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INDEPENDENT COMMISSION AGAINST CORRUPTION

THE HONOURABLE DAVID IPP AO QC

PUBLIC HEARING

OPERATION CHARITY

Reference: Operation E10/0035

TRANSCRIPT OF PROCEEDINGS

AT SYDNEY

ON THURSDAY 17 FEBRUARY 2011

AT 2.05PM

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This transcript has been prepared in accordance with conventions used in the Supreme Court.

THE COMMISSIONER: Mr Alexis.

<EMMA LOUISE KNOWLAND, on former oath

[2.06pm]

MR ALEXIS: Thank you, Commissioner.

10 Ms Knowland, before I sit down could I just show you again part of the document that I showed you before lunch with the patient names having been redacted and would you confirm for me that save for the removal of patient names, we have here the same document that was shown earlier but obviously not the complete list for the month of April 2008. Is that right?  
---Yes.

Yes, thank you. I tender that document, Commissioner, to make sense of Ms Knowland's evidence.

20 THE COMMISSIONER: Well, what do we call it?

MR ALEXIS: (NO AUDIBLE REPLY)

THE COMMISSIONER: It's a patient list for what?

MS FURNESS: Well, might I make a suggestion?

MR ALEXIS: Yes, please.

30 MS FURNESS: The witness's evidence was that it was probably from Dr Champion's clinic because of the- - -

THE COMMISSIONER: Yes.

MS FURNESS: - - -the software at the bottom.

THE COMMISSIONER: All right.

40 MS FURNESS: It could be described at Dr Champion's waiting list for the period, a period in April 2008.

THE COMMISSIONER: Well, it's a patient list for Dr Champion for a period, for a day in April 2008.

MS FURNESS: I think it's more than one day, Commissioner.

MR ALEXIS: Yes, it goes over- - -

THE COMMISSIONER: Okay. For a period- - -

MS FURNESS: In April.

THE COMMISSIONER: - - -in April, 2008. It's a patient list for Dr  
Campion for a period in April 2008 and it's Exhibit 24.

10 **#EXHIBIT 24 - PATIENT LIST FOR DR CAMPION FOR A  
20 PERIOD IN APRIL 2008**

MR ALEXIS: Thank you, Commissioner.

THE COMMISSIONER: Yes, Ms- - -

MS SOARS: Thank you, Commissioner. Ms Knowland, my name is Julie  
20 Soars and I'm a barrister for Sandra Lazarus and I'm going to ask you some  
questions?---Sure.

You've given some evidence about your role as a registered nurse in the  
gynae-oncology department today. That's correct?---That is correct.

In 2008. Could you just describe your general duties and responsibilities  
during that period?---General duties would be ensuring that the clinic rooms  
are set up for whatever clinics were to take place that day, to assist the  
doctors consulting their patients in their various clinics, chasing up patients  
that did not attend certain appointments or chasing up results of tests.

30 And could the witness be shown Exhibit 12, please. Are the clinic rooms  
you referred to what's marked on that Exhibit 12 as consulting rooms or are  
they something else?---Yeah, no, they're the same.

Thank you. If you could just keep Exhibit 12 there I'll ask you a few  
questions. Did you say in your evidence in chief that you also sometimes  
accompanied patients who were having chemotherapy treatment?---As, as  
um, that's not listed as my primary role.

40 Right?---But sometimes when there were not clinics running on a Monday I  
would occasionally go to help with the chemotherapy clinic which was run  
to the left of the waiting room.

And it's your evidence, is it, that you only did that when there were not  
otherwise clinics running in this general gynae-oncology department?  
---That's correct, yes.

And were there any other activities that you did as part of your general responsibilities that might have taken you off the floor which is the gynaecology floor?---Not really, no.

No. And what hours did you work?---8.30 to 5.00 give or take.

And how, was that full time?---Yes.

Five days a week?---Yes.

10

And you gave some evidence about various lists that were used, presumably they were available at the reception desk in the waiting room by reference to Exhibit 12. Is that - - -?---Available to the admin - - -

The receptionist?---The receptionist, yes.

Yes. The receptionist at the reception desk in the waiting room each day had a general list - - -?---Yes.

20

- - - for the doctors that would see patients that day. Is that correct?---She did, yes.

And when you were talking about the general list that receptionist had that would also include a list of Dr Campion's patients?---Yes, that's correct.

Who were part of colposcopy clinic?---Yes.

30

And is it correct is it that the colposcopy clinic sees women who present with abnormal pap smears?---The majority of those patients would present with abnormal pap smears, yes.

And is it correct that the colposcopy clinic operates every day?---No, that's incorrect.

How many days a week?---It runs all day Tuesdays and all day Wednesdays.

40

And is it only Dr Campion who sees women of that health - - -?---Dr Campion and usually the registrar would assist him in seeing patients.

And you gave some evidence or I'll ask you, could the witness by shown Exhibit 24, please. Is it correct is it that the general lists that the receptionist had at the waiting room would show whether a patient was new or a follow up?---Yes, that's correct.

And that's each list for each doctor?---Usually, yes.

Including the colposcopy list?---Yes.

And it's true isn't it that a new patient is likely to present an abnormal pap smear?---You could assume that the majority of patients would be presenting with an abnormal pap smear for the colposcopy unit, yes.

THE COMMISSIONER: But does that, that question is a little bit in the air.

MS SOARS: Yes. I'll keep asking.

10 THE COMMISSIONER: I don't know what that means, because I don't know whether that means just the colposcopy clinic patient?---That means just the colposcopy clinic patients just for Dr Michael Campion.

MS SOARS: And in relation to the other general lists could that assumption be made for the lists of the other doctors for new patients?---No. You wouldn't make that assumption at all.

But there would be a possibility that some of the patients would be there - - -?---It would actually be highly unlikely - - -

20

Highly unlikely?--- - - - that those other patients seeing Professor Neville Hacker, Dr Greg Robertson and Associate Professor John Marsden, they would usually not be referred with an abnormal pap smear to those doctors.

Highly unlikely but possible?---The rare occasion, I would say only.

But in relation to Dr Campion's colposcopy list the majority of the women on it - - -?---Yes, that's correct.

30 - - - would present with abnormal pap smears?---Yes.

And do you know how many patients were on the colposcopy list generally each day during the period 2008?

THE COMMISSIONER: Well, twice a - - -?---Can I ask how relevant this is because the patients that attended the colposcopy clinics were not cancer patients generally.

They were not, I beg your pardon?---They didn't have cancer.

40

MS SOARS: I don't, I think it's for you to take an objection of relevance. I would ask you to answer my question?---Sure.

THE COMMISSIONER: That's not every day. They only had the clinic twice a week.

MS SOARS: Correct. And I'm asking how many patients were on the list twice a week generally speaking, please?---Okay. So a Tuesday morning clinic would typically have 15 patients booked.

Yes?---A Tuesday afternoon there would be probably three to five patients booked for a procedure and five to eight patients booked for follow up appointments. And then on a Wednesday probably 30 patients in total would be booked on those days, on average.

10 And I want you to assume for the moment that Sandra Lazarus was operating on the assumption that she'd completed a pilot study and was able to proceed with the clinical trial of women with abnormal Pap smears in early 2008. And it's entirely possible, making that assumption, that Sandra Lazarus could have recruited and treated patients, being women with abnormal Pap smears, by taking patients from the waiting room of the colposcopy clinic?---(NO AUDIBLE REPLY)

MS FURNESS: I object. There's no evidence that Ms Lazarus treated any patient.

20

MS SOARS: Okay. I take that back. In relation to that question I mean treated by tested with the Medex device.

THE COMMISSIONER: I think you have to start again. It's too difficult.

MS SOARS: Thank you, yes. So making the assumption that Sandra Lazarus was operating on the belief that she'd completed the pilot study and was able to proceed with the clinical trial of women with abnormal Pap smears in early 2008, it's entirely possible, isn't it, that Sandra Lazarus could have been recruiting and testing patients with the Medex device, being women with abnormal Pap smears and they, they could be patients she's obtained from the waiting room of the colposcopy clinic. Is that correct?---That's exceptionally unlikely.

30

And why do you say that?---Because I was in that clinic every day from 8.30 in the morning till 5.00pm and I would have seen her either recruiting patients, my secretaries would have questioned me in regards to her seeing patients and she would have had to have come to either myself or Ellen to find a room to recruit those patients in.

40

I have no further questions.

THE COMMISSIONER: Yes, Mr Hogan?

MR HOGAN: No, no, I have no more questions.

THE COMMISSIONER: Ms Furness?

MS FURNESS: You indicated earlier that the patients who presented with an abnormal Pap smear at the colposcopy clinic were not cancer patients. What were they?---The most majority of the patient that came to the colposcopy clinic presented with an abnormal Pap smear which meant that they potentially could have what we could call pre-invasive disease or pre-cancer, which is usually referred to as CIN1, 2 or 3, which is not defined as, called cancer, and most of those women would fall under that category. So all those women that fell under that category would not be eligible to meet Sandra's proposed research anyway.

10

Thank you, Ms Knowland. Ms Knowland, you were asked a question about paragraph 10 in your statement. Do you still have that in front of you? ---No, I don't. Can I have a copy?

Do you see paragraph 10?---Yes.

