

Date: April 15, 2019

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

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Bracco Ex. 2006
Jubilant v. Bracco
IPR2018-01449

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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 III

April 15, 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
9:01 a.m., before the Honorable CLARK S. CHENEY,
Administrative Law Judge for the United States
International Trade Commission.

1 is Bob Hails. I'm not sure we've been introduced on
2 Thursday, but just for the record. We are going to call
3 Dr. Robert Stone to the stand.

4 Can we have two minutes to check out the AV
5 hookup and make sure everything is up and running.

6 JUDGE CHENEY: Yes. Let's go off the record for
7 two minutes.

8 (Recess.)

9 JUDGE CHENEY: Let's go back on the public
10 record.

11 Dr. Stone, please stand, raise your right hand
12 and I'll swear you in.

13 Whereupon,

14 ROBERT THOMAS STONE,
15 was called as a witness, and having been duly sworn, was
16 examined and testified as follows:

17 MR. HAILS: Thank you, Your Honor.

18 DIRECT EXAMINATION

19 BY MR. HAILS:

20 Q Good afternoon, Dr. Stone. Would you introduce
21 yourself to the Court give them your name and tell them
22 where you work.

23 A My name is Robert Thomas Stone. I'm the CEO of
24 a company called Medical Designs Solutions, Incorporated.

25 Q And what does your company do?

1 A We do medical device development, everything
2 ranging from feasibility studies to full-fledged design and
3 handing over to manufacturing.

4 Q And how long have you been at your position?

5 A I formed the company in November of 2011.

6 Q Okay. Would you please briefly summarize your
7 education for the Court.

8 A My education began with a year of premed at
9 Pepperdine University, after which I joined the United
10 States Navy. I had three years and eight months of formal
11 schooling in the Navy being trained as a nuclear
12 electronics technician, spent two years teaching nuclear
13 engineering, and then spent time on the USS Bainbridge,
14 after which leaving the Navy I went to Virginia Tech where
15 I obtained a bachelor of science in electrical engineering
16 and a master of science in electrical engineering. And
17 then I went to Stanford University and obtained a Ph.D. in
18 electrical engineering with a specialty in medical imaging.

19 Q You've touched on it a bit, but would you
20 explain your professional experience working with
21 radioactive materials.

22 A Certainly. The time in the Navy was either at a
23 prototype for the USS Bainbridge or teaching at the
24 prototype. We handled all forms of radioactive material.
25 Everything from contamination to sources, to the

1 instrumentation that would be used in measuring and have
2 internal sources, to transferring highly radioactive
3 nuclear fuel.

4 Q That was the Navy. You do you have other
5 experience working with radioactive materials?

6 A Yes. When I left the Navy and went to Virginia
7 Tech, I managed a nuclear reactive facility where we did
8 neutron activation analysis and other types of research in
9 teaching students as well as maintaining an analytical
10 laboratory.

11 Q Can you give us some type of ballpark how many
12 years of experience do you have with working with
13 radioactive materials?

14 A I believe it was eight years at Virginia Tech
15 and six years in the Navy. That's about 14 years.

16 Q 14 years. Okay. Do you have professional
17 experience working with medical devices?

18 A I do.

19 Q Why don't you explain that experience to the
20 Court?

21 A My first experience working with medical devices
22 was as a student at Stanford when I assisted in the design
23 of a medication infusion system and then met two physicians
24 where in 1983 I left Virginia Tech and joined a company
25 called Nellcor, which was a medical device company. I've

1 been working with medical devices ever since.

2 Q What kind of devices do you have experience
3 working on?

4 A Everything from noninvasive diagnostic devices
5 to implantable therapeutic devices.

6 Q Okay. And do you have experience preparing
7 prototype medical devices for market?

8 A Yes.

9 Q And, again, can you give us a for-instance with
10 representative devices.

11 A Sure. One for-instance would be working with a
12 company called Natus Medical. I took a prototype of a
13 breath analyzer that had been developed at Stanford and
14 converted it over into something that could measure the
15 rate at which blood was breaking down in the baby, and that
16 became a commercial product.

17 Q Okay. Are you familiar with how design
18 processes for medical devices might be different from
19 non-medical devices that might be released commercially in
20 the market?

21 A Surely. In the United States in order to obtain
22 approval from the FDA to put a medical device on the
23 market, its design and development and manufacturing all
24 are controlled by something called GMP, good manufacturing
25 procedures. That process has evolved over the years from

1 basically handling only the manufacture where now it
2 handles everything from the time the product design process
3 begins.

4 Q Okay. And again in some type of ballpark range
5 can you please tell the Court how much experience you have
6 working on medical device design and development.

7 A Medical device and design development from 1983
8 to the present, I believe that's about 36 years.

9 MR. HAILS: So, Your Honor, we tender the
10 witness as an expert in the field of medical devices and
11 radiation protection systems.

12 MR. DAVIS: No objection, Your Honor.

13 MR. KOO: No objection, Your Honor.

14 JUDGE CHENEY: Without objection, Dr. Stone will
15 be accepted as an expert in the fields offered.

16 BY MR. HAILS:

17 Q Will you please explain your role in this
18 investigation?

19 A I was asked to look at the patents that are in
20 concern here and determine whether I believe those patents
21 were valid. I was also asked to look at the -- at the
22 Ruby 3 product to determine if it infringed those. I was
23 asked to look if I saw any indication, any evidence of
24 copying in this matter.

25 Q Were you asked to develop opinions regarding

1 inventorship in this investigation?

2 A Yes.

3 Q And with respect to your invalidity opinions,
4 were you asked to develop an opinion on obviousness issues
5 for this investigation?

6 A Yes, I was.

7 Q And how about anticipation?

8 A No. Other than the Ruby 3 anticipation.

9 Q Let's -- did you prepare demonstrative materials
10 to explain your opinions to the Court?

11 A Yes, I did.

12 Q Can we pull up the PowerPoint version of RDX-2.
13 What is this exhibit, sir?

14 A This is the first slide of the demonstratives
15 that I prepared for this testimony.

16 Q Do you have a clicker?

17 A I do.

18 Q All right. Why don't we start and walk through,
19 why don't you just take us through the first set of
20 materials, please. Working?

21 A No.

22 Q We had this working. So now we are at slide
23 two. I think we've talked on it, discussed it through
24 other witnesses, but would you please explain to the Court
25 what is positron emission tomography at a high level?

1 A Positron emission tomography at a high level is
2 injecting a radioactive tracer into the body which emits
3 positrons. That positron rapidly loses any excess energy
4 it has and unites with an electron and annihilates
5 converting the mass of the electron and the positron into
6 energy, reducing two gamma rays which go in exactly
7 opposite directions.

8 Q Okay. So we have two images. One here on the
9 left and one here on the right. What is the animation on
10 the left showing?

11 A The animation on the left is showing the
12 radioactive tracer giving off its energy. The one on the
13 right shows the process whereby that energy ends up
14 ultimately being converted into an image in that the
15 photons if emitted at the same time or exactly the same
16 time as can be measured by the instrumentation is counted,
17 and a line is drawn between two elements of the detector,
18 and after a large number of those lines have been drawn,
19 then an image can be computed using a process called back
20 projection using the most common tracers.

21 Q Can we break it down a little bit. What's the
22 blue ring shown in the image on the right?

23 A The blue ring is an array of detectors,
24 typically they are crystals which emit light in a
25 photodiode or photomultiplier, which counts those light

1 flashes --

2 Q I'm going to call it a green blob and a red blob
3 inside of the green glob. Do you see that?

4 A Yes.

5 Q What's that?

6 A We have cross section of the torso, the red blob
7 would be the constructed image of in this case cardiac
8 tissue that's been generated as a result of those many
9 lines being drawn.

10 Q We have the tracer and arrows coming out in
11 opposite direction from the tracer. It hits the rings.
12 And explain again how does that phenomena get turned into
13 useful image data?

14 A Well, as shown here we have a line drawn across
15 -- I'm sorry.

16 Q Back. Back. One more. All right.

17 A As shown here we have a line drawn across, and
18 that line, when many, many of those lines are drawn, and
19 using appropriate mathematical algorithm, in CT it's called
20 convolution back projection, and an image of where those
21 emissions took place in a computer.

22 Q Okay. And the -- I think the time frame we are
23 going to be discussing is the mid-2000s. In the mid-2000s,
24 what were the common PET tracers in use?

25 A The most common PET tracers in use in the year

1 2000 would have been fluorodeoxyglucose.

2 Q What about rubidium, was rubidium popular at the
3 time?

4 A It was being used. CardioGen 82 had already
5 been in use so Rubidium-82 was in use at that time.

6 Q Let's move forward, please. All right. And on
7 slide three you have a little bullet for an infusion
8 system. What's an infusion system?

9 A Just to make clear, we are not talking about the
10 imaging system that's on the right. What we are talking
11 about is the electromechanical fluidic system which
12 controls the elution of the source as it goes from the
13 saline bag through a source of radioactive material and
14 into the patient.

15 Q And so what's the job of the infusion system?

16 A It is to safely inject the correct dose into the
17 patient while maintaining radiation safety for the user.

18 Q Let's move forward please. I'm going to jump to
19 slide six. Here you have a timeline presented. Will you
20 please explain Bracco's development of its CardioGen
21 system?

22 A Certainly. In 1989, the FDA approved the
23 CardioGen 82 which is the device shown there in the
24 diagram. This is a device that had manual strontium
25 breakthrough tests still on the market today. It has no

1 computer interface and from 1989 to 2006, they were the
2 sole supplier of Rubidium-82 infusion systems in the U.S.
3 and they made no significant upgrades during that time.

4 Q You said it didn't have a computer interface.
5 What kind of interface did it have?

6 A It had some digital logic that had included
7 controls such as sub wheels, knobs, switches push buttons
8 and indicators.

9 Q Let's kick out of the PowerPoint for a moment,
10 please, and pull up RX-216. Do you recognize this
11 document, sir?

12 A Yes.

13 Q What is this document?

14 A This is a user guide for the CardioGen 82 also
15 known as the 510.

16 Q Can we pull up page 22 of this document. What
17 is this?

18 A Well, as I stated we have light emitting diodes,
19 knobs, switches, buttons, all of which are the control
20 process that is done manually through the system.

21 Q And you said it was a manual strontium
22 breakthrough test is that correct?

23 A Correct.

24 Q Let's move to page 45 of this document. So what
25 is this document?

1 A This is the first page of a worksheet that
2 describes what a user would do in order to do a strontium
3 breakthrough test.

4 Q And if we can move forward two pages. Three
5 pages. You see this chart. This is on page I think 48 of
6 RX-216.

7 A I do.

8 Q This is the chart that, a chart similar to the
9 one that Dr. Lewin was explaining earlier in testimony, is
10 that correct?

11 A That's correct.

12 Q So am I correct that people are measuring
13 activity and putting these figures in by hand to calculate
14 strontium breakthrough in the CardioGen Model 510?

