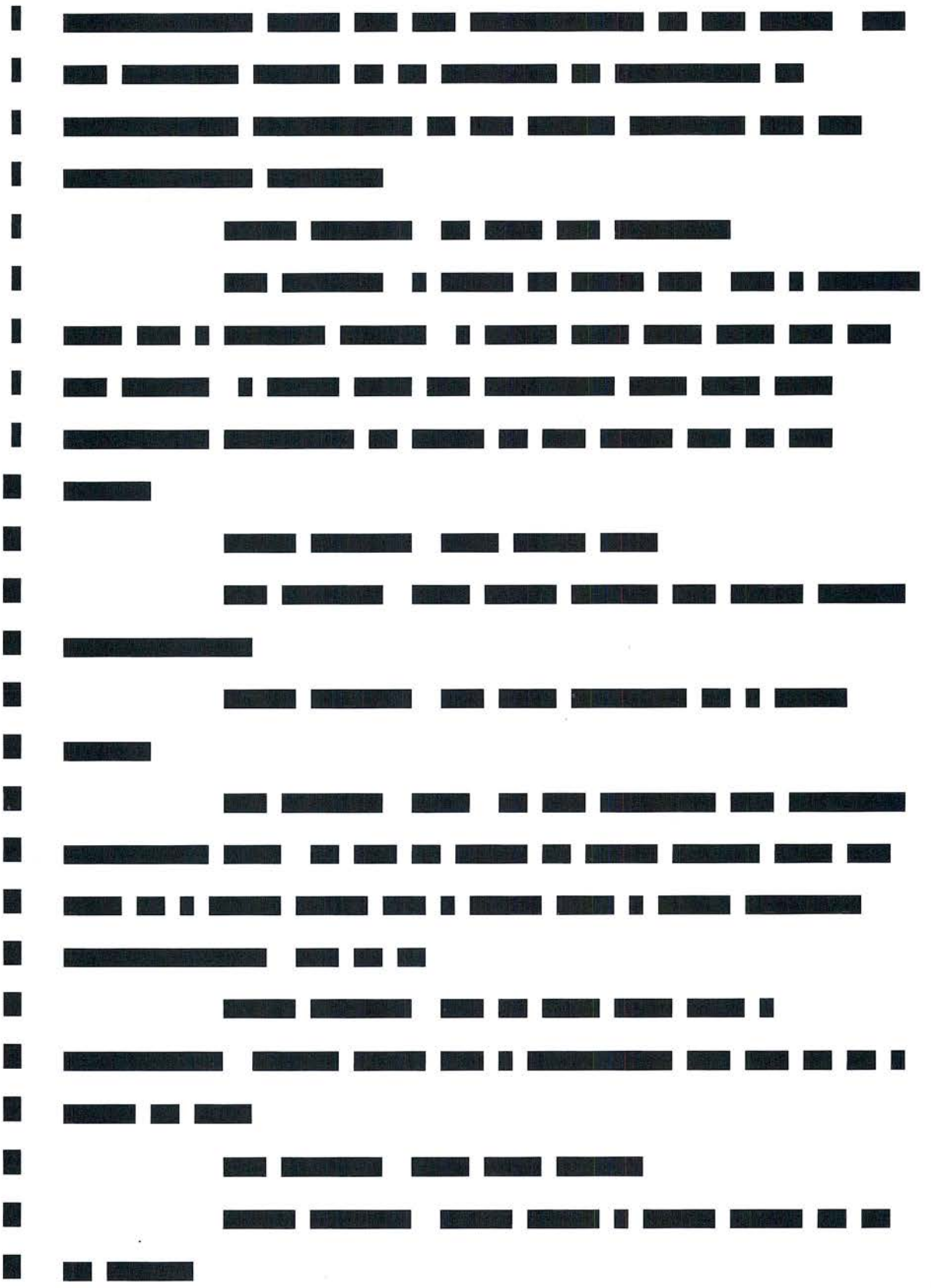
Q So you need to connect the dose calibrator to the cart with a tube, correct?