Is it the case that you have no clear recollection as to when you observed Ms Lazarus in the adjacent room as set out in that paragraph?---That's true, I don't recall the exact date.

20

It could have been August or September 2008?---It could have been either or those days, yes.

THE COMMISSIONER: Mr Alexis?

MR ALEXIS: I have nothing further. Could Ms Knowland be excused from further attendance?

THE COMMISSIONER: Yes. Thank you for attending, Ms Knowland?

30

---Thank you.

You may be excused. You are excused.

**THE WITNESS EXCUSED**

**[2.18pm]**

MR ALEXIS: Commissioner, could I now call Professor Gilbert Burton.

40

THE COMMISSIONER: Do you represent Mr Burton?

MS FURNESS: I do represent Dr Burton, thank you.

THE COMMISSIONER: Do you want a Section 38?

MS FURNESS: I do, thank you.

THE COMMISSIONER: Please sit down, Professor Burton. Pursuant to section 38 of the Independent Commission Against Corruption Act, I declare that all answers given by Professor Burton and all documents and things produced by him during the course of his evidence at this public inquiry are to be regarded as having been given or produced on objection and accordingly there is no need for him to make objection in respect of any particular answer given or document or thing produced.

10 **PURSUANT TO SECTION 38 OF THE INDEPENDENT COMMISSION AGAINST CORRUPTION ACT, I DECLARE THAT ALL ANSWERS GIVEN BY PROFESSOR BURTON AND ALL DOCUMENTS AND THINGS PRODUCED BY HIM DURING THE COURSE OF HIS EVIDENCE AT THIS PUBLIC INQUIRY ARE TO BE REGARDED AS HAVING BEEN GIVEN OR PRODUCED ON OBJECTION AND ACCORDINGLY THERE IS NO NEED FOR HIM TO MAKE OBJECTION IN RESPECT OF ANY PARTICULAR ANSWER GIVEN OR DOCUMENT OR THING PRODUCED.**

20

THE COMMISSIONER: Professor Burton, do you wish to give your evidence under oath or do you wish to affirm the truth of your evidence?

PROFESSOR BURTON: No, under oath.

THE COMMISSIONER: Would you swear Professor Burton in, please.



THE COMMISSIONER: Mr Alexis?

MR ALEXIS: Thank you, Commissioner. Sir, is your full name Gilbert Burton?---Yes.

10 And are you the current head of the Department of Obstetrics and Gynaecology at the Royal North Shore Hospital?---Yes.

You've held that position since 2006?---Yes.

And could I show you please a statement bearing dated 9 July, 2010. Sir, would you confirm that that's a copy of the statement of evidence that you gave to ICAC investigators on the date that I've just identified?---I can confirm that, yes.

20 And is the content of that statement true and correct to the best of your ability?---Yes.

Thank you. I tender the statement.

THE COMMISSIONER: Yes. The statement of Professor Burton is Exhibit 25.

**#EXHIBIT 25 - STATEMENT OF PROFESSOR GILBERT BURTON**

30

MR ALEXIS: Now, professor, should we understand that your qualifications and experience is relevantly set out in paragraph 5 of your statement on the second page?---Yes.

And we should understand that you also conduct a private obstetrics and gynaecology practice from premises within the North Shore Private Hospital. Is that right?---Yes.

40 Now, in relation to arrangements with the University of Sydney do we see reference to that in paragraph 6 where you tell us that a visiting medical officer you hold a position of clinical professor with that university?---Yes.

Does that put you in touch at all with Professor Ross Smith?---No, only socially, not, not - - -

Now, could I come to some detail which commences at paragraph 8 of your statement and particularly the occasion you refer to in paragraph 8 where a

young woman introduced herself to you as Michelle Lazarus and what happened as a result of that, do you follow?---Yes.

Now, is it the case that you have met both Michelle Lazarus and her older sister Sandra Lazarus?--- I think I've only met one woman called Michelle Lazarus.

10 All right. So can you tell us please your best recollection of when you first met Michelle Lazarus in mid-2008 as you tell us in paragraph 8?---When or how?

What, what were the circumstances in which you came to meet her for the first time?---Well, she made an appointment in my private office to come and tell me about some research programme that she was thinking of doing, using a device, an impedance device looking for changes in cancer in the human body.

20 Now, I just want to come back to that but can you be shown Exhibit 1, the examination bundle which may already be before you there in the witness box. Could you just pardon me one moment, Commissioner.

Now, at page 146 of the examination bundle, professor, and you can either follow it on the screen or you can follow it in the book, we have a copy of a computer access form which relates to a Michelle Lazarus and I think we see your signature under the heading "Department Head Signoff." Do you see that?---Yes.

30 Now you give some evidence I think that the woman who identified herself at Michelle Lazarus came to see you and ask you to sign that form?---Yes.

And is there any doubt in your mind that that's your signature that appears on the form at page 146?---No, that's my signature.

Now do you think you might be mistaken as to the identity of the woman that asked you to sign the form that we see at page 146 and the woman that came to see you on the earlier occasion wanting to engage in a discussion with you about a clinical trial using the Medex device?---From my memory I've only seen the same woman the whole time.

40 All right. Now can I come back to the first occasion when you had a conversation with who you've described as Michelle Lazarus and can you recall to mind please how she introduced herself in terms of undertaking any course of study or any existing relationships with any colleagues of yours at the Royal North Shore Hospital?---She said she was a student who was doing a research study with Professor Ross Smith.

And did she identify the course of study that she was undertaking with Professor Smith?---Yes, it was to use the Medex device looking for breast changes, cancer changes.

And how did she describe herself in terms of her status as a student? An actual student or a proposed student or something else?---Just a student.

10 And if you look at paragraph 9 of your statement, you refer to an understanding that you derived from Michelle, as you describe her, that is an understanding that she had undertaken a study with Professor Smith and you refer to Concord and the Royal North Shore Hospital using the Medex device. Do you see that?---Yes.

Yes. Now you've expressed yourself there in the past tense and should we understand that when you were informed of this you took that to mean that she had already undertaken these studies with Professor Smith as you've described?---Yes.

20 And when you derived that understanding from her and before engaging in further discussions either with her or with her sister perhaps, and I'll come to some detail, did you ever take any step to check with Professor Smith or verify what you were being told by this woman?---I can't remember when, I run, I run into these colleagues casually, and I can remember at some stage just talking about Michelle in a general sense with him about the project and where it was going, probably on two to three times. I don't think I formally verified that she was doing the study, but I knew from speaking to Ross Smith that he was involved with some study with her.

30 Right. All right. Now you tell us in paragraph 10 that you asked Michelle Lazarus to put a proposal together for a pilot study and should we understand that you, having made that request, received a document at some later point in time concerning the proposal for a pilot study?---Yes.

What was the form of the document?---It was a, pieces of paper with sort of a trial base document with, set out how this, the proposal to the pilot study.

40 Now with respect to the form at page 146 that we've just spoken of, that's the computer access form, and particularly the date adjacent to your signature, 22 October, 2008, are you able to recall to mind whether you received the protocol for the pilot study before or after signing the computer access form?---It was before.

So should we understand that there were two meetings with Michelle Lazarus and then a third meeting during which your signature was obtained on the computer access form?---That's correct.

All right. Thank you. Now, in relation to your response to the receipt of the protocol document and you tell us in paragraph 11 that you asked Michelle to speak with Dr Sue Valdermere?---Valmadre.

Valmadre, thank you. When was it with respect to signing the computer access form that you told her, that is Michelle, to speak with Dr Valmadre? ---Before, it was at the second meeting.

10 So you'd obtained the protocol and you'd made the request of Michelle to speak with Dr Valmadre, there was then the further meet during which you were asked to sign and did sign the computer access form, is that right? ---Yes.

Thank you. Now, in paragraph 19 if you could look at that please in your statement you tell us that when you signed the document which is the computer access form at page 146 you thought that might have something to do with a Human Research Ethics Committee application form, is that right? ---Yes.

20 And so could you just explain please the connection if there be one between signing the computer access form at 146 and following and enabling Michelle Lazarus to be able to obtain access to the Human Research Ethics Committee application form?---To do a pilot study you still need to get full ethics approval and so you have to go online and, in 2008 you had to go online and get the form to fill it in to then get the pilot, to get the ethics to say the pilot was okay and then, yeah, so she needed access to get the form to do the pilot, to get the pilot ethics committee thing done.

30 And so in order to complete the relevant forms on line did you believe at the time that one had to have access to the hospital's computer network to do so, did you?---Yes, you have to be able to get onto the Intranet, the hospital Intranet.

In order to lodge the ethics application online?---Well, to get the application and then to lodge it.

I see. All right. And is that what you believe was to happen after you signed the computer access form at 146?---Yes.

40 All right. Now, is your recollection that it was Michelle Lazarus, that is the same person that you'd previously spoken to on I think you told us on two occasions that came to you with the request to sign the computer access form?---Yes.

And after you signed it did you give it back to her?---Yes.

In other words, you didn't process it yourself - - -?---No.

- - - or had your staff process it?---No.

You gave it to her to deal with, is that right?---That's correct.