15 A That is correct.

16 Q Let's move back to the PowerPoint please. All
17 right. Can you move forward please. 2006. What happens
18 in 2006?

19 A 2006, the Klein thesis was published it's also
20 called the University of Ottawa infusion system. They
21 invited Bracco to participate in a request for information.
22 Bracco showed no apparent interest.

23 Q Okay. Just for the record this exhibit number
24 that's shown here is JX-51, but it has kind of evolved over
25 time. It is now RX-1 44 page 10. Let's move forward.

1 Then what happens?

2 A In 2008, Bracco filed a patent application a
3 figure of which is shown on the right-hand side and then in
4 2009, they supplemented that application to disclose an
5 on-board dose calibrator.

6 Q That's slide seven of your presentation. Will
7 you continue. We are at slide eight. Please explain what
8 was the University of Ottawa doing at this time?

9 A The University of Ottawa had developed something
10 they called the RBES system that possessed some really
11 significantly advanced features. They had a touch screen
12 interface they had automated the strontium breakthrough
13 test they had three types of elutions instead of a single
14 type that included the constant activity elution we
15 discussed earlier in this, we, it's been discussed earlier
16 in this proceeding. They provided the saline push to the
17 patient maintaining more accurate, achieving more accurate
18 doses and they had a longer generator life.

19 Q Let's move forward please. 2016, you talked
20 about how Bracco was invited to participate. What about
21 Ottawa's dealings with DraxImage?

22 JUDGE CHENEY: Just to clarify the record,
23 Counsel, did you mean 2006 or 2016.

24 MR. HAILS: 2006. I'm sorry. Did --

25 JUDGE CHENEY: Please continue.

1 BY MR. HAILS:

2 Q Yes, sir. Please explain what happened in 2006.

3 A Well, as we said Ottawa invited several
4 companies to have a request for information. They were
5 looking for a partner to commercialize their prototype
6 system. Bracco showed no interest and DraxImage ultimately
7 won that request for information.

8 Q Please move forward. All right. Then what?

9 A 2007, Ottawa licenses the RBES technology to
10 Jubilant DraxImage.

11 Q Now, here you show a picture taken from Exhibit
12 106. Is this the only document that you reviewed that
13 explains the development of the University of Ottawa team?

14 A No. It's not.

15 Q Do you have a binder in front of you that
16 contains other materials that you've reviewed?

17 A Yes, I do.

18 Q Would you pull it out, please. All right. I'd
19 like to just check that my list of exhibits is the same as
20 the one that you have. Does your binder include RX-80,
21 RX-86, RX-88, RX-89, RX-90, RX-91, RX-92, RX-93, RX-97,
22 RX-100, RX-102, RX-104, RX-105, RX-106 and 107?

23 A Yes.

24 Q All right. Thank you. You can put that aside.

25 Let's move forward, please. Okay. Now we are

1 on slide 9.

2 What are you showing here on this slide?

3 A What we are showing here is the similarity, in
4 fact, the identical system components functionally between
5 the University of Ottawa system that was developed first
6 disclosed in 2005 and then Bracco's asserted patents which
7 were filed in 2009.

8 Q So why don't you walk us through this. How do
9 the components of the Ottawa system from 2005 compare to
10 the system disclosed in Bracco's asserted patents?

11 A Well, they both have a saline source. They both
12 have a pump for moving the saline. They both have a
13 pressure sensor for monitoring the pressure in the system.
14 They both have a generator valve which can divert flow
15 either to the generator both systems or to a bypass line in
16 both systems. They also have an activity counter to
17 monitor the dose of radiation as it's being delivered.
18 They have a patient valve which can direct the dose either
19 to the patient or the calibrator line or divert that to the
20 waste bottle where they both have a waste bottle and why
21 they both have a dose calibrator it's not shown here on the
22 Bracco system.

23 Q Okay.

24 A Sorry.

25 Q No. That's fine. Let's move forward please.

1 Slide 10. On slide 10 you have the subtitle generating
2 rubidium eluate through the strontium rubidium generator.
3 Can you explain?

4 A Both systems operate essentially any in the same
5 fashion. Saline is pumped through the generator valve out
6 the output port of the generator through the radiation
7 counter through the patient valve to the patient. Same
8 path both systems.

9 Q I was going to ask just for the record, does the
10 same process occur in the Bracco system?

11 A Functionally the same system.

12 Q Let's move forward please. Okay. We are at
13 slide 11 and you have part of your title automating
14 strontium breakthrough testing. Will you please explain
15 how does this phenomenon occur in the two systems?

16 A Well, it's almost identical with regard to the
17 fluid path in both systems with the difference -- only
18 difference being at this far end instead of going to the
19 patient it goes to an eluant reservoir not shown here
20 that's in the dose calibrator where, in the case of the
21 University of Ottawa, that dose comes -- where the
22 calibration takes place.

23 Q In the University of Ottawa system eluant comes
24 out of the generator through that pink path through the
25 dose calibrator?

1 A That is correct.

2 Q And does that process also occur in the system
3 disclosed in the Bracco patent?

4 A Yes.

5 Q The eluant comes out of the hot pink path into
6 the dose calibrator; is that correct?

7 A That's correct.

8 Q Move forward please. Slide 12. You have a
9 reference to a bypass path in your title. Please explain
10 how this phenomenon occurs in the two systems.

11 A In both systems we have the opportunity to
12 switch the flow from going through the generator to go
13 through the bypass line. Instead. Going on to the
14 patient. The bypass line can be flushed, so that the
15 patient line can be flushed and any residual radioactivity
16 can be removed.

17 Q Earlier in testimony we've been hearing about
18 saline pushes. Are you familiar with that?

19 A Yes.

20 Q Is this concept related to that saline push
21 concept?

22 A It is. That's how the saline push would occur.

23 Q All right. And does the operational, the
24 operation of the bypass path, is that the same in both
25 systems?

1 A Yes, it is.

2 Q Let's move forward please. We are on slide 13.
3 Part of you're title says "diverting rubidium eluate to a
4 waste bottle." Would you please explain how does this
5 phenomenon occur in the two systems?

6 A Yes. On a daily basis whenever the generator or
7 lines are changed, they need to be flushed. The generator
8 needs to be flushed to remove Strontium breakthrough, so we
9 once again pump saline through the generator valve through
10 the generator and actually through on -- to the waste
11 bottle. So any of that material that we don't want to
12 eluate to a patient goes to a waste bottle.

13 Q So that was you describing the Ottawa design.
14 Does that process occur in the Bracco disclosure?

15 A Same process occurs in the Bracco.

16 Q Let's move to slide 14, please. Okay.

17 JUDGE CHENEY: Probably a good place to take our
18 afternoon break. Take 15 minutes. We are off the record.

19 (Recess.)

20 JUDGE CHENEY: We are back on the record in the
21 1110 investigation.

22 We are in the midst of the direct examination of
23 Dr. Stone, Respondents' witness, here to talk about the
24 validity of the considered patent.

25 Please proceed, Mr. Hails.

1 BY MR. HAILS:

2 Q I think when we broke we were referring to slide
3 14. Here we have a timeline referring to Jubilant. Will
4 you please walk us through this material?

5 A Certainly. In 2007 Jubilant had taken a license
6 and began working with the version 1 system that had been
7 developed in 2004, and by 2010 they had developed a version
8 2 system. Then beginning in 2010 they began development of
9 the so-called V3, which is the -- a product that's been
10 under consideration today.

11 Q Let's move forward, please. All right. That's
12 V2; is that correct?

13 A That is V2.

14 Q Move forward, please. All right. And then
15 again walk us through the material on the V3?

16 A All right. On the material in the V3 in 2010
17 Jubilant had completed version 2 and began development on
18 V3 by 2013 they submitted a user manual to the FDA. And
19 then in 2015 they completed the design of the version 3.
20 Then in 2016 the FDA approved the Ruby system that's here
21 today.

22 Q Earlier you had testified that the system
23 developed by the University of Ottawa provided several
24 advantages over Bracco's predecessor CardioGen product.
25 Did you remember that?

1 A Yes, I do.

2 Q Does the -- does the JDI's Ruby system employ
3 the same advantages?

4 A Yes, it does.

5 Q Let me rattle them off just to be sure. Does
6 the Ruby system have a touchsreen interface?

7 A It does.

8 Q Does JDI's Ruby system perform an automated
9 strontium --

10 A Yes, it does.

11 JUDGE CHENEY: The court reporter is doing a
12 great job, but -- let's -- both you and the witness can
13 just breathe a little. Relax. This is fun.

14 MR. HAILS: Well, I'm glad.

15 BY MR. HAILS:

16 Q Does JDI's Ruby system perform constant activity
17 elutions?

18 A It does.

19 Q Does JDI's Ruby system perform a saline push to
20 patients?

21 A Yes, it does.

22 Q And does JDI's Ruby system have a longer
23 generator life than the predecessor CardioGen 82?

24 A Yes, it does.

25 Q Do you mind if I refer to that CardioGen 82 as

1 the Model 510 to keep it distinct from for example the
2 1700?

3 A That would be fine.

4 Q All right. Thank you.

5 You have an exhibit here shown as JX-052C. Do
6 you see that?

7 A Yes.

8 Q All right. And is this the only document that
9 you reviewed to develop your understanding of the JDI
10 development product?

11 A No.

12 Q All right. Will you look in front of you and
13 see if you have a binder labeled JDI development documents.
14 Can you pull them out.

15 A Yes.

16 Q Will you pull it out for me. Does that binder
17 contain other documents that you reviewed to develop your
18 understanding of the Jubilant design product?

19 A Yes, it does.

20 Q Let me ask you if those binders include the
21 following exhibits. I have it as JX-007?

22 A Yes.

23 Q JX-013?

24 A Yes.

25 Q JX-14C?

1 A Yes.

2 Q JX-15C?

3 A Yes.

4 Q JX-22C?

5 A Yes.

6 Q JX-32C?

7 A Yes.

8 Q JX-33C?

9 A Yes.

10 Q JX-39C?

11 A Yes.

12 Q There is JX-52 on the screen.

13 A Yes.

14 Q RX-78C?

15 A Yes.

16 Q RX-143C?

17 A Yes.

18 Q RX-155?

19 A Yes.

20 Q And RX-172C?

21 A Yes.

22 Q All right. Thank you.

23 Can we move forward, please. So now we are on

24 slide 15.

25 What is shown here on slide 15?

1 A On the left-hand side of the slide is the
2 University of Ottawa's RBES system which was disclosed in
3 the Klein thesis in 2005 and 2006. On the right-hand side
4 is Jubilant's FDA filing that they filed in 2011 which is
5 the same components of the diagram with a minor
6 repositioning of one element.

7 Q I was going to ask. Is this how Jubilant
8 explained its system to the FDA?

9 A Yes, it is.

10 Q And here you show an excerpt from a single
11 exhibit, RX-31, at page 11. Is this the only document that
12 you reviewed to developing your understanding of Jubilant's
13 representations to the FDA?

14 A No.

15 Q Do you have a binder in front of you containing
16 JDI FDA documents?

17 A I do.

18 Q Can you pull it out, please. Did you review the
19 documents in the binder to develop your understanding of
20 Jubilant's dialogue with the FDA regarding its system?

