COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Reference: Gene patents

TUESDAY, 4 AUGUST 2009

MELBOURNE

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SENATE COMMUNITY AFFAIRS

REFERENCES COMMITTEE

Tuesday, 4 August 2009

Members: Senator Siewert *(Chair)*, Senator Moore *(Deputy Chair)*, Senators Adams, Boyce, Carol Brown and Williams

Participating members: Senators Abetz, Back, Barnett, Bernardi, Bilyk, Birmingham, Mark Bishop, Boswell, Brandis, Bob Brown, Bushby, Cameron, Cash, Colbeck, Jacinta Collins, Coonan, Cormann, Crossin, Eggleston, Farrell, Feeney, Ferguson, Fielding, Fierravanti-Wells, Fifield, Fisher, Forshaw, Furner, Hanson-Young, Heffernan, Humphries, Hurley, Hutchins, Johnston, Joyce, Kroger, Ludlam, Lundy, Ian Macdonald, McEwen, McGauran, McLucas, Marshall, Mason, Milne, Minchin, Nash, O'Brien, Parry, Payne, Polley, Pratt, Ronaldson, Ryan, Scullion, Sterle, Troeth, Trood, Wortley and Xenophon

Senators in attendance: Senators Adams, Boyce, Heffernan, Humphries, Moore, Siewert and Williams

Terms of reference for the inquiry:

To inquire into and report on:

The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

(a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:

  (i) the provision and costs of healthcare,

  (ii) the provision of training and accreditation for healthcare professionals,

  (iii) the progress in medical research, and

  (iv) the health and wellbeing of the Australian people;

(b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of the any matters identified by the inquiry; and

(c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

WITNESSES

Committee met at 8.59 am

DAVIES, Dr Trevor John, Councillor, Institute of Patent and Trade Mark Attorneys of Australia

ROURKE, Dr Ian Jeffrey, Partner, FB Rice and Co.

SLATTERY, Mr John, Consultant, Davies Collison Cave

CHAIR (Senator Siewert)—Welcome. The Senate Standing Committee on Community Affairs is continuing its inquiry into gene patents. I welcome representatives from the Institute of Patent and Trade Mark Attorneys of Australia, Davies Collison Cave and FB Rice and Co. I understand that information on parliamentary privilege, the protection of witnesses and evidence has been provided to you. We have received your submissions. I invite each of you to make a brief opening statement and then we will ask you some questions. We have set aside a substantial time; we have an hour and a half with you. Thank you for making that time available. We tend to do a little bit more of a discussion process when we have a bit more time and we share the questions around. I invite whoever wishes to commence to do so, but if each of you wishes to make a statement, that is fine.

Dr Davies—The Institute of Patent and Trade Mark Attorneys, IPTA, represents over 90 per cent of Australian patent attorneys. IPTA is of the view that the Patents Act does not require amendment as the law as it presently stands adequately protects innovators and the public in relation to human and microbial genes and non-coding sequences, proteins and their derivatives, including those materials in an isolated form.

Contrary to some assertions, valid patents do not cover naturally occurring genes or biological materials when present in nature. Patents do not result in an individual's genes or genetic make-up being owned or controlled by third parties. IPTA refers the community affairs committee to the Australian Law Reform Commission report No. 99 of 2004 entitled, 'Genes and Ingenuity: Gene Patenting and Human Health'. The ALRC report did not identify any fundamental flaws in the patent law and practice, and found that the Patents Act should not be amended to exclude genetic materials and technologies from patentable subject matter. Rather, the ALRC's report found that social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of a patented invention, and not patentability per se.

Mr Slattery—On behalf of Davies Collison Cave I submit, firstly, that the matters set out in the terms of reference are matters which have been dealt with previously at length in a number of inquiries, including the ALRC report to which Dr Davies has just referred. My submission is that the implementation of the recommendations of these reports is appropriate and important, and will go a long way towards addressing many of the concerns which the general public seem to have in relation to the matters raised in the terms of reference.

I would also like to emphasise that the issues raised in the terms of reference of the present inquiry are encompassed already by an ongoing inquiry by the Advisory Council on Intellectual Property, ACIP. In our submission we think it would be appropriate to await the ACIP report and any recommendations from that report before any action is taken as a result of this inquiry.

Finally, and perhaps more generally, I submit that any amendment to the Patents Act to prohibit the grant of patent protection in respect of these so-called genetic patents or genetic materials will be in conflict with Australia's obligations under international agreements, particularly the so-called TRIPS agreement, the Agreement on Trade-related Aspects of Intellectual Property Rights, and the Australia-US Free Trade Agreement. It would not only be in conflict with those international agreements but also would constitute a move away from harmonisation of Australia's patent laws with the patent laws of other major jurisdictions, particularly the US and Europe.

Dr Rourke—The patent system promotes the disclosure of scientific advances by providing a short-term monopoly. The Department of Innovation, Industry, Science and Research estimated that in 2008 and 2007, venture capital and later-stage equity alone invested over $1.2 billion for research in Australian biotech, pharmaceuticals and health sectors. Furthermore, as at June 2008, the department identified 487 Australian biotechnology companies, both listed and private. Restricting patentable subject matter in the area of medical research can lead only to less funding, a loss of jobs and logically a decrease in the rate of advances in medical science.

Picture this: a company investing in medical research identifies a link between a human gene sequence and a disease. If this important development cannot be patented, there is absolutely no incentive for the company to disclose this information. The company might as well keep its invention as a trade secret and embark on the long journey of trying to develop a drug which they might then be able to patent. Thus the limiting of patentable subject matter will promote secrecy and a reduced rate of disclosure in the field of medical research.

Like most things, the patent system is not perfect. Governments should be looking at measures for improving the system while rewarding investment to assist in the advancement of medical research. Unlike section (c) in the terms of reference, sensible examples of such measures include recent IP reviews into experimental use exemptions, raising the standards of examination, and reducing the complexity of patent oppositions.

CHAIR—Senator Heffernan, you can start questions.

Senator HEFFERNAN—In your document you say in (c) Patents—can you go to that?

Dr Rourke—This is in ours?

Senator HEFFERNAN—I believe it is yours. Wait a minute, it might not be yours.

Senator MOORE—There are three. It is submission No. 31. Which one do you want?

CHAIR—Yes, which is 31.

Senator HEFFERNAN—Well, it is on page three.

Dr Rourke—I do not have a page three.

Dr Davies—Which person's submission?

Senator HEFFERNAN—It is from the Institute of Patent and Trade Mark Attorneys of Australia.

CHAIR—It is submission No. 31.

Senator HEFFERNAN—Right. You say:

A patent is a limited monopoly … For an invention to be patentable … it must be a manner of manufacture within the meaning of section … In return for obtaining a patent, the inventor must fully describe the invention including the best mode for carrying out the invention at the time of … the patent application.

That is pretty sensible, is it not?

Dr Davies—Yes.

Senator HEFFERNAN—In the case of patent application Australia 2004200978B2, 'A diagnostic method for epilepsy', there is no diagnostic method.

Dr Davies—I do not have a copy of that patent in front of me.

Senator HEFFERNAN—There is not an invention like that. They have patented something that does not exist, and there are several cases of that. There is a haemophilia one. They are shaking their heads down the back, but we will see. There are three that have been patented for something that does not actually exist.

CHAIR—You had better explain a bit more what you mean because we went into the epilepsy one all day yesterday, so we know a bit more about it. But you had better explain what you mean when you say, 'You have patented something that doesn't exist.'

Senator HEFFERNAN—The patent says it is 'A diagnostic method for epilepsy'. That is the title of the patent. So you go inside the patent and it says, 'Abstract: A method for the diagnosis of SME1 in a patent comprising detecting an alternation', which is the gene mutation for epilepsy. Right? It is the diagnosis of it.

Dr Davies—Yes.

Senator HEFFERNAN—You go further into the patent—the boundaries of the patent monopoly—to the claims, such as '1. A method for determining the likelihood that a patient's suspected …' and then it refers to testing a sample. It then states that what they have done is patented 'any method' for the test in a generalisation, which excludes anyone else doing the test or having a test. You go further into the patent and it defines the gene that is part of the claim. It actually patents the isolated gene, so no-one else can do the work on the gene.

Mr Slattery—No, that is not true.

Senator HEFFERNAN—Tell me why it is not true.

Mr Slattery—Other people can do research into the gene. They can research the gene. You just made a statement that no-one else can use the gene. That is not correct.

Senator HEFFERNAN—This mob have the patent on the isolated gene. If you want to use it—as evidence that we have taken from several witnesses indicates, including—

Mr Slattery—But you cannot use it commercially as distinct from biomedical research.

Senator HEFFERNAN—Yes, they want to use it. Like the mob down there at Westmead Hospital, who were asked to surrender all their research and data they had on patients from whom they had collected samples back in the nineties: they were asked to surrender the research, or face litigation in return for. Do you reckon that is a reasonable thing?

Mr Slattery—I do not know the circumstances of it but—

Senator HEFFERNAN—I will bet you do not know the circumstances, and do not want to know.

Mr Slattery—At one stage we are talking about a diagnostic method, and at the next stage you are talking about a claim to a gene.

Senator HEFFERNAN—The actual patent includes the gene.

Mr Slattery—He has a claim for the isolated gene, I understand.

Senator HEFFERNAN—Yes. So that excludes anyone else unless they go through the business.

Mr Slattery—They can give permission.

Senator HEFFERNAN—So if you are tucked away in a laboratory somewhere—I mean there is no-one here who knows. You have not read this, I will bet you.

Mr Slattery—No, I have not.

Senator HEFFERNAN—So how do you expect a technician in a laboratory somewhere, who has given their life's work of research to something, to know that some group of bankers and bloody financial planners somewhere have a patent on the thing. As the evidence we have had indicates—and as the evidence I have received indicates, which will come before this committee eventually—people, who have done their well-meaning 10 years of research, have written their letter to someone and got a letter of litigation back because they had a gene patent that the people did not know about. Do think that is the way we ought to do medical research?

Mr Slattery—In the commercial world, people who are doing research conduct what are called freedom to operate searches. They investigate the situation, or the technologies that they are going to do research into, at an early stage. Freedom to operate searches are things which are done by patent attorneys at an early stage in a research program to identify what patents and other things may be in existence—what prior right might be in existence.

Senator HEFFERNAN—This is legal gobbledy-gook. You said earlier on the report of the national whatever it is in—

Senator ADAMS—In 2005, the ALRC report.

Senator HEFFERNAN—What is the name of the body?

Mr Slattery—The Australian Law Reform Commission.

Senator HEFFERNAN—Yes, the Law Reform Commission's report. The reason that they said, 'Leave it as it is', as you would be well aware, was not because they addressed the challenges that I have referred to, such as the monopolisation of research. It was not because of that at all. It was because they said, 'We're too far into this system. We've issued these patents. They would be too bloody complex to unscramble the egg', as it were. That was the main driver behind that. It would become a nightmare to sort it out. You do not agree with that?

Dr Davies—No, I do not agree with that, Senator.

Senator HEFFERNAN—Tell me what you agree with. But that was in their proposition. Do you agree with that? They did say that—because we were so far into the process—

Dr Davies—No, I do not know that I agree they said that.

Senator HEFFERNAN—What do you think they said. Put it on the record.

Dr Davies—They reviewed the system and believed that the system, how it stood, did not need significant changes.

Senator HEFFERNAN—Why did they justify that, or have you not read it?

CHAIR—Hang on.

Dr Davies—I have read it.

Senator HEFFERNAN—What did they say?

Dr Davies—I cannot recall what the underlying justification was.

Senator HEFFERNAN—In ordinary man's language, what I interpreted them to say was that because we have layers of lawyers and layers of agreements and layers of patents, we are too far in. That has been said to this committee, and that is fair enough. It is a reasonable argument. But that was really the main driver. They did not actually address the complexity of what I have just spoken about, which is: how do you unscramble the egg? The restrictions absolutely have put away a lot of well-meaning, dedicated, vocationally driven people, who are doing research for the good of human kind, and at the mercy of people who have separated it out into financial trading instruments. I will tell you where this is going to go, and you blokes are probably part of the gravy train. What is going to happen eventually is exactly—

Senator HUMPHRIES—Chair, I am sorry. I appreciate that Senator Heffernan wants to go in hard, and that is his right, but—

Senator HEFFERNAN—That is not hard. It is soft.

Senator HUMPHRIES—But these people have come here in good faith to give evidence, and they do not need to have motives aspersed by being here.

Senator HEFFERNAN—That is fair enough. All right, I withdraw that.

CHAIR—Make your point, but do not make personal comments.

Senator HEFFERNAN—I do not always do that. All right—but you have to make allowances for passion. But with water, they separated land from water. I objected strongly. I contended that the only purpose and people who ought to be allowed to trade water are the environment, the farmers and the urban water users. We are separating with a paper tradable title, which gene technologies agree they can trade if they go bust, and we will have people who own all these patents and who are just financial traders. That is what is going to happen eventually, I will bet you. These will just become another river of gold. Would you explain to me how you can issue a patent for something that does not exist? Certainly you are saying that you are hoping to get a solution, but you do not have one. How do you patent something that does not exist? The patent says 'A diagnostic method for epilepsy'. In trying to tie up the diagnostic method, they are saying, 'But we need to claim the isolated gene.'

Dr Rourke—No.

Senator HEFFERNAN—Well, it says so here.

Dr Rourke—There are two fundamental types of claims in a patent: one is a process, one is a product. You do not need to have the product patented—for example, a gene sequence—to have a valid method to the claim for diagnostic method.

Senator HEFFERNAN—Yes, but do you want me to take you through all the patents that actually do that?

CHAIR—Before we go there—

Dr Rourke—We can go through a thousand patents.

Senator HEFFERNAN—Yes, but they claim the isolated gene.

Dr Rourke—Yes.

Senator HEFFERNAN—They do not own the gene, and they do not own your body—as you are trying to say we are saying, which is a colourful way to put it. No: they claim the isolated gene, which allegedly is an inventive step. Do you think it is an inventive step?

Dr Davies—The Patent Office considered that it was an inventive step at the time the patent application was filed—

Senator HEFFERNAN—That is right, but—

Dr Davies—And was examined under our laws.

Senator HEFFERNAN—That is right, but a modern-day scientist would say, 'Anyone could do it these days.'

Dr Rourke—That is appalling because—

Senator HEFFERNAN—Others do not say that.

Dr Rourke—When it comes to unravelling complex familial genetics, that is a massive task.

Senator HEFFERNAN—That is why you think it is still an inventive step.

Dr Rourke—That takes an awful lot of years.

Senator HEFFERNAN—You think it is still an inventive step.

Dr Rourke—You are calling a lot of scientists who publish nature papers—I do not know whether it was published. It was probably published in *Nature* or a very high-impact journal. Are you saying that they are just a bunch of dull people and anyone could do it?

Senator HEFFERNAN—No. I did not. I did not say that at all.

Dr Rourke—That is what you said.

Senator HEFFERNAN—Excuse me—

Dr Rourke—You said that anyone could do it.

CHAIR—Hang on, hang on.

Senator HEFFERNAN—I did not.

CHAIR—One person at a time!

Senator HEFFERNAN—I said that I do not think that the isolation of the gene from the human body these days is an inventive step.

Dr Rourke—So you are saying that it is simple.

Senator HEFFERNAN—Yes.

Dr Rourke—That is how I understood it.

Senator HEFFERNAN—The technology is complete.

Dr Davies—I will make a comment: 'inventive step' is considered at the time the patent application is filed.

Senator HEFFERNAN—I understand that.

CHAIR—Let him finish.