Now, I just want to raise with you one matter, professor, which relates to some evidence that's been given at page 276 of the transcript from about line 30, and professor, that's a reference for the Commissioner, it's been suggested that the completion and, of the computer network access form was the result of an instruction that you had provided to, to Ms Lazarus. In  
10 other words, it was, it's suggested that you informed her that she would need to obtain computer access so as to proceed with what it was that was being proposed at the time. What do you say about that?---No, she brought the form to me to get computer access, I didn't suggest it or, I thought she probably had access already or - - -

THE COMMISSIONER: Well, she must have had access if she had the form, I assume?---I don't know where she got the form from but (not transcribable)

20 MR ALEXIS: Now, Professor, if I can come back to the occasion which I think you told us was the meeting before the occasion when the form was signed at page 146, where you told her to speak with Dr Valmadre. Do you understand that such a conversation between Michelle Lazarus and that doctor occurred?---Yes.

And how do you know that?---I asked Sue Valmadre.

And are you able to recall approximately how long after the meeting when you told her to have that conversation that it in fact occurred?---I can't recall  
30 accurately so- - -

Can I understand from you what the purpose was or the object of you informing Michelle Lazarus that she ought to speak to your colleague about the protocol?---I am a uro-gynaecologist. I don't see any patients with Pap smear changes or cancer of the cervix and Dr Valmadre is a gynaecological oncologist and would probably, would see quite a lot of those sort of patients and that's her specialty area and her specialty, you know, research area. My role as head of department is often to put people in the direction  
40 of certain people with, with interests within our department.

Thank you. Now, can I draw some attention to the draft application for ethical approval. You deal with that subject in paragraph 20 of your statement and there you tell us that you have an awareness that Michelle Lazarus did actually put together a draft application. Do you see that?  
---Yes.

Now, in the examination bundle at page 151, if you turn to that, please. On your right-hand, on your right-hand side is the examination bundle?---Oh, sorry.

It might be easier for you to deal with just in the hard copy, Professor. So I'm asking you to go to page 151 in the top right-hand corner?---Sorry. Is it within the Royal North Shore section or is it- - -

Shortly before?---151.

10

Yes. Thank you. Now, did you actually see the form of document that's at page 151, addressed to the members of the ethics committee at Royal North Shore Hospital?---Yes.

And you saw this document which included the reference to you in the second paragraph and provision for you to sign at the foot of the page? ---Yes.

20

And just moving through what follows behind that document at 153 you'll see the commencement of the online national ethics application form and if you could just take a moment to work your way through that document just to ensure that it's familiar to you. And if you could just keep working through you'll get to the site-specific assessment form at page 193 and the document ends at 204. Just let me know when you've finished doing that? ---Yes. I'm up to page 190.

You've worked through to page 204 have you?---Yes.

30

Now can you tell us please whether you were provided with a copy of those two draft applications under cover of or with the document at page 151, which is where we started?---I'd have to check my records. It appears it's the same document. There's some, some differences. There's a picture of Sandra Lazarus on page 145 that was not in the document I have.

No, I think you've gone back a bit far?---Oh, sorry.

It starts at 151?---Okay, sorry.

40

And it travels towards the back of (not transcribable) 204 inclusive?---Sorry. It appears to be the same document, a very big long document and I'm familiar with it.

So we should understand that you were provided with that draft and who provided that to you?---I don't know. It just appeared in my in-tray some time.

Do you recall having any conversation with Michelle Lazarus or Sandra Lazarus about the document that appeared in your tray?---No.

Do you recall having any conversation with her or indeed anyone about reviewing the draft and responding with comments about the draft?---No.

Now in paragraph 21 you make reference to the application appearing to have been done online and I gather that's a reference to the fact that the forms which I've just invited you to look at are the sorts of forms that can be submitted online. Is that what you mean?---Yes.

10 And then you say, but I don't, do not know, I'm in paragraph 21, sir, but I do not know if this application was ever submitted to the hospitals HREC or approved. Do you see that?---Yes.

So have you taken any step to check whether in fact the application was ever lodged at all?---No.

20 So your state of knowledge is neutral as to the question of lodgement and or approval. Is that the position?---Yes, I didn't sign it, like logic is that I haven't signed it therefore it hasn't gone in. But I'm neutral.

And you had an expectation that because you've been identified as the head of the relevant department undertaking part of the proposed study that you would at some point be presented with a document for signature?---Yes. You have to sign it 14 times. It's 14, you make 14 copies.

It sounds like you've done that before?---I have.

30 Now in 2008 and indeed into 2009 did you have an understanding as to the policy or directive basis for the need for ethical approval for the conduct of a clinical trial or study involving humans?---Yes. All studies involving humans in New South Wales require ethics approval, be it a pilot study, any, any study.

And did you in 2008 and 2009 have an understanding as to what professionally the consequence might be if you were either involved in or supervising a clinical trial involving humans that did not have ethical approval?---It would be assault. Doing something to a patient without their consent or without the approval of the hospital.

40 All right. Now were you informed at any time by Ms Lazarus, be it Michelle or Sandra that ethical approval had been obtained for the pilot study?---No.

Now could I just raise with you a matter following from a witness earlier in the week at page 274 of the transcript, and again this is just a reference for the Commissioner, and it's been suggested that after speaking with you and before the very first test was undertaken on any patient at Royal North Shore Hospital, Ms Lazarus was told that she could proceed with the

examination of that first patient without obtaining ethics approval. And that the person who - - -

MS SOARS: (not transcribable) interrupting my learned friend, but there is, could I just have a word with you for a moment, please.

10 MR ALEXIS: I'll withdraw that question. I'm sorry. The suggestion has been made by Ms Sandra Lazarus that she spoke with you before the first test was undertaken on the first patient at Royal North Shore Hospital and that you told her, that is Sandra Lazarus, that she could proceed with the examination of that first patient without obtaining ethics approval. What do you say about that suggestion?---I thought I was always dealing with Michelle, like someone I called Michelle, but that would, I would never allow that to happen.

20 All right. Now perhaps putting to one side for the moment whether or not the occurrence of such an occasion had such a discussion occurred there with Michelle or Sandra, do you recall having ever had a conversation about the conduct of a clinical trial such as the one we're concerned with here without ethics approval?---No.

30 Now can I turn to the subject of funding and the cost of the conduct of any clinical trial using the Medex device. If we look at paragraph 22 of your statement, we see that you refer there to some discussions with Michelle Lazarus about that subject matter. Can I try and just get some clarity around the timing of the discussion about the subject of funding? You refer I think to three occasions when you met Michelle Lazarus, including the occasion when the computer access form was signed. Was it during any one of those discussion where the subject of funding was discussed?---The first, the first meeting.

And can you relay to us please what you said on the subject of funding to Michelle Lazarus or the woman that you were speaking to about the subject of a clinical trial involving the Medex device?---I pointed out to her that research has to be independent of the funding entity, independent of the results and of the work within the study itself. And that there's to be no, you know, link between the two. We basically had a discussion about, you know, the role of private money in research.

40 Now did you have any understanding at all when you were having those discussions with either Michelle or Sandra Lazarus that the hospital would be incurring some cost with respect to this?---No. The, we didn't ever get to the financial side of it. We had a general discussion about it. And we, never even got to the pilot study let alone to discussing money and things like that.

All right. Well, just in that regard, could I ask you to look at paragraph 42 of your statement where you tell us about a telephone call you received and



again, professor, I should ask you this question: could you be mistaken as to whether or not it was Michelle Lazarus or her sister Sandra that you were speaking to during these various conversations?---That was a telephone call so it could, someone called Michelle rings up I think it's Michelle. I think I've dealt with the same person each time.

Yeah, all right. Now during this telephone conversation a request was made about some account information. Is that right?---That's correct.

10 And can you tell us a little about the trust fund you refer to in paragraph 42 which you say is run by Professor Morris?---It's a research trust fund within the hospital, the university hospital that holds money for all the research projects going on at the time, it's actually a multiple, multiple trust fund, it has many accounts within it.

Now, did the person who telephoned you identify that fund by reference to Professor Morris or was there what I like to call a generic reference to a fund?---No, there was a generic reference to a fund.

20 So how did you know she, she, the caller was referring to that run by Professor Morris?---She asked me did I know the account number, I said no, Professor Morris has that account number and I'll ring him and find out what it is and ring you back.

I see?---Mmm.

So when we look at paragraph 43 of your statement and we see that you provided the caller with the trust fund details we should understand that as an independent telephone - - -?---Yes.

30 - - - communication to the earlier one where the request was made?---Yes, it's two telephone calls.

Thank you. And if we look at the very last page of your statement we see it has an attachment to it, what appears to be a handwritten telephone message with J Morris written on it and some numbers apparently relating to the fund, do you see that?---Yes.

40 And how should we understand this telephone message to fit into the returning of the telephone call and the conveyance of the account number details?---Jonathan Morris rang back and my secretary's taken this message and he's given the account number to my secretary who's put it on a reminder slip for me.

All right. Now, after the telephone communication about the trust fund account details can you recall any further communications with either Michelle or Sandra Lazarus about the subject of trust funds, trust accounts and moneys being paid from sponsors in relation to the conduct of any

clinical trial?---There was a meeting some time in 2009, get this right, with two people from Perth who were from Medex who provided, who were saying they would provide money. We had a fairly general discussion about all of that with Michelle there.