21 A Yes, I did.

22 Q Let me ask you if these exhibits are contained
23 in that binder. RX-31?

24 A Yes.

25 Q RX-48?

1 A Yes.

2 Q RX-57?

3 A Yes.

4 Q RX-58?

5 A Yes.

6 Q RX-59C?

7 A Yes.

8 Q And RX-62C?

9 A Yes.

10 Q Move forward. Okay. Now we are on slide 16 and
11 I think you've taken us through 2016, at least the
12 beginning. Why don't you pick it up there. What happened,
13 what else happened in 2016?

14 A Well, in 2016, the FDA approved the Ruby system.
15 Bracco obtained the Jubilant product literature from the
16 FDA via a Freedom of Information Act request. And they
17 copied the Ruby features into new claims that have become
18 the asserted patents here today.

19 Q Okay. Move forward, please. I want to jump
20 ahead to slide 70 and talk about prior art. Will you
21 advance, please. Here on slide 71 you have a title "Major
22 Sources of Prior Art." Would you please explain --
23 introduce these prior art references to the Court.

24 A Well, first we have Bracco's own CardioGen 82,
25 which was publicly used in 1989, a PET infusion system with

1 Rudidium-82. Next we have the Klein thesis published in
2 2006, it discloses a PET infusion system for Rubidium-82.
3 Next, we have the Tate application filed in 2007, it
4 discloses a PET infusion system using FDG. And then
5 finally we have the Medrad Intego product, which was
6 offered and sold in 2008, and it also includes -- there's a
7 PET infusion system. Its material has been requested to be
8 redacted, I understand.

9 MR. HAILS: So, Your Honor, it was produced to
10 us under CBI so we have redacted slides here and we will
11 ask eventually to go on to the confidential record for this
12 third-party CBI, to discuss just so you are aware.

13 JUDGE CHENEY: I'm a little confused.

14 MR. HAILS: Well, I don't blame you.

15 JUDGE CHENEY: So we are going to have an
16 argument about something known to the world that will not
17 be known to the world.

18 MR. HAILS: We are not making the claim of CBI.
19 The claim of CBI was made by the producing party. I'm not
20 sure this is confidential and we have evidence that it was
21 publicly sold, offered for sale and used, but this is what
22 it is.

23 JUDGE CHENEY: So when you pushed back on the
24 party from whom you sought this information, what did they
25 tell you was the basis for keeping this confidential?

1 MR. HAILS: They did not explain in depth. They
2 maintained their claim of CBI. And we -- we don't have
3 their information. We are not in a position to challenge
4 that.

5 JUDGE CHENEY: So if I were to make an
6 adjudication about whether or not this is CBI, which I am
7 entitled to do under the Commission rules, who will be
8 representing their interests?

9 MR. HAILS: We have contact information for
10 their counsel and we can certainly get in touch with them
11 and notify them of your issues, see if they want to come
12 here and defend that claim.

13 JUDGE CHENEY: Like tomorrow?

14 MR. HAILS: We can ask. But as a practical
15 matter, I doubt it, but I will certainly have somebody make
16 that -- make that --

17 JUDGE CHENEY: Surely this is something that you
18 would foresee when you are going to present a prior art
19 argument based on secret prior art that you would have made
20 some arrangements about this.

21 MR. HAILS: Again, we have shown these slides to
22 counsel for -- they're called the Bayer Company, for the
23 Bayer Company. We have explained to them that we would
24 like to disclose that in court and they declined to waive
25 the confidentiality claim to this material.

1 JUDGE McNAMARA: This is a -- so what kind of an
2 argument are we relying on this art for? Is it a 102B?

3 MR. HAILS: It's prior art under --

4 JUDGE CHENEY: Or is it under the AI? What are
5 we talking about here?

6 MR. HAILS: It's 102A. It's all publicly known
7 beforehand. Before their invention.

8 JUDGE CHENEY: So are you relying on the
9 article, the sale of the article itself, not on a printed
10 publication?

11 MR. HAILS: That's correct.

12 JUDGE CHENEY: Do they sell this thing under an
13 obligation of confidentiality?

14 MR. HAILS: I don't know the circumstances.

15 JUDGE CHENEY: How did you become aware of it?

16 MR. HAILS: We found material -- again, this is
17 not -- we found material online that suggested they were
18 being sold and marketed. It is a different document than
19 the document presented here. And we pursued it through
20 discovery and we obtained information on their sales of
21 product.

22 JUDGE CHENEY: Does the third party contend that
23 the sale is confidential or only that the document that
24 they provide you in discovery is confidential?

25 MR. HAILS: I don't know to that level -- I

1 certainly know that they have -- we have sales documents
2 which we will -- we are prepared to discuss, again, on the
3 confidential record, and we have materials on the product,
4 which we are prepared to discuss. And it's not our claim
5 of confidentiality.

6 JUDGE CHENEY: But it is your burden to prove by
7 clear and convincing evidence that this was known to the
8 public. And I would expect you to have a few more answers
9 than you have today.

10 MR. HAILS: I understand.

11 JUDGE CHENEY: Okay. Well -- it's not looking
12 good for your burden so maybe you want to do something
13 about that.

14 MR. HAILS: We'll check.

15 JUDGE CHENEY: Okay. Proceed.

16 BY MR. HAILS:

17 Q Okay. You talked about the CardioGen cart. How
18 do you know it was publicly used in 1989?

19 A That's what Bracco claims in their original
20 complaint.

21 Q We have an except from RX-0207. Do you see
22 that?

23 A Yes.

24 Q Is this the only document on the CardioGen 82
25 that you reviewed to develop your opinions regarding its

1 operation and construction?

2 A No.

3 Q Do you have a binder labeled CardioGen 82 prior
4 art documents?

5 A I do.

6 Q Are those the documents that you reviewed to
7 develop your opinions regarding the CardioGen 82 product?

8 A Yes.

9 Q I'd like to read off the exhibit list and make
10 sure that you have what I have. Does your binder include
11 RX-98?

12 A Yes.

13 Q RX-216?

14 Let's go across.

15 RX-98, RX-207?

16 A Yes.

17 Q RX-211?

18 A Yes.

19 Q RX-212?

20 A Yes.

21 Q RX-213?

22 A Yes.

23 Q RX-214?

24 A Yes.

25 Q RX-215?

1 A Yes.

2 Q RX-216?

3 A Yes.

4 Q RX-217?

5 A Yes.

6 Q RX-218?

7 A Yes.

8 Q RX-219?

9 A Yes.

10 Q And RX-357?

11 A Yes.

12 Q Put that aside.

13 How did you determine that the Klein thesis was
14 published by 2006?

15 A I have seen declarations by a Dr. Andy Adler, as
16 well as by Carol Watdke, that declare that those were
17 posted on a website first in 2005, taken down as Andy Adler
18 moved to a different location, and then posted permanently,
19 and have been posted permanently since 2006.

20 Q Can we kick out of the PowerPoint, please, and
21 go to RX-333. Is this the declaration that you referenced
22 from Dr. Adler?

23 A That's correct.

24 Q Can we pull up RX-334. Is this the declaration
25 from Ms. Watdke?

1 A That is correct.

2 Q Move forward, please. All right. On slide 71
3 this bubble just came up. The priority date is no earlier
4 than June 2009. Why don't you explain briefly what is your
5 analysis regarding priority date?

6 A My analysis is that it could be no earlier than
7 June 2009, which is the first time we have a disclosure of
8 an on-board dose calibrator in the patent history record.

9 Q All right. Do you have a -- have you -- do you
10 have an opinion whether June 2009 is the proper priority
11 date of the asserted claims?

12 A I have. I do not believe it is the proper
13 priority date.

14 Q So let's get into that when we discuss
15 anticipation. Let's move forward, please. Slide 72. What
16 are we looking at here?

17 A This is a cover page from Ran Klein's master
18 thesis which was published -- completed in February 2005,
19 published in 2006, and again relating that the priority
20 date could be no earlier than 2009.

21 Q All right. Let's move forward. Now we are at
22 slide 80. Are you aware that in an obviousness analysis
23 one assesses the differences between the claims at issue
24 and the priority art?

25 A Yes, I am.

1 Q All right. I'd like you to summarize for the
2 Court what are the major differences between the asserted
3 claims and the Klein thesis.

4 A Well, one of the major differences is that the
5 dose calibrator, the eluant reservoir and the shielded well
6 are on board the cart in the claims. However, in the Klein
7 thesis, the dose calibrator and the eluant reservoir and
8 the shielded well are not on the cart.

9 Q Just to be clear, claims require a dose
10 calibrator?

11 A Yes.

12 Q Does Klein disclose a dose calibrator?

13 A It does.

14 Q Do claims require an eluant reservoir? Is that
15 correct?

16 A That's correct.

17 Q Does Klein disclose an eluant reservoir?

18 A He did.

19 Q And do the claims require a shielded well?

20 A They do.

21 Q And does Klein disclose a shielded well?

22 A He does.

23 Q But you say that Klein does not disclose them on
24 board a cart; is that correct?

25 A That's correct. Klein's system, all connected

1 together, had the materials -- a number of materials on the
2 cart, but the dose calibrator and the shielded well and the
3 eluant reservoir were all off the cart.

4 Q Let's move forward, please. The blue
5 highlighting, are those the components on the shelf?

6 A That's correct.

7 Q Please proceed. So what are you showing with
8 that little animation?

9 A So we are showing that simply taking those three
10 components and putting them on to the cart we are now would
11 infringe those claim elements.

12 Q And you said infringe?

13 A I'm sorry, would not meet those claim elements.

14 Q Not meet those claim elements. Okay, let's move
15 forward. So now we are on slide 81. Why don't you explain
16 these differences between the asserted claims and the Klein
17 thesis?

18 A Well, we have other claim elements that have
19 compartments with openings for the generator that at -- are
20 at a lower elevation than the waste bottle. Klein had
21 those same shielding compartments for a generator and a
22 waste bottle but he placed them on a common shelf not at
23 staggered locations.

24 Q Let's go through this one as well just to make
25 sure we understand it. The claims, do they require a

1 generator?

2 A They do.

3 Q And do they require shielding for a generator?

4 A Yes.

5 Q And does Klein disclose those elements?

6 A He does.

7 Q The claims, do they require a waste container?

8 A They do.

9 Q And do they require shielding for a waste
10 container?

11 A They do.

12 Q And does Klein disclose those elements?

13 A He does.

14 Q Okay. Now explain the staggered elevation
15 stuff, please.

16 A The staggered elevation in the claim elements
17 calls for the opening of the generator to be at a lower
18 elevation than the opening for the waste bottle.

19 Q But in Klein, these components are on common
20 shelf; is that correct?

21 A They are on common shelf.

22 Q Let's move forward, please. All right. So what
23 are you showing with that arrow in that animation here on
24 slide 81?

25 A Here I'm showing that simply by taking the

1 shielded generator and moving it to the lower elevation
2 would meet that claim term.