Dr Davies—It is state of the art at that time. So 10 years or 20 years after maybe the first gene was isolated or there was mutation in a gene which was recognised had some disease implication, at that stage it was considered an inventive step. Today if someone filed a patent application for a particular mutation, the inventive step would be considered against what is known now and at the state of the art.

Senator HEFFERNAN—I understand that.

Dr Davies—As technology evolves, then what is considered to be inventive now might be quite different from what was considered inventive five or 10 years ago.

Senator HEFFERNAN—That is fair enough.

CHAIR—I just want to follow that up. The implication of what both of you have just said, and evidence we heard yesterday, is that perhaps the patents that were granted in the past over gene sequences would not necessarily be granted now. Is that it?

Mr Slattery—Absolutely correct, particularly because, as Dr Davies said, the state of the art, the prior art today, is quite different to what the state of the prior art was 20 years ago. It has to be adjudged.

CHAIR—Let me follow this up.

Mr Slattery—It is not possible to address these things with the benefit of hindsight. They have to be looked at as at the relevant date—what we call the priority date.

CHAIR—To follow up from that, it would seem to me to say, 'Okay, you wouldn't grant patents over certain sequences or the same process that you had in the past.' Therefore some companies or some entities now own gene sequences that you would not allow now.

Mr Slattery—Which you may not allow now.

CHAIR—That you may not allow now.

Dr Davies—That is correct.

CHAIR—So the argument that is being put to us is: that the system works okay now, and that if you change the system, it will be an unequal playing field because you will have some people who have patents over genes that would not be allowed if you changed the system.

Mr Slattery—Yes.

CHAIR—But it seems to me that you have a situation in which people or entities will not be able to own genes under the same circumstances because we know more.

Mr Slattery—No, I do not think it is quite like that. You might not grant patents now that you would have granted 10 years ago because the prior art has changed, not because the system needs changing. Even today there could still be circumstances in which, in my view, an isolated nucleotide sequence would be patentable because it met the requirement of novelty inventive step and usefulness. It could still be patented in a particular circumstance.

Senator HEFFERNAN—Given that the law, as I am instructed this morning by some backroom wise people, has been in place for 80 years, has it?

Senator ADAMS—The IP law?

Senator HEFFERNAN—IP.

CHAIR—Are you talking just in general now, are you?

Senator HEFFERNAN—Not 20 years, or whatever, but it has been in place for a long time.

Mr Slattery—It was 1990.

Senator HEFFERNAN—Is it not possible, like a lot of things, that technology overruns the law eventually and you need to amend the law? Is that not what is happening here? Can I just point out that this patent application was 10 March 2004. We are well into the ordinariness, which is a quaint use of words, but the uneventfulness of the isolation of a gene. I mean, it is still great work, and there is still work going on in all the laboratories with the bankers and everyone who are into it, including the lawyers who are into it and getting a smidgen of money out of it, but what I am worried about is that eventually they will be the only ones. If these things are tradable certificates like an exploration licence or a share certificate—

Mr Slattery—It is a piece of property.

Senator HEFFERNAN—Yes. That is exactly right. If someone goes bust, they put it on the market. You can have someone living up on the Gold Coast, looking out over the surf, who owns all the IP.

Mr Slattery—But that is not the fault of the patent system, Senator.

Senator HEFFERNAN—No.

Mr Slattery—That is what you have when you have a company whose property is in stocks.

Senator HEFFERNAN—But it is a fault to challenge nature and the human race in that we want a reasonable outcome for health. Bear in mind there are 69 million people in the US who will retire in the next four years who cannot at the present time fund their health requirements. We want to get a good outcome. You may laugh, but it is true. The US is technically insolvent. You may think this is a joke. I do not think it is a joke at all.

Mr Slattery—I do not think it is a joke.

Senator HEFFERNAN—Because we are receiving evidence of good vocationally driven people who are being intimidated because somewhere locked away in a bank somewhere, there is a tradable instrument that says, 'You pay me, or you don't proceed.' That is actually what is happening. You think that is a good thing?

Mr Slattery—I do not think it is. I do not understand the full scenario, but I think the system is dealing with property rights. This is a form of property. If the property exists then other people respect the property. As I said to you before, I act on behalf of quite a large number of research entities around Melbourne. As they are doing the research, when it is getting to the stage where it is looking as though there will be a favourable outcome from the research, we advise them to do what I indicated earlier, freedom to operate searches. Do searches to understand the field of the technology and the property rights in the technology you are working in.

Senator HEFFERNAN—I accept that.

Mr Slattery—That is good practice.

Senator HEFFERNAN—I accept that, but what you are saying, and what we heard evidence of yesterday, is there is an understanding that you can do research, right, not commercialisation—

Mr Slattery—Yes.

Senator HEFFERNAN—And not breach the patent. Is that your view?

Mr Slattery—That is my view.

Senator HEFFERNAN—And you do not have to apply to the patent holder?

Mr Slattery—To do research. It is an area in which there has been some uncertainty, I agree.

Senator HEFFERNAN—Yes, and confusion.

Mr Slattery—It is an area that has been addressed in two inquiries at least to date. Part of my submission to this inquiry was, 'Let's get off our backsides and let's implement those recommendations so that the situation is a lot clearer.'

Senator HEFFERNAN—It is not clear. You are at the beck and call of the lawyer, under the present arrangement. Gene Technologies Australia withdrew its letter of demand from the various laboratories, such as Westmead, Peter MacCallum, et cetera, not because they are hail-

fellow-well-met or public pressure; they had the law on their side. They can execute that if they want to, but because they were probably advised by their lawyers to go steady or this might become messy, they withdrew it. That is not the way to conduct business. That should not be the way to conduct business. Yesterday we received evidence from a person who started off pretty gung-ho, like yourselves, and finished up saying, 'Well, it is unclear. Perhaps it should be clarified.'

Senator MOORE—Chair, I state for the record that that is not absolutely accurate in those terms. I think I know the evidence to which Senator Heffernan is referring, and that is not exactly how it transpired. People should read *Hansard* to form their own opinion.

Senator HEFFERNAN—You might interpret it for me.

CHAIR—There are different interpretations. We had a discussion yesterday over the assumption of research exemptions. I think we all came to agreement that it needed to be clarified. While there is a break, I know that Senator Adams wants to follow up a particular issue around the recommendations.

Senator ADAMS—Mr Slattery, you have commented about the 2004 ALRC report. Have you followed up with the government why those recommendations have not been implemented, or why there has not been any progress?

Mr Slattery—No. I know that there has been some discussion and that IP Australia is now following up a recommendation in terms of the so-called research exemption and that IP Australia recently issued a discussion paper or something like that—I have forgotten what it is called—to follow it up, and there are steps being taken. But I have not followed up any other of the recommendations that are in the ALRC report.

Senator ADAMS—That has just sat there, and the recommendations are just sitting there and nothing is really happening, despite the fact that this could perhaps help to solve the problem.

Dr Rourke—I am sorry to interrupt, but there are some IP Australia consultant papers on experimental use and increasing the standards of examination, which I understand were some of the issues raised by the ALRC so that is some degree of movement. Relevant to experimental use is that one of the proposed changes is to make it clear in the act that seeking an improvement to the invention is not an act of infringement, as I understand it. I am not sure where they are actually at.

Senator ADAMS—It just seems unclear. I am really just curious because everyone keeps mentioning the recommendations, and they do support them, but nobody seems to have actually pushed the government or say, 'Well, are you actually going to do something with them?' That was why I asked the question. Thank you.

CHAIR—Senator Moore?

Senator MOORE—Following up on Senator Adams' very strong point, we asked some people yesterday about the apparent disquiet in some of the submissions that there has not been progress since the series of papers that came out with legal counsel's process and that no-one

seems to have been pushing it. That is a bit of a surprise to us because it seems that within that circle, this is a really important thing.

I have looked at your submissions and I am interested in your statement that the current system is operating and that there is openness for people to be engaged in research, which is a core issue. Senator Heffernan and others have been raising the point that by someone taking a patent, in effect that stops anyone else being able to use material or being able to progress research, which will end up with progress that we can benefit from. We went through that with a couple of witnesses yesterday. Are any of you gentlemen involved professionally with the BRCA1 and 2 cases? I do not want to ask you questions if it would cross professional lines.

Dr Rourke—I have done a lot of work with genetic technologies, but I have had very little to do with the whole BRC story. But yes, I have spent a bit of time.

Senator MOORE—I do not want to cross professional lines here, but I think what has stimulated people to ask questions to a large extent in the community has been the public coverage of that case and the particularly sensitive areas of breast cancer and the impact. We had evidence yesterday from people who are—I hate using the term—consumers, I suppose, in that sense and who spoke about their own views. In that case, and we will be talking to Peter Mac personnel later today, it was said publicly that there was an attempt to have commercial fees paid for testing that was being used to help people who were going through familial genetic testing to seek their own health and to see their own futures, which we all agree is a good thing.

There was an allegation or a presumption that this intervention would cause huge financial difficulties for people who were having testing done and problems for people who were providing that testing with a commercial process for payment. That is the core issue that many people have been concerned about. From the patents process, how would that work? Seemingly, or the way it was publicised, that was the perfect right of the company that owned the patent and they had absolute control over whatever costings that were involved, which was the trigger for pushing the panic button for people. Services they were getting now and that were being used for health and research were now going to be outside their control and ability to have that done.

For me, that is the issue that is scaring me. Also, there has been evidence provided about international situations that have led to some horrific results, as presented to us, in terms of differential costings for people who are having tests made through genetic processes that were subject to patent involvement. Have I got that right? That is the kind of thing we need to know? I just want to make sure that I am reflecting the kinds of issues raised. That is the case, and we use BRCA1 and 2 because we know it has been in the public mind, but we just want to know how that would operate and if the patent process leaves people open to that kind of lack of control and fear that that could occur.

Mr Slattery—Firstly, as you mentioned the BRCA patents and so on, I point out that the issues which have arisen in relation to those patents do not arise from the fact that those patents have claims to isolated genetic material. The claims that are relevant in those patents to claims to diagnostic techniques.

Senator MOORE—Absolutely.

Mr Slattery—So there is no issue before this inquiry as to whether diagnostic techniques should be patented or not; they are recognised as patentable inventions. The terms of reference for this inquiry do not address the question of should you be able to patent diagnostic techniques.

Senator MOORE—Mr Slattery, we often go beyond our terms of reference.

CHAIR—Sometimes too often.

Senator MOORE—But I understand your point.

Mr Slattery—Where I am coming to is that the issue which has arisen in relation to those patents relates to claims in the patents which are directed to diagnostic techniques.

Senator MOORE—Okay.

Mr Slattery—When those patents were granted, they were based—and I have forgotten the dates on which they were granted but it was 15 years ago or something like that—

CHAIR—We will be able to tell you.

Mr Slattery—They were based on technology which had been developed and research which had been done at that time. In the light of the prior art at the time, those claims to diagnostic techniques were considered appropriate to be patented at that time, in the light of the prior art at the time. In my view—and I do not know the full circumstances—it seems quite clear that there were justifiable circumstances for the grant of valid claims to a diagnostic technique in those patents. Just as there might be a basis for granting a claim to a new drug developed at that time, there is a valid basis for granting a claim for a diagnostic technique at that time. The patentee supposedly has a valid patent on the diagnostic technique. Just as in any patent, the patentee then gets an exclusive right in relation to that. In practice it works as a negative right. It is a right to stop someone for the next 20 years.

Senator MOORE—Yes. All your submissions point out that factor—the negative right.

Mr Slattery—That is right.

Senator MOORE—It is a negative right rather than a proactive one.

Mr Slattery—So they get the right to stop other people using that diagnostic technique for 20 years just as the person who gets a patent on a new drug—for example, for the treatment of breast cancer—gets an exclusive right which enables them to stop other people using that new drug for the treatment of breast cancer for 20 years without their permission. The two have a direct parallel. Perfectly legitimately, the person who owns the patent on this diagnostic technique has the right to say to someone else, 'Yes, I will licence you to use my patent' or 'No, I will stop you using my patent on the diagnostic technique.'

Senator HEFFERNAN—Senator, can I point out a flaw in that argument? It is directly related, Madam Chair.

CHAIR—Senator Moore, had you finished?

Senator MOORE—I am still waiting to get the whole impact, so we have got as far as the diagnostic technique.

Mr Slattery—They have the right to do so. How the patentee then manages that patent is up to the patentee. There are other ways. In my personal view, I do not think those BRCA patents were well managed, but it is a question of IP management, not of the patents themselves. I point out that the ALRC report, for example, addresses various other ways in which, if the public does not like the way in which the patentee is managing its patents, that may be addressed in the public interest, Crown use and things like that, and compulsory licensing provisions. They are all available within the current Patents Act. The fact that the way those patents were managed may not have met everyone's approval, including mine, does not in my view give a reason for changing the patents system.

Senator HEFFERNAN—Right, so—

CHAIR—Hang on.

Senator MOORE—Mr Slattery, I am sure Bill is going the same way, but I am just trying to see the impact in such a high-profile area on people's health and the development of health knowledge in our country. Is there any limitation into the way the patent can operate? I understand the point that there is the patent and then there is the management of the patent.

Mr Slattery—Yes.

Senator MOORE—But in this case it was the management of the patent that caused the concern. There did not seem to be any way of controlling what that person with the patent could say or do about what would happen with tests. They could either demand that the testing be exclusively done by them—and their process was a kind of monopoly in that way—or significant charges could be placed on anybody else who would do it. That is the core element of the management of the patent, which is part of our terms of reference.

Mr Slattery—I have mentioned that there are other areas of the Patents Act, such as the Crown use provisions and the compulsory licensing provisions and so on that also are available under the current system.

Senator HEFFERNAN—They are never used.

Mr Slattery—They are available. Whether they are used or not is another issue.

Senator HEFFERNAN—Well—

Senator MOORE—Is there a cost involved in that? That is my last question, Chair. Yesterday I asked about the cost of challenge.

Mr Slattery—The cost of challenge or the cost of—

Senator MOORE—The whole thing. We have the process there of what can happen and, as Senator Heffernan has said, they are rarely used, from what we have seen from our indications.

Mr Slattery—I have not stated it other than a general comment on the Crown use provisions. As I understand it, the cost is that the patentee has to have reasonable reimbursement or reasonable licence fee imposed and paid back to the patentee. Compulsory licence is a procedure that has to be undertaken to obtain the grant of a compulsory licence, and no doubt the terms of a compulsory licence also would require a form of reasonable royalty back to the patentee.

Senator WILLIAMS—How do you define 'reasonable'?

Mr Slattery—The courts define that. I do not.

CHAIR—Right. Senator Humphries and Senator Williams, are your questions around specifically this issue?

Senator WILLIAMS—Yes, certainly. Do you mean the issue of the use of patents?

CHAIR—The issue of the use of patents, yes.

Senator WILLIAMS—No.

CHAIR—Okay. I think we will finish this discussion and then go on to your questions, if that is okay.

Senator WILLIAMS—Yes.

Senator HEFFERNAN—Can I just retrace my footsteps slightly because I did notice the shaking of heads at the back of the room, and the back of the room was right.

CHAIR—I presume we cannot take names.

Senator HEFFERNAN—With the patent of 2004 regarding epilepsy, the tradable instrument's title is 'A diagnostic method of epilepsy'. That is pretty simple language?

Mr Slattery—Yes.

Senator HEFFERNAN—That is what the patent is for. It was taken out in 2004. It includes the isolated gene, by the way. In 2004 they still thought it was pretty inventive to isolate the gene. You then go to the terms of the claim and methods which they then convert from the title, which is 'A diagnostic method of epilepsy', to 'A diagnosis and treatment of epilepsy'. They have taken the patent on the treatment in the described claim: not the diagnosis, but the treatment. We then go to claim 49, 'A method of treating epilepsy'. That is in the claim. How can you patent a method of treatment which does not exclude everyone else, if there is no method of treatment?