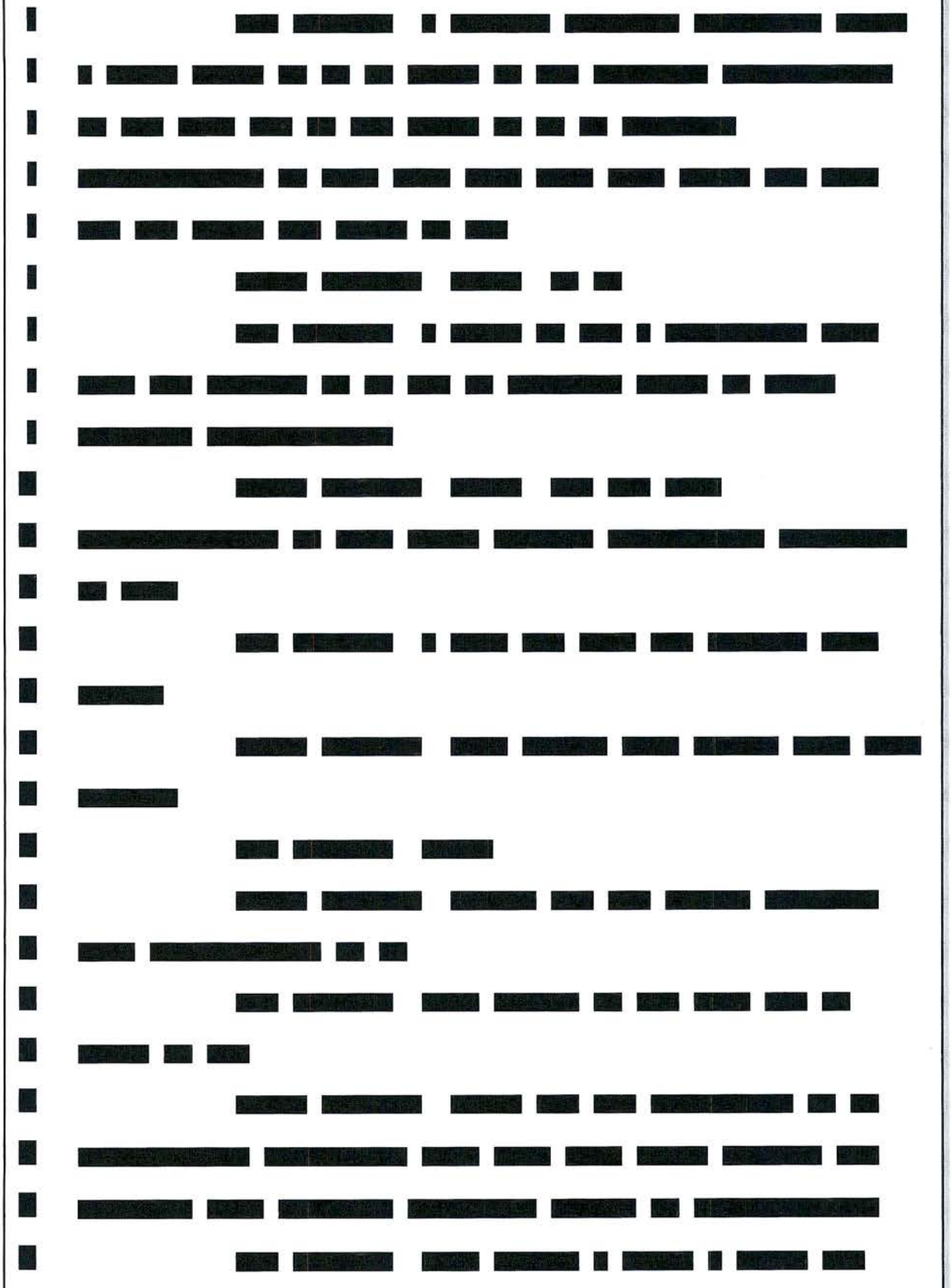
A No. You need to connect the vial that's in the dose calibrator to the cart with the tube.

Q So you need -- so you had various vials used with the dose calibrators?

A That's a possibility. I don't know the answer to that.

Q All right. Now, please turn to CX-413C -- excuse me. Let me just check. Your Honor, I'm sorry. We need to go on the confidential record. [redacted]





[redacted]

MR. DAVIS: Your Honor, I can switch to a different line of questioning to give him time to review.

JUDGE CHENEY: Okay.

BY MR. DAVIS:

Q So before we address 413, could I ask you to turn to JX-2 and specifically page 43 and I want to pull up claim one and the claim relating to an exterior shell which is the first main clause after the preamble. I'm going to blow that up. Okay. So do you see the claim language there where it talks about a shell that extends upwardly above the platform and has a front side, a rear side, and two side walls connecting the front side to the rear side?

A Yes.

Q Okay. So let's go back to RX-106, page 34, but let's keep this as well. Sorry. So let's blow up that top photo and blow up that one paragraph. Okay. So we've got a shell and it extends upwardly above the platform and it's

got a front side, a rear side, and two side walls that connect the front side to the rear side. You know, we've established that, so where is the front side of the shell in the Klein, in the device shown in the Klein thesis?

A The front side of the shell is this portion right here with a large opening in the center of it.

Q Okay. So can you identify anything that's not the opening that's the front side that would constitute the shell?

A Certainly at least these folded-down edges are part of the front side.

Q Okay. Those edges don't enclose the components that are shown in the photo, correct?

A I'm not sure what you're trying to get at here. These are a front side. These are part of the front side. They are certainly not of the side walls. They are not at the backside. They are not at the top side. They are part of the front side and they have helped form the enclosure of the entire system, interior of the shell.

Q Okay. So it's your position that the, those narrow sides in the front that that encloses the, the equipment that's shown in the photograph?

A I see nothing there that requires a front wall. It says a front side. Sides don't necessarily make a total enclosure.

Q Okay. But you would agree that the claim language is an exterior shell that has a front side?

A It has a front side. It doesn't say it forms a complete enclosure.

Q All right. So okay. Now, let's look at the next element. So you've got an opening through the exterior shell configured to provide access to the generator. What part is the opening to provide access and what part is the shell in the front?

A There is an opening right here. There is a shell through, in the front that extends around from the sides. I'm not sure where you're trying to go.

Q Do you recall Mr. Donnelly's testimony earlier, that given the variety of things that can go wrong when you implement design changes to a device like the RUBY-FILL that you typically don't change a feature that's -- that -- let me repeat the question for you. You heard Mr. Donnelly testify that given the variety of things that can go wrong when you implement design changes to a device like the RUBY-FILL, you typically don't change a feature that is known to work?

A I think that's an incomplete opinion. You wouldn't change a feature that's known to work where your change could affect how it works. You might change a feature if it would not affect how it works.