3 Q Let's move forward. So now we are at slide 82.
4 What are you describing here?

5 A These patents have some specific reminders and
6 warnings that are part of the claim elements. Klein indeed
7 has reminders and warnings, but for different purposes than
8 what are claimed.

9 Q Okay. Can you give the Court a for instance as
10 to what kind of reminders or warnings might be listed in
11 the claims?

12 A Shown in yellow is the warning that the eluated
13 volume --

14 Q Dr. Stone, I'd like to stop you because you're
15 pointing to the Klein thesis. I just want to be sure my
16 question was clear. Specific reminders and warnings from
17 the claims. Can you give the Judge --

18 A I'm sorry.

19 Q -- a for-instance as to what kinds of warnings
20 or reminders are we going to see in the claims?

21 A Yes. Certain reminders, for example, to put a
22 waste bottle, sorry, a sample bottle into a well. We'll
23 see claim elements that relate to an indication that there
24 is -- how much saline is in the reservoir.

25 Q Okay.

1 A Things of that nature.

2 Q Okay. And so then you were pointing to this
3 material shown on right-hand side for Klein. Please, why
4 don't you explain that one more time just to make sure the
5 record is clear.

6 A Thank you. Indeed, Klein has alerts and
7 warnings. He has a warning here that the generator volume
8 is nearing the maximum amount consider rebuilding the
9 generator. He also has a notice that there is
10 communication failure with the pump and asking them to
11 check wiring.

12 Q Okay. Let's move forward, please. Now we are
13 at slide 83. Will you please explain to the Court your
14 definition of the person of ordinary skill.

15 A Yes. A person of ordinary skill in the art
16 would have had a graduate degree with some emphasis in
17 equipment design automation or controls such as electrical
18 engineering, systems engineering, mechanical engineering or
19 a related field or an undergraduate degree in one of those
20 fields with two or three years work experience in
21 radioactive protection systems or in medical device product
22 or instrumentation design and development including working
23 with prototypes and finished products. Such a person would
24 have had a basic understanding through education or
25 experience of general design control principles and

1 processes and practices for partial or full automation of
2 existing processes or test procedures.

3 Q Why is -- in your view, why is this definition
4 appropriate for subject matter of an infusion system?

5 A We are talking about building a system,
6 automating it making it safer, that is an electrical
7 mechanical fluidic system with shielding. These are
8 engineering things that a person would do. They are not
9 the practice of medicine.

10 Q Okay. We'll see it probably, I guess, tomorrow.
11 Dr. Pelc's definition refers to somebody, for example, with
12 a graduate degree in medicine, with degrees in biology or
13 physiology, somebody with design experience with respect to
14 PET imaging and/or PET imaging systems. Are you familiar
15 with those characteristics of Dr. Pelc's definition of a
16 level of skill?

17 A Yes.

18 Q Okay. You did not adopt those here in this
19 definition?

20 A I did not.

21 Q And why is that?

22 A We are dealing with a system to inject a fluid
23 safely. We are not dealing with the practice of medicine.
24 And we are not actually dealing with the imaging process.

25 Q All right. Let's move forward, please. Now we

1 are at slide 89. Before we get into specific elements of
2 teachings would you please explain -- I think you talked
3 about GMP design processes. I'm not sure if I got that
4 right. Will you please explain, what kinds of things
5 happen when people take medical devices to market as a
6 finished product.

7 A We begin with a design input requirement that
8 says -- or a medical -- actually start off with a market
9 requirement. What's it supposed to be? Next we convert
10 those into design input requirements and we break it up
11 into the various systems, lay it out, consider all the
12 standards, all the requirements in order to get such a
13 product on to the market, particularly here in the United
14 States, and then develop it in accordance with that process
15 so that all of those are incorporated into a system
16 incorporating good engineering practices for safety, for
17 ergonomics, for emissions. There are many factors that go
18 from going through what we would refer to as a bench top
19 prototype to a finished product.

20 Q Do you think a person of skill would look at the
21 Klein cart and think it is market-ready?

22 A No.

23 Q Okay. Why don't you explain to the Court what
24 kinds of things people do ordinarily when getting -- you
25 said a prototype, getting a prototype ready for market?

1 A They look at the prototype, its functionality,
2 determine whether it was arranged in the best ergonomic and
3 the safest in the -- in the situation where it met the
4 required standards and usabilityes.

5 Q Let's move forward, please. We talked about
6 ergonomics. What kinds of ergonomic considerations do
7 people concern themselves when they are taking devices to
8 market?

9 A Well, one would be where do we put heavy items
10 and particularly heavy items that might need to be moved
11 and we would place those in such a place where it had the
12 least adverse -- least potential for adverse impacts on the
13 person using it.

14 Q You have an excerpt here from the right-hand
15 side of the slide from I think a reference called Chaffin.
16 Can you please explain, what does Chaffin describe?

17 A Chaffin describes occupational biomechanics. In
18 particular, he is dealing with how one would deal with a
19 heavy object, so he is talking about in this case reducing
20 the distance of lift for a heavy object in order to
21 minimize any adverse effects from doing that lifting.

22 Q And what kinds of adverse affects can arise
23 through lifting of heavy objects?

24 A One can develop muscle strain. One can have
25 problems with one's back. One could drop the object and

1 process. There are a number of things of trying to
2 minimize the distance of the heavy object.

3 Q Let's move forward, please. Slide 91. In
4 connection with the Klein design, what does -- what do the
5 teachings of Chaffin tell somebody of skill?

6 A Well, we have a generator that's a shielded
7 generator. It's a heavy object. From Klein it provides
8 teaching to keep those items where they might be lower to
9 reduce the distance of lift, for example, roll up a
10 generator on a cart, remove it from the cart and place it
11 in the lower portion of the generator.

12 Q Will you move forward. Okay. And in your view,
13 does -- do the teachings of a reference such as Chaffin
14 provide motivation to move the generator to a lower
15 location within an infusion system?

16 A Yes, it does.

17 Q Let's move forward, please. All right. We are
18 at slide 92. Why don't you explain some other
19 considerations that someone might encounter when taking a
20 device to market.

21 A Well, for example, we have the Klein thesis
22 which had objects that are -- system components that were
23 not on the same location and yet the two system components,
24 the various system components all had to be in the same
25 location for performing a daily test. It only makes sense

1 to place those system components on a single unit.

2 Q Okay. You have an excerpt from the Tate
3 reference here on the right-hand side. Will you walk us
4 through this material?

5 A Yes. This is a PET infusion system that
6 includes radiopharmaceutical, pardon me, a
7 radiopharmaceutical source waste bottle and dose calibrator
8 and shielding all of which are integrated into a single
9 cart.

10 Q So am I right that Klein discloses a
11 radiopharmaceutical source?

12 A He does.

13 Q Does Klein also disclose a waste bottle?

14 A He does.

15 Q Does Klein also disclose a dose calibrator with
16 shielding?

17 A Yes, he does.

18 Q Would you explain that the dose calibrator is
19 off cart, is that correct?

20 A No. I'm sorry. In Klein it is off cart, that's
21 correct.

22 Q In Klein, that's correct.

23 But here, does this reference show that those
24 three components can be integrated into a common cart?

25 A It does.

1 Q All right. Let's move forward. Again, we've
2 got an excerpt from the med RAD system which we will
3 discuss shortly. Please remind the court what is the
4 radiopharmaceutical that is disclosed by Tate in med RAD?

5 A Tate and med rat both us FDG.

6 Q Is Tate's disclosure limited to FDG?

7 A Tate's disclosure is not limited to FDG.

8 Q And does Tate say that his teachings apply
9 solely to FDG radiopharmaceuticals?

10 A No. He teaches that it could apply quite
11 broadly.

12 Q Let's move forward, please. We are on slide 94.
13 Actually, before we get here are you familiar with
14 Ms. Gelbach's testimony regarding an on-board dose
15 calibrator?

16 A Yes.

17 Q What did she say about the idea of placing a
18 dose calibrator on board a cart?

19 A She said it only made sense to do so. It kept
20 people from having to move a heavy cart back to the nuclear
21 medicine lab.

22 Q Let's move to -- if we can kick out of the
23 PowerPoint, please, and pull up JX-176C at page 151.
24 Starting at line 15 and continuing to the next page on line
25 12. All right.

1 She was asked, is that consistent with your
2 recollection, putting the dose calibrator on the cart was a
3 goal for the version 3, she's talking about the JDI
4 designs; correct?

5 A Yes.

6 Q If we can have the rest of the quote, please,
7 this will carry over to line 12.

8 JUDGE CHENEY: I'm confused.

9 MR. HAILS: Sure.

10 JUDGE CHENEY: You asked the witness if he heard
11 Ms. Gelbach's testimony. Were you talking about this
12 deposition testimony or were you talking about the
13 courtroom testimony?

14 MR. HAILS: The deposition testimony.

15 JUDGE CHENEY: Okay. Thanks.

16 MR. HAILS: And this is the deposition -- the
17 excerpt from the deposition.

18 JUDGE CHENEY: Let me just ask the witness. Was
19 that your understanding of what the question was about?

20 THE WITNESS: Yes.

21 JUDGE CHENEY: Okay.

22 BY MR. HAILS:

23 Q Okay. She was asked putting the dose calibrator
24 on board the cart was a goal for the version 3. She
25 answered, yes, because from the usability perspective, we

1 were all, not we -- but customers that were using in
2 research were already hooking it to a dose calibrator, they
3 had to roll the machine into the hot lab where the dose
4 calibrator sat made of lead, it's heavy -- you can't -- and
5 it was very difficult to do that and so it only made sense
6 that if we had to talk to the dose calibrator that it be
7 closer to everything. Are you familiar with that
8 testimony?

9 A Yes, I am.

10 Q Explain to the Court, what is the concept of
11 usability?

12 A Usability is the process of designing a
13 component or a part so that the user can use it safely,
14 efficiently, effectively -- other factors come in, but
15 those are the ones we are dealing with.

16 Q Do you think a person of skill would recognize
17 that infusion system such as Klein's as heavy?

18 A Yes.

19 Q Do you think a person of skill would recognize
20 that an infuse system such as Klein would be difficult to
21 roll it into a hot lab to connect it to a dose calibrator?

22 A Yes.

23 Q And you would agree with Ms. Gelbach's
24 characterization that it only made sense to place the dose
25 calibrator on a cart?

1 A Yes.

2 Q We can kick out of this and return to the
3 PowerPoint, please. All right. So now we are at slide 94.
4 Please explain, how do the teachings of, for example, Tate
5 apply to a design such as Klein's?

6 A Well, what Tate teaches and what he had done was
7 to take the dose calibrator and put it on board the cart
8 with its shielding.

9 Q And do you, if someone were to apply it to Klein
10 what would that entail?

11 A As we just showed we take this assembly and
12 place it here on the cart.

13 Q All right. Let's move forward, please. We are
14 at slide 95. Earlier you had testified about warnings and
15 reminders. Do you remember that testimony?