Mr Slattery—I do not understand the question.

Senator HEFFERNAN—Well, this claim, which includes the isolated gene, claims the treatment. It says, 'A method of treatment including SMEI'—I will put my glasses on—'comprising …' and a lot of legal lingo. Do you think it is a reasonable thing for a patent that was taken out in 2004, which says 'for the diagnostic method'—which is a good idea—can, in the guts of the claim, be actually for the treatment, when there is no treatment?

Dr Davies—There are several issues. Firstly, the title of a patent application or grant of patent does not necessarily reflect the scope of monopoly that is sought.

Senator HEFFERNAN—That is very obvious.

Dr Davies—And the scope of the monopoly that is sought and granted is based on the information provided by the applicant. That is based on experimental data. Ultimately the claims are examined in the light of the information that was provided together with what was known of the art at the time. During examination, if there was reasonable support for a method of treatment, based on the information that was provided or the understanding of the underlying disease, then it is quite possible that a patent can be granted for that.

Senator HEFFERNAN—That is fair enough.

CHAIR—Do not interrupt.

Dr Davies—However, if, in the light of information that comes to the public that maybe that claim is unduly brought, then that claim is challengeable for its validity.

Senator HEFFERNAN—All right.

Dr Davies—So always for all patents, even though they are issued, there is no presumption of validity. Third parties always can challenge, whether that is at the Patents Office or through the courts.

Senator HEFFERNAN—But you say 'comes to the public'. How the hell could that happen? You would have to be a very lonely person to read these documents—which probably means I am lonely.

Dr Davies—But we do not licence them.

Senator HEFFERNAN—I know, but you draft them, and they are absolutely flawed. The epilepsy one is absolutely flawed. Could I retrace my footsteps while I am at it on haemophilia?

Dr Davies—Yes.

Senator HEFFERNAN—The patent here was taken out in 2002.

CHAIR—I think we have been conned.

Senator HEFFERNAN—I made a mistake. It says, 'methods and compositions for use in gene therapy'. In fact, there is no gene therapy that works.

Dr Rourke—The eye colour one is a very good recent example, but it is very hard—or are you talking particularly about the example broadly? Can I just say something?

CHAIR—Yes. Get a word in edgewise if you can.

Senator HEFFERNAN—How can you patent—

Dr Rourke—Can I just say something which is quite relevant to what you are saying?

Senator HEFFERNAN—Yes.

Dr Rourke—In defence of IP Australia—and please, John and Trevor, correct me or add to this if you think that it is an inappropriate statement—but they have been hobbled for quite a number of years in relation to being able to examine when it comes to whether the claims are too broad.

Senator HEFFERNAN—I understand that.

Dr Rourke—Through the courts, there are decisions relating to sufficiency and fair basis. It is very hard for them to knock out claims.

Senator HEFFERNAN—Yes.

Dr Rourke—So you have nearly answered the question.

Senator HEFFERNAN—I understand that, but does that not mean that the law is outdated? They have to act on what the law says, and the law is from 100 years ago, or whatever. Is the law not outdated in this sort of stuff? I could take you also to the ageing gene story, if you like.

Dr Rourke—I have already said that the discussion paper is out there to try to raise the standards of examination more akin to the US and Europe to narrow the scope of protection and to try to get to that point at which the granted claims are more in accordance with the advance provided. Those things are in place, or the wheels are in motion. If you do not like what they find at the end of that, maybe you will have a reason to complain but—

Senator HEFFERNAN—You would have to say that the present law allows a monopoly.

Dr Rourke—That is the whole point of the system, yes.

Senator HEFFERNAN—Can we afford the monopoly in a way that actually prevents other research which would overcome diseases? If there is a test, there might be a better test. But if you have not got access to the gene, there will never be a better test. Thanks. That is where I will leave it.

CHAIR—Okay. I have a long list of people who want to ask questions. Sorry, did somebody want to say something?

Dr Davies—I would make one comment about that. Part of the underlying issues with a patent system is that a patentee tells the world what his or her invention is, and others can use that information to make improvements. It is in all technologies. You could go further and say that maybe no-one should own the rights to solar technology because everyone should be able to generate power from solar energy without having to reimburse or compensate people for doing extensive research in that area. Gene technology may be an emotive area but the underlying patent system encourages the development and improvement in technology. The Australian patent system is very flexible in that it can adopt changes in technology to allow patentees or inventors to obtain this limited monopoly right in order to carry out the research and development and get some return for that effort.

Senator HEFFERNAN—But in the case of the epilepsy patent, they have isolated the gene. They have taken a patent on access to the gene, but they also then said in the document that they want to patent the treatment, even though the treatment does not exist. Is that a fair thing?

Senator HUMPHRIES—Can I come in here and ask a question to clarify this? It is my understanding that when you take out a patent you are taking out almost a speculative claim on what a particular process that you have invented might achieve. You are not required to prove categorically to the Patent Office when you file the patent that your process will work; it is not absolute proof of its being effective. You believe it will be. You seek the right to use it to get that effect, but in a sense there is something speculative about these processes in many cases, is there not? If it is actually working, you cannot get the patent because it is already in operation. Is that not the case?

Mr Slattery—I would not use the word speculation. I would use the term reasonable scientific prediction, or something like that. You have to remember that this is done at a very early stage. The patent system works in a competitive environment. The researcher sometimes, for example, even has what I call a smudge on a gel, but it is an indication to the researcher and a reasonable scientific indication that you have a process or product that is working, or something like that. Because the patent is a competitive system—first in, best dressed—There is often pressure to file a patent application at an early stage.

For example, if a scientist also wants to publish a paper in Science or something like that, in most countries he has to file a patent application before that publication occurs as well, although not necessarily in Australia. There are pressures to file a patent application early, to file an application on the basis of results which you have now got, and which reasonably and genuinely scientifically provide an indication to you that this is a potential diagnostic, a potential new treatment, or a new drug for the treatment of breast cancer, or whatever it might be.

Senator HUMPHRIES—If you believe that you have discovered some process in your laboratory for diagnosing or treating epilepsy, you are entitled to proceed and put that evidence in front of the Patents Office to claim the patent over the process that gives you that outcome, are you not?

Mr Slattery—Yes.

Senator HUMPHRIES—You might not have reached the stage at which you have successfully either diagnosed or treated the epilepsy in practice, but you are entitled to put what

you have got there in front of the Patent Office and obtain the patent over that process, are you not?

Mr Slattery—Quite true. All of us here will have clients or researchers for whom we have started the patent process on the belief and understanding that this will provide a reasonable diagnostic or treatment, and down the research track, it does not pan out so they drop the patent application. There are lots of patent applications that fall along the wayside for that very reason.

Senator HUMPHRIES—You are also entitled to claim a method of treatment, are you not?

Mr Slattery—Yes.

Senator HUMPHRIES—Every drug that is patented in Australia is a drug for treatment, is it not?

Mr Slattery—The claims in those patents have claims to the product per se and claims to a method of treatment using the product. That would be the standard patent application.

Senator HUMPHRIES—That is not legally possible but also entirely reasonable because that is the way in which people invest in the process of doing the research to get those drugs and putting them on the market to treat illness, is it not?

Mr Slattery—Quite right, yes.

Senator HEFFERNAN—But if the product does not exist, you still have the patent.

Senator HUMPHRIES—How do you check when you do not have the express product?

Mr Slattery—How does the product not exist?

Senator HEFFERNAN—If they have not produced the product but they have taken—

Mr Slattery—If they have produced a new drug which indicates that it can be used to treat cancer, they have the new drug. They might only have microgram amounts of it, but they have the new drug, the product.

Senator HEFFERNAN—But in the case of haemophilia, there is no gene therapy, yet they have taken the patent out.

Mr Slattery—That is a method of treatment.

Senator HEFFERNAN—Yes, but they have actually—

Mr Slattery—I do not know the case—

Senator HEFFERNAN—Well, I do.

Mr Slattery—But I assume they have some research indication which indicates to them, as a reasonable scientific prediction—

Senator HEFFERNAN—All right, okay. Fair enough.

Mr Slattery—That it can treat haemophilia.

Senator HEFFERNAN—The middle man says in his document, 'In return for obtaining a patent'—there is the patent—'the inventor must fully describe the invention including the best mode for carrying out the invention at the time of filing the patent application.' That is not the case in that patent there because there is none.

Senator HUMPHRIES—The witness cannot answer that question. They have not got the patent in front of them.

Senator HEFFERNAN—All right.

Senator HUMPHRIES—You can put that on the record, but that is your evidence, not theirs.

Senator HEFFERNAN—Patent specification—

CHAIR—You have been doing that for the last day.

Senator HEFFERNAN—You have to make allowances for me.

Senator HUMPHRIES—Yes, I know. It is always too late to shut that gate, is it not?

CHAIR—Yes.

Senator HEFFERNAN—Patent specification is your document. 'Patent specifications are published and available to the public 18 months from the earliest priority date of the invention.'

Mr Slattery—Yes.

Senator HEFFERNAN—Well, we are still waiting.

Mr Slattery—I am sorry, you are still waiting for?

Senator HEFFERNAN—This thing here—and there are several I could take you to, but I will not burden you because I know you are not familiar with them, and that will be your answer—where there has been a patent taken out for something that does not exist and there has been no publication.

Senator BOYCE—Why ask the question if you are going to answer it as well?

Senator HEFFERNAN—There has been no notification—other than, if you are lonely enough, by going through these documents—to let the person who is buried in a laboratory at the

back of the University of Sydney know that they can proceed because that patent will be invalid as it will not going to come up with anything. The epilepsy thing so far came to a bucket of custard.

Dr Davies—The notification is the publication of that patent application by the Australian Patent Office or, if it is filed internationally, by the World Intellectual Property Organization. That is that publication. With regard to claims to a method of treatment—if there is sufficient information about a particular gene or an aberration in a gene at the time when that application was filed, and there was knowledge and understanding that you could have an effect on that gene by doing gene therapy, the Patent Office would have examined that application on the basis of what was known at the time and what was possibly reasonably expected could be done. That is why that claim is granted.

Senator HEFFERNAN—What could be known to the Patent Office at the time would be the information that came from the patent application.

Senator HUMPHRIES—I have a point of order.

CHAIR—Yes.

Senator HUMPHRIES—Senator Heffernan has had the lion's share of almost an hour of the first hearing.

CHAIR—Yes. I was just going to raise this.

Senator HUMPHRIES—I think it is time for someone else to have a go.

CHAIR—I was just in the process of starting to say that it was your turn.

Senator HUMPHRIES—Thank you. Can I take you back to the evidence you gave at the beginning of the hearing about what is patentable. Your submission states:

… valid patents do not cover naturally occurring genes or biological materials when present in nature.

But you seemed to be saying earlier, particularly Mr Slattery, that genes or gene sequences, which obviously occur in nature, have been patented at least in the past in Australia. Does that statement stand, or are you relying on the fact that the phrase 'when present in nature' is the only distinction between when a patent might be granted and when it might not be granted?

Mr Slattery—No. I rely on the fact that the claims which are granted, including the claims that Senator Heffernan is quoting, used the word 'isolated' or in other instances 'synthetically produced' or 'recombinant' or something like that, and you do not ignore the impact of that in the claim. You emphasise that the form is not the gene or the genetic sequence as it occurs in nature. It is the isolated sequence.

If I could perhaps give you a parallel; for example, an isolated product. We have heard of the cone snail whose toxin is toxic, but people are doing research to isolate a particular compound out of that, which is a very useful analgesic. The claim for that compound will be an isolated

compound X, which has been isolated from the overall toxin. It is a perfectly valid claim. It is not being claimed as it exists in nature. It is being claimed as it is isolated.

CHAIR—Would the gene be isolated though and be claimed, or the compound?

Mr Slattery—I am sorry?

CHAIR—Would the gene creating it be claimed, or the compound itself?

Mr Slattery—No, I was talking about compounds per se in that particular instance.

CHAIR—Yes. It is a different issue.

Mr Slattery—In the case of an isolated genetic sequence, you are in fact claiming an isolated compound. It is a polymer of certain ATCs and ATGs, and it is in fact a compound.

CHAIR—This is where we are getting into the semantics. I am sorry, Senator Humphries.

Senator HUMPHRIES—That compound occurs in nature.

Mr Slattery—Not in that particular form. Not as an isolated compound. It occurs in a great long string of thousands and thousands of genes, but none of them is actually isolated in nature.

Senator HUMPHRIES—The question this is that we are facing: is the process of isolating these naturally occurring phenomena so startlingly original and inventive that they deserve to be given protection of the law as a privilege or as a monopoly that the person can then use for 20 years to exploit? It has been put to us that those things are not really very inventive at all. They occur in nature. Nature produces them and makes them happen. We just identify them, take them out and just reproduce them in a laboratory, which appears to us—we are not scientists—to be a fairly easy process to do.

Obviously, with a century of research behind you, it is a lot easier to do it in those circumstances, but having done that, the process of extracting it from nature and being able to use it out of nature is now relatively easy. It is put to us that that is a matter that should not be patentable because it is not really very inventive. What is your comment about that?

Dr Davies—In a lot of these inventions, it is an observation or the finding that there are changes within a particular genetic marker or even a product of a gene, and it is the recognition that there are changes that are implicated in disease. It is that isolation and that recognition of changes of what would normally occur in a healthy individual that typically underlie a lot of the gene-related technology. So it is not the normal gene; it is actually changes that have been identified often through quite extensive research. The observation of those changes has allowed a new use, which may be a diagnostic. We would say in relation to BRCA1 and 2, that observation has allowed the possibility of running tests to allow women to determine whether they are in a high-risk sector of the population so that they may apply a patent.

Senator HEFFERNAN—But you have actually allowed the patent on the gene as well as the apparent mutation of the gene, so you lock out everyone else from having a look at the possibility of other mutations.

Dr Davies—Not necessarily.

Senator HEFFERNAN—Without the licence agreement.

Dr Davies—You can still carry out research on that isolated gene. Quite often, and it still happens, more and more genetic markers are identified in either that particular gene or that area in a particular chromosome. There has been a great advance in science in a lot of diseases by looking for multiple mutations, and they are owned and patented by different people. The commercialisation of that technology may require licence or some sort of deal done with the original innovator, but that is normal business. The technology of isolation per se, in hindsight may be said to be relatively simple, but it is not the isolation per se; it is actually protecting these changes or these mutations that provide some useful result.

Senator HUMPHRIES—But the changes or mutation also themselves occur in nature, do they not?

Dr Davies—Yes, they do.

Senator HUMPHRIES—So it is that the genes are natural and the gene sequences are natural, and the mutations and changes are natural. All that the scientist or inventor has done has been to identify them or to see them and work out how they might be useful in some other way.

Senator HEFFERNAN—Discovered, not invented.

Senator HUMPHRIES—The argument is whether that is sufficient? As one of the other submissions puts it today, it is like walking through a forest and discovering a new brand of orchid. You take that orchid away, get the seeds from it and you propagate it and make something out of it, and you start to sell the new orchid. You claim, 'Oh, that's my orchid. No-one else can sell that orchid.' Is that really a level of inventiveness, given the background of scientific advancement that at this stage warrants a monopoly?

Mr Slattery—I believe the overall process does warrant the monopoly. I go back to my example of isolating an analgesic from a cone snail toxin. In a sense, in your terms all that has happened is identification of the toxin, separating it out, and picking out one that works. But it is the overall process, the sum total of the process, which in my view provides the justification for saying that there is an invention is involved.

Senator HEFFERNAN—But is that not a discovery, not an invention?

Mr Slattery—It is more than discovery. It is an indication that you have something that is useful. Just to discover a compound without having identified that it has properties that can be used in some other way is not it. The overall process in my view gives you the basis for an invention.