Q Okay. Well, let's look at his testimony at page 349 of the transcript, lines 7 through 19. To the question, well, when you're designing, if you know something works you're loathe to change it to something else because you're going to have to go back and verify that the -- that the new design works and there may be unforeseen consequences like the tubing or the bending of the cart so you try to avoid changing something that you know works?

Answer, we would -- I think it's common in the industry that you don't make changes if not necessary, but of course there are changes that you have to make if there are expected to be any issue with the design that you have so we always make a change if we need to make a change. If we don't need to make a change we would not make it.

A I see that he said that.

Q Do you agree with that principle?

A In general.

Q Okay. And at your deposition you admitted that you did not identify in your report any market forces that would prompt one of ordinary skill to make the various changes to Klein that you opine would have been obvious, correct?

A I may have said that in my deposition.

Q Okay. And the -- you still agree with that?

A The changes to Klein that would have been obvious.

Q I'm sorry. Let me restate the question. You have not identified any market forces, have you, that would prompt one of ordinary skill in the art to make the various changes in Klein that you opined would be obvious, correct?

A I believe I've identified what Miss Gelbach said that market forces were saying that it would only make sense to put the dose calibrator on board the cart.

Q So let's look at your deposition, page 340 -- 354, lines 11 to 23. So -- I'm sorry. I'll get -- there appears to be an error. The weight of the shielding can also complicate placement of the dose calibrator on the cart, correct?

A I would say it would complicate the design of the frame of the cart.

Q Right. And as late as 2015, JDI was still having issues with the cart bending and pieces not fitting because of the weight putting the dose calibrator on board the cart, correct?

A I think what they actually had was a problem with the enclosure not closing correctly, having a little bit of warp to it so when you refer to bending there was a displacement that occurred that somehow they were trying to track down exactly what prevented the enclosure of the

cart, the plastic panels from fitting correctly.

Q Right. Because of the weight of the dose calibrator?

A That was theorized as the cause. That's correct.

Q Okay. So multiple years into the design they were still addressing issues that they thought related to putting the dose calibrator on board?

A They discovered a minor issue and decided, and determined how to correct it. The minor issue was they hadn't quite handled the weight plus the strength of the materials or how they were arranged so they did a finite element, suggested doing a finite element analysis to determine if that were the cause.

Q All right. And you also rely on what you describe as the Medrad system, correct?

A Yes. We do.

Q All right. And the exhibit you use for your analysis of that Medrad system is RX-200C.

Don't put it up.

Correct?

A You're asking me if I recall the exhibit number yet you don't want to put it up?

Q Yes. Let's look at RDX-2.100. Right.

So I'm sorry. What?

[redacted]

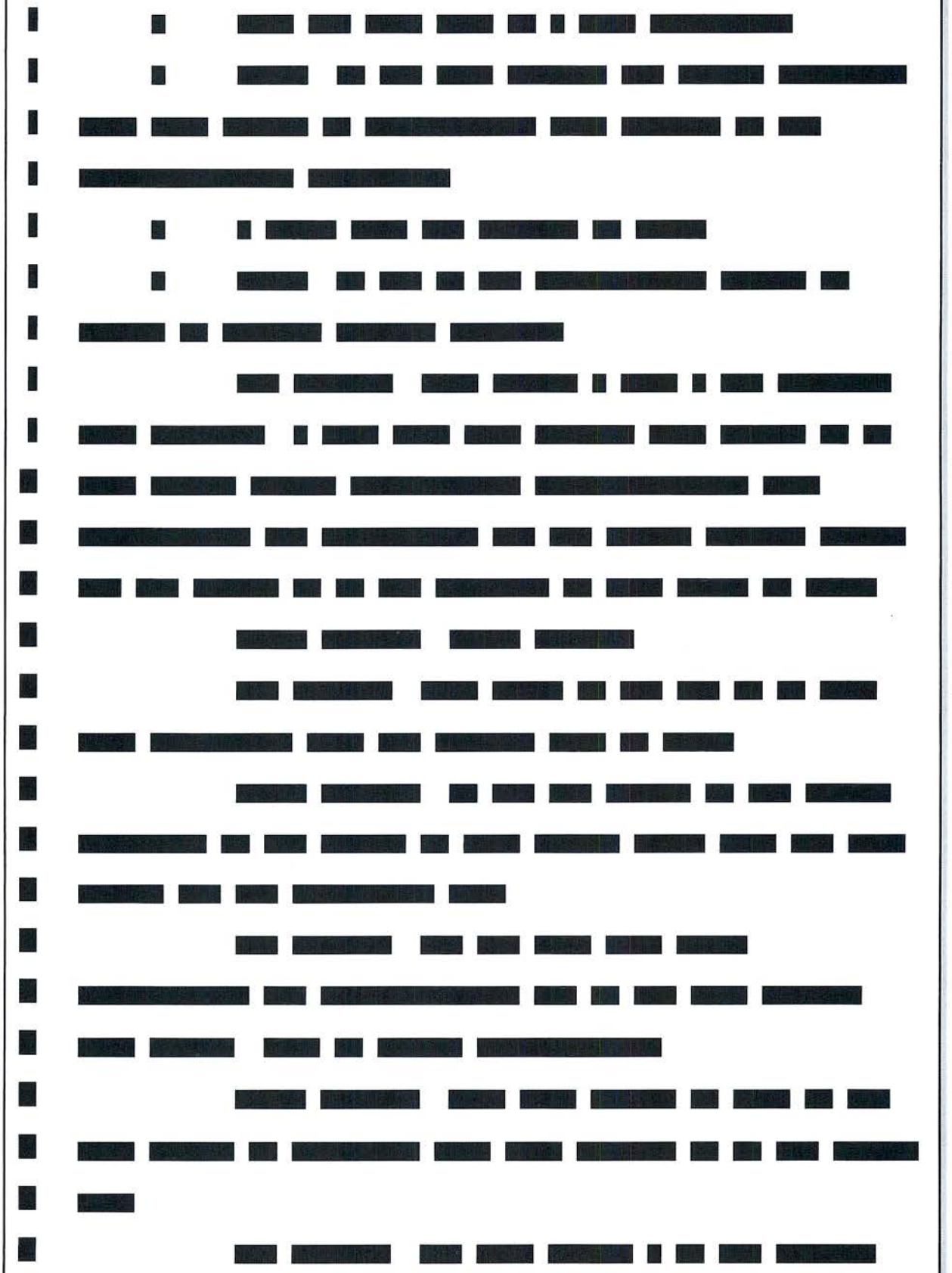
JUDGE CHENEY: Okay. We are on the Medrad confidential record. That means if you're not authorized on either side to view Medrad confidential information, you need to leave the hearing room now.