16 A Yes, I do.

17 Q Okay. Did you find any description in prior art
18 discussing or providing teachings to people about warnings
19 or reminders?

20 A Yes.

21 Q Please explain.

22 A It was an international standard so-called
23 IEC62366, which is a standard for usability of medical
24 devices in particular. And this device has instructions
25 with regard to the usability standards that should be

1 utilized in designing such a system.

2 Q Okay. So you have a couple of excerpts here.

3 The first one is on page 18 of this international standard.

4 And it says "The manufacturer shall design and implement

5 the user interface as described in the usability

6 specification utilizing, as appropriate, usability

7 engineering methods and techniques." Do you see the

8 discussion?

9 A Yes, I do.

10 Q And, again, what is usability engineering

11 methods and techniques? What does that clause refer to?

12 A Those are techniques that are utilized to make

13 the device easier to use, safer to use and more effective

14 in its use.

15 Q Okay. And then you have a second excerpt from

16 the standard taken from page 63 of this Exhibit RX-114

17 saying that the user has to be aware of the use of the

18 correct consumable, the remaining amount of them whether

19 accessories might be used with a medical device, how to

20 assemble them and how to check their correct functions.

21 Just explain what is the international standard teaching a

22 person of skill with this kind of description?

23 A To provide the user with indications of what, of

24 how to use consumables, how much remains of them and any

25 accessories, how to assemble them, how to correct their

1 correct functioning, making sure the user has everything he
2 needs to do the task. Making sure the user does it in a
3 safe and effective manner.

4 Q Please move forward. Now we are at slide 96 of
5 your presentation. And we've already talked about this
6 screen with the yellow box. Again, remind the Court, what
7 is Klein describing with this screen shot?

8 A He is reminding the user that it might be time
9 to replace one of the consumables, in this case, he is
10 talking about rebuilding the strontium rubidium generator.

11 Q Do you think a person of skill would recognize
12 any other components within the Klein system as qualifying
13 as a consumable or an accessory?

14 A Yes.

15 Q Please explain.

16 A So we have a saline bag which is a consumable.
17 We have a waste container which is either a consumable or
18 an accessory and we have a sample vial which is also a
19 consumable or an accessory.

20 Q Let's move forward. Okay. So that's what
21 you're showing here with the animation on slide 96; is that
22 correct?

23 A That's correct.

24 Q Let's move forward, please. Did you see
25 application of this teaching in any other prior art

1 reference?

2 A Yes.

3 Q Please explain.

4 A In Tate, we see an indication of the amount of
5 saline that's remaining in one of his sample screen
6 diagrams.

7 Q All right. I'm sorry. What is he -- what is he
8 tracking in this example?

9 A I believe he is tracking the saline there in
10 this example.

11 Q I just didn't hear your answer. All right.
12 We'll talk about Medrad in a minute. Let's move to slide
13 98, please. Okay. As part of your analysis, did you
14 undertake a review to identify any secondary consideration
15 as evidence in this investigation?

16 A Yes, I did.

17 Q All right. Did you see any objective evidence
18 to suggest that the differences between the asserted claims
19 and the prior art are not obvious?

20 A No, I did not.

21 Q Are you are aware of Bracco's allegations that
22 JDI copied the feature of the onboard dose calibrator from
23 Bracco?

24 A Yes, I am.

25 Q Were you here for Mr. Troger when he confirmed

1 Bracco had not developed a system with an on board dose
2 calibrator during the time of Ms. Gelbach's tenure?

3 A Yes, I was.

4 Q Were you here for Mr. Troger's testimony that
5 confirmed that Bracco had not developed a system with on
6 board --

7 JUDGE CHENEY: Slow down, Counselor, when you're
8 reading long paragraphs like that. It's easy to go fast.

9 BY MR. HAILS:

10 Q Were you here for Mr. Troger's testimony where
11 he confirmed that Bracco had not developed a system with an
12 on board dose calibrator during Worrell engineering's
13 tenure with Bracco?

14 A Yes, I was.

15 Q Have you seen any materials that suggest that
16 JDI copied any Bracco design materials when developing the
17 RUBY product?

18 A No, I have not.

19 Q Have you seen any materials that suggest JDI
20 copied any Bracco patent materials while developing the
21 RUBY product?

22 A No, I have not.

23 Q All right. Did you have an opinion whether JDI
24 copied this on board dose calibrator feature from Bracco?

25 A It is not -- it is my opinion that they did not

1 copy anything from Bracco.

2 Q Okay. Are you aware of Bracco's argument there
3 was a long felt need for an on board dose calibrator or
4 that others had tried but failed to place a dose calibrator
5 on board a cart?

6 A Yes.

7 Q Have you seen any evidence that this is true?

8 A No.

9 Q Have you seen any material that suggested that
10 anyone in the field had recognized a need for an onboard
11 dose calibrator, but was unable to satisfy that need?

12 A Not that's anyone was unable to supply that
13 need.

14 Q Okay. Were you here for Mr. Davis's opening
15 statement?

16 A Yes.

17 Q I'm going to -- and I will try to go slow.
18 Mr. Davis said in his opening that there is real life
19 evidence that shows JDI tried unsuccessfully for years to
20 make a Rubidium-based PET scanner using the technology that
21 was described in the primary reference that relies upon for
22 obviousness. But that it only succeeded after it hired
23 multiple Bracco employees and design firms, including the
24 inventors. Were you here for that argument?

25 A I heard that.

1 Q Okay. Do you agree with this characterization?

2 A I do not.

3 Q Were you present for Mr. Donnelly's testimony on
4 Friday when he testified that the University of Ottawa
5 imaged 667 patients in 2004 using the V1 system?

6 A I was.

7 Q What does that tell you about whether there was
8 a failure by anyone to make a rubidium-based PET scanner
9 using the technology described in the Klein thesis?

10 A That belies that statement.

11 Q Do you recall Mr. Donnelly's testimony when he
12 said that the V2 was used on patients starting in 2010?

13 A I do recall.

14 Q Okay. And that V2 was developed by JDI, is that
15 correct?

16 A That is correct.

17 Q What does that tell you about whether there was
18 a failure as Mr. Davis said to make a rubidium-based PET
19 scanner with technology described in the Klein thesis?

20 A That means that that statement is not true.

21 Q Okay. I'd also like to return to Ms. Gelbach's
22 testimony for a moment. We are going to go to JX-176C
23 starting at page 122. And this is starting at line 17.
24 Actually let's start at line 10, please. Go to the bottom
25 of the page. She was asked about what existed when she

1 arrived at JDI in 2010. First, she was asked did JDI
2 already have an infusion system developed and she answered
3 yes. Do you see that?

4 A Yes.

5 Q Okay. She was asked about the version number.
6 And what did she identify it as?

7 A She identified it as the version 2.

8 Q And she was asked was the V2's system's
9 development complete when she arrived in 2010 and what did
10 she say?

11 A She said no.

12 Q We can pick up that piece on line 20 on the
13 prior page and then go through here to let's say line 12
14 so, and can we get the question on the preceding page.
15 Okay. She was asked if JDI had a prototype of the V2
16 infusion system developed when she arrived. Do you see
17 that?

18 A Yes.

19 Q And what did she say that JDI had developed
20 prior to her arrival at the company?

21 A She says that they had a working system.

22 Q Right. And then she was asked but the
23 development and activities were not complete. Is that what
24 you said earlier and what did she say needed to be done?

25 A She said it wasn't pretty yet.

1 Q All right. And then there should be one more
2 excerpt. Can we go okay. And then if we can pick up from
3 actually line seven on page 123 down to line 17. The line
4 that you had referenced it wasn't pretty yet is on line 12
5 and then she expanded a little bit. Please explain what
6 Ms. Gelbach explained about the V2 system.

7 A She stated that the outside still needed a
8 little work in terms of making it commercially ready,
9 functionalitywise it was already there.

10 Q Okay. Does that tell you anything about JDI's
11 supposed failures to develop anything when it was working
12 on the V2?

13 A It means there was no failure.

14 Q Let's return to your PowerPoint, please. All
15 right. I think we can move forward. Okay. So let's walk
16 through the Klein thesis in a little bit more detail. You
17 have, we are on slide 101 and you have a drawing by, I
18 guess, subtitle labeled "Tubing Circuit." Please walk us
19 through this material.

20 A Tubing circuit includes saline IV.

21 Q And let's just touch an each component just to
22 make sure that we've got it all explained. So what's the
23 job of the saline IV?

24 A That's the source of the material that's going
25 to cause the elution of the rubidium chloride from the

1 generator.

2 Q The second bullet in this list is a peristaltic
3 pump. Please explain, what does that pump do?

4 A This supplies the movement and meters the amount
5 of flow that is pumped through either the generator or the
6 bypass line.

7 Q Let's go to the next component. What is the
8 generator valve?

9 A The generator valve diverts flow through the
10 bypass line or directs it through the generator to eluate
11 rubidium chloride.

12 Q We don't have the bypass line marked. Will you
13 show the bypass line to the Court, please.

14 A Bypass line is here.

15 Q All right. What's the next component in the
16 Klein thesis? The next component is the strontium-rubidium
17 generator?

18 Q And what's the job of the strontium-rubidium
19 generator?

20 A It's a column that exchanges rubidium 82 that's
21 held on the column for the sodium and sodium chloride
22 switch that rubidium chloride.

23 Q So saline comes in; is that correct?

24 A That's correct.

25 Q And rubidium chloride comes out?

1 A Rubidium chloride solution comes out.

2 Q Let's keep going. What's the next component?

3 A The next is the activity counter which monitors
4 the dose while it's being administered.

5 Q Okay. And what is it monitoring in this
6 drawing?

7 A That's the radioactivity from the Rubidium-82.

8 Q All right. Let's move forward, please. What's
9 the next component?

10 A The next is the patient valve which directs the
11 eluant either to the patient line or to the waste
12 container.

13 Q Okay. What's the next component?

14 A The next component is the waste container with
15 which receives waste that we don't want to eluate to a
16 patient.

17 Q All right. And then the next one, please. The
18 dose calibrator, what's it's job?

19 A The dose calibrator has two functions. It is
20 used to confirm the operation of the on board activity
21 counter and it's also used to measure Strontium
22 breakthrough.

23 Q And then the final component is what?

24 A The final component is the computer which
25 controls the functions of each of these components or takes

1 information from them.

2 Q Let's move forward, please. Slide 103. Let's
3 talk about the computer. How is the computer configured?

4 A The computer is configured to control the
5 system. To have all of its inputs via a touch screen and
6 to guide the user through all the command operations.

7 Q You have here a bullet touch screen computer.
8 Is it a touch screen computer?

9 A It is a touch screen computer.

10 Q And you have an excerpt from the reference in
11 text. Can you just summarize what is relevant about this
12 excerpt?

13 A What's relevant is that it informs the user. It
14 displays all the functions. It limits the user input so
15 that it's all valid. Make sure it operates it safely. All
16 the operations take place through that touch screen. It
17 can add others at relevant states and as you can see here
18 there are certain buttons that are black and available to
19 use. There are other functions that are grayed out so that
20 the user cannot perform those in this modality.