Senator HUMPHRIES—What is the difference between that process and, say, discovering for the first time today that a mineral called uranium could be extracted and processed in a certain way so as to create energy? Would we say that uranium was patentable in those circumstances?

Mr Slattery—If no-one had ever published. If the prior art was such that no-one had ever identified or isolated uranium before, then I believe so, yes. You have to look at it in the context of what is known at the relevant date.

Dr Rourke—I think you are trying to summarise an amazing array of different procedures for isolating genes. I mean, there are a lot of patents, and you can certainly question their merits, in which there has been this massive amount of sequencing, just a thrown-in bunch of stuff and a guess as to what it might do. There is a lot of public disclosures like that and there are a lot of patentee disclosures like that. You might question where the inventiveness is in that.

When it comes to some of the examples that Senator Heffernan has raised, I am not familiar with those sciences. I understand the science behind BRCA and what actually happened, but there are massive bodies of work. I think there were over 40 people—I counted them—in one of the BRCA publications and I cannot think that you just walked in the forest and there it was. I have one colleague who has been working on trying to find a gene linked to diabetes and who has been working on it for 12 years. Do you think that is simple? Do you think that is easy?

Senator HUMPHRIES—No, it is not. I agree with you. It is not simple.

Dr Rourke—He still has not found it.

Senator HUMPHRIES—That is clearly not simple.

Dr Rourke—There are other examples.

Senator HUMPHRIES—And you need a high level of training and the background of a great deal of prior research to be able to reach the point at which you can take that step, but the question is whether you are discovering something or whether you are inventing it. That is the question. Are you inventing it if you see it in nature and you simply take it out of nature?

Dr Rourke—The question before was whether it was simple, and whether it was discovery or invention. I think that is, dare I say it, playing semantics. Really, the patent system has existed for many years.

Senator HEFFERNAN—The law says you cannot play semantics.

Dr Rourke—Excuse me. We are a member of TRIPS, which says that we have to patent inventions in all areas of technologies and their sum exclusions, so to me the argument of discovery or invention just comes down to an excuse to ignore an international agreement. If you look at the developed countries in the world, the only one that people keep mentioning, and that I cannot even confirm, is Brazil. All the others allow patents to gene sequences. An exception was India, but they have now changed their laws so that they do now allow such subject matter.

To me, we seem to be taking a step away from the rest of the world, and are looking for an excuse to do it.

Senator HUMPHRIES—Just on that point—and I will come to international agreements in a minute—are there not disadvantages in isolating yourself from international processes in terms of the transfer of technology? Would you not find, if you were not part of an international consensus or agreement on sharing or protecting intellectual property, that you would not have the advantage of some technology being transferred into your country because you could not give protection?

Dr Rourke—So I suppose we ought to use barrier types; is that what you are saying?

Senator HUMPHRIES—Well, I am saying—

Dr Rourke—That could work, if we all do it.

Senator HUMPHRIES—I am saying that, because you do not offer protection for intellectual property in your particular country, who will not use that property or transfer it to that country?

Dr Rourke—The information would be out there, so you could steal it and use it, if you wanted to. I am not sure; I have no idea of international politics.

Dr Davies—I would make one further comment that each and every patent application is examined in its own right. So having a blanket statement saying 'The isolation of a mutation is not an invention' or '… is just a discovery'—the Patent Office in Australia and in countries around the world will consider each application on the basis of the information that has been provided by the innovators and how much support they have for the invention. There may be situations in which a patent has not issued because there has been not enough support or it was considered that there was not an invention. That happens all the time.

Senator HEFFERNAN—Dr Davies, you keep talking about the mutation, but I am concerned about the gene, not the mutation of the gene. In BRCA, they took three on the gene and one on the mutation. I could not see why Westmead Hospital could not do the work it was doing. You may say it was mistake by Gene Technologies Australia but it was supported by the law, what they did.

Mr Slattery—Senator Heffernan, I think the issue is: what were they doing? I do not know the full circumstances. Were they conducting research, or were they providing a diagnostic test service?

CHAIR—Senator Williams, do you have some questions?

Senator WILLIAMS—Just on that issue, Dr Davies, during your life and my life we have seen a tremendous amount of advancement in medical health and medical cures and medical ways of fixing things, and so on. Here is a problem. On the BRCA issue, South Australian Pathology received a letter from Gene Technologies Australia saying, 'You have been researching on this gene. We hold the patent. You forward all your research results to us within seven days, or we're going to put you through the court.' This is the problem we are facing.

When someone or some company has a patent over an isolated gene, there is a clear case of obstructing research into medical health. Do you think that is right, or wrong?

Dr Davies—I am not aware of that particular situation.

Senator WILLIAMS—Let me just explain it to you. This is the situation: South Australian Pathology was going through the research into this BRCA, and they received the letter saying 'you can't do it because we hold the patent on it', and they were simply researching for this cure or to solve some of the problems of breast cancer.

Senator HEFFERNAN—The Peter MacCallum Cancer Centre and Westmead got the same letter.

Senator WILLIAMS—Here is where there is a problem as I see it. People who want to research into solving a chronic medical problem are being obstructed. If you were here when the four ladies were before us yesterday, you would be even more aware of it. Do you see as a problem that people cannot research into solving a terrible cancer?

Dr Davies—I would question whether that company had the rights to prevent others from doing research in that area. I do not know whether any of those parties got legal advice and whether they can still continue what they were doing.

Senator WILLIAMS—Can those parties research into medical issues if some other company has the patent on a particular gene?

Dr Davies—I think that they can continue their research in that area. If they are doing research for a commercial outcome, then there may be concerns by the patentee that that commercial research is an infringement of their rights. As mentioned earlier, the clarification of having a research exemption in Australia is being looked at, just to clarify the situation.

Senator WILLIAMS—Who is looking at that?

Dr Davies—It is IP Australia. There is a discussion paper at the moment.

Mr Slattery—It is a recommendation in the ALRC and in the ACIP report.

Senator WILLIAMS—I address this question to Dr Rourke. It refers to the person he knows who, for 12 years, has been looking into the research of diabetes.

Dr Rourke—Yes.

Senator WILLIAMS—If that research that that person was undertaking was publicly funded, or if the government was funding the research, do you think it would be right, if that person discovered the gene that identified the flow-on of diabetes through generations, that that could be patented by that person, even though that person was publicly funded in doing that research?

Dr Rourke—There are all sorts of public funding. When you look at the NHMRC, clearly in its guidelines it states, as I understand it or certainly when I looked at it a few years ago, that it

encourages the patenting process. The CSIRO is a government body, although it acts like a pseudo company. There are the CRCs and they direct other ARCs. I do not know what their policies are, but there are lots of examples of government funding. I do not think that is an unreasonable question for government to ask itself. Will they get some sort of kickback from that, whatever that might be?

Senator BOYCE—It was government funding when they discovered IVF.

Dr Rourke—Yes. That is not an unreasonable thing to think about, as long as it is reasonable and there are gains on either side.

Senator HEFFERNAN—And in relation to BRCA1.

CHAIR—Senator Humphries, had you finished? I had allowed Senator Williams to jump in.

Senator HUMPHRIES—I have one more. Following on the question by Senator Williams, I point out that I spoke to a representative of a large pharmaceutical company with a large number of patents. He said to me that it was his company's policy that there should be relatively free access given to people conducting research. That was the policy of their company and someone approached them and said they wanted to do some research into a particular thing that the company owned and would the company grant them the licence to do that.

We are not having many pharmaceutical companies coming to give evidence to us, so I do not know who else to direct this question to. Presumably as representatives of those companies from time to time, gentlemen, is that your understanding of their general approach, or is the sort of example to which Senator Williams referred earlier commonly found among owners of patents?

Dr Davies—Most major international pharmaceutical companies are keen to work closely with researchers and research organisations, whether to further development even on their own drugs—I am aware of companies that provide drugs and new drugs maybe for new uses that have been developed—ultimately, if that research is successful and there is a commercial outcome, there will be a reward for both parties. So there is more and more interaction between big pharma and big biology with researchers around the world and research institutes.

Senator HUMPHRIES—Have you encountered a circumstance in which a company you have represented has said no to a request for research into a patent that they own?

Dr Davies—I have no experience of any of my clients being involved in that.

Senator HUMPHRIES—I assume you have had experience people saying no to the use of a patent for the purpose of diagnostic testing? We have had evidence of that already in the committee, and that is what happened with the BRCA1 and 2 cases, at least initially here. Have you had experience of that occurring?

Mr Slattery—It seems to me that the situation really is that, generally speaking, if a company has a patent, say on a diagnostic test, if it is not in a position to supply the test in Australia itself, or to perform the test in Australia, it will look for licensing opportunities. It may very well look for an exclusive licensee, in which case of course it would not license anyone else because of its

relationship with its exclusive licensee, but there are plenty of instances in which a test is also non-exclusively licensed. The rationale is that these people are able to perform the tests in Australia and they will pay us a reasonable fee, which we can negotiate, for performing the test.

Senator HUMPHRIES—It is hard for us to know what the behaviour is of companies in these circumstances, is it not, because there is no register that exists of when someone grants use of their patents.

Mr Slattery—That is right.

Senator HUMPHRIES—They do not have to go somewhere and report that fact, do they?

Mr Slattery—I might say also that, as patent attorneys, we do not see all of these situations, either. There is a lot that happens in commercial negotiations that does not actually affect the patent attorneys.

Senator HUMPHRIES—In the IPTA submission, there are a couple of tables that show the pattern of patent granting or patent applications. It seems to show that there was a peak in 2001 in grants of patents over biotechnology processes, which has declined for all applicants since 2001 at least. It was put to us yesterday by somebody that we had peaked with patent over biotechnology processes or genetic process, and that the number is now declining. Is that what you would say about these figures?

Dr Davies—I think that reflects the state of the knowledge, the growth of the knowledge and that it is more difficult to obtain patent protection for advances in a more mature technology, and so I think that clearly reflects that.

Dr Rourke—The human genome has been sequenced. There are all sorts of companies and public institutions that are publishing these EST or cDNA libraries. It is very hard now. It is very rare a client comes to us and says, 'I want to patent a human gene', and it is novel—very rare.

Senator HEFFERNAN—Actually any laboratory anywhere, which is competent that is, can tap it into a computer and get the sequence anyhow.

Dr Rourke—Yes, but the real drama is working what they actually do and how they interact with everything else.

Senator HEFFERNAN—Oh, yes.

Senator HUMPHRIES—I want to ask about international agreements, if I could. I will not take long.

CHAIR—I think Senator Boyce had a question she wanted to follow on from your previous question.

Senator BOYCE—Yes. It is following on a bit from your question about what the commercial reality is. It has been put to us in evidence that the holder of a patent could require someone else using their test to pay whatever they liked to charge. I was wondering if you

perhaps, not even in this area, but could just talk us through what the commercial reality is when a patent holder might give notice to a company that they believe the company is breaching their patent. What happens in the real world after that?

Mr Slattery—Really, if you like, it is a warning shot, perhaps, fired over the bows. The reality in most instances in my experience is that it gets the parties talking. The end result is that you end up with a negotiated licence agreement. That is probably the most usual outcome of those situations. If you look at the law cases, there are very few instances in which a letter like that has ended up with litigation and a company being sued for infringement of a patent.

Senator HEFFERNAN—Because the little bloke cannot afford the case.

Mr Slattery—No, because the party with the patent, if he is not exploiting the patent in Australia itself, it is in its own interests to have a licensee to exploit the patent in Australia and pay it a negotiated royalty.

Senator BOYCE—And what would be the principles underlying the level of that royalty?

Mr Slattery—It is difficult to know. Usually, it is commercially confidential, but there are reasonable royalties. It is a question of what the company that is performing the test can afford to pay and is willing to pay.

Senator BOYCE—In your experience would companies such as you are referring to, who are not exploiting the market, be interested in making some profit rather than no profit.

Mr Slattery—That is exactly right.

Senator BOYCE—Thank you.

Senator HEFFERNAN—Do you think, as a result of the outcome of that, that at the patient level—of which we heard evidence yesterday, bearing in mind that you are at the banker level and make a living out of the tradability—in Europe for instance at the present time with the Jewish extraction, you have seriously greater likelihood of getting breast cancer, you pay four times the amount that a non-Jewish extraction person pays for the same test because of the quirk in the law. Do you think that is fair?

Mr Slattery—I do not know the facts that you are citing.

Senator HEFFERNAN—You might acquaint yourself with them. In Canada—

Mr Slattery—But if it is the same test carried out on a Jewish person as on a non-Jewish person, I do not think I have ever experienced the situation in which the fee payable would be different, depending on the patient.

Senator HEFFERNAN—We will provide you with that evidence.

Senator BOYCE—Rather than patent law, it is human rights law, I would have thought.

Senator HEFFERNAN—It is a matter of fact, though. If I can just take you to the BRCA—

CHAIR—We said we were going to go back to Senator Humphries. I promise we will come back and you can ask those questions. But let us continue the line of questioning that Senator Humphries had begun.

Senator HUMPHRIES—Thank you very much. I just wanted to ask about international agreements. You say that the Patents Act cannot exclude 'human microbial genes and non-coding segments, proteins, and their derivatives, including those materials in an isolated form' from patentability because that would conflict with Article 27 of the TRIPS agreement. We have been told that there is an exception in the TRIPS agreement for diagnostic, therapeutic and surgical methods for the treatment of humans or animals. You are saying to us that we could not exclude people having the right, under those international agreements, to patent the isolation of the genes, but if people want to use those gene sequences in isolation in a therapeutic, diagnostic or treatment process, that could be excluded from patentability if we chose to do so. Is that your understanding?

Mr Slattery—It is permissible under the TRIPS agreement. There is a parallel in terms of Europe, for example, which has an exclusion along those lines. But it is interesting to note that the exclusion, for example, in Europe does not exclude in vitro diagnostic tests. They are still patentable in Europe, as they are in New Zealand.

Senator HUMPHRIES—The Royal College of Pathologists makes this point about that exclusion under the TRIPS agreement:

> It appears that this has generally been interpreted by IP officers to refer to diagnostic tests performed on a person's body, but not to diagnostic procedures where a sample is removed from the body and tested in a laboratory.

Would that by your position?

Mr Slattery—That is the point I am making.

Senator HUMPHRIES—Okay. We can create an exclusion, if I have got this right, for tests done on a person's body, but not an exclusion for tests conducted in a test tube.

Mr Slattery—That is the way in which that type of exclusion has been interpreted in the past, yes.

Senator HUMPHRIES—Okay.

CHAIR—That is the way it has been interpreted. It is not what is written into the law: it is the way it has been interpreted. Is that it?

Mr Slattery—It is an interpretation of what is written down there.

CHAIR—Yes.

Mr Slattery—If it is a diagnostic, therapeutic and surgical method for the treatment of humans and animals. That is the exclusion.

CHAIR—Yes.

Mr Slattery—It is a matter of how you interpret that language, yes.

Senator HUMPHRIES—That is allowed under the TRIPS agreement. Have we actually legislated in Australia for such an exemption?

Mr Slattery—No.

Senator HUMPHRIES—We have not. In your opinion, should we do so?

Mr Slattery—No.

Senator HUMPHRIES—Why not?

Mr Slattery—Historically, we have not, and I believe that there has been absolutely no reason why those patents, which have been granted in, for example, methods of treatment, have caused any difficulty, as we discussed quite early in the piece.

Senator HUMPHRIES—Well, they almost did in the BRCA case.

Mr Slattery—But they are in vitro diagnostic tests. In my view, they would be patentable, even if you put in an exclusion of the type you are talking about.