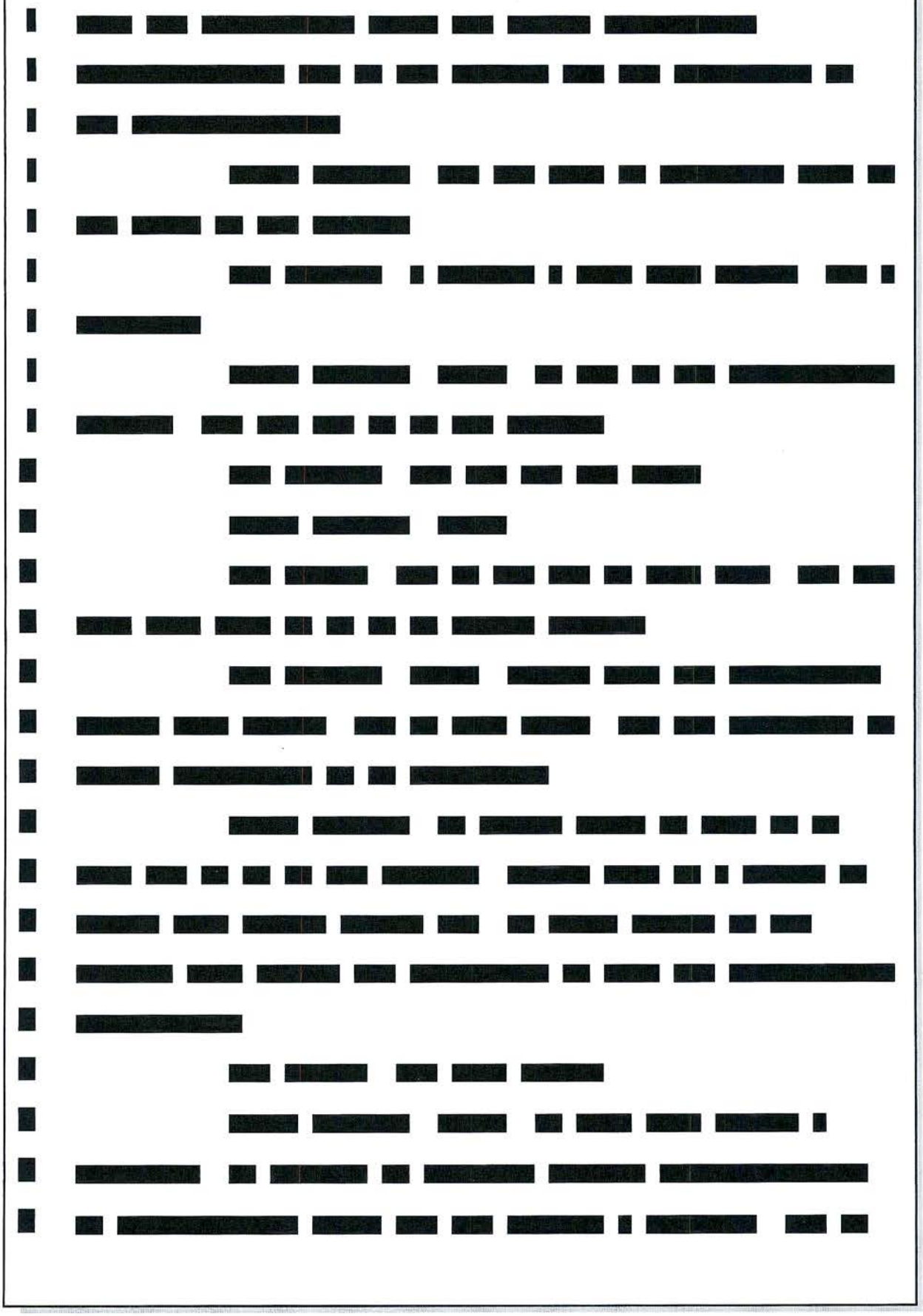
(Confidential session follows.)