21 Q So is it possible to use the Klein system
22 without going through the touch screen computer?

23 A No. It is not.

24 Q And I'm not sure that we, go through it in depth
25 but just at a high level this screen shot shown in the

1 upper right, choose run type. What is this an example of
2 with this screen shot?

3 A This is an example of how the operator would
4 perform functions. It's set up so that he can, from this
5 point he can do a flush, a calibration or he can do any of
6 three types of activity.

7 Q And then you mentioned that there was some
8 others that were grayed out. Why would those be grayed out
9 in this particular screen?

10 A Because apparently this user has entered a user
11 identification that allows them to perform normal functions
12 but it does not allow them to perform some of the research
13 functions.

14 Q Let's move forward, please. So we are at slide
15 104 and you added a button. I'm sorry a bullet on the
16 left-hand side about tracking performance during operation.
17 Please explain how Klein described the subject matter.

18 A So this is a very strong influence of his
19 usability that he has already incorporated into his
20 prototype. It says the real-time graphics display includes
21 a system diagram and we see a system diagram here with
22 updated information about the state of the system. So we
23 can see what's happening in this case. It includes the
24 current activity rate reading, the flow rate, the valve
25 status, the expected accumulated activity at the patient

1 outlet. It also provides progress bars that are included
2 for each stage of the elution so as to facilitate
3 monitoring of the system and provides an emergency stop
4 button that's enabled throughout elutions to take immediate
5 effect to bring the system to the safe mode.

6 Q Do you see a progress bar in the screen shot
7 that he has provided here?

8 A I do. In this case it's a progress bar for the
9 function taking place.

10 Q Do you see an emergency stop button in this
11 screen shot that's been provided?

12 A I believe if I back up and clear that we can see
13 the stop button that's displayed for the user's input and
14 put the system into a safe mode.

15 Q On the prior slide you had mentioned that there
16 were five run types and then there were three others that
17 were grayed out is that correct?

18 A That's correct.

19 Q Does Klein provide screen knots for each and
20 every one of his run types in his disclosure?

21 A No, he does not. That was not the purpose of
22 his thesis but he says those functions are supplied on
23 every elution screen.

24 Q Let's move forward, please. We are at slide
25 106. There is a new bullet providing statistics at the end

1 of infusions. Please explain, how does Klein disclose this
2 subject matter?

3 A Well, as his thesis states at the end of the
4 elution reports must be generated based on the type of
5 elution and its mode of completion. On successful
6 completion, a gray screen must list statistics relevant to
7 the elution. In addition, a separate window must list a
8 comprehensive display of all the statistics in addition to
9 activity curves relating to the activity rate and the
10 integrated activity at the patient outlet.

11 Q Okay. And so this screenshot is entitled "Test
12 Activity Elution Results." Do you see that?

13 A Yes.

14 Q And does he provide samples of the kinds of
15 statistics and other information that he has described in
16 this excerpt?

17 A He does.

18 Q Why don't you just walk us through this briefly.

19 A So we have the elution time. We have the
20 eluated volume. We have a volume deviation that occurred.
21 We have an eluated activity. We have the profile of the
22 generator. We have the activity deviation. We have the
23 requested activity. And down in the right-hand side we
24 actually see graphs of what occurred during that elution.

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

1 right. We are at slide 108. You have a bullet about
2 providing alerts and warnings. And I think we've discussed
3 this, but why don't you just kind of walk us through this
4 next excerpt that you provided and explain again, how does
5 Klein disclose this subject matter?

6 A As he puts it at the end of elution reports must
7 be generated based on the type of elution and its mode of
8 completion. If an error is detected a red screen including
9 details of the error and recommendations to resolve the
10 issue must be displayed. If the emergency stop button is
11 pressed a yellow screen must contain an appropriate
12 message.

13 Q Is this the only warning this generator elution
14 warning that Klein describes in his thesis?

15 A No. He also has a warning for when the waste
16 bottle is nearly full.

17 Q So Klein provides screenshots for all the other
18 warnings described in his thesis?

19 A He does not.

20 Q I should have asked on the previous slide that
21 was the one dealing with test results the results screen.
22 Do you remember that?

23 A Yes.

24 Q Did Klein provide screenshots for each and every
25 elution type that he describes in his thesis?

1 A No, he did not. He simply describes what each
2 of those would contain.

3 Q Let's move forward, please. Slide 110. Here,
4 you have a subtitle referring to a daily protocol. Will
5 you explain, what does Klein describe as the daily
6 protocol?

7 A The daily protocol is a procedure which must be
8 carried out prior to doing any patient elutions.

9 Q Okay. Why don't you walk us through this flow
10 chart and let's start with the little ascending arrow at
11 midnight.

12 A At midnight, the system permissions are reset so
13 that no patient elutions are enabled and before any of that
14 can take place this daily protocol has to be performed.

15 Q So the three pieces, do you see that, the daily
16 flush, the calibration and the patient elution runs?

17 A Yes.

18 Q And so let's walk through each piece. Why don't
19 you start us off with the daily flush that begins after
20 midnight.

21 A The daily flush is the process of flushing
22 the -- any accumulated waste products that we don't want to
23 go to a patient Strontium breakthrough that might eluate
24 from the generator. I'm pointing at the wrong thing. That
25 might be in the generator and in the solution. Clearing

1 out the lines and pumping all of that into, first, the dose
2 calibrator. And also flushing the remainder of the lines
3 for any accumulated air.

4 Q Do you have an animation to show how that might
5 occur? The system just basically pushes saline
6 everywhere, am I right?

7 A It pushes through all of the lines to make sure
8 it's clear.

9 Q Let's move forward, please. Let's go to slide
10 1121. Here you have some description on the calibration
11 phase. Please explain how this phase works in the Klein
12 thesis.

13 A After the flush occurs after a 10-minute wait,
14 which the computer determines, a calibration elution takes
15 place. In this case as the animation shows, saline is
16 pulped through the generator through the on board activity
17 counter into the reservoir that is in the dose calibrator
18 taking the data that would be necessary for that
19 calibration function to take place.

20 Q All right. So the system eluates rubidium into
21 the dose calibrator; is that correct?

22 A That's correct.

23 Q All right. And then you have two bullets listed
24 here under the, I guess, the major heading "Calibration."
25 One is recalibrate the calibration constant of the activity

1 detector. Remind the Court where, is the activity
2 detector?

3 A The activity detector is here.

4 Q Okay. And then how does the system
5 recalibration the calibration constant of that unit?

6 A So as Klein describes in his thesis, the
7 activity measured while the eluant is flowing through the
8 activity counter is integrated while that takes place and
9 then as soon as that eluant is, has filled the dose
10 calibrator to the proper level a reading is also taken
11 place and the calculated or reported activity here, the
12 total activity is compared with what's measured by the dose
13 calibrator and if necessary the calibration constant to
14 make sure that it is correct as adjusted.

15 Q Okay. So there is a reading from the purple
16 activity detector; is that correct?

17 A That is correct.

18 Q Who does that reading in the component here?

19 A The computer.

20 Q And is there a reading from the dose calibrator
21 as part of this effort?

22 A Yes.

23 Q And, again, who does that reading?

24 A That's done by the computer.

25 Q And then who computes the calibration constant

1 of the activity detector?

2 A The computer.

3 Q All right. All right. So the next phase is
4 computing strontium breakthrough levels; is that correct?

5 A That's correct.

6 Q All right. Let's move forward and talk about
7 that. All right. Tell us how breakthrough testing occurs
8 in the Klein thesis.

9 A Well, beginning with where we were the last you
10 eluate the sample to the dose calibrator and Klein uses
11 that same dose that he uses for the calibration sample. He
12 samples the activity in the dose calibrator once that
13 sample that has been placed in the dose calibrator. He
14 waits. I say he. The computer then waits 30 minutes, and,
15 once again, takes a reading from the dose, from the sample
16 that has remained in the dose calibrator and then it
17 computes the breakthrough levels for Strontonium-82 and
18 Strontium-85 using the formulas shown below.

19 Q So let me make sure I understand. We have a
20 sample in the dose calibrator. We have dualing clickers.
21 We have a sample in the dose calibrator; is that correct?

22 A That's correct.

23 Q And who does the reading of activity from the
24 dose calibrator?

25 A It's done by the computer.

1 Q And then there is a wait; is that correct?

2 A That's correct.

3 Q And then a second sample. Is that correct?

4 A That's correct.

5 Q Again, who does the -- who reads the activity
6 from the dose calibrator?

7 A The computer.

8 Q And which component computes the breakthrough
9 levels for strontium-82 and strontium-85?

10 A The computer.

11 Q All right. And what's the significance of this
12 math here on the left-hand side of the slide?

13 A Those are the formulas for computing the ratio
14 of strontonium-82 at the -- that's still in the eluant and
15 the strontium 85 still in the eluant based on those
16 measurements and the time.

17 Q Let's move forward. What does Klein say happens
18 if the system fails a strontium breakthrough test?

19 A The system fails a strontium breakthrough test,
20 then patient elutions are not enabled by the system.

21 Q Can you walk us through how Klein describes this
22 aspect.

23 A Certainly. In his thesis, he states that the
24 system must ensure compliance with the daily protocol
25 described in the previous chapter. A flush followed by a

1 calibration run and a successful breakthrough measurement
2 must be completed in order to enable patient elutions for
3 the remainder of the day. The system should delay at least
4 10 minutes between runs.

5 Further, he says the amount of strontium
6 breakthrough activity is strictly limited to the Health
7 Canada guidelines. And this issue is addressed by the
8 daily breakthrough tests as part of the daily protocol
9 that's ensured by the system. And then also he states the
10 Rubidium-82 infusion system software must ensure that the
11 protocol is followed. That is, each run is enabled only
12 after the prerequisites have been completed successfully.
13 So system software that is making sure that this is
14 accomplished.

15 Q Okay. And then this sentence in the middle of
16 this excerpt on page 39 so the first major excerpt that you
17 have. You said a flush followed by a calibration run and
18 successful breakthrough measurement must be completed in
19 order to enable patient elutions for the remainder of the
20 day. If you're a person of skill and you read that
21 passage, and you read the other passages that you have,
22 what is your conclusion about what happens if there is an
23 unsuccessful breakthrough measurement that occurs during a
24 calibration run?

25 A Patient elutions are not enabled. They can't

1 take place.

2 Q Let's move forward. Slide 114 and we are back
3 to the flow chart of the daily protocol. All right. And
4 we've just talked about the calibration run. Is that
5 correct?

6 A That's correct.

7 Q And is that where the strontium breakthrough
8 test occurs?

9 A That is correct.

10 Q All right. And then the next stage in this
11 drawing is the patient elution runs; is that correct?

12 A Yes.

13 Q And are those the ones that Klein is referencing
14 when he is talking about enabling the patient runs for the
15 remainder of the day?

16 A That is correct.

17 Q Please explain, how do the patient elution runs
18 occur?

19 A The patient elution runs as they occur, the
20 three types that occur are constant flow and constant time
21 elutions and he also has a constant activity elution.