Senator HEFFERNAN—Can I just interrupt for one second on that. Westmead was told to surrender. They took out the patent in 1995. Westmead had collected data from 1990 and was asked to surrender all the data. I am going to nail you on something else in a minute too.

CHAIR—He means he will ask you some questions politely in a short while.

Senator MOORE—Ask for information—that is what you are doing, Bill.

CHAIR—Senator Humphries?

Senator HUMPHRIES—I have one last question. I come back to an earlier point about what can be patented and what cannot. I understand the sort of general principles about patentability having to be invented and having to be useful and novel, et cetera. It has been said repeatedly to the committee that the processes for patenting the application of gene sequences or the isolation of gene sequences is not in that same vein of the patent law of Australia; it is a different set of principles at work. What is your reaction to that? Are these exactly the same principles we apply to other patents, or have they been varied for the sake of patenting a gene?

Mr Slattery—I believe they are the same principles that are being applied. Ever since the Patents Act was first proclaimed, the way in which the principles are applied have had to deal

with different emerging technologies. If you studied patent law you will see that first of all it started off with patenting products. Then was a very significant case in Australia dealing with the question: could you patent a biological method, a method of selectively killing weeds in plants?

The High Court of Australia said, yes, you can patent that. That was a technology that was developing. The patent system was flexible enough to allow and adapt to cover those sorts of methods of treatment. Methods of treatment of humans have been considered in more recent cases and have been allowed by the High Court within the whole concept—without changing the law as it is written, but by developing that concept over time. I believe that the same principles are being developed and applied in the case of patenting of genetic sequences.

Senator HEFFERNAN—But is this a sequel to terminator gene in the plant world? Australia does not allow the terminator gene, if you know what that is: but the Yanks do.

Mr Slattery—I do not know.

Senator HEFFERNAN—The question is: do you allow a terminator gene psychology in human gene patenting? The terminator gene absolutely against the global food task is a threat, but it is also a cartel monopoly for the seed growers.

Mr Slattery—But that is not at issue in patent law, in my view.

Senator HEFFERNAN—But the patent was taken out by a Canadian company and a Japanese company, which were applicants for the BRCA1.

Mr Slattery—Yes.

Senator HEFFERNAN—In Canada last year, there was a quaint letter went in there putting up the price of the test 400 per cent. It is a fact of the European context, and we will prove that later in the day. But my question is: if it was the case that in Europe at the present time because of the quaint interpretation of the law on the patent that the community of Jewish extraction pays four times what is paid by the non-Jewish community, would you think that is unreasonable?

Mr Slattery—I think it is unreasonable as a general proposition. I agree with you. But I suspect it does not arise from the patent system per se. It is the way in which IP is being managed.

Senator HEFFERNAN—It was because of the patent attorneys going to court and the court made a legal interpretation which provided the outcome. As Senator Boyce has said, it is almost a bloody infringement of human rights; but it is the case at the present time in Europe. With the stroke of a pen, given that there is a Canadian company on the application here, they just said, 'We're going to whack the price up 400 per cent.'

This is the practical outcome of all the legalese and garbage that goes on as well as the arguments about patents. You blokes make your living from arguing all this stuff, but the outcome for mankind is the absolute lockup and monopolisation, which means that you just charge what you want. And I will bet you—and I put it on the record today—that in 10 or 20 years from now, all these tradable instruments will be held by bankers and not researchers.

CHAIR—I think that was a comment. I have a question. Senator Heffernan may have some more questions, but I have a question in terms of this issue around whether it is the gene being owned or whether it is the diagnostic test. An example is when somebody is carrying out tests and are having to rely on a series of genes to do the test. They have come up with the test. What happens when a body owns one of the genes that is involved in quite a complicated genetic test?

Dr Davies—First of all, that combination of genes would be patentable, even in the light of someone owning some rights to the use of the particular gene or gene marker. To commercialise that invention, you would require a licence or cross-licence with the owner of the one marker.

CHAIR—So they own that gene then, are they not? The researcher or the tester who is testing for a particular illness or condition has to go to that particular patent holder for that particular gene. The person or company that holds the IP over that particular gene, they are not actually using any diagnostic test that that particular company owns; it is just the fact that they own that gene.

Dr Davies—If they own a marker in that gene, depending on what that first party has claimed off and what sort of use. It all comes down to: what are the actual claims; what is the scope of monopoly that has been granted in any particular patent; and then what is the use of that technology by a third party as well as whether that is considered an infringement or not? If it is an infringement, then you need permission, whether that is licence or cross-licence.

Senator HEFFERNAN—But the ultimate test of that is the vagary of the law.

Dr Rourke—No. It is the circumstances of the test. There is a huge array of different tests and you may not have to have the isolated gene to do the test.

Senator HEFFERNAN—But none of this has been tested in a court in Australia.

Dr Rourke—No.

Senator HEFFERNAN—So why don't we?

Dr Rourke—I have already just commented on the problems with what the courts find and how it has actually hobbled or made it more difficult to get an outcome.

Senator HEFFERNAN—In Europe, the outcome is this attack on bloody human rights.

Dr Rourke—Senator, I find part of your question quite an interesting concept. If we get to this point at which it is relatively cheap to sequence a person's entire genome and screen it pretty quickly by sequence for what you may or may be susceptible to, which has its own ethical and insurance issues and all sorts of public problems, of which how reimbursement of all the individual entities can be achieved is one. I think that each of those individual advances, as I have explained—particularly complex disease associations, which we are going to get into in the future—is an extremely important advance. Investment from non-government money helps to get that forward.

You can wave that SCN1 patent around, but you could ask the question: would that test exist now without investment to this point? Yes, government money might have caught up, but maybe it would not have. I think it is a question of having to be sensible about this and say, in that hypothetical situation: how can the government regulates it so that the patentee is still rewarded for their contribution, but at the same time the test is not so exorbitantly expensive?

CHAIR—That is the issue. Say you have seven or eight genes involved, and just say each one of these is owned, but not the test.

Dr Rourke—That is quite possible.

CHAIR—Yes. Not the test. Here you are not talking about an inventive process because you are not using a test that the holder of the gene or the marker has invented. You are using just the fact that it is the marker or the gene. Say you have seven and you have seven different patent holders. You then are paying them for the use of the gene. You have come up with the test but you are still paying them because you are using their gene. Potentially you could be paying seven lots of royalties.

Dr Rourke—Yes, for a complex break. Potentially, yes.

CHAIR—You are starting to make that very expensive.

Senator HEFFERNAN—Can I also take you to an analogy, which is a development site on which you buy half a dozen houses and consolidate it to put up a high rise and make a quid, like my old mate Harry Triguboff. Harry Triguboff says, 'We need-a more immigration because-a I can build-a units but cannot-a fill the units.' You often see the person holding the last block of land—and I cite the example of the Olympic site at Homebush—holds out and holds the market to ransom. With these gene patents, if you are the last person holding the patent and you are saying, 'No, you can't have access, sorry', you enable the premium.

In the case of BRCA, it has not been traded, but in the case of the anti-ageing gene, it is a tradable gene. It will finish up as a tradable commodity in much the same way as the global financial crisis was about trading financial instruments, the creation of credit, and every time you passed the parcel you got a feed until someone dropped the damned thing when they extended the credit to 100 times the capital base of the bank. That will happen to this. These patents will become tradable financial instruments for bankers and lawyers eventually, I will bet you.

Dr Rourke—The point I wanted to make on that, I have now lost. But I do have a very good analogy with someone at Armidale. McDonald's wanted to put a McDonald's on the main drag.

Senator HEFFERNAN—You get the last house there. That does happen.

Dr Rourke—Yes, so you have to be smart about it. The people who are investing have to be smart about it.

Senator HEFFERNAN—That is why you have all these lawyers. I would shoot two of three lawyers, philosophically.

Dr Davies—Can I just make one further comment?

CHAIR—Yes, Dr Davies.

Dr Davies—In areas where there have been a large number of patent applications filed or patents granted, one way of moving forward is something called patent pools. That is where the owners of the intellectual property rights sort of throw all the intellectual property rights into a pool, so all of them share and so that ultimately there can be a reasonable commercial outcome for that technology. I would not be surprised going forward in the area of biotechnology that there will be more examples of patent pools in which technology is cross-licensed so that ultimately it will made available to the public.

Senator HEFFERNAN—But the difficulty in the longer term is that a lot of the dinky-di people who are tucked away in these laboratories are doing it—not because they want to be the next millionaire down the road—but because they want to have an outcome that provides a solution for mankind. Under what is happening now—and I have been out to Westmead—these people are dinky-di people who go to work and do not get paid a lot of money, and they are so pleased with their vocation in life. They have been absolutely trampled on by people who want to get a quid out of the system. That is the problem.

CHAIR—We are just about to wind up, but I just want to follow up the patent pool issue. You can form a patent pool around a condition or a disease, or do you just generally release your patents into a pool that could be used for any particular research?

Dr Davies—Depending on the organisations that own that intellectual property. There are examples of owners of rights have said, 'Okay, I'm going to allow this to be freely available.' There are examples in a number of technologies where they have just said, 'Well, we've got the rights, but we're actually not going to enforce these rights. We're going to allow these rights to be used by anyone', and it could be opened up for genetic testing.

CHAIR—For instance, software.

Dr Davies—Yes.

Senator MOORE—But that can be revoked at any time, can it not?

Dr Davies—Oh yes.

Senator MOORE—They can make that statement—

Senator HEFFERNAN—You watch: Gene Technologies Australia, once they overcome this little review or inquiry by whoever is doing it, the ACCC or ASIC, they will be back at it.

CHAIR—Can we follow up the issue that Senator Moore has raised. You could put open up access to your IP or your patent. Somebody might discover something and you go, 'Oh, sorry. I didn't really mean that.' Is that the idea.

Senator MOORE—I just thought it could be revoked at any time. I did not actually think through that you would only revoke it if there was some advantage to you. But I would imagine that it could be revoked at any time. If you have the patent, you are able to come in and out of such a position of pooling.

Dr Davies—Depending on the commercial and legal arrangement that made between all the parties. You would have an agreement that would cover those sorts of outcomes to stop that from happening. Whatever solution—

Senator MOORE—So it is how you write your contract.

Senator HEFFERNAN—Gene Technologies Australia did that. Back four years ago they said, 'As a gift to the people of Australia, we're not going to impose our licence. Oops! We're in financial trouble as at July last year. You've all got to pay up.'

Dr Davies—That is a commercial entity making a commercial decision.

Senator HEFFERNAN—We are talking about mankind here. We are not bankers.

CHAIR—I think we have given you a fairly good session.

Senator MOORE—Is there anything further that we asked you that you want to get on record? Sometimes there is something that we have not picked up on that you want to put into your evidence. Is there anything?

Dr Davies—I will make one comment. A number of us were research scientists before we came into this profession. We are here as servants to our clients, utilising the laws of this country.

Senator HEFFERNAN—That is right.

Dr Davies—We do not drive the patents system. We are here simply interpreting.

Senator HEFFERNAN—Yes.

Dr Davies—We are trying to get the best outcomes, either for our local clients who may be research organisations, universities and small spin-off companies as well as large multinational companies.

Senator HEFFERNAN—It depends on the person who pays you.

CHAIR—No, hang on. Just let him make his statement.

Dr Davies—I just thought I would make that sort of comment. The patent attorney profession, or the legal profession, is not making the laws. We are here to work with them.

CHAIR—Thank you very much. Thank you for giving so much of your time. We very much appreciate it. As you can tell, there is a great deal of interest in this issue. We will break now until 10.45 and resume with evidence from the Royal College of Pathologists of Australasia.

Proceedings suspended from 10.34 am to 10.52 am

RALSTON, Mr Michael, Member, Genetics Advisory Committee, Royal College of Pathologists of Australasia

SUTHERS, Dr Graeme, Chair, Genetics Advisory Committee, Royal College of Pathologists of Australasia

WATERHOUSE, Dr Tamsin, Deputy Chief Executive Officer, Royal College of Pathologists of Australasia

CHAIR—Thank you, everybody. I welcome representatives from the Royal College of Pathologists of Australasia. I understand that you have been given information on parliamentary privilege and the protection of witnesses. We have received your submission. I invite whoever wants to make a brief opening statement to do so, and then we will ask you some questions.

Dr Waterhouse—Thank you very much, and thank you for inviting us to attend today. We commend the Senate for initiating this inquiry and we are pleased to be able to contribute. The Royal College of Pathologists of Australasia is the leading organisation representing pathologists in this country. Our mission is to train and support pathologists and to optimise the use of pathology testing to achieve better health care. When your doctor arranges a blood test or a biopsy, pathologists are the people, working with their medical scientist colleagues, who perform and interpret those tests to provide you with accurate and useful results. The college trains genetic pathologists and has a keen interest in the rapid expansion of genetic testing opportunities currently taking place.

We initiated the first and thus far only national survey of genetic testing across Australia. We have begun exploring the development of a national framework for genetic testing with the Australian Department of Health and Ageing. The college recognises that patents have been a successful method for fostering innovation in health. Many of the methods and instruments used in laboratories today were developed because of the commercial incentives and protection that patents afford, but we do not support the patenting of genes. Genes are natural objects that do not fulfil the fundamental requirements for an item to be patentable because they are discoveries of nature. I would like to hand over to Dr Graeme Suthers, who is the Chair of our Genetics Advisory Committee, to complete this opening statement.

Dr Suthers—Senators, gene patenting is wrong in principle and it is also wrong in practice. Gene patents already have impeded the delivery of medical genetic testing in Australia. We have documented instances of this in our submission and we would be pleased to expand on this, if required.

Could I note that obtaining these examples was not straightforward and at times was discouraged. We can give a further example of the difficulty in this process as well. We explained in our submission that gene patents can compromise the training, quality, accessibility and research that have underpinned the delivery of accurate and useful medical tests in this country for generations. This is our fundamental of concern: it is our core business. This is not a trivial issue. Internationally medical testing is currently available for about 1,700 different genes and this number continues to grow. In Australia we have five gene tests that are covered by

Medicare and a further 400 gene tests that are provided by state-funded laboratories, predominantly, in a piecemeal fashion across Australia. Approximately half of the tests provided by state-based funding involve patented genes.

We are not seeking to have genes regarded as a special case. The current patent legislation should be implemented using a rational interpretation of words such as 'invention' and 'discovery'. The problem principally has been with the interpretation of the law and the amendment required is one to ensure that this distinction between inventions and discoveries is made explicit.

For existing gene patents, our principal concerns would be addressed by ensuring that the patents do not provide a monopoly on medical testing. Gene patents must be broadly licensed so that laboratories are free to perform the test and improve on it as required. However, unrestrictive licensing is not the whole solution. We must address the anomaly of patenting a discovery. There are 25,000 human genes, most of which have not been patented yet. These genes produce a further 100,000 natural products, each of which could be the subject of a patent application. So if this underlying issue is not addressed, the benefits of the genetic revolution for Australians' health care will be severely restricted.

CHAIR—Thank you.

Senator HEFFERNAN—Thank you very much for your attendance. Could I just ask you in terms of the way the gene law is interpreted and IP Australia is involved, is it a balanced presentation? Do the researchers et cetera have a fair crack at prosecuting their case under the present system, or is it just lawyers?

Dr Suthers—There are mechanisms in place for researchers, service providers and so forth to address what are perceived to be problems with the patents system. What is one-sided about it is that the framework has been set up principally as a commercial IP issue where the principal players involved in running those processes are members of the IP industry rather than professional service providers, such as ourselves, patient groups, ethicists, health economists and so on.