Apart from that, and I'll come to some detail concerning that meeting in a moment, there was no other conversations about those subject matters?  
---No.

10 All right. Now, if I can bring you back to paragraph 15 and following of your statement have you ever seen the results of any initial pilot study of patients using the Medex device?---No.

Have you ever seen and actually felt the device itself?---Never.

Have you ever seen or had occasion to observe the device being used with a patient?---No.

20 Have you ever asked to see the use of the device with a patient or have you ever seen the results of any such use?---No.

In paragraph 15 you tell us in the second sentence that you have asked for these, that is to say results from Michelle Lazarus but they had never, apparently, materialised. Do you see that?--Yes.

Could I ask why it is that you ask Michelle Lazarus for results in circumstances where you I gather well understood that no tests to be undertaken because no ethical approval had been obtained?

30 THE COMMISSIONER: What's the objection?

MS SOARS: Commissioner, I think this is the important point and that the witness shouldn't be lead for this (not transcribable).

MR ALEXIS: He's not being lead.

MS SOARS: Okay.

40 THE COMMISSIONER: I don't regard that as a leading question. He asked for an explanation?---The results, I'll have that again if I can. Can you ask the question again?

MR ALEXIS: Yes, I will---

THE COMMISSIONER: In fact it doesn't reflect on your client.

MS SOARS: (not transcribable)

MR ALEXIS: In paragraph 15, Professor, you tell us that you asked for results from the initial pilot studies from Michelle Lazarus. You see that?  
---Yeah.

And we should understand that as the same person whom you'd met on previous occasions?---Yes.

10 Now, can I ask you to explain to us why you would've made that request when you knew that no pilots had been undertaken because you knew that no ethical approval had been obtained?---I knew that it had never done on my patients or I'd never signed off on any, any you know ethics committee thing but she had gone to see Dr Sue Valmadre and I, I just presumed they had done a pilot study and, and they'd done ethics got it all organised. If it was like that I wouldn't, that wouldn't normally come across my desk it was a, an ethics committee thing unless it had my name on it which it didn't. So, I, I was sort of in, in the presumption that if had been done it would've been done with Sue Valmadre and - - -

20 But professor, if you made a request for Michelle or Sandra Lazarus to produce for your review results of the pilot study that would rather suggest wouldn't it that you had some knowledge or insight into the performance of such a study?---No, I, I, all I wanted I, is anything happens, is any results happening, have you got any results.

THE COMMISSIONER: Well how did you regard your role in this pilot study, Professor?---My role was to ask Ms Lazarus to go to Dr Sue Valmadre and to facilitate them to get going on the pilot study if they could get it going.

30 So you assumed that because of your particular speciality but because you were the head of a department?---That's correct.

And that's how you regard your involvement, please correct me if I'm wrong, you regarded your involvement in this pilot study as existing simply because you were head of the department not because you had a role to play in research?---That's correct.

40 MR ALEXIS: So when you made the request should we understand that you had assumed that the rigours of ethics, applications and approvals and the like had been submitted and obtained and the study had actually occurred?---Yes.

And having made the request did you anything in return?---No.

Nothing at all?---No.

Did you, at any time observe either Michelle or Sandra Lazarus examining any patients using the Medex device?---No.

THE COMMISSIONER: Do you know if any of your patients were examined by one of those persons Michelle or Sandra Lazarus?---No, they were not examined by them.

Well you say that positively?---Yes, your Honour.

10 Well how do you know?---Well, they're the wrong patients, I'm a uro-gynaecologist so I look after women with prolapse and incontinence. It's the wrong study. I don't have any space in our office. We've got a, it's - - -

Right. That answered the question.

MR ALEXIS: Now, Professor, it's been suggested that in relation to your patients, you were approached by Ms Lazarus, I'm at page 347 of the transcript on line 30, Commissioner, that you were approached by Ms Lazarus and you were shown some patient files. And we should understand by that a file containing a patient consent form that Ms Lazarus had  
20 obtained from the patient, some paperwork which recorded the result of the use of the Medex device on the patient which contains a colour graph, and the suggestion is that with that file you were shown that material, you were asked to circle if it's a negative or a positive result, and that you went through that process at least ten times in respect of ten separate patients. Professor, what do you say about that suggestion?---That's not true.

And perhaps it may not matter for you, but may I be plain with you that the suggestion I make relates to either Michelle Lazarus or Sandra Lazarus or both. Is your answer still the same?---It's the same.

30 Okay. Now, I need to ask you a question or two about the content of the patient lists and at your clinic is such a thing called a patient list produced on a daily basis in relation to your patients?---Do you know which clinic this is, is it my rooms or the public clinic at Royal North Shore?

The public clinic at Royal North Shore?---The public clinic.

Yes?---Yeah. So the public clinic is, has a list that's generated from a book that has basically just the times the patients are coming.

40 And who would have that list available? Let me withdraw that, sorry. To whom would one go to get such a list?---You'd go to the receptionist.

And in what form does that list take? And I should be plain with you, we're talking about the period from late 2008 through to mid-2009?---Mmm. And we're talking about the public clinic, not my rooms.

I'll come back to your rooms?---Yeah, so the public.

Yes, public?---It's a book, it comes in a book. It's like an A4 book and it's basically got one day and it's got patients ordered in new patients, old patients, we see a lot of obstetric trauma, so they've got a special little box and then there's post-operative patients.

Now, what sort of information is on the list about each patient?---Just their name and the time they're coming.

Anything else?---No.

10

Would there be any description of what the patient's result or what they were there waiting for would be on the list?---No.

Now, what about in your private consulting rooms, is a list produced on a daily basis with respect to patients that you see there?---No, it's computerised, my office, so there's no list.

So there's not paper list that's produced on a daily basis?---No.

20

And so far as the computer list is concerned, can you tell us the information available on that list on a daily basis?---It's a screen, it's got multiple fields. It's got time, patient, phone number, they're categorised into new patient gynae, old patient gynae, obstetrics. That's it, roughly. And sometimes comments on when they're coming, you know, ringing up and delaying and we send a text message to every patient so there's a field for that.

But again if one was to look at the daily patient list on the screen of the computer, would one see a description, perhaps a slight description of what the patients' results are or what their, or what they are there waiting for?

30

---No.

Professor, it's also been suggested that following what is said to be the conclusion of the pilot study involving ten patients, Commissioner, I'm referring to page 290 of the transcript at about line 32 following, it's suggested that you were provided with the complete pilot study after it was completed and that you were then spoken to about it. What do you say about that suggestion?---That's not true.

40

Now, I want to come to a meeting that occurred, which I think you obverted to in your evidence earlier, but before I do can I ask you to open the examination bundle, Exhibit 1, that's before you and go to page 277. So do you see reproduced there is a copy of a letter addressed to the Medex Test Corporation dated 6 May, 2009, which appears to have been signed by you? ---Yeah.

Can I show you the original of that letter, please. And in paragraph 51 of your statement you tell us that the letter does not look like one that would

have been typed from your office. You tell us that all your Royal North Shore Hospital typing is conducted at your private practice rooms?---Yes.

Can you tell us what we should understand is the feature or features of the letter that tell you that it doesn't look like a letter that would have been typed from your office?---Ah, the font is different to what we normally use, the way we set up addresses and things is different, the, the words sort of don't appear to be the words I would (not transcribable) Generally on the Northern Sydney (not transcribable) stuff I would normally be called  
10 Professor Burton.

Now, having had the benefit of examining the original of that letter, what do you tell us about the signature and whether or not you signed this letter on or about 6 May, 2009?---It does look like my signature.

THE COMMISSIONER: If you look at the content of the letter, what are you saying about signing a letter with that content?---I think it refers to, I'd have to read it again if you want me to - -

20 Well, it sets out the research outcome for a preliminary research trial evaluating the Medex test?---Yeah. So it's, as I've stated already, that's false.

And it's, yes, but I mean, it goes into detail. For example, if you look at the paragraph in the middle it sets out the results of the test, "These test show that eight out of ten patients were correctly diagnosed by the Medex test screening method", et cetera, et cetera?---Yeah.

30 Did you, did you know anything about that?---No, never.

So- - -?---Like I stated before, there was never a, as far as I knew there was never any- - -

So would you have signed a letter which contains material that you knew nothing about?---No.

MR ALEXIS: Now in terms of the, sorry, Commissioner, did you - - -

40 THE COMMISSIONER: No, no.

MR ALEXIS: In terms of the preparation of the letter, sir, could I draw attention to some evidence that has been given to the Commission already in this inquiry at page 291 from about line 30 and following of the transcript. And again that's a reference for the Commissioner. It's been suggested, sir, that the letter was drafted by Sandra Lazarus and the draft letter was put on a USB or a computer stick and brought to your office, was handed to your secretary and that the secretary then printed out what had been drafted by

her on a blank piece of paper. Do you have any knowledge of that?---No, we don't use USB sticks at all.

But one, presumably bring a USB stick to your office and plug it into the back of a computer and - - -?---No, it's - - -

- - - print the document?---About five years ago we got a virus through a USB stick and the secretaries know no USB sticks ever.