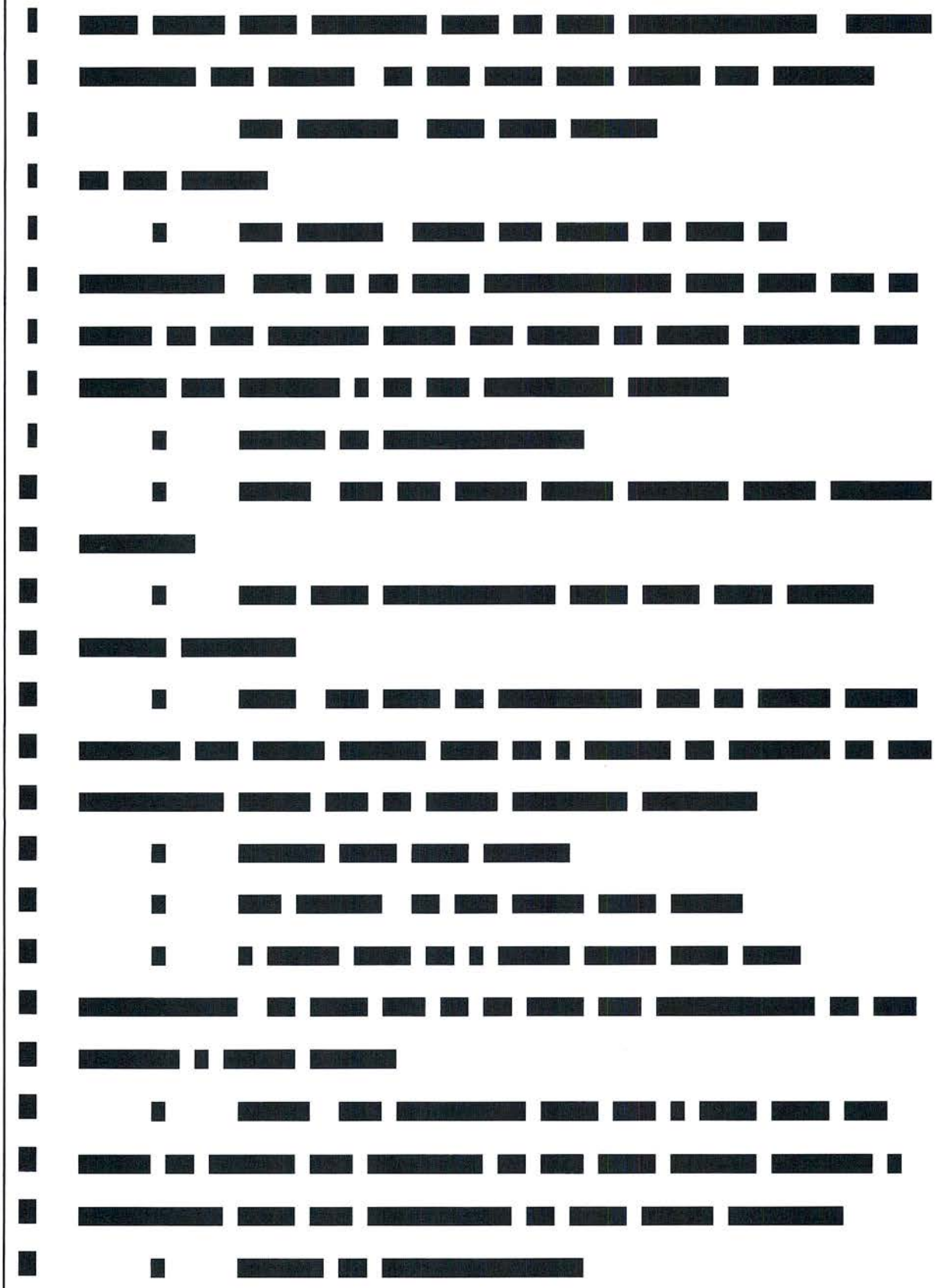
CONFIDENTIAL SESSION

BY MR. DAVIS:

Q The courtroom is cleared, Your Honor.







[redacted]

[redacted]

JUDGE CHENEY: Back on the public record.

(End of confidential session.)

OPEN SESSION CONTINUED

BY MR. DAVIS:

Q Is there any indication in the Klein thesis that there was a problem with the user not keeping an eye on the volume of saline which is in plain view of the user?

A No. There is no such indication in the Klein thesis. That's not a product that's out for ordinary users. We've talked about that being motivated instead by the usability guide when a product is out for use.

Q So the only, the only prompts or alerts that you point to in Klein are for the generator and waste bottles which are in the shielding and out of your sight, correct?

A Those are the only prompts or alerts. There are other warnings that he discusses.

Q Okay. Now, there were multiple versions of the RUBY-FILL system, correct?

A That's my understanding.

Q Right. The -- so let's go to RDX-2C14. All right. So here is your slide that talks about the evolution of the elution system. We've got Version 0 in '97, Version 1 in 2004, Version 2 in 2010 and Version 3 in 2015, correct?

A That's correct.

Q All right. Now, neither the Version 0 -- well, Version 0, 1 and 2 never were approved for commercial sale

in the U.S., were they?

A In the United States. That's correct.

Q Okay. And in 2007, Ottawa licensed to JDI the technology regarding the rubidium PET imaging technology that they had developed, correct?

A That's correct.

Q All right. And JDI and Ottawa worked together on Version 2 and 3, correct?

A That's my understanding.