The other element of this, which is clearly related, is the cost. A patent can always be challenged in court, but that costs millions of dollars. If you are wanting to challenge the patentability of something—not who owns it but whether in fact it is patentable—you are not going to get any cash return out of that if you win. If I want to challenge a patent holder and say 'I own the patent so I can get the revenue stream', then it might be worth investing the $3 million or $5 million to take that issue to court. But if you are looking to challenge it to say 'This is not patentable and there should be no revenue stream attached to this', then there is no return for, if I can put it this way, the investment in the court process.

Senator HEFFERNAN—Pardon my colour and movement. The evidence we have received today is that the ageing gene has been traded and the Walter and Eliza Hall Institute mob have now got that, but we have not traded BRCA1 yet. Could it be that, as mankind is driven in a lot of cases by greed, these tradable instruments—which are the certificates of title to the patent—finish up quite legitimately in the hands of bankers and lawyers; that the more you trade them, the more value attaches to them; and that the further away it gets from the person in the

laboratory at Westmead Hospital, the more remote becomes the argument about the public good? Is that not where we are headed?

Dr Suthers—Senator, certainly there is the possibility of that. We already have clear evidence from the last 10 years that the ownership or providence of individual gene patents gets very complex and patents are passed through many hands. About eight years ago, there was a very telling review in Nature, which is one of the premier scientific journals, and it tried to draw a map of the ownership of the patents involved in a particular gene. The committee may be aware that many genes that are patented currently have multiple patents on the one gene. If you track the ownership of each individual patent applying to this gene, you end up with a dense thicket of arrows. Your concern is that some of those arrows will end up with the patents being held by financial institutions or whatever, and yes, that is certainly plausible.

Senator HEFFERNAN—In terms of BRCA1 and 2 and furthering the research for a better test, which is what Westmead was doing—and Westmead has been collecting its data since approximately 1990 and the BRCA patent was issued in 1995 I think—

Dr Suthers—No, it was 1994, I think.

Senator HEFFERNAN—No, 1994, sorry. In terms of the public good and fulfilling a vocation which is not driven by having the biggest yacht on the harbour but rather involves being tucked away in a laboratory at Westmead Hospital, if you can come up with something that improves the wellbeing of your familial cancer clients, under the present law you are restricted. That was graphically demonstrated by Gene Technologies Australia.

What happened with Gene Technologies Australia is that they were starting to get shaky. They might not like anyone stating this publicly but they were getting financially shaky, according to the guy who got the sack with whom I had a discussion. So they called up their assets, and one of the assets they called up was of course the licence on the BRCA, having said some years earlier that it would be patented for the public good.

When push comes to shove, it is the money. The more you have the money argument and influence in the debate and opportunity to argue the public good and the public laboratory in opposition to the granting of the patent, the more lopsided this will become. There is a danger confronting good, well-meaning institutions. I see that the Royal College of Pathologists is at odds with the Walter and Eliza Hall Institute mob because they are in the business of being in the business. I take it that is the reason.

Dr Suthers—It would be fair to say that there is a lot about the current patents system and about patents in principle that we would endorse. If we turn to our laboratories and look at the methods and the machines and so on that are providing the high-quality, consistent and quick turnaround testing that is available in Australia at the moment, that is very much driven by great inventions that have been patented and with appropriate returns going to their inventors.

We do not have an aversion to patents per se; nor do we have an aversion to people developing good tests on the basis of genetic information. If the Walter and Eliza Hall Institute, or indeed any institution, commercial or otherwise, wants to develop a good test to define risk of breast cancer or dementia or epilepsy, or whatever it might be, we have no problem with that being a

patentable invention. But the basis of the invention is a discovery. That is something that is common to humanity. It is not a commercial asset. That is part of our common heritage.

Senator HEFFERNAN—This committee needs to wend its way through the forest of legalese that says that a naturally occurring issue is actually not a discovery, but an invention. That is the problem, is it not?

Dr Suthers—That is the nub of the problem. If we can venture a comment on one of the submissions from IP Australia, the IP Australia comment that the threshold of inventiveness required to turn a discovery into an invention is very slight: there is in fact no minimum threshold requirement for how inventive you need to be. It takes only a scintilla of inventiveness to turn a discovery into an invention. We have grave difficulties with that. Surely the distinction of such a profound issue in terms of what is patentable or not requires more than a scintilla of inventiveness.

Senator HEFFERNAN—Thank you very much.

Senator HUMPHRIES—I am glad that that question was asked because I want to turn to that very point. I think you are right: I think it is true that the threshold is very small. The concern I have about what you have argued to the committee is that you are attempting to treat genetic discoveries, if I may put them in those terms, differently to discoveries in other fields of endeavour in which law grants patents.

It is not true to say that the threshold that turns discovery into invention is very slight only in the area of genetic science. It goes across the entire law of patenting. Some people say a potato peeler, which I gather once had a patent, is only a slight degree of invention, but it got a patent at one time and that is the way that the whole of the law works.

The lawyers have asserted to us that the principles that apply in this area of science and the exploitation of discoveries in that area is no different to any of the patent law anywhere else in Australia or indeed in almost every other part of the world. Can you give us a convincing argument that we should attempt to isolate genetic science and say, if what the lawyers are saying is true, that we will discard the law in that area alone and treat it differently to the rest of the law applying to patents?

Dr Suthers—Senator, I do not think we can make that distinction. We would in fact argue that there should not be a special case for genes and genetics; that in fact this is a fundamental principle under patent law that needs to be resolved. The reason that we have couched this in terms of genetics is partly because that is a theme of interest for the committee and that is also our patch.

But there have been other instances where non-genetic chemicals that are important in medical testing have been patented. We can go back to 1912 when adrenalin, which comes from the adrenal gland and which is part of the fight or flight response. Once that chemical was in a test tube, an American court deemed that that was patentable subject matter.

There is indeed a very longstanding precedent for the patentability of a natural chemical being placed within a test tube. We have real trouble with that initial decision, as do many other

players in this field, and we are not persuaded that that precedent is a good precedent. To answer your question directly, we think that we should not strive to make genetics a special case. This is in fact too important for genetics to be a special case.

Secondly, the fact that there is international acceptance of these patents is only half of the story. There is also international opposition to these patents. It is focused around the gene patents for the reasons that we are having this inquiry now. But there are professional bodies across Australia, across North America and across Europe and in the legislatures there are UN groups who are saying, 'Do not do this. Do not allow genes to be patented. By all means patent the inventions that arise from them, but the genes are discoveries.'

Senator HEFFERNAN—Hear, hear.

Senator HUMPHRIES—They have not been very successful anywhere, though, in terms of changing the law.

Dr Suthers—That is true. But I venture to suggest that that might come back to Senator Heffernan's initial question about the diversity of players making these decisions. If most of the decisions are being made in the commercial and IP environments—and I do not want to disparage the contributions that those professionals have made—they are only part of the players. Patenting is a societal function. It needs to have societal input.

Senator HUMPHRIES—I wonder if the test we are applying here to measure the degree of commercial value assigned to a particular discovery is the wrong test. You point out that the threshold from discovery to invention is very slight, but even the process of discovery can be extremely time consuming and require huge investment to achieve.

I am told with respect to what Senator Heffernan refers to, the BRCA patent, that it was developed at the University of Utah. The National Institute of Health in America put at least $5 million into it and presumably there was a lot of other money invested, so it was a multimillion dollar process to discover this genetic sequence that led to a diagnostic test. One of the scientists who worked on the process was a Nobel Laureate in medicine. All of that suggests an enormous intellectual investment to reach the point at which this test could be devised.

People would say that even at the end of the day they used this huge intellectual investment to get to the point at which they made that discovery, which they turned with that slight bit of extra effort into an invention, and that all of that effort warrants their having a patent over that to exploit it. If you do not create that right to exploit through giving someone a patent, you will discourage that level of investment.

Dr Suthers—Where is the incentive, yes.

Senator HUMPHRIES—Yes. What is your response to that?

Dr Suthers—I think that is a line that my colleagues and I have heard many times. It misrepresents the situation because the technologies that were used to identify the BRCA1 and BRCA2 genes by Myriad Genetics have been developed over decades. There was an enormous amount of work that had been done by a wide variety of people—thousands of people—in

developing the mathematical models, the genetic probes and tests and all that sort of stuff. They came in at one part of the story for the final push to the finish.

At the same time as they were doing this in Utah, there were publicly funded research laboratories in Seattle that were about two months behind in terms of getting over the line. At the same time there was the cancer research campaign in the UK that was tracking down the same genes, and in fact in the UK system they beat Myriad Genetics to getting the BRCA2 patent into the UK patent system. It is wrong to suggest—and I am not saying that you suggested it but it is wrong for people to suggest—that it was solely due to Myriad Genetics. They got a free ride from the enormous amount of infrastructure and development required for their final product.

Mr Ralston—It is called the last brick in the wall.

Senator HUMPHRIES—Yes. Okay. Obviously I have chosen a bad example.

CHAIR—Would you like to try another one?

Dr Suthers—It is a more general issue.

Senator HUMPHRIES—Yes. But would you not say there would be many cases of what you would call discoveries, or discoveries with a little bit of invention added onto the end, that are the product of a huge amount of effort and work by some laboratory or even some corporation that entitles them to some reward for that level of effort? Presumably all the other organisations were all racing for this line. They were almost competing to get to the line first. If you took out the ability to patent what they ended up with, is there not a chance that you would have some of them falling back out of that race because there is not the incentive to be there, and that you would end up without the same investment in that process of discovering those sorts of inventions or discoveries?

Dr Suthers—I think patenting is a very recent-comer to the drivers of scientific endeavour in human affairs. They have really only driven things in the last 10 to 15 years in this sort of area.

Senator HUMPHRIES—The area has only been in existence and genetic science has only really come into its own in the last 15 or 20 years.

Dr Suthers—That is true, but we have an enormous amount of development in other areas as well. I am just thinking more of—

Senator HUMPHRIES—And they have all been subject to patents.

Dr Suthers—No, not all of them. I am just arguing that patents have not been the principal driver for scientific developments in medical research in the last 100 years. They are certainly a key driver at the moment; there is no doubt about that. I would not want to suggest that patents are the only driver.

Senator HUMPHRIES—But would we have had the same level of investment in these discoveries if there was not the capacity to commercially exploit the outcomes?

Dr Suthers—I do not know that anyone can give you a black and white answer on that. We have an enormous amount of public money put into doing this sort of research. If we look back through the research publications in the sixties, seventies and eighties, it has been coming out for the benefit of the community to take the whole issue of science, et cetera, forward—not for the commercial benefit of particular players.

Dr Waterhouse—The actual identification of the gene is not what is going to bring benefit to the people. Ultimately it is the test and therefore there is no problem patenting the test.

Senator HEFFERNAN—Hear, hear.

Dr Waterhouse—They have to get to a point at which they have identified the gene and then develop a test. Therefore discovering the gene is part of the process; it is not the end product because then they need to develop a test.

Senator HUMPHRIES—We have been told, though, that the test is relatively easy, once you have discovered the gene and that that process is only a small threshold that you were talking about before between discovery and invention.

Dr Waterhouse—But ultimately that is the inventive aspect to it. That is why we are saying that the line needs to be drawn—discovery is the process and, yes, it may take a great deal of scientific effort, but in fact the inventive bit comes when you develop a test that will relate back to that. I think also we need to consider that there are many areas of science where in fact enormous effort is put in, and yet the end product of discovery is not patentable. Consider, for example, that from time to time we hear about a new planet being discovered. There is no way somebody can patent that new planet in spite of the fact that it may have taken many, many years and all sorts of inventions along the way, in terms of telescopes et cetera, to find that planet. Ultimately the discovery, the planet, is not patentable.

Senator HUMPHRIES—But I do not quite understand the point you are making there. Are you saying that, with some science, you should not be able to have a commercial application? If there was some commercial application to the discovery of a planet—and I cannot imagine what it would be, but if there was such an application—would it not be reasonable to patent it?

Senator HEFFERNAN—Send me there!

Senator HUMPHRIES—Send you there? Don't tempt me!

Senator WILLIAMS—Leave you there.

CHAIR—Order!

Dr Waterhouse—My only point was the fact that, ultimately, the argument saying that there was enormous scientific effort that goes into making the discovery and that therefore it should be rewarded is not carried through in other areas of science. Therefore it is not an automatic argument.

Senator HUMPHRIES—But if there was some commercial advantage in discovering new planets and you could somehow exploit that, you would have more commercial investment in discovering new planets. If it were commercially valuable, then it would be a good thing for humanity, would it not?

Dr Waterhouse—The commercial advantage is in the test and to actually test the gene. It is not in the gene itself. That is the way it has actually come out—that it is in the gene—but it should really be in the test.

Senator HUMPHRIES—I am about to turn to a different subject.

Senator HEFFERNAN—So the actual locking up under all these patents of access to the isolated gene if the problem.

Dr Waterhouse—Yes. If you have five people who develop five different tests for a particular gene, they should all be able to patent their tests.

Senator HEFFERNAN—Pardon my confusion. God help us. Is it epilepsy or the one that the patent was there for 20 years and we did not get research—

Senator WILLIAMS—Hepatitis C.

Senator HEFFERNAN—Thank you.

Senator WILLIAMS—That is all right. It is my job to look after you, as counsel assisting.

Senator HEFFERNAN—And in the meantime, no-one else could have a crack at it because they had limited access to the gene.

Dr Suthers—That is the problem, but if you lock up the discovery, you then preclude people from doing anything better with it. You are limited to what the patent holder wants to do with it.

Senator HEFFERNAN—Can I just extrapolate that, with the generosity of your agreement, Senator Humphries?

CHAIR—You have a couple of minutes.

Senator HEFFERNAN—In the case of the ageing gene, which Eliza Hall's mob have acquired—they did not invent it—it was a tradable instrument which they acquired. In that particular patent for the isolated gene—and I notice that the agent in that acquisition is appearing today and we will talk to him about that when he gets here—they also in the claim claimed an 'antibody specific to the polypeptide according to any of the claims above'. My interpretation of that, as a welder, is that if the human body creates an antibody, they claim the patent of the antibody that is produced naturally in the body. Is that right?

Dr Suthers—I do not know the details of that patent, but that is certainly plausible. There are 25,000 different genes and each gene produces four or five different proteins within the body. If

isolated genes are deemed to be patentable, then isolated proteins would be deemed to be patentable.

Senator HEFFERNAN—Is it fair to say that the body does produce antibodies naturally?

Dr Suthers—It does.

Senator HEFFERNAN—Well, is it not fair to say that it is the human body that is inventing that and not in this case Eliza Hall?

Dr Suthers—They may have some method which, rather than isolating the antibody from human tissue or serum, uses some other mechanism, and I do not know the details of the patent to be able to comment on that.

CHAIR—So you are saying it could be the mechanism that they have the patent for?

Dr Suthers—It would be plausible to patent a method for creating an antibody rather than patenting the antibody itself. It is that distinction that we have got.

Senator HEFFERNAN—This is well out of my depth, as everyone knows. Claim 18 relating to the ageing gene, and you can see I have it, states 'an ageing composition comprising BCLW or a derivative thereof'. Therefore they have claimed the pharmaceutical composition which contains the gene, and by having it contain the gene, they have shut out everyone else from the proposition. Is that not right?

Dr Suthers—That is a general consequence of gene patents. Again, I do not know the details of the specific patent.

Senator HEFFERNAN—This is absolutely monopolising into a cartel.

Dr Suthers—That is our principal concern—that a patent holder can have an absolute monopoly on things that flow from knowledge of that gene.

Senator HEFFERNAN—Just to give colour and movement to the story, Eliza Hall is a great institution, but they are also in the business of trading. They have picked up a tradable instrument which they can then trade on to someone else, if they run short of money at some time, and away they go.

Mr Ralston—Senator, I think a very good example of that is the haemochromatosis gene, which caused a lot of angst in the United States. The owners of those patents have stopped laboratories from testing and people have given up testing. They actually tried it here too, but they were the 20-somethingth owner of that patent, it had been traded on so many times.