22 Q All right. Please move forward. Now, we are on
23 slide 115 of your presentation. Why don't you explain how
24 this constant flow rate and constant time elutions occur in
25 the Klein thesis?

1 A The profiles shown are, could be a profile for
2 either constant flow or constant time. What happens is
3 saline is pumped through the generator. The rubidium
4 chloride that is existing in the generator begins to be
5 pushed out. That concentration of radioactivity increases
6 to a maximum level and then begins to drop off as what was
7 in the generator, a generator begins to be washed out and
8 then it approaches a level that's proportional to the rate
9 that's reflective of the rate at which strontonium-82 is
10 decaying into Rubidium-82.

11 Q Okay. So these curves marked in blue, do they
12 represent radioactivity?

13 A Yes.

14 Q And we have heard discussion earlier today about
15 something called a bolus profile. Are you familiar with
16 that discussion?

17 A Yes.

18 Q All right. Is this -- is this curve -- are
19 these curves indicative of bolus profiles?

20 A Yes, they are.

21 Q Okay. So again there is a peak. Why does the
22 peak exist in this drawing?

23 A Because there is already a stable if you would
24 an equilibrium level of Rubidium-82 in the generator when
25 we start to pump through. The radiation level rapidly

1 increased to represent that concentration but that
2 concentration now starts to die off as it's pumped out and
3 we have only what's being produced combined with what's
4 mixed previously and it decays off to a steady state value.

5 Q And so the steady state value, is that the -- is
6 that represented by this tailing off level that's shown
7 here on the right-hand side of these two graphs?

8 A That is correct. That's approaching at end
9 topically the steady state production rate.

10 Q And there are two different sets of curve, I
11 guess, with two different peaks. Why are these peaks
12 different from each other?

13 A One is taken on March 23rd, 2001, the higher
14 one. The lower one April 2nd. That represents the decay
15 in the amount of Strontium-82 that's in the generator
16 available to produce Rubidium-82.

17 Q What's represented on the y-axis of this graph?

18 A On the y-axis is the activity in megabecquerels
19 per milliliter.

20 Q So the activity that's represented on the March,
21 I guess, 23rd graph that peak is roughly you call it 85
22 megabecquerels. Does that sound right?

23 A That's correct.

24 Q And in the curve that corresponds to the April
25 2nd date that's at a lower value, is that right?

1 A That's correct.

2 Q And what is that value?

3 A That value is approximately 60.

4 Q All right. So those are constant flow and
5 constant time. Let's move forward, please. Why don't you
6 explain how constant activity elutions are described by the
7 Klein thesis.

8 A Klein's whole motive in doing this or, sorry,
9 primary motive was to come up with a better control
10 algorithm to produce constant activity elution. In green
11 is constant activity elution at an activity level of
12 roughly three megabecquerels per second.

13 Q Okay. And does the Klein system hit that
14 idealized curve?

15 A No.

16 Q What does Klein's system do?

17 A Well, he is showing one of the algorithms and
18 its results. What he does is alternate between the peak
19 value, a peak value of roughly five year, back down to
20 about one and a half, and then oscillates about that mean
21 value. That's what would be measured at the activity
22 detector.

23 Q Okay. In the testimony that we heard this
24 morning there was a discussion relating constant activity
25 elutions to avoidance of sensor saturation. Are you

1 familiar with that discussion?

2 A Yes, I am.

3 Q Will you explain, how does this constant
4 activity elution avoid that phenomenon?

5 A Certainly. If you notice in the previous slide
6 we went up to levels of roughly 60 and 90 megabecquerels
7 which would produce a very rapid count rate at the detector
8 and result in saturation, the detector unable to keep up
9 with the rate at which photons were arriving. Here, we
10 never exceeded five megabecquerels a much lower level and
11 that's a level that the sensor would be able to keep up
12 with and thus be able to efficiently use more of the
13 photons that are emitted.

14 Q And Mr. Walker's opening, he represented that
15 constant activity elutions permit radiation dosing to
16 remain at consistent level as a generator ages. Are you
17 familiar with that discussion?

18 A Yes, I am.

19 Q Will you explain, how does constant activity
20 elutions achieve that goal?

21 A Certainly. By starting out to receive
22 radioactive material from the generator and then as soon as
23 it reaches a given threshold stopping receiving the fluid
24 flow from the generator instead from the bypass line and we
25 start until it drops to a given level and once again from

1 the generator oscillating between the two sources and
2 resulting in this lower level in order not to achieve, and
3 we can do that whether we start off with a very high
4 concentration of rubidium in the generator or whether they
5 start off with a significantly lower concentration.

6 Q Let's move forward, please. We are at slide
7 117. Why don't you explain, how does the system achieve
8 that sawtooth wave form?

9 A We are going to have to back up in a moment and
10 show the animation. Let's talk our way through it. We,
11 first of all, as we stated allow the fluid to flow through
12 the generator to the activity counter. When it reaches a
13 given level it shifts and stops flow from the generator and
14 instead allows saline until it drops below a given level.
15 Both of those continuously being administered on to the
16 patient so that the average value that's administered to
17 the patient is closer to that same ideal square wave.

18 Q So if we can just work from memory. But we saw
19 earlier in the prior graph that when the sawtooth wave is
20 rising there is a switch and then it causes the system
21 causes the radiation to decline. Do you remember that?

22 A That's correct.

23 Q All right. And so who, how does that occur?

24 A The computer is sensing the radiation level
25 detected by the activity counter and repositions the

1 generator valve to direct flow in the bypass line instead
2 of through the generator.

3 Q So is that the purpose of the activity detector?

4 A That's correct.

5 Q And it goes through the computer and the
6 computer is making that decision; is that correct?

7 A The computer does all the control.

8 Q And similarly, when that sawtooth wave was
9 dropping, we saw that it would drop to a certain level and
10 then it would switch and it would start to rise again. Do
11 you remember that?

12 A I do.

13 Q Okay. And, again, how does that phenomenon
14 occur?

15 A That takes place once again with the computer
16 accepting the level and repositioning the generator valve
17 based on the reading from the activity counter.

18 Q We are going to get into claims shortly, but
19 before we do I would like to flip to RX-106, please, page
20 49. Let's start with Section 3.3. Highlight to the end of
21 the page, please. Mr. Davis's opening, he put up this
22 passage, and he argued that it would dissuade a worker of
23 ordinary skill from altering the Klein system in the way
24 that you have proposed. Are you familiar with that
25 argument in the opening?

1 A Yes.

2 Q I'd like to walk through this material to make
3 sure we understand it. Okay. And he highlighted, I think,
4 the second sentence of this passage saying that the layout
5 of the saline lines sensors and actuators is crucial to
6 implementing a physical system that is easy to control. Do
7 you see that?

8 A I do.

9 Q All right. So what kind of control is Klein
10 trying to achieve?

11 A Klein is trying to achieve constant level
12 elutions.

13 Q Okay. And then the next passage says during a
14 flow of -- during a flow of a radioactive volume through
15 the lines, both a transport delay and a radioactive decay
16 take place. Therefore, the activity at output is delayed
17 and reduced in relation to the activity at the input. So
18 please explain to the Court, what is transport delay and
19 what is radioactive decay?

20 A Transport is the delay that is the time that it
21 takes from fluid to move from one location to another.

22 Q And a rubidium system is there decay of the
23 radioactivity as it moves from point A to point B in the
24 system?

25 A Yes. The rubidium has a 76-second half life

1 that has been spoken of, that is, in 76 seconds it decays
2 to half the value of what it was previously. So the amount
3 of time that it takes to transport, one can readily compute
4 how much it has decreased from where it was measured to
5 that second spot.

6 Q And you said one can compute it. Does Klein
7 give you information to figure out how to compute these
8 values?

9 A He does. These are the physical equations that
10 can be used to compute that value.

11 Q Let's turn to the next page, please. We are at
12 the top of page 50, the first major paragraph. "However."
13 Let me just highlight the paragraph or show the paragraph,
14 please. All right. Klein goes on and says "However, if
15 the flow rate is not constant computation of the delay time
16 becomes more difficult." Do you agree with this
17 characterization that computation of delay time would be
18 difficult in a system without constant flow?

19 A Yes. Because each material -- each piece of
20 material would have a different amount of time passing
21 through there and that would make that computation more
22 difficult.

23 Q Let's skip ahead to the next paragraph, please.
24 The one under the equation. Klein further says that
25 variation of flow rate would make prediction of activity at

1 the end of a line difficult and potentially inaccurate. Do
2 you see that passage?

3 A I do.

4 Q Do you agree with that discussion?

5 A Yes.

6 Q All right. And let's move forward again. I
7 think we have to talk about the pump speed variation so
8 let's go to the next page and talk about bypass ratio
9 control. Can you show the text and also the drawing,
10 please. All right. This is the section called bypass
11 ratio control. And Klein says the above problems can be
12 resolved by setting a constant flow rate at the start of
13 the elution process and controlling the ratio of the saline
14 that flows through the generator, point G in figure 3-3.
15 The remaining portion of the saline would flow through the
16 generator bypass line. Can you explain, what is Klein
17 saying here?

18 A Well, he is saying that we set a constant flow
19 rate here so that the sum of these two would always be
20 constant. So we have point G was coming out of the
21 generator and we have this point, which is what would come
22 out of the bypass line at alternate times.

23 Q Okay. And then the next part of this passage
24 says the two lines would then be merged, point M, upstream
25 from the activity counter, point C, thus the flow in the

1 combined line remains constant. This allows computing of
2 the transport delay from the counter to the patient outlet,
3 point O.

4 Okay. So let's just walk through it. Where
5 does the merger occur in this drawing?

6 A The merger occurs here, point M.

7 Q And is that upstream of the activity counter?

8 A Yes, it is.

9 Q All right. Just point out point C, please.

10 A Here is the activity counter.

11 Q And the patient outlet is where?

12 A The patient outlet is here.

13 Q And so is it correct that the flow in the
14 combined line after the point M remains constant?

15 A In Klein's thesis and in his design, yes.

16 Q Okay. Let's move to the next part of this
17 paragraph. It says the flow rate only varies in the line
18 volume connecting the generator to the merger VGM based
19 upon flow ratio R in order to reduce the variability in
20 transport delay and decay this line volume must be kept to
21 a minimum. Okay, so where is the generator?

22 A Generator is here.

23 Q And where is the merger?

24 A Merger is here.

25 Q And what is the line volume that Klein is

1 recommended to keep to a minimum?

2 A Only this volume between this point G and this
3 point M.

4 Q Okay. Do you see any discussion in this passage
5 referring to the relative elevations between the waste
6 bottle and the generator?

7 A No. Those are completely irrelevant.

8 Q And how about any discussion of the relative
9 elevations of the shielding structures for the waste bottle
10 and the waste generator?