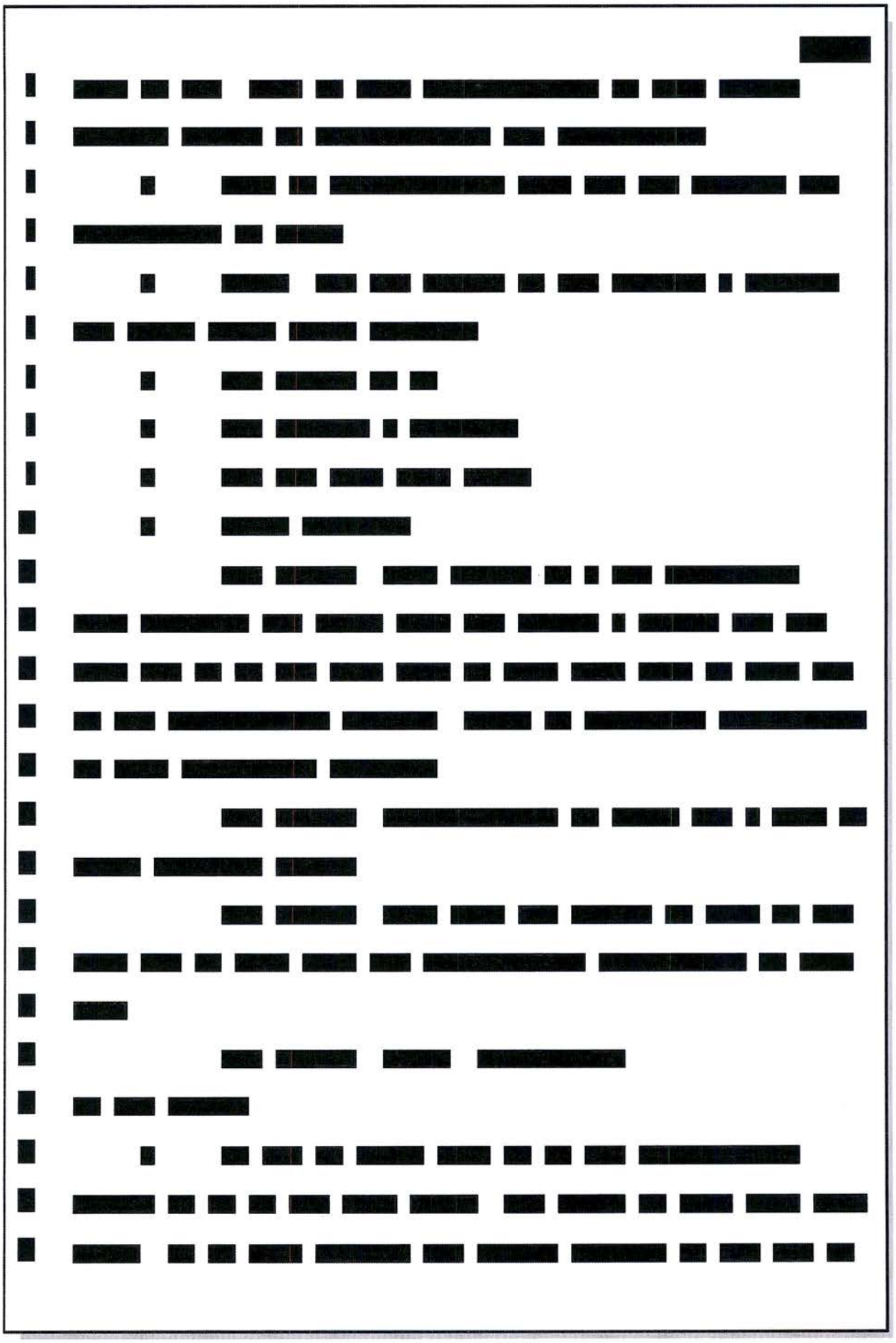
Q And so, but prior to working on Version 3, so Ottawa Heart and JDI had worked on a rubidium PET system either together or on their own for approximately 13 years without creating a system that was approved for commercial sale in the U.S.?

A They began working together, it's my understanding, in 2007. And they ended up with the device release in 2016. That would be nine years.

Q So I was asking either together or alone. So either Ottawa on its own or Ottawa and JDI were working over this time period?

A Ottawa was not developing a product. Ottawa was developing a technology, a prototype that would be licensed for development into a product.

Q Okay. Now, and they started trying to get a commercial partner to develop that at least as early as



MR. DAVIS: Your Honor, I pass the witness.

JUDGE CHENEY: Okay. Is there cross-examination by the Commission investigative staff.

MR. KOO: Yes, Your Honor. If you would just give me one minute to find a page number.

EXAMINATION BY ITC STAFF

BY MR. KOO:

Q Good afternoon, Dr. Stone.

A Good afternoon.

Q I just wanted to follow up on something, to things that Mr. Davis discussed with you earlier today. If we could turn to, I believe it's RX-106. And it's the page that has figures 2-3. So you don't have to expand it or anything. But looking at that top figure, Mr. Davis asked you about the front view of that cart that has the opening so that we can see the computer and the printer and the other components inside.

A Yes.

Q Do you recall that discussion? Okay. And I think you were trying to make the point that because it's an opening, it's not a side. Would you agree with that characterization?

A I believe that characterized what he was trying to make. Yes.

Q All right. I think what puzzled me up to this

point is you'd agree since there is a shielded waste container, a shielded generator inside the cart, you'd agree with me that at least there are some, some amount of tubing that goes inside the cart. Would you agree with me?

A Yes.

Q Okay. And the materials that are inside the tubing will carry at least at some point some radioactive materials?