10 I see. And tell me on or about 6 May, 2009 who was your secretary?---Do you know what day that is?

Do you have a different secretary on a different day of the week do you?  
---Yeah. It's rotated. There's three secretaries - - -

Can you give us the name of those three secretaries?---Cherylin Connors, Wendy Hanson and Sue Cutler.

20 We'll endeavour to find out what day of the week 6 May was. Can I inform you that 6 May is a Thursday. Does that assist in refining the - - -

MS FURNESS: A Wednesday.

MR ALEXIS: I'm sorry, a Wednesday. A Wednesday. Does that assist in refining the secretary?---If it's the way it normally works it would be either, they've changed, it would have been either Wendy Hanson, probably Sue Cutler.

30 And is your evidence, sir, that your secretaries are not to use or receive a USB stick and attach it to the office computer for the reasons that you've (not transcribable)?---Yes.

40 All right. Now it's also suggested that after the document was printed out on a blank white piece of paper, Sandra Lazarus showed you the document. You were seen to take the document and make a few small changes here and there with a pen. It's suggested that after those amendment have been made the draft letter was returned to Ms Lazarus who then attended with the assistance of your secretary to have those amendments made. The draft was then printed out on a letterhead that we see at page 277 of Exhibit 1. The letter in its final form was then presented to you for signature and you were seen to sign the signature as we see represented by the signature on that document. What do you say to those suggestions, professor?---No, that's not true.

Do you have any recollection at all of ever reviewing a draft of this letter and making the amendments to which I've referred in the suggestion I put to you?---No.

I tender the original of that letter, Commissioner.

THE COMMISSIONER: The original of the letter of 6 May, 2009, Northern Sydney Central Coast New South Wales Health to Medex Test Corporation is Exhibit 26.

**#EXHIBIT 26 - ORIGINAL OF LETTER FROM DR GILBERT BURTON TO MEDEX TEST CORPORATION**

10

MR ALEXIS: Professor Burton, in May of 2009 had you ever heard of the Medex Test Corporation?---No. I'd heard of Medex, I don't think I've ever heard of the Medex Test Corporation.

And did you at that time have any understanding about whether that company conducted its business from Western Australia?---No.

20 Now I want to come to the meeting that you made reference to a little while ago and if you could look at paragraph 27 of your statement. And you'll see that you've indicated there that you received a telephone call from Michelle Lazarus in about October of 2009 with a request for an urgent meeting. Do you see that?---Yeah.

And again could you be mistaken as to who it was that rang and spoke to you, be it Sandra Lazarus or Michelle?---Yeah, it could have been either.

30 How is it that you're able to relate the timing of not only the receipt of that call but also the subsequent meeting that you tell us about in paragraph 28 to the period approximately October 2009?---I think it's a very approximate, I really, I don't have a date on the note that I wrote, so - - -

THE COMMISSIONER: So you're uncertain about the date?---Yeah.

MR ALEXIS: And if it was suggested that in fact the meeting was in May of 2009, what would you say to that?---No, quite impossible.

40 You made some notes of the meeting which I think you've attached to your statement and it should come up on the screen in front of you momentarily. During that meeting, first of all, did you receive the business cards that we see forming part of your notes at that meeting?---Yes.

And so we should understand that both the gentlemen referred to in the business cards were present in your office?---Yeah.

And was the meeting one that occurred in your private consulting room?  
---My private consulting room, yes.



And you tell us that, in paragraph 28, the other person attending the meeting was Michelle Lazarus?---Yeah.

And is that because the person who attended or I should say the female that attended was the same that had attended on you during those earlier occasions that we've discussed including the occasion where you signed the compute access form?---Yes.

10 Now would you mind, we can show you, perhaps it might be easier for you to look at the document attached to your statement, which I think is at the second last page of your statement. But could you just step us through your notes of this meeting?---We had, do you want me to refer to my statement or just talk - - -

We perhaps if you can just slowly work from the top of the page down and tell us what your notes contain?---So I worked out they were from Perth. They told me about a, they had a patent from Dr Alec Kinevski (?). They were running their own trials on breasts and they did some possible work on  
20 bowel, ovary, gastro (not transcribable) screening results of 80 or 85 per cent. We had a discussion about statistics and false positives and false negatives in terms of screening and all that sort of stuff. And then we had quite a big discussion about who owns the data, marketing and that sort of stuff. And then sort of resolved a plan, if I can read through it, ML needs to put together full ethics, show to Sue Valmadre and Greg Guard, who's the other gynaecologist. And then submit if she wants.

THE COMMISSIONER: Sorry, can you just go through, just read what your writing reads there?---Sorry, your Honour.

30 Starting with, is that, that says (not transcribable) that's - - -?---ML, so plan - - -

Plan?---Yeah. Plan, so ML needs to get together full ethics, show to SV and Greg, GG, which is Sue Valmadre and Greg Guard.

Yes?---And then submit.

Yes. And then - - -

40 MR ALEXIS: I'll just pause you there. What should we understand by the letters ML immediately after the word plan and the colon?---Michelle Lazarus.

All right. Yes?---Finances must be transparent and independent of results.

And then at the foot of the page?---Well, that's some notes. I've now got a file essentially running so that's a note made on the 6<sup>th</sup> of the 12<sup>th</sup>, 2009, not

fully on the page here, but I discussed with Ross Smith how something finances at Prince of Wales.

But the note below the line at the foot of the page we understand is unrelated to the meeting?---Not, yeah, yes, that's right.

Now, you've then given some detail about what was discussed in paragraphs 28 and following of your statement. Is that right?---Can I see paragraph 28? Yes.

10

Now, I just won't be a moment, sir. Now, Professor, I just want to raise a couple of matters with you concerning the content of this meeting with the two gentlemen from the Medex Test Corporation. Prior to this meeting had you heard of or did you have an understanding of Mr Vern Plisenka or David Plisenka?---No, I'd never heard of them before.

And could I suggest that during this meeting there was reference made to the letter of 6 May, 2009, to which we've already referred which is the letter at page 277 of Exhibit 1?---No, there was no reference to that.

20

And can I suggest to you that Mr Plisenka - -

THE COMMISSIONER: Pleiksna.

MR ALEXIS: Pleiksna raised with you the content of the letter during the meeting and expressed a desire to expand from the pilot study to a larger study involving 200 patients to see if the results received could be replicated into a larger study?---I have no memory of that.

30

Now, it's not clear to me at this stage, sir, which of those two gentlemen raised that with you but my suggestion conveys with it the suggestion that either or both raised that subject matter with you at that meeting?---What do I say about that? I've got no memory of that.

THE COMMISSIONER: And did you or did you not or had you or had you not seen a pilot study by the time of that meeting?---No, I've never seen a pilot study.

40

MR ALEXIS: Now, after the meeting that we've just referred to, be it a meeting that occurred in May of 2009 or October of 2009, did you ever hear of or see Michelle Lazarus or Sandra Lazarus again, prior of course to attending the Commission today?---No.

Thank you, Professor. That's all I wish to ask.

THE COMMISSIONER: Ms Soars?

MS SOARS: Commissioner, what I wish to do is ask the witness a question regarding the identity of my client and then I wish to seek a short adjournment to get some instructions on the matters that have been produced orally today so I can be sure that I can- - -

THE COMMISSIONER: Yes. We'll have to finish Professor Burton today.

MS SOARS: I understand. I don't expect to be too long, but I just need to get instruction.

10

THE COMMISSIONER: All right.

MS SOARS: Professor Burton, my name's Julie Soars, I am a barrister for Sandra Lazarus. I'm going to ask my client Sandra Lazarus to stand up and I'm going to ask you whether it's your recollection that the woman that you've referred to in your statement as Michelle Lazarus is my client, as identified in the court is her sister Sandra Lazarus?---Yes.

20 Yes. At this point I'd like to seek an adjournment and obtain some instructions please, Commissioner.

THE COMMISSIONER: Yes. How long will you be?

MS SOARS: 15 minutes.

THE COMMISSIONER: Yes. But we will finish by 5.00.

MS SOARS: I won't be very long in cross-examination.

30 MR HOGAN: Commissioner, I can indicate that I will be short with the professor.

THE COMMISSIONER: Yes, thank you.

### **SHORT ADJOURNMENT**

**[3.26pm]**

40 THE COMMISSIONER: Yes, Ms Soars.

MS SOARS: Thank you, Commissioner.

MR HOGAN: Commissioner, if I could interrupt perhaps I should raise that my friend did ask for Michelle Lazarus to come into the Commission. I have had her outside (not transcribable). I don't know whether she was going to be required but (not transcribable) ask that she'd be (not transcribable)

THE COMMISSIONER: Well, I think we, thank you for that, Mr Hogan, but I'm sure either you or Ms Soars or Mr Alexis would deal with it so it's dealt with in some way or another.

MR HOGAN: Yes, thank you, sir.

THE COMMISSIONER: Yes, Ms Soars.

10 MS SOARS: Can I take you to paragraph 8 of your statement first, Dr Burton. Dr Burton, when you met this young woman you refer to in paragraph 8 of your statement it's entirely possible that she introduced herself as Sandra Lazarus, isn't it?---No, she introduced herself as Michelle Lazarus.

And what's the basis of your recollection of (not transcribable)?---She called herself Michelle Lazarus.