Senator HEFFERNAN—And this is the river of gold that I talk about. Thank you for confirming that there is a river of gold.

Senator HUMPHRIES—If there is a river of gold, presumably it is suffering from drought a bit at the moment because the number of patents over genetic technology—

Senator BOYCE—A river of lead, perhaps, Senator Humphries?

Senator HUMPHRIES—Well, a slightly reduced flow because we are told that the number of patents for biotechnology products, including genetic products, has been diminishing since 2001 in Australia, and that reflects the pattern around the world. Now that the human genome has been mapped, it is harder to create the element of inventiveness that is required to get a patent over a gene or an application of a gene. Is that your experience?

Dr Suthers—I think the ground rules have been changing over the last 10 to 15 years. Despite the broad acceptance of gene patents in many jurisdictions, there has been this persistent outcry and it has meant that the level of inventiveness or the definition of discrete utility, et cetera, that applicants need to supply has been changing over time. So that the gene patents that were accepted, at least in the US in the early nineties, were much more general and had an ill-defined utility compared to what they are doing in the late nineties and through into the 2000s.

So I do not know that just the raw numbers necessarily give the reasons as to why there has been this shift. It may also relate in the Australian context to a lack of clarity about the patentability of some genes and the potential costs of enforcing it. I just want to phrase that generally. GTG, referred to by Senator Heffernan, was or is the exclusive licensee for BRCA1 and BRCA2 genetic testing on Australia, and has on two occasions sought to enforce its legitimate monopoly on that testing. And on two occasions that has not eventuated. It may well be that other players in the field, noticing that experience, are reflecting on whether it is worth engaging in the fight at that level, or will they seek to put their energies elsewhere. It is much more complex than the graph from IP Australia would suggest.

Senator HEFFERNAN—What was the reaction? Did your institution in Adelaide receive one of these put-you-on-notice, legalese litigation letters?

Dr Suthers—Senator, I would need to limit my comments today to representing the Royal College of Pathologists because I am not authorised to speak on behalf of myself.

Senator HEFFERNAN—Okay, no worries. Could you confirm to this committee something that was challenged earlier, which is that in the interpretation of BRCA1 and 2 in Europe, the present situation in Europe is that those of the particular extraction of the Jewish community pay a huge premium to access the test compared to everyone else?

Dr Suthers—That is correct. The European Patent Office over the last couple of years overturned the BRCA1 and 2 patents held by Myriad Genetics, but in a decision late last year, it gave back to Myriad Genetics the patent over particular mutations that occur at relatively high frequency among the Ashkenazi Jewish community. If you are going to do a test for the Jewish mutations, typically in a woman or man of Jewish ancestry, that falls within the scope of Myriad's patent. If you are going to test someone for the non-Jewish mutations, irrespective of their ethnicity, it does not fall within the remit of Myriad's patent.

Senator HEFFERNAN—So does that challenge human rights?

Dr Suthers—Some people have suggested that it does. I find it makes it very difficult to know, from a pathologist's perspective, how you partition your tests.

Senator HEFFERNAN—Yes.

Dr Suthers—How do you test only for these particular mutations and skip over the others because of the additional cost in case you find something there.

Senator BOYCE—Would you suggest the appointment of an ethics committee to work within the patents application process? How would you see that working?

Dr Suthers—It my earlier response to Senator Heffernan, I just go to the point of saying that patents operate within a societal framework, and that where there are contentious issues, as we are facing at the moment, it may be appropriate to have a broader view.

Senator BOYCE—Such as the one you have mentioned, although it is very remote from Australia.

Dr Suthers—I do not have a particular framework to put to you as to how that might work. There would need to be broad consultation with the community as to how best to set up that sort of process. But I think Senator Humphries earlier raised a relevant point that we should avoid making genetics a special case. Genetics if the hot potato for the moment, but the issues that are captured in the ethics story are not peculiar to genetics. If indeed there is a case for having some broader consultation about patenting issues, then it should apply to other patents and not just genetic patents.

Senator HUMPHRIES—I respect the logic of what you say. I think it is sound not to try to make a separate case for the treatment of genetics to be different to other areas of science, but in turn what you are proposing is really a very fundamental rewrite of the law of patents. It seems to me that that thin threshold between discovery and invention is applied all over the place in patent law and would need very major rewrites or change of culture to effect the changes you are suggesting. Perhaps it is a good thing. Perhaps we should have a higher threshold. You are not proposing that there be a specific amendment of the Patents Act with respect to genetic science.

Dr Suthers—Correct.

Dr Waterhouse—That is correct.

Senator MOORE—I am interested in terms of the response of the college to the Law Reform Commission that looked very deeply into all these issues. On my understanding, it went to extraordinary lengths of consultation in trying to get public interest. I do not know how successful that was because certainly what we have seen since it came out, there has not been much action taken and there has not been much pressure put on either. I am interested in the range of suggestions the Law Reform Commission put up and the college's response to what the commission said should happen.

Dr Suthers—Thank you. The ALRC did an excellent job in canvassing opinion and they do good reports. A number of the key issues they flagged there was the fact that although in hindsight you might consider gene patents were probably not a good idea, the reality was that they were there. So they concentrated their recommendations on saying, 'What are the things that could be implemented to improve the administration of this in the future?'

The talked about providing more resourcing and more training for the patent examiners and indeed raising the bar in terms of the degree of inventiveness that is required without changing the law per se, but by making that clearer for prospective patents. They also talked about the importance of broad licensing arrangements for gene patents. We would agree that for the current gene patents, some mechanism for ensuring broad or open licensing would address many of our concerns. Those were the key practical issues. There are others that have fallen off the back of my brain for the moment.

Senator MOORE—Sure. They are the ones we talked about last year.

Dr Suthers—But we think that there are indeed ways that that could certainly advance the story. Our concern remains though that we are at the beginning of the gene protein patent story. We are not here in a situation where in fact most of the fuss has already happened and it is yesterday's news. It is going to be tomorrow's news because in IP Australia's submission, or when it gave evidence to this committee back in March, they said that they think there are about 400 genes, human and animal, that have been patented in Australia.

We have 25,000 different human genes. Scientifically we are just on the threshold of getting some inkling of what most of them do. We have a long way to go. Huge amounts of data have been collected and analysed internationally at the moment in an attempt to get clarity on this. What is happening in parallel but not so prominently in the public eye is the analysis of proteins. We have genomics, which deals with lots of genes, and proteomics, and they are the current buzz phrase. They are all going to yield potentially commercialise-able investigations. We have no problems with commercial tests, but the discoveries that underpin those should remain discoveries. So the ALRC makes great suggestions to deal with the legacy, but we do need something different prospectively.

Senator MOORE—So the recommendation that the ALRC made, about which we have heard a lot—which is the research exclusion—that does not go far enough, in your opinion? My understanding is that the lack of clarity around that has been raised consistently. In your paper you talk particularly about where people overseas—and you use the overseas example with Myriad rather than what has happened here and I understand that—have just ignored them instead of going ahead. But that is more from the commercial side. Specifically in relation to the process of clarity, you get a patent for what you believe you have, but that does not preclude anyone else from researching in the area. That would not be sufficient to meet your concerns?

Dr Suthers—Correct. It would not be sufficient. The reason it would not be sufficient, Senator, is that on the research side of things, there may be provisions as per the ALRC recommendations. But we are primarily dealing here with medical testing, not in a research setting but in a service delivery setting.

Senator MOORE—So we have a double argument: one is the research, and one is specifically the testing.

Dr Suthers—Yes, the medical testing. And we already have evidence that that is being compromised. We also have evidence that our evidence is limited; that there are other compromises.

Senator MOORE—That we do not know about.

Dr Suthers—That are just not appearing on the radar. So we are very concerned about the direction in which this is going.

Senator MOORE—Okay. Thank you.

CHAIR—Senator Adams?

Senator ADAMS—My questions follow on, but Senator Williams can go first.

Senator WILLIAMS—We have evidence of the problems with medical testing. Can you give us some examples of that?

Dr Suthers—Sure. At the hearing held in Canberra in March Senator Heffernan asked whether any state or federal department of health had been encouraged not to make a submission to the inquiry. The person to whom the question was directed was not aware of any such discouragement. We are aware and we wish to advise you of that. Our written submission includes a number of specific examples of gene patents compromising the delivery of health care. We sought to get more cases to strengthen our argument that diagnostic genetic tests should not be subject to patents. We were advised of one very telling instance that we did not include. This was a situation where a laboratory in a major public hospital wanted to develop a new genetic test for patient care and it contacted its supplier to request the necessary chemicals to do the test.

These chemical reagents are specific for each gene so that the supplier could tell what gene the laboratory was planning to test. The supplier recognised that the gene the laboratory wanted to test was patented and the supplier advised the laboratory that the necessary chemicals would not be provided unless the laboratory had approval from the patent holder. Of course, I do not know why the supplier refused to supply the chemicals but you can be held in breach of patent law if you contribute to the infringement by somebody else—and presumably that was part of the concern.

Senator BOYCE—There is a protocol in place that requires them to do that.

Dr Suthers—The outcome was that the hospital laboratory did not develop the tests and patients are not being tested. We thought this was a key example to present to this inquiry because it introduced the suppliers of laboratory chemicals as the de facto enforcers of gene patents and as controlling the introduction of genetic tests by a medical laboratory. But the host institution for this public sector laboratory would not give permission for any details of this case to be revealed. As a result, we are left with having to present this instance to you as hearsay rather than as being substantiated.

Senator BOYCE—Did the hospital go back to the owner of the patent and say, 'We want to do this?'

Dr Suthers—I am afraid that I have no further information.

Senator BOYCE—That is only half a story, really.

Dr Suthers—Absolutely. But my point was to flag that we were constrained in what information we could get to present to you.

Senator HEFFERNAN—The question I asked was incomplete by a long way.

Dr Suthers—Yes.

Senator ADAMS—I would like to follow on with a question about costs. Some submissions have suggested that genetic testing has been rationed in Australia due to costs. Do you have any evidence about that?

Dr Suthers—We do not have direct evidence that it has been rationed on the basis of costs but we have very clear evidence that the rates of testing for different genes is unequal across the country. Earlier I mentioned that only five genes are tested under Medicare. Medicare would provide a universal form of funding across Australia. Four hundred or so different gene tests are funded by a variety of state government, research and commercial laboratories in a piecemeal fashion across the country.

A couple of years ago the Royal College of Pathologists of Australasia did the only national survey that there has been of genetic testing. At that time we found that three-quarters of these different genetic tests were being used at very different rates in different parts of the country, corresponding principally to what the funding mechanism was in a particular state.

We can provide plenty of anecdotes that someone in one state can have the test for free because it is provided by a public sector laboratory there, but someone in another state has to pay, or a private sector patient in the state hosting the public sector laboratory has to pay. There are anecdotes at that level but I think that the most telling evidence is from the survey. Seventy-five per cent of the tests being offered are utilised at very different rates across the country.

Senator ADAMS—I am thinking about our new Health Commission's report and where we go with costs. I think that these health care costs could have some future implications on gene patents in the future. Could you comment on that? Have you read the report or have you read the executive summary?

Dr Suthers—It is in the 'to read' list. You raised an important point. Did you want to add to that?

Mr Ralston—I have an example which was in our submission that relates to IgH and TCR gene rearrangements in leukaemia, which is marketed in this country by a company called InVivoScribe Technologies. We have just started applying and forcing that patent. The cost for reagents for doing those tests have gone from $28 per patient to around the $300 mark.

Senator ADAMS—Why?

Mr Ralston—Because they are insisting on people using their reagents. They are not only insisting on them using their reagents; they are also using them in the test volumes that they

specify. The first thing most chemical laboratories do is work out how they can reduce the amount of reagent to make it more efficient for the health institution to provide the tests.

Senator BOYCE—Is this a Medicare-funded test?

Mr Ralston—No.

Senator BOYCE—Is it privately funded?

Mr Ralston—It is privately funded.

Dr Suthers—Privately funded or paid through state health departments through public sector institutions.

Senator HEFFERNAN—Part of what we are looking at is funding the public cost to health. As a fixed administrative overhead to public health how much will the licence fees be, as opposed to what happened to those women who were here yesterday? I have said to this committee a few times that people in Canada said, 'We will up it by 400 per cent.' That particular cost is more than 400 per cent. It is pretty handy that the GTG experience happened, with my knowledge of what happened at Westmead. When I originally rang the guy—the fellow who got the sack—he said, 'We are not threatened by anything that the parliament can do to us.' I said, 'That is fair enough.'

However, he did say that Australia was lucky; it had a good outcome for this test even though it had just put all our laboratories on notice to surrender their research and data and to do their testing here in lieu of litigation. That is what the letter says and I have your letter. He said, 'We have a great outcome because we discovered that Myriad was breaching one of our patents.' As part of the settlement of that dispute, Myriad decided that Gene Technologies Australia could do the tests for the BRC in Australia instead of having to send it to the United States, as they do in Japan. If they had not discovered that breach of the other patent, all these tests would, in theory, be going back to the United States for a test. How much would that have cost?

Dr Suthers—Lots.

Mr Ralston—It is interesting to look at what happened to Myriad in the United Kingdom where they tried to enforce their patents there. Essentially, the health authorities in the United Kingdom closed them down and said, 'Sorry, but we are not going to do it.'

Senator HEFFERNAN—They told them to bugger off. That is what we ought to do here.

Mr Ralston—They have not been able to apply their patents in the United Kingdom at all.

CHAIR—We have Senator Boyce next, and then Senator Humphries and I also have a question.

Senator BOYCE—Mr Ralston, I wanted to follow up on your earlier comments about the patent involving the haemochromatosis gene, which you mentioned had been traded 20 times. Do you know whether it was traded for a profit?

Mr Ralston—I assume that it would have been, but I do not know.

Senator BOYCE—The point I am making is that we have no idea whether it was traded that many times because it was valuable, or whether it was something you got rid of because it was not a lot of use.

Mr Ralston—It was not valuable, yes. I cannot answer that.

Senator BOYCE—You do not know?

Mr Ralston—I know that in the United States that patent is strictly enforced.

Senator HEFFERNAN—The point is that the tradability was not about the research; it was about the money trail. That is why you trade the damn thing. Either way the answer to the question is that it was worth nothing or it was worth a lot. The reason you trade the thing is—

Senator BOYCE—Dry gullies or rivers of gold, Senator Heffernan.

Senator HEFFERNAN—No, you are talking about the fact that you trade to get rid of it out of the system, as you see it, for a benefit, either because it is not worth much or it is worth a lot more to trade it. It is all about the money trail.

CHAIR—We can ask committee members questions later. Senator Humphries, do you have any questions?

Senator HUMPHRIES—By extraordinary coincidence my question flows on from that. Professor Christie in his submission—and he will be giving evidence later today—says that the appropriate response to people owning patents in a particular area where there are medically useful applications is the same response that we have with respect to the pharmaceutical benefits scheme. That is, the government enters the field, it subsidises the sale of the product, or it acquires the rights to sell the product and it goes out into the marketplace, identifies what is needed and ensures that it is available to people at an affordable price. Basically he is not necessarily arguing for a PBS in respect of genetic testing; he is arguing for some kind of government intervention to make that more available. Would you support that contention?

Dr Suthers—With a large caution. In principle, our concern is to get accurate and useful medical testing available in a timely fashion to the patients who seek health care in Australia. If that is a vehicle that achieves that goal, we have achieved our goal. My big concern is that the PBAC has been a superb and innovative mechanism for Australian health, but it is slow. When we look at the rapidity with which gene tests are added, modified, improved, changed, et cetera, in Australia at the moment we find that no vehicle of that ilk would be able to respond quickly enough. When we did this national survey looking at genetic testing across Australia in 2006 with projections into 2007 we found that the diversity of genetic testing increased by seven per cent just in that period. This is a very rapidly moving field, and we would need to have a very responsive mechanism if that were to be successful.