11 A They are completely irrelevant.

12 Q All right have you reviewed respondents' Ruby
13 product in the course of your analysis?

14 A Yes.

15 Q And have you seen any evidence indicating
16 adoption of these teachings from Klein in the real world?

17 A Yes, I have.

18 Q Can you pull up JX-0007. All right. Do you
19 recognize this document?

20 A Yes.

21 Q All right. What is this document?

22 A This is the user manual for the Ruby 3 system.

23 Q Let's switch to page 9, please, and specifically
24 figure 2. Will you explain to the Court, where is the
25 generator in this drawing?

1 A Generator is here.

2 Q Where is the merger point in this drawing?

3 A Right here.

4 Q And where is the activity counter in this
5 drawing?

6 A Right here.

7 Q When Klein says he wants to keep the line volume
8 between the generator and the merger point to a minimum,
9 does the design of the Ruby system reflect this concept at
10 all?

11 A Yes, it does.

12 Q All right. Let's move forward, please. Let's
13 go back to the PowerPoint, please, and if we can advance.
14 Let's talk about the claim. Let's talk about your
15 obviousness opinion first. We are at slide 119 of the
16 presentation and if you'll move forward and start with the
17 '869 patent on slide 121 and then if you will move forward
18 one more time, let's talk about claim 1 of the '869 patent,
19 please. The claim 1 begins with an infusion system on
20 board a cart that comprises a cabinet structure that
21 comprises a platform with an exterior shell. Did you see
22 this subject matter taught by the prior art?

23 A I do. We see the cabinet structure shown here.

24 Q All right. Do you see a platform?

25 A They have a platform here at the base.

1 Q And do you see an exterior shell?

2 A We have an exterior shell.

3 Q Does that exterior shell extend upwardly above
4 the platform?

5 A Yes, it does.

6 Q Please move forward. The claim says that the
7 exterior shell must have a front side and a rear side and
8 two side walls connecting the front side to the rear side
9 and the top surface. Did you see that subject matter
10 taught by the prior art?

11 A Yes.

12 Q Please explain.

13 A We have a front side. We have two side walls.
14 We have a rear side, though it's not shown in the picture.
15 And we have a top surface.

16 Q Continuing, the claim says wherein the platform
17 and the exterior shell collectively defined an interior
18 space of the cabinet structure. Did you see that subject
19 matter taught by the prior art?

20 A Yes.

21 Q Please explain.

22 A We have an interior shelf that's defined by the
23 platform and the exterior shell -- I'm sorry, the interior
24 space that's defined by the platform and the exterior shell
25 of -- defining the interior space of the cabinet shell.

1 Q Let's move forward, please. Is that it?

2 A That's it.

3 Q All right. Let's move -- continue. And what's
4 the significance of citation to Tate or to CardioGen?

5 A Well, those are two other examples of carts, a
6 cabinet structure that meet all these claim elements.

7 Q Let's move forward, please. Let's go to slide
8 123. The claim says wherein the interior space of the
9 cabinet structure is configured to receive a strontium
10 rubidium generator. Did you see that subject matter taught
11 by the prior art?

12 A We have a strontium rubidium generator.

13 Q Is it in the interior case of the cabinet
14 structure?

15 A It is, whether it's in this lower position or
16 whether it's in the original position that Klein showed.

17 Q The claim says that the strontium rubidium
18 radioisotope generator has an inlet tubing port configured
19 to receive saline. Do you see that subject matter taught?

20 A Yes, I do.

21 Q Please show me, where is the saline?

22 A Here is the saline and it discharges it through
23 the generator which has an inlet tubing port.

24 Q The claim also refers to an outlet tubing port
25 configured to discharge a rubidium radioactive eluant. Do

1 you see that taught by the prior art?

2 A Indeed, strontium rubidium generator as
3 disclosed by Klein has an outlet port configured to
4 discharge the radioactive eluant.

5 Q Let's move forward, please. Claim 1 says you
6 have to have an opening through the exterior shell
7 configured to provide access to the strontium rubidium
8 radioisotope generator. Did you see that subject matter
9 taught by the prior art?

10 A Yes.

11 Q Please explain.

12 A We have an opening in the front, the access to
13 the strontium rubidium isotope generator can be -- the
14 cabinet structure can be accessed through the front.

15 Q The claim repeats the requirement that the
16 generator must be within the interior space of the cabinet
17 structure. Just point out where is the exterior space?

18 A The interior space is here.

19 Q Let's move forward. So that was slide 124 and
20 now we are at slide 125. The claim refers to an opening
21 through the top surface of the exterior shell configured to
22 provide access for inserting a waste bottle into or
23 removing the waste bottle from the interior space of the
24 cabinet structure. Did you see that subject matter taught
25 by the prior art?

1 A Yes, I did.

2 Q Please explain.

3 A It was shown in the green outline that we have
4 here and then the photo where it's labeled there is a
5 generator access which would allow access to the waste
6 bottle for removing the waste bottle from the interior face
7 of the cabinet structure.

8 Q Let's move forward. All right.

9 A Sorry.

10 Q Let's go back. Let's remind the Court, where is
11 the waste bottle inside the cabinet structure?

12 A Klein shows the waste bottle here.

13 Q Let's move forward. That was slide 125. Now we
14 are at 126. The claim requires a computer with a touch
15 screen display. Did Klein teach that subject matter?

16 A Yes, he did.

17 Q Show me, please.

18 A There is the touch screen display and here is
19 the LCD touch screen on the cart.

20 Q The touch screen display must be configured to
21 receive an input from a user for controlling operation of
22 the infusion system. How does the prior art teach that
23 subject?

24 A As we discussed, the Klein thesis says that all
25 inputs are via the touch screen display. Here is a sample

1 touch screen display.

2 Q It says wherein the touch screen display is
3 mounted on a vertical post having a top end extending above
4 the cabinet's structure. Do you see that subject matter?

5 A Yes, I do. And here is the post mounted that
6 extends above the top end of the cabinet structure.

7 Q Let's move forward, please. Page 127. A first
8 shielding compartment in the interior space of the cabinet
9 structure having a first opening facing vertically upwardly
10 through which the strontium rubidium generator can be
11 inserted into and removed from the first shielding
12 compartment. So does Klein teach a first shielding
13 compartment for the generator?

14 A Yes.

15 Q All right. Show me.

16 A He has the generator was placed in the cart and
17 surrounded by lead rings to provide maximum radiation
18 shielding. And we talked about where the generator was
19 placed here in the top shelf or down below.

20 Q Okay. Do lead rings define a first opening
21 facing vertically upwardly?

22 A Yes, they do.

23 Q Would that opening be one through which
24 strontium rubidium radioisotope generator can be inserted
25 into or removed from the lead ring?

1 A Yes, it is.

2 Q Move forward, please. You have a citation to
3 Tate. Why did you cite to Tate?

4 A Because Tate has his radioactive source
5 configured such that it can be -- has an opening that's
6 facing vertically upward and the radioactive source can be
7 inserted into and removed from that shielding compartment
8 and that's on the interior of the cart.

9 Q If you're going to go to market with a
10 newfangled rubidium infusion system let's say in 2006, are
11 you going to sell it with a shielding structure made out of
12 lead rings?

13 A No.

14 Q Why would you say that?

15 A They could easily be displaced. It's not in a
16 tight configuration. They could bounce around. There are
17 lots of reasons. Just standard thing to make this an
18 integral part of a system that's put together.

19 Q What kind of alternate configurations might you
20 consider?

21 A I could use a molded assembly. I could use a
22 machined assembly, assembling those together. I'd make
23 something that's sturdy and not easily shaken apart.

24 Q And does Tate have relevance to that discussion?

25 A I'm sorry?

1 Q Does Tate have relevance to such a
2 configuration?

3 A Yes, it does.

4 Q Please explain.

5 A Tate has a product or a drawing of a product
6 very similar of a product that actually went to market. He
7 has that where the -- there is a well that is basically
8 molded into the top surface itself is shielding material
9 and it's a shielded well that he puts that material in. It
10 has vertical access.

11 Q Let's move forward, please. Claim requires a
12 first door accessible by the opening through the exterior
13 shell. That door is being configured to provide access to
14 the first shielding compartment and to close over the first
15 opening. All right. So let's talk about the shielding
16 compartment. Well, why don't you just walk us through
17 actually what are you showing here in slide 128?

18 A Well, what we are showing here is a generator on
19 Klein that had -- surrounded by lead rings. His first
20 shielding compartment, Klein doesn't necessarily talk about
21 a door for it. However, he did have an access door as he
22 woo talked about here that could give access to the
23 generator, but Tate indeed has a door over his radioisotope
24 source. Doors are standard things that are used in
25 virtually every facility that I've seen with regard to

1 shielding compartments.

2 Q Okay. So that's actually a good question. This
3 claim refers to a first shielding compartment with a
4 vertically facing upward opening for the shielding
5 compartment. Are you familiar with that?

6 A Yes.

7 Q Do you have a view as to whether that is a
8 unique configuration in shielding design or is it a common
9 configuration in shielding design?

10 A That's a very common configuration it allows a
11 user to approach a radioisotope source and be able to get
12 easy access to it without being exposed to radiation that's
13 coming directly out. He would have to lean over the source
14 in order to be exposed to radiation if the access is
15 vertical rather than coming horizontally.

16 Q All right. So if you're approaching such a
17 structure and it were open and radiation were issuing from
18 it, where would the radiation go as you -- from such a
19 configuration?

20 A At the person approaching it.

21 Q I'm sorry. Vertically facing upwardly --

22 JUDGE CHENEY: Maybe this is a sign that we need
23 to stop because --

24 MR. HAILS: Can't argue with that, your Honor.

25 JUDGE CHENEY: Because you cannot be helped.

1 Okay. So please mark that you're going to re-ask this
2 question tomorrow when everyone is fresh.

3 You may step down for now, Dr. Stone. I'll
4 remind you not to discuss your testimony with anyone over
5 the evening.

6 How are we doing on time, Counsel?

7 MR. DAVIS: Your Honor, Complainants are a
8 little bit over their estimate, but we are on track. We'll
9 be able to come in within the time limits.

10 JUDGE CHENEY: What about Respondents?

11 MR. WALKER: My timers are telling me we are
12 about the same. We are close. We are a little over.

13 JUDGE CHENEY: Staff.

14 MR. KOO: I understand the Staff is coming in
15 under. So -- I think we should be okay.

16 JUDGE CHENEY: Okay. So I'm hearing that we are
17 going to wrap this hearing up on Wednesday, presuming that
18 we get a full day in tomorrow. Does that sound like what
19 everyone understands?

20 MR. DAVIS: Yes, Your Honor.

21 JUDGE CHENEY: Any housekeeping matters that we
22 need to discuss before we adjourn for the evening?

23 MR. DAVIS: Not right now, Your Honor. Not for
24 Complainants.

25 MR. WALKER: None for Respondents.

1 MR. KOO: Nothing from the Staff.

2 JUDGE CHENEY: Get some rest. Practice speaking
3 slowly in the mirror. And we'll see you tomorrow.

4 We are off the record.

5 (Whereupon, at 4:40 p.m., the hearing was
6 adjourned, to be reconvened at 9:00 a.m., on Tuesday, April
7 16, 2019).

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