20 And is it your evidence is it that at each time you met with her or spoke with her she, she called herself Michelle Lazarus?---Yes.

I take you to paragraph 27 of your statement. Have you got that?---Yes.

And you've already said that the date, the exact date of that meeting you're unsure of, is that correct?---And I put it to you it's entirely possible that the date of that meeting was in May.

THE COMMISSIONER: He's already said yes.

30 MS SOARS: To that proposition?

THE COMMISSIONER: Yes.

MS SOARS: Thank you, Commissioner. I'm just, all right.

And, Dr Burton, during that meeting Mr David and Vern Pleiksna referred to my client as Sandra Lazarus, didn't they?---I don't know.

Is that possible?---I don't know.

40 And if that had occurred wouldn't you have said no, I think that woman is Michelle Lazarus?---I don't know.

But you have no recollection for example of it striking you that they were referring to someone as Sandra Lazarus who you knew as Michelle Lazarus.

THE COMMISSIONER: If they were.

MS SOARS: If they were?---No, I've got no memory of them referring to her as Sandra.

And can I take you to the document which is attached to your statement and which is the letter and ethics application which is at page 151 of the evidentiary bundle, Exhibit 1. Do you have that, page 151?---Yes.

10 And if I ask you just to have a look through that document, the references to the researcher in that document are references to Sandra Lazarus aren't they?

THE COMMISSIONER: Have you ever seen this document before, Professor Burton?---Yes. This is the one that was - - -

At 151?---It was just in my in-tray, it arrived in my in-tray one day.

I see. Yes, Ms Soars?---Yes.

20 Yes, all right.

MS SOARS: So you're agreeing with me that the references to the researcher within this document are to Sandra Lazarus?---Yes.

Would you like to take some more time to look at it or you're happy to agree?---No, I'm happy to agree. It's a big long document, I'd have to check every word of it but my - - -

Well, for example, it's on the first page isn't it?---Yes.

30 And while I'm here I just want to ask you some questions about that document. Did you ever discuss that document with, for example, Professor Ross Smith?---No.

Professor Robert Baxter?---No.

Dr Ken Vaux?---No.

Or Dr Sue Valmadre?---No.

40 And can I take you to paragraph 19 of your statement please. Dr Burton, it's possible isn't it that my client's sister, Michelle Lazarus, came to see you on 21 October, 2008 in relation to the ethical - - -

THE COMMISSIONER: That's what he said, he says that.

MS SOARS: He's now identified the person he's referring to as Michelle in there as Sandra Lazarus so I'm putting to him - - -

THE COMMISSIONER: Well, then I misunderstood the question.

MS SOARS: I'll ask some questions, thank you.

THE COMMISSIONER: Wouldn't it short-circuit this perhaps if you, if Michelle Lazarus would stand up - - -

MS SOARS: I was just getting to that, Commissioner. I will get to that within a question or two.

10

THE COMMISSIONER: Yes, all right.

MS SOARS: Paragraph 19 of your statement, Dr Burton - - -?---Yes.

- - - the, the meeting you had on 21 October, 2008, it says in your statement it was a meeting with Michelle Lazarus, it was the person you knew as Michelle Lazarus you now know to be Sandra Lazarus, is that your evidence?---Yeah.

20 And could I ask Michelle Lazarus who's in court to stand up. And - - -

THE COMMISSIONER: It's all right, thank you.

MS SOARS: And now that Michelle Lazarus has been identified are you still happy that the meeting was with my client, Sandra Lazarus, is that correct?---Yes.

30 And at that meeting it's correct, isn't it, that Sandra Lazarus asked you to sign that form that's referred to in paragraph 19 of your statement, the, the - - -

THE COMMISSIONER: Sorry, I beg your pardon Ms Soars, I think it would be, just so that there's no misunderstanding when you put that question you should make it clear the person that Professor Burton now knows to be Sandra Lazarus, because he, his evidence is that he thought that that person was Michelle. The first time that, on his evidence, that he knew that that person was Sandra was now, today.

40 MS SOARS: Thank you, Commissioner. I will - - -

THE COMMISSIONER: So if you could just, when you ask the question, so that there's no misunderstanding, that's all.

MS SOARS: Yes, yes, Commissioner. Dr Burton, Dr Burton, I'm putting to you that at that meeting on 21 October, 2008, my client who you now know to be Sandra Lazarus, who you've given evidence you thought to be Michelle Lazarus at the time, asked you to sign the application which is

referred to in that paragraph on behalf of her sister, Michelle Lazarus, who was going to be an associate researcher. That's correct isn't it?---No.

It's possible isn't it?---No.

10 You accept don't you that it was possible that the person who you thought to be Michelle Lazarus, who you now know to be Sandra Lazarus, had gone on and conducted some testing using the Medex test device on patients who you don't consider to be your patients, but who may be patients of the colposcopy clinic or patients of Dr Sue Valmadre?

THE COMMISSIONER: There's an objection.

MS FURNESS: I object to that. (not transcribable) how could this witness answer a question about patients that weren't his without there being some preliminary questions about what his knowledge was?

20 MS SOARS: All right. Can I take you to paragraph 53 (not transcribable) please. Are you aware that you have a written copy? You're happy to watch on the screen, Professor Burton?---(NO AUDIBLE REPLY)

Do you have a written copy with you?--- I do.

Is that easier? I'll just mention it to you?---No, this is fine. Thank you.

Can you see paragraph 53?---Yes.

30 You accept don't you that it's entirely possible that the person you thought to be Michelle Lazarus who you now know to be Sandra Lazarus, had conducted some testing using the Medex test device on patients in the colposcopy clinic?

THE COMMISSIONER: This is entirely outside his knowledge isn't it?

MS SOARS: I just want him to accept the possibility, Commissioner.

40 THE COMMISSIONER: There isn't, I mean it's like, I don't know what the value of it is, he just doesn't know one way or the other. He's not denying, he can't say.

MS SOARS: But that means he can accept the possibility.

THE COMMISSIONER: I can accept the possibility if they were discovering a universe tomorrow, but it doesn't actually help the modern universe. I mean it is really, it doesn't help.

MS SOARS: It doesn't help. All right. Thank you. Can I take you to the document which is at pages 277 to 278 of the evidentiary bundle. And do

you have with you Exhibit 26, Dr Burton, the original letter that we're talking about? Could I just see that first, please, because I haven't seen it. Thank you. Could that be shown to - - -?---Thank you.

Dr Burton, I suggest to you that that is your signature on that letter. That's correct isn't it?---It appears to be my signature.

10 Is there anything about that signature that suggests it's not your signature?  
---There's some subtle aspects that would appear not to be normally what I do, but they're subtle.

Well is it the case that you cannot deny on oath that that is your signature?  
---Okay.

All right.

THE COMMISSIONER: But can you, we've been through this before. Can you say on oath that it is your signature?---No.

20 What are the subtle things that you mentioned?---See G- B-U-R-T-O-N, the big circle goes up to the top, normally I come down and go up quite sharply, and (not transcribable) mostly across, it goes across which is a T. And the G just doesn't quite look how I normally do my G's.

But of course signatures differ from day to day depending on how tired or energetic you are?---Oh, yeah, I agree.

These things can happen, it's just difficult to say?---I agree.

30 MS SOARS: And just in relation to that letter, Dr Burton, you gave some evidence about why you didn't believe it being prepared and printed by your secretary. Do you remember that evidence?---Yes.

Part of that evidence related to, there was a direction made not to put a USB stick into the computer slot within your office. Is that correct?---Yes.

And it's possible isn't it that a secretary may forget or not follow that direction and in fact put the USB key in. Is that correct?---Yes.

40 And I put it to you that perhaps you don't, you just can't remember the preparation of that letter and your signing of that letter because you've got a lot on your plate, so to speak. That's correct isn't it?---No. It's a very unusual letter and document. I would remember it.

And Dr Burton, that letter was discussed at the meeting with Vern and David Pleiksna, which on my instructions occurred on, in early May, 2009. That's correct isn't it?---I can't remember.



Do you accept there's a possibility that that letter was discussed at that meeting?---Yes.

Yes. You don't deny that there's a possibility it was discussed?---Well, I have no memory of it.

10 THE COMMISSIONER: The letter's, the letter discusses a number of things. I suppose the most important thing is that the, that the, that the subject of the letter concerns Medex tests that have been carried out on 10 patients. It doesn't say where and it doesn't say what hospital. So is it, there are a number of questions that can be put in connection with this letter because of the, the overall vagueness of it. And one of the questions is that at the meeting there could have been a discussion about past tests conducted through the Medex instrument?---Yes.

And were there discussions about that?---Yes, in my notes, which is on the file, we've discussed five or six different studies that were being, in the pipeline I think they called it (not transcribable).

20 And, and they could have a discussion of the merits of the Medex test as a cervical cancer screening device?---Yes.

But there are other aspects, like I'm not sure what's been put as to what aspects, well what, also what could have been discussed is the very letter, in other words this letter of 6 May, 2009, which you've signed, it could have been a discussion about that, for example?---Yes.

But as I understand your evidence there was not?