A That's correct.

Q As a person of ordinary skill in the art, does it make sense to you that this cart would only be shielded on three sides?

A Absolutely not. If there is radioactive material in open tubing, one would supply shielding in order to reduce the exposures outside the cart.

Q Okay. And would you agree that that is what they have done on the exposed tubing on the top of the cart with the heavy-duty plastic shield that's shown, I believe, in figure 2-4?

A Yes. I believe it's referred to as high density polycarbonate shielding that's used to provide shielding from the beta radiation.

Q Okay. Would it surprise you if they had a door on a hinge that closed that opening on that cart there?

A Not in the least.

Q There has also been a lot of discussion over the past two days, I believe, about the features that Ms. Janet Gelbach had invented or is alleged to have invented as one of the named inventors in the three asserted patents. Do you recall that?

A Yes.

Q And I believe you testified that you agreed that Miss Gelbach is alleged to have invented the aspect of bringing the dose calibrator on board the cart?

A I believe I used the terminology she brought that idea to the team.

Q Okay. You stated that you read her deposition transcript?

A Yes.

Q Okay. Do you recall if, if -- do you recall if she stated how she came up with that idea?

A Yes. She talked to the sites that were using these devices and she said they were asking for it and said it only made sense to put the dose calibrator on the cart.

Q If we could turn to JX-176C at page 101. Let's start at page 100 at line 16 and go through 101, line 11.

Is this the -- I'll let you read this to yourself, Dr. Stone, but is this the portion of the transcript that you're referring to?

A Yes.

MR. KOO: Okay. I don't think I have anything further at this time. Thank you.

JUDGE CHENEY: Okay. Dr. Stone, I have just a couple of questions for you. If we could go back to what Mr. Koo had on the screen, RX-106, page 34. If someone among the trial wizards could help me with that.

Dr. Stone, have you seen this device represented in this image in real life?

THE WITNESS: I'm not certain that I saw the very one that was in the Klein thesis. I have seen representations of the Version 1 which includes all of those components arranged in exactly the same fashion.

JUDGE CHENEY: Do you see any Version 1 device in this hearing room?

THE WITNESS: Yes, Your Honor.

JUDGE CHENEY: Will you identify it for me.

THE WITNESS: It's right there, this first shiny cart.

JUDGE CHENEY: Will someone please identify for the record the exhibit number that Dr. Stone has identified.

MR. WALKER: Yes. It's RDX-12.

JUDGE CHENEY: Okay. Do you see any doors on RDX-12?

THE WITNESS: Yes, Your Honor. It tried to make

itself shown as I moved it around. There is a, there are hinges there for the door. It's not clear from the photograph whether that door was on the cart that was actually used by Mr. Klein as he did his work. But it's certainly obvious to put one on it.

JUDGE CHENEY: So looking at the paper documentation of Klein, you don't find express disclosure of the door that we see in the courtroom on RDX-12, is that right?

THE WITNESS: That's correct, Your Honor.

JUDGE CHENEY: Can we go back to the demonstrative Exhibit RX -- RDX-2, which I believe are slides illustrating your testimony. I'd like to look at slide 52. Do you recall giving testimony illustrated by this slide, Dr. Stone?

THE WITNESS: Yes.

JUDGE CHENEY: I seem to remember you making some points about what was claimed in the PCT application identified on this slide. Do I recall you making a point about the claims of that PCT application correctly?

THE WITNESS: Yes. Those relate to computer controls.

JUDGE CHENEY: And then I also recall, if we could advance or go back one slide. Let's try slide 53. I'm not, I'm not seeing -- did you have a slide where you

discussed the provisional application to which the patents in suit claim priority?

THE WITNESS: The PCT application?

JUDGE CHENEY: Was there no provisional application?

THE WITNESS: I don't recall, Your Honor.

MR. HAILS: Your Honor, there is some 2008 filings, those are all non-provisional filings filed in parallel. Is that what you're asking about?

JUDGE CHENEY: Well, I guess what I'm hearing is a clarification about my memory that there is no provisional application to which priority is claimed, is that right, Counsel?

MR. HAILS: Yes. That's correct.

JUDGE CHENEY: Okay. Returning to slide 52 where you talked about the PCT priority application. Why was it important to you to evaluate what was claimed in the PCT?

THE WITNESS: To determine whether there was a claim of actually putting the dose calibrator on the cart as a patentable feature as opposed to it was disclosed as an idea that was incorporated but it was not claimed until we get all the way down to 2016.

JUDGE CHENEY: Why is it important to you that it -- well, let me, let me back up one step and say, did

you find that putting the dose calibrator on the cart was disclosed in the PCT, but not claimed?

THE WITNESS: I did find that it was disclosed but not claimed. There was a couple of lines that say you could put the dose calibrator on the cart. Had that been significant to me I think we would have claimed an enablement issue but we did not because there was no claim that that was a patent at that time.

JUDGE CHENEY: So in your mind, there is a legal distinction between what was disclosed and what was claimed on the issue of priority? That's how I understood this testimony -- that's the context in which I understood this testimony about slide 52. Am I misunderstanding?

THE WITNESS: I believe there is an issue there, Your Honor.

JUDGE CHENEY: Okay. And how did you come to this legal understanding about what is disclosed versus what is claimed and its importance to priority?

THE WITNESS: It's a very, it's a broad issue. I discussed it with the patent attorneys. Know that very often things are disclosed in a patent that are not patentable, they are not considered patentable and in this case it looked like the, the complainants in this case didn't consider it patentable until they saw it utilized in someone else's device.