30 MS FURNESS: I think the witness' evidence was he has no memory.

THE COMMISSIONER: Well, no memory, well, was there a discussion of a letter dated 6 May, 2009 which you signed?---I've got no memory of that. It's not on my file note either so- - -

MS SOARS: And just to repeat that, was there a discussion of any tests that had been carried out on cervical, on patients at Royal North Shore at that meeting?---No, definitely not.

40 Dr Burton, you- - -

THE COMMISSIONER: Sorry, was there a discussion of any tests that were carried out at any particular named hospital at that meeting?---I can't remember, Your Honour. There was a general discussion. I think we might have had a discussion about Nepean Hospital and there was a colo-rectal-type study going on out there. Professor, starts with a W, I have a memory of that vaguely, emphasising the vaguely.

Yes.

MS SOARS: Dr Burton, you gave some evidence that my client came to you with a protocol which you discussed fairly early on in your meetings with her. Is that correct?---Which, which protocol?

Well, her evidence is that she came to you with a protocol.

10 THE COMMISSIONER: I think that one was put to Professor Burton. Is that the one you're referring to?

MS SOARS: Was, was one actually put to Professor Burton?

THE COMMISSIONER: I'm not sure if it was a protocol or not. I think so.

MS SOARS: I'll check with my learned friend. Have you got a copy of that protocol, of the proposal? Do you have a copy of that? Sorry. Let me take you to (not transcribable) Thank you. Paragraph 11 of your statement. Do you have that?---No, that was taken to Sue Valmadre.  
20

So just so we can be clear, you're referring in that paragraph to a document, the protocol document. Is that correct?---Yes.

And it was given to you at that meeting. Is that correct?---Yes.

And what is your evidence as to what happened to it?---It was, I asked her to take it to Sue Valmadre and show it to her.

30 And you didn't retain a copy?---No.

Can I show you a document. I want to see if it is the document that you were shown at that meeting.

THE COMMISSIONER: Sorry, is this a document that's previously been in the Commission's possession?

MS SOARS: It came from my client, Mr Commissioner. I'm not sure if it comes from the documents- - -

40 THE COMMISSIONER: Well, the practice is that no document should be produced without being put to counsel assisting.

MS SOARS: I apologise, Commissioner.

THE COMMISSIONER: And I'm really surprised that there's a document produced now at this stage that has not previously been shown to the Commission.

MS SOARS: I'm not, I, it would have formed part of my client's records which the Commission has in the entirety of her records.

THE COMMISSIONER: Well, that's why I asked whether this is a document that's been given to the Commission.

MS SOARS: I think it's a matter for the Commission's lawyer to let us know, I apologise, Commissioner, so- - -

10 THE COMMISSIONER: Right. Thank you.

MS SOARS: It was only that the detailed questioning I became aware of it.

MS FURNESS: It's similar to but not (not transcribable)

THE COMMISSIONER: I mean I think if it's not a document that's been part of the documents given to the Commission we will need an explanation as to where it came from and why it wasn't given, but I don't want to stop the cross-examination now so this can be done later.

20

MS SOARS: Thank you.

THE COMMISSIONER: And it may not be, it may not be a different document so- - -

MS SOARS: Could I just get it marked for identification at this stage, Commissioner- - -

30 THE COMMISSIONER: Yes.

MS SOARS: - - -and then ask some questions if appropriate? Dr Burton, have you had- - -

MR ALEXIS: Commissioner (not transcribable) indicate that we're seeking to determine one way or the other whether the protocol document that's been provided was previously made available to the Commission and (not transcribable) indicate that as I understand it.

40 THE COMMISSIONER: Yes, I understand.

MR ALEXIS: (not transcribable) in a position to respond (not transcribable)

THE COMMISSIONER: Yes, I understand that. The document can be tendered as an exhibit, Ms Soars, I'm not stopping its tendering, but I mean it has, there are implications if it hasn't been previously produced.

MS SOARS: I understand, Commissioner.

THE COMMISSIONER: That's all.

MR HOGAN: So may I assist, it is very similar to Exhibit 4 which is a Clinical Study Protocol.

THE COMMISSIONER: Yes, thank you, Mr Hogan.

10 MS SOARS: Dr Burton, have you had a chance to look at the document I handed to you?---Yes.

Commissioner, just for the transcript, could it be given a MFI reference at this stage?

THE COMMISSIONER: Are you going to tender it?

MS SOARS: I'm happy to tender it.

20 THE COMMISSIONER: All right. The Clinical Study Protocol with the heading, Study Synopsis, is Exhibit 27.

**#EXHIBIT 27 - CLINICAL STUDY PROTOCOL WITH THE HEADING SYNOPSIS**

30 MS SOARS: Dr Burton, this is the protocol that my client came to you and she discussed with you which is referred to in paragraph 11 of your statement. Is that correct?---Just show me paragraph 11, please. (not transcribable) No, this is not the document.

And why do you say that?---Well, it's, it's (not transcribable) it's on patients with abnormal, if I go to the third paragraph, the third block on the first page, there's 200 female patients with abnormal Pap test, 200 female random patients with breast disorders and 200 male patients undergoing prostate biopsy. It's not what we were talking about. This is cut and paste from the online document that's in this. It's the same. It's part of the big, you know, the big protocol that was put in.

40 MS SOARS: Excuse me for a moment, Commissioner, I'll just, is it possible, Dr Burton, that my, my client came to you with a proposal for 200 patients which you discussed in terms of a pilot even though the original proposal was for 200 patients. Is that possible?---(NO AUDIBLE REPLY)

THE COMMISSIONER: Sorry, I may have misheard you. Do you mind repeating the question?

MS SOARS: Is it possible, Dr Burton, that my client came to you with a proposal with had 200 patients in it but in the course of discussions with you, the discussions related to a pilot of that clinical trial proposal. Is that correct?---(NO AUDIBLE REPLY)

THE COMMISSIONER: With a lesser number of patients?

MS SOARS: With a lesser number of patients, Commissioner?---Are you referring to this document?

10

Yes?---No. It's a 600-patient document.

Well, I'm only referring to the, the patients, female patients with abnormal Pap tests.

THE COMMISSIONER: Are you talking about a different protocol?

MS SOARS: No. I think Dr Burton's referring to the third paragraph.

20

THE COMMISSIONER: Yes. No. He was. But my question is, in putting the question to Dr Burton, are you referring to some other protocol, not Exhibit 27, or are you referring to Exhibit 27?

MS SOARS: I was referring to Exhibit 27, Mr Commissioner.

THE COMMISSIONER: So then you have to say, is it possible that this, this proposal exhibit, this protocol, Exhibit 27, was put before Professor Burton but they discussed a pilot, but in addition they discussed a pilot project of ten. Is that right?

30

MS SOARS: That's correct, Commissioner?---It's not to my memory.

Thank you, Dr Burton. That's all, Commissioner.

THE COMMISSIONER: Yes, thank you. Mr Hogan?

MR HOGAN: Commissioner, could I just ask my learned friend to just confirm her instructions as to the providence of this document and whether or not we should understand that Exhibit 27 is said to be a Clinical Study Protocol that was provided to Dr Burton by Sandra Lazarus? It would help us to know whether that's the position or not.

40

MS SOARS: Commissioner, that was my understanding but the instructions were taken on the run and - - -

THE COMMISSIONER: Yes, I understand that.

MS SOARS: I am happy to - - -

THE COMMISSIONER: You, you can tell us tomorrow morning.

MS SOARS: If that's possible.

THE COMMISSIONER: Yes. Mr Hogan.

MR HOGAN: Yes, thank you, sir.

10 My name's Hogan. I am a barrister representing Michelle Lazarus.

THE COMMISSIONER: The real Michelle Lazarus.

MR HOGAN: Thank you, sir, not the second young lady that stood up?  
---Thank you.

And your evidence is clear that the woman who first came and saw you and outlined a proposal who you now know as Sandra, the women that (not transcribable) the meeting in May 2009 is who you now know to be Sandra  
20 and the woman who showed you the form which is the web access document is Sandra?---Yes.

The same person on each occasion. Now, you mentioned in your statement that that person provided you with an article, paragraph 18, a medical article, in relation to the detection and diagnose of breast cancer?---Which paragraph?

Paragraph 18 of your statement, professor. Did you keep a copy of that article with your file in relation to this matter?---No.  
30

And to the best of your recollection you state it was a, well, was it, was it an article in relation to the detection and screening of breast cancer using bioelectrical impedance analysis method, something like that?---Breast cancer might be overstating but it was looking for abnormal breast changes, yes.

And you were making your statement on 9 July, 2010 and you're casting your mind back to events to 2008 in that paragraph and you remember that associated with that article was Professor Ross Smith, the last line of that  
40 paragraph?---No, I think it was a - - -

Or not?---The literature doesn't have Ross Smith in it at that stage, I think that - - -

All right. Now, in relation to the draft application for ethics approval and the covering letter at page 151 which is in the white folder at the front of you, and my friend's asked you about this, you see that the research PhD

student Sandra Lazarus is nominated in the letter which you read when it came into your in-tray?---Yes.

And then at several places throughout the application, for instance at paragraph, page 156 in the white folder, again the nominated research PhD student is Sandra Lazarus?---Yes.

Then again on page 163 all research personnel are listed including yourself at item 17 on 163?---Yes.

10

And then on page 184, name and position of contact person for any concerns Sandra Lazarus again and then yourself and three other professors and doctors?---Yes.

And you saw, did you observe that at the time when you looked at it in your in-tray, did you observe that Sandra Lazarus or indeed that there is no mention at all of Michelle Lazarus anywhere in the documentation then? ---I noted it, yes.

20 THE COMMISSIONER: Sorry, I beg your pardon?---I noted it, it was - - -

MR HOGAN: All right. And you've given evidence that you had a conversation with Professor Ross Smith in relation to his dealings with who you thought was Michelle Lazarus. Could it be the case that he was talking to you and he did have only discussion with you about a Sandra Lazarus and that you've confused the names?---The discussion was, you know, a very informal one. I can't remember, I would have said Michelle Lazarus but I can't remember what Ross would have said.

30 All right. But certainly when you had a look at this application and the covering letter you, you observed that it was Sandra Lazarus who's the PhD research, medical researcher?---Yes, the name on the document is Sandra Lazarus.

All right. And similarly in relation to your discussions with Dr Sue Valmadre could it be that she informed you that she was having dealings with Sandra Lazarus and you've blurred them?---The discussion with Sue Valmadre is more around what's happening, you know, is anything going on. I can't remember the names. I would have called her Michelle and - - -

40

Yes?--- - - - I can't remember anything more than that.

Could it be that the application for access to network services which you've, is attached is your statement and certainly is in the name of Michelle Lazarus and you said that you now know it to be Sandra Lazarus who attended on that day and obtained your signature on that document, could it be that that's, may have led to some confusion about the name, where you

had the first meeting, the Pleiksna meeting?---No, I always thought I was dealing with Michelle Lazarus.

All right. When you were asked this morning by counsel assisting you were asked whether you had met perhaps Michelle and Sandra Lazarus, you answered, "I think I've only met one woman." Do you recall giving that evidence?---Yes.

10 And also you were again asked whether you, no, I withdraw it, you said, "My memory is I only saw the same woman the whole time." Do you concede the possibility that you may have had a short meeting with Michelle Lazarus, that is the real Michelle Lazarus, the second woman who stood up, at your, at the Royal North Shore Hospital about another matter? ---No, I've never met her.

20 All right. By you choosing the words "I think I've only met one woman," do you agree that that does have an element of that you're conceding the possibility it's, it's the best recollection you have, you think it's one but it could have been two woman?

MS FURNESS: Well, Commissioner, I object on the basis that that evidence was given by this witness at the very beginning of his examination. Since then he has been shown or had observed two young women and he has clearly identified which was the woman on each occasion that he dealt with.

THE COMMISSIONER: I think the question's fair?---Could you say it again.

30 MR HOGAN: Well, when you were being asked by counsel assisting the question whether, whether you may have met Michelle and Sandra Lazarus or two, two women and you supplied this, "I think I've only met one woman." I'm asking you by that answer do you concede that there's a level of uncertainty?---No.

Or a possibility that you may have met more than woman?---No.

40 Because you said, "I think I've only met one woman," you didn't say I only ever met one woman?---What's your question?

Do you concede there's a possibility by your answer that your memory I only saw the same woman the whole time or I think I've only met one woman or indeed I thought I was dealing with one woman, I think I've dealt with the same person every time, you haven't locked in with the sort of level of certainty which you now assert, do you agree with that?---I'd have to say the question again is (not transcribable).

(not transcribable).



THE COMMISSIONER: I really think that you, you have flogged this horse.

MR HOGAN: Exhausted the, yes.

I want to suggest to you that you had a meeting with the second woman who stood up in 2008, late 2008?---That's not true.

10 You do agree that with the passage of time you may have made some errors in relation to when you saw people, for instance the Pleiksna meeting, you thought was October and now your best recollection is that it's probably May?---Yes.

MS FURNESS: I object to that, Commissioner.

MR HOGAN: Did you, can see the possibility that you may have mixed up the names Michelle and Sandra because of the application for network services which was signed Michelle?---No.

20

I want to suggest to you that in late 2008 you did indeed meet Michelle Lazarus, the second woman and you had a conversation about the marketing of the device, the Medex device. Do you agree that's a possibility?---No, that's not true.

And she, I want to suggest that she, in relation to the, the draft application, you're listed there as a point of contact. Are you there also as a principle investigator, in that the draft application which is page 152 onwards, your - - -

30

THE COMMISSIONER: Does it not speak for itself Mr Hogan?

MR HOGAN: Yes. It has you listed as a contact person, but not principle investigator, however the covering letter refers to you as an investigator of the matter. Your evidence is that it was only ever a draft anyhow and your dealings with Ms Lazarus were in relation to a proposed pilot programme. Is that right?---Sorry, say the question again?

40 Well you've given evidence that, that the proposed pilot programme, you weren't to be a principle investigator in that, you were a, because you're the head of department. Is that right?---Yes.

Okay. Well I, I want to suggest to you that Ms Michelle Lazarus had a short conversation with you at, at Royal North Shore Hospital where she told you that some of the marketing that she'd be involved in and that given that Royal North Shore Hospital is where a pilot trial was being conducted, that would be good for the hospital, something along those lines?---That's not true.

And you had, I suggest a conversation where - - -

THE COMMISSIONER: On the same date?

MR HOGAN: On the same day, this is late 2008.

10 THE COMMISSIONER: But Mr Hogan, the evidence is, you don't have to put it all, Mr, Professor Burton denies that there was a conversation with Michelle Lazarus - - -

MR HOGAN: About marketing.

THE COMMISSIONER: - - - about marketing. And I don't think - - -

MR HOGAN: Yes, I think that's right, sir. Was marketing discussed at the Pleiksna meeting on 6 May, 2009 or you can't recall?---Looking at my notes, am I allowed to look at my notes?

20 Yes?

THE COMMISSIONER: You'll find it within the statement.

MR ALEXIS: Professor Burton, Commissioner, is going through his notes, we should have objected to the question, it hasn't been answered in substance and perhaps when my learned friend re-puts the question he ought to take out the assumption that 6 May was accepted as the date of the meeting.

30 MR HOGAN: Yes.

THE COMMISSIONER: Did you find the notes?---Yes. Can you screen down a little for me. There's nothing written here in my notes, but my memory is that we discussed the issue of the marketing of the results.

MR HOGAN: Yes?---And the trial.

40 Right. And in your statement at paragraph 29 you state that there was discussion about the funding of the research trials and in your mind was there any problem the company, Medex Test Corporation Pty Limited funding research trials?---No.

And at paragraph 32 you state that you noted finances must be transparent and independent of consultants. What did you mean by that?---The finances have to be sort of held by a separate entity and be seen to be, everyone can see what's going on all the time with the finances. And regardless of the, the paper turns out to be supportive of a, of a, of this test or not, the finances would be locked in. It's more about the results than the - - -

And that's why you had the, whatever the results they would have to wear, live with the results in paragraph 35?---Yes.

And would there be any problem with the owner of the unit Medex whatever corporate vehicle paying the researches?

THE COMMISSIONER: Directly, directly?

10 MR HOGAN: Paying them directly?---Yes.

There would be a problem with the integrity of the tests?---Yes.

What about if the corporate people, Medex in whatever from paid the money into a trust account with the hospital which then paid the researchers? So using like the hospital as a conduit?---That would be the, if it's a pilot, yeah, that's fine.

20 Yes. And that's in paragraph 35 you state that Ms Lazarus contacted you and gave you that mobile phone number. See that, paragraph 35?---No, that's - - -

I'm sorry, I've (not transcribable) the wrong paragraph. I'm looking for the one in relation to where you gave out the trust account number, paragraph 43?---Yes.

All right. And that was presumably so that funds from Medex would be put into that account?---Yes.

30 Yes, thank you. Nothing - - -

THE COMMISSIONER: Ms Furness.

MS FURNESS: No, I have no questions of the witness.

THE COMMISSIONER: Yes, Mr Alexis.

40 MR ALEXIS: Just in relation to the last question, sir, concerning the provision of the trust account number and the suggestion of that account being available to receive a deposit of monies, did you ever hear or learn as to whether any monies had been deposited at all in relation to any trial concerning the Medex device?---No money was ever deposited.

And is that, is your evidence in that respect based on the inquiry you've made and a response to that inquiry?---Yes.

Who did you inquire of?---Professor Jonathan Morris.

And the response to that from him was that the trust account had not received any monies?---Yes.

All right. Yes, thank you, professor. And I seek to have Professor Burton excused from further attendance to the Commission.

THE COMMISSIONER: Yes. Professor Burton, thank you for your evidence?---Thank you.

10 And you're excused. Thank you.

**THE WITNESS EXCUSED**

**[4.38pm]**

MR ALEXIS: Commissioner, could I seek confirmation for the benefit of those appearing before the Commission in relation to the programme for tomorrow, should we understand that you're proposing to rise at lunchtime?

20 THE COMMISSIONER: Yes.

MR ALEXIS: Thank you.

THE COMMISSIONER: Are we starting at, what time are we starting tomorrow?

MR ALEXIS: 10.00am.

30 THE COMMISSIONER: 10.00am. We'll adjourn until 10.00am.

**AT 4.39pm THE MATTER WAS ADJOURNED ACCORDINGLY**

**[4.39pm]**