JUDGE CHENEY: So in some sense your opinion is based on your understanding of the inventor's subjective intent about what the invention is?

THE WITNESS: When they recognize that it is an invention, Your Honor.

JUDGE CHENEY: Okay. Can we go to slide 143. Same Exhibit, RDX-2. And Dr. Stone, do you recall giving testimony about this international standard disclosed on this slide?

THE WITNESS: Yes, Your Honor.

JUDGE CHENEY: I think you testified that the international standard requires a user to track consumables. Is that right?

THE WITNESS: Yes, Your Honor.

JUDGE CHENEY: Is there anything in the standard that requires a user to use a computer to track consumables?

THE WITNESS: The standard relates to a user interface, Your Honor. If we go back to the first slide. The first components there. It's referring to user interface in order to do that.

JUDGE CHENEY: A computer user interface.

THE WITNESS: Not necessarily. Whatever interface there is.

JUDGE CHENEY: Could it be a pad of paper with

some columns?

THE WITNESS: That's typically not considered a user interface, Your Honor.

JUDGE CHENEY: So what is a noncomputerized user interface?

THE WITNESS: I could have a digital system that actually is, would be noncomputer. It might be something called a programmable logic array. There are a number of ways of coming up with a user interface that's a display that the user, or controls that the user interacts with.

JUDGE CHENEY: Dr. Stone, did you offer any opinion about the field of endeavor of the patented invention?

THE WITNESS: I'm trying to recall from my report, Your Honor. I believe I would have stated that we are dealing with a device to administer radiopharmaceutical, but I don't recall specifically.

JUDGE CHENEY: Okay. Those are all the questions I have. Are there any more questions or redirect for this witness. It looks like Mr. Hails has some redirect.

MR. HAILS: Yes, sir, there is.

REDIRECT EXAMINATION

BY MR. HAILS:

Q Can we go to slide 52 of the presentation, 223.

I think there has been some confusion on the priority analysis here. Do you recall your testimony talking about slide 57?

A Yes.

Q What are the features that drove your priority analysis for the asserted patents?

A The features are related to the openings for the generator compartment and those openings for the generator and the waste bottle being oriented upward and the section elevation for the waste bottle, for example, being at a greater elevation than the first elevation. Same thing in the new patents. They have openings that face vertically upward and they have a shielding compartment that has a second opening facing vertically in a first opening located at a lower elevation and the second opening.

Q So in 2008 when Bracco filed the first wave of applications who did Bracco identify as the inventors of these shielding assembly features?

A Mr. Quirico, Mr. Balestracii, Mr. Dorst, Mr. Krause, Mr. Lokhande, Jacob Childs, Peter Madson, and Daniel Clements.

Q Thank you.

Can we go to page 89, please. Can we put up RX-103. Can you put up paragraph 2 which should be the first major paragraph.

At first there was a lot of discussion on cross-examination about the differences between FDG and rubidium. Are you familiar with that discussion?

A Yes.

Q Are you suggesting to turn Klein's system into an FDG system?

A Would you repeat that.

Q In your obvious analysis were you suggesting that you're trying to change Klein's system from a rubidium system into an FDG system?

A Klein? No.

Q Here, this is the background of the invention talking about what Tate is directed to. Do you see the reference to positron emission topography?

A Yes.

Q Are FDG and rubidium variants of positron emission topography?

A Yes.

Q Can we go to paragraph 7, which is the second column of the same document.

What kinds of radiopharmaceuticals or radioisotopes does Tate discuss?

A He discussed a large number such as fluorine 18, technetium 99, carbon 11, copper 64, gallium 64.

Q You don't have to read it. Do you see rubidium

in that list?

A He has rubidium-82 in there, Your Honor, as well as others.

Q You had discussed about Tate's teachings for monitoring saline for locations of dose calibrators and other kinds of things. Do people run out of saline in both an FDG system and rubidium system?

A They do.

Q Do people have to change waste bottles in both systems?

A They do.

Q With respect to the dose calibrator that's described in Tate, do you recall what kind of dose calibrator Tate used?

A Yes. It's an ion chamber.

Q And do you recall what kind of design dose calibrator Klein uses?

A Ion chamber with a well force sample.

Q With FDG positron for -- in that dose calibrator in an FDG system, what kind of energy levels are being measured from the photons?

A 511,000 electron volts.

Q And what kinds of energy levels are being measured in a rubidium system using a dose calibrator?

A 511,000 electron volts.

MR. HAILS: Thank you. No further questions.

JUDGE CHENEY: Any other questions for this witness?

MR. DAVIS: No, Your Honor.

MR. KOO: Nothing from the staff, Your Honor.

JUDGE CHENEY: Thank you, Dr. Stone. You may be excused.

Respondents, call your next witness.

MR. BRANDYBERRY: Respondents call Dr. Thomas Vander Veen.

JUDGE CHENEY: Let's go off the record for a moment.

(Discussion off the record.)

JUDGE CHENEY: Let's go back on the record.

Dr. Vander Veen, please raise your right hand. I will administer the oath.

Whereupon,

THOMAS V. VANDER VEEN,

was called as a witness, and having been duly sworn, was examined and testified as follows:

JUDGE CHENEY: You may be seated.

Please proceed when you're ready, Mr. Brandyberry.

DIRECT EXAMINATION