Dr Waterhouse—We do understand that the health technology assessment review that is going on at the moment is looking to address some of the delays that have occurred, not so much

with the PBAC process as with the MSAC process. A big part of the problem is that there are disconnects at the moment. For example, at least one drug is listed on the PBAC that requires a genetic test in order to be eligible to have the drug, but the test itself is not funded. Therefore, people can pay up to $1,000 in order to have a test only to find that it proves they are not eligible for the drug because they do not have the gene. A lot of anomalies like that need to be ironed out. However, work is being done and we are certainly contributing to that as well.

Senator HUMPHRIES—Some would say that the slowness of the process is a cost-saving mechanism but I would not suggest that.

CHAIR—You would not say that, would you, Senator Humphries?

Senator HUMPHRIES—No.

CHAIR—My question comes back to the issue of whether or not genetics is a special case. It seems to me that a lot of the evidence you have provided indicates that it is. You said earlier that instead of being at the peak—some people are suggesting that that is where we are going with genetics into the future—we are just at the bottom. I agree with you; I think there will be a tremendous amount of development in this area. Why is it not a special case when clearly some issues here are not specific to some of those other issues and we are at the start of the process?

Dr Suthers—In some areas of public policy genetics is a very special case because of family issues, implications and so on. We are dealing here with accessibility to testing and that is our perspective as pathologists. We would argue that it is not a special case. In fact there is a real risk if it is regarded as a special case. As soon as we make genetics a special case we need to start developing the workarounds to maintain its special status into the future. That will build layer upon layer of regulations and workarounds, et cetera.

It really comes back to this core issue of what is a discovery verses an invention. Much of the discussion in which we have been involved over the past seven years of this story—it is clearly there in all the applications—is caught up in the consequences of discoveries essentially being patentable. Allowing for the fact that anomalies will occur we are caught up with all sorts of workarounds. If we could go back to the core issue and address that core issue in a generic and not a genetic sense we would not need to come back to lots of workarounds for special situations.

The genetics arena will change very rapidly. As a professional in the area I find it really hard to keep up, even in my small domain, because so much is happening. The last thing we need is to have more crisis workaround in this area.

CHAIR—Thank you. Are there any final burning questions?

Senator HEFFERNAN—What is the answer to my question about the defining moment of what this is all about—that is, the definition between discovery and invention? How the hell do we answer that question?

Dr Suthers—We are not patent attorneys. I think the critical issue will be coming up with a tighter definition of what level of inventive step is required. I have informal comments from

some players in the field that Australia has a very low threshold of inventiveness—the scintilla of inventiveness as per the IP Australia submission. Somehow we need to reassert that discoveries of nature are not patentable. That was written in the original 1642 document. Somehow we need to capture that again. The patent system has done great things for developing and developed societies over hundreds of years. We do not want to throw that out but we have to get back that definition.

Senator HEFFERNAN—My point is how many bits of the body can be patented?

Dr Suthers—We have 25,000 genes so we have lots to go.

Senator HEFFERNAN—I ask a question, as they did of the slaves in the Roman empire: what is their legal status as they were not chattels? I get into trouble when I ask a question about—

CHAIR—You will not get into trouble now.

Senator HEFFERNAN—I ask the question, 'Who owns your body?' which I realise is not quite right. Because they are allowing the patent of the actual gene and not the discovery of good work from the gene, possession is nine-tenths of the law. If you have the patent on access to the gene you own that bit of the body.

Dr Suthers—We agree with that interpretation. IP Australia has raised an issue in an attempt to try to clarify a misunderstanding that a patent holder does not own your genes. That is to be found on page 23 of their submission. To us the following sentence is the nub of the issue. IP Australia states:

A patent is a right to restrain others from using or exploiting the claimed invention without permission

In other words, you need permission from somebody else to access your own genes.

Senator HEFFERNAN—Yes.

Dr Suthers—That does not make sense.

Senator HEFFERNAN—Can I have your approval to ask, 'Who owns your body?'

CHAIR—Ignore that question. That is the end of our questions. Do you have anything that you would like to add? Have we covered everything that you wanted to cover?

Senator BOYCE—Could we get a copy of the survey that you did of funding sources for tests?

Dr Suthers—Yes, we can certainly provide that. Senator, I emphasise that we did not explicitly seek information about how the 400 tests were funded across Australia. However, we can say that of the 53 laboratories that provided data—the great majority of laboratories Australia-wide were doing this stuff—60 per cent were in the public sector, 20 per cent were in the academic sector providing medical testing, and 20 per cent were in the private sector. In

relation to issues about access to testing and the problems there, we could document different rates of utilisation in different states and territories but we do not have hard data to show why there were different rates of utilisation. We would be delighted to provide you with that paper.

Senator BOYCE—But it is your contention that the sources of the funding were in some way—

Dr Suthers—They would be a factor, yes.

Senator BOYCE—Yes.

Senator HEFFERNAN—Is the underlying problem for the future protection of the human species that the cost will become more relevant than the outcome by cartel type monopolisation of the rights to bits and pieces?

Dr Waterhouse—It does not relate only to costs; there are also things such as training issues, quality assurance and so on. If you are having genetic tests done in only one laboratory you do not have the opportunity to implement those sorts of things. Those are just as important to many of us.

Senator MOORE—I seek clarification of your survey where you refer to public, academic and private. Would a place like a hospital come under public?

Dr Suthers—That is correct. It was an arm wave grouping because many laboratories would, in fact, have a private stream, an academic stream—

Senator MOORE—They would have academics so there is a difference.

Dr Suthers—There were broad brush strokes.

Senator MOORE—Thank you.

Mr Ralston—Could I leave you with one thought? In answer to your query a few moments ago, go back and look at what the OECD said about licensing practices. The OECD made some very reasonable comments about licensing and the broad licensing that is keeping health care affordable.

Senator HEFFERNAN—Myriad in the United States wanted to have broad across the community screening from BRCA1 and BRCA2, but that is not necessary if you go to a familial centre. They wanted to commercialise it and exploit it by having this broad screening, which would have been wrong.

CHAIR—Thank you. As you can see we could keep going for hours. Thank you very much; it is much appreciated.

Dr Suthers—Thank you.

[11.52 am]

CHRISTIE, Professor Andrew, Private capacity

CHAIR—Professor Christie, I welcome you to the committee. I understand that you have been given information on parliamentary privilege and the protection of witnesses. We have your submission. I invite you to make an opening statement. I know you were sitting in the back of the committee room so you would know that we will ask you a whole lot of questions.

Prof. Christie—I will commence with my opening statement. Specifically, thank you for letting me continue to contribute to your inquiry today by having me appear personally. I am very grateful for that and I am looking forward to talking with you and to answering questions, et cetera. Secondly, thank you in a general sense for having this inquiry. I have been observing patent law, practice and policy in Australia and overseas for getting on to 25 years and I know that the situation is not optimal. There are things that we need to fix up.

Gene patents have become a key focal point—it is not the only one; there are others—for concerns about the patent system. I hope that this inquiry will allow us to improve the patent system for both genetic conventions and generally because there are improvements to be made. I will make one additional comment beyond what I put in my submission. I apologise in advance if it seems in any way to be patronising as I do not mean it to be. Because I think it is so important I have to put it in this straightforward language. I exhort this inquiry to be very clear about what problems it is trying to resolve. I say that because over 25 years I have been able to observe lots of concerns expressed in lots of different ways. Often it is very hard to know what that means. You need to scrape away and go down to work out exactly what is of concern.

I have put in my submission what I believe to be four commonly recurring themes that lie below the various concerns I have heard over the years about patents for genetic conventions. There may be others and no doubt your inquiry will uncover them if there are. Those four common themes are examples of the fact that you need to go down that extra level to know what problems have to be fixed and so that your recommendations are appropriately focused.

You will see from my submission I have suggested that the four most commonly recurring themes are, firstly, a concern about the width of patents that have been granted in the past and may be granted in the future; secondly, a concern about access, which is part of what I heard today just before I appeared. Of course, we want to make sure that Australians—women with breast cancer, men with cancer and all Australians with health problems—are able to access the appropriate tests, technologies and therapies.

There is a concern about the preclusion of further research in this area. It is fundamental that further research be undertaken in the medical space to ensure that Australians can be appropriately treated. There is another concern that I think is different in genre from those first three concerns. Those first three concerns essentially are economic. They are saying ‘The patent system either as it is applied, as it could be applied or as it may be seen to have been applied to genetic conventions is having the wrong economic result.’

The fourth concern cannot be categorised that way, yet it is equally valid. It is non-economic—which is probably a lawyer phrase—and it is a social or moral concern, or both. Independent of the economic consequences of granting or not granting patents there is something abhorrent about granting patents to some subject matters. Genes is one of those subject matters about which such concerns have been expressed for a long time. But there are others, for example, plants or animals. Believe it or not, some people believe morally that software should not be patented. It is not just life forms about which this concern has been expressed. From my involvement I have identified at least those four commonly recurring concerns. I have suggested that when one scrapes away and looks at what that means there are, or can be, mechanisms in our law, our practice and our policy that address them.

To conclude this observation, I again say that I strongly encourage the committee to be clear about the concerns being expressed to it and to go down those levels of understanding. In that way I am confident you will be able to identify the right solutions to the problems.

Senator HEFFERNAN—Is it fair to say that we have some of it wrong?

Prof. Christie—Absolutely. Nothing in life is perfect, not even patent law.

Senator HEFFERNAN—With an ageing population et cetera, there will be increased costs for medical care and things that we tend to take for granted and do not appreciate until we lose them. We are building into the cost of care a whole lot of administrative fixed overheads, part of which you have just talked about. You referred in paragraph 3.2 of your submission to 'restriction on access to genetic conventions with BRC.' Do you think that licence was too broad or was its interpretation too broad?

Prof. Christie—I do not believe I have seen the terms of the licence.

Senator HEFFERNAN—I do not think you want to have a look.

Prof. Christie—Could you perhaps thumbnail sketch me which bits you want me to consider?

Senator HEFFERNAN—In good faith I can speak about Westmead hospital, having collected data from 1990 about a number of families that have had cancer as part of their familial history. They go back to the sample in 1990 and say, 'We will go back and do this test' and eventually they find something. Gene Technologies Australia said to them, 'Surrender all your data.' Is that not too broad? Is that not what you are talking about here? What is wrong with Westmead improving the test? Under the terms of the patent they could not.

Prof. Christie—Let me make some assumptions about that scenario and simplify it for my benefit, if that is okay. I think I am hearing a question about whether or not patents may preclude further research being undertaken. Is that one example?

Senator HEFFERNAN—Yes.

Prof. Christie—I agree. That is one of the common themes that I have observed. I believe that the patent system must not do that. If that were to happen it would be completely antithetical to its economic objectives let alone its social objectives.

Senator HEFFERNAN—That begs the question: is that not what is already happening? By locking up access to the gene—not to some discovery downstream from the gene but to the actual gene—do you not preclude better testing, which is one way of putting it?

Prof. Christie—That may well be the case because we have uncertainty in Australia as to whether or not we have anything like an experimental use exception.

Senator HEFFERNAN—That view has certainly been expressed.

Prof. Christie—I would say the better view is that we probably do not, but uncertainty cannot be argued against.

Senator HEFFERNAN—The other side took this to the courts and they have a mess. Bloody lawyers!

Prof. Christie—I suggest that we try to resolve that problem.

Senator HEFFERNAN—Don't you shout! I was with 300 lawyers last night.

Prof. Christie—I am one of the three that you do not shoot; the other two you can. I heard your comment last night.

Senator HEFFERNAN—You two are excluded. I am speaking philosophically and not physically about the shooting.

Senator HUMPHRIES—I think you made some very good points in your submission. You referred to a problem with what we patent and you said:

The matter of manufacture test should be reviewed because aspects of this test are ambiguous and obscure and the test may warrant reform.

Can you tell us what you mean by that?

Prof. Christie—Yes, I can, at least partially. As all of you would well know, the phrase we use in our current 1990 Patents Act is 'manufacture' or 'new manufacture', depending on which part of the act you are reading. It refers to the 1623 statute of monopoly which is obscure in some sense. It is not that we do not know where it has come from but we are not quite sure what it means now that it has come to us through those centuries. The meaning is not clear to interested laypeople, or for that matter to interested non-laypeople.

It is ambiguous in the sense that we are not sure whether everything that was in the 1623 legislation, including the preclusion for general inconvenience, has come forward 400 years. It is uncertain in that it is inherently flexible to be able to be used 400 years later. We may have to accept the trade off between uncertainty and flexibility, or maybe we can get a better trade off. I think the ambiguity, obscurity and uncertainty are captured in that way.

Senator HUMPHRIES—Let us establish how that hits the ground. Are we patenting too much as the previous witnesses were suggesting? They were saying that the threshold between

discovery and invention was very slight—a scintilla of inventiveness gives you that transition. Are you saying that we are patenting too much because that level of investment in intellectual property in the process is not sufficiently great to warrant the granting of a patent?

Prof. Christie—I think it is largely that way. Let me elaborate if I may. There are a couple of ways in which we could be patenting too much. One would be through threshold subject matters. Economically or socially we do not want to ask questions about whether or not we should be granting them monopoly rights. That is one thing; that is not the scintilla of the testing. The other way would be to determine whether or not our tests would show that a certain subject matter was in the right space. Economically, does that justify the grant of a 20-year monopoly?

As you know, the key ways to do that are through novelty, inventiveness and utility. Our Australian laws have their own unique additional features about threshold inventiveness and the like. I would say there is a danger. In the first instance, once we have let the subject matter in, sometimes we are patenting too much, to use your phrase, through not applying a sufficiently rigorous test or tests. I do not think that one of the tests I mentioned in my submission is applied sufficiently rigorously. Utility has finally been recognised by most stakeholders—an issue to which I will come back in a moment.

Let me deal now with your inventiveness or inventive step threshold. It has also been said that our inventive step test in Australia is too low. If that is true—let us assume for a moment that it is—it means that the subject matters are coming through and are passing that test. We might have said retrospectively that we should not have granted a monopoly there. We should not have done so because inevitably we would have got to that point. Inventive step is about what is not obvious. Obvious means 'obvius' or 'on the way'. We do not want to grant exclusive rights to developments that would occur on the way, in the usual course of events; we want only to grant monopoly rights to innovations that required some spark or leap off the obvious. Inventive step seeks to do that.

If the inventive step threshold is too low we are granting too many patents, not necessarily to the wrong subject matter but to a subject matter that would have occurred anyway. We did not need to give away 20 years of rights to get this invention; it would have occurred in the ordinary course of events. I might go back to the other key test that we need to focus on here, which is usefulness or utility. It is clear that Australia's provisions on this are out of kilter with other major jurisdictions, and I think inappropriately so. Because of the way the act has been worded over the years and its history we have ended up with a mixed but low-level test for usefulness.

Five or six years ago the ALRC and a few other bodies have recommended that we apply the United States style utility test. If we did that I would be confident that that would improve our patent system and it would stop the grant of some patents that you or others may say were too much. I think this is where we get to the invention discovery dichotomy because they are not really advances; they are simply new understandings that have not been given practical application.

My submission briefly makes the point that we should adopt the recommendations to improve utility to ensure that we do not get what I think is a blurring and a falling on the wrong side of the line cases where we would say, 'That is a discovery, not an invention.' I suggest that we focus on utility as much as on inventive step.

Senator HUMPHRIES—I apply the comments that you made to the area of genetic discoveries. Are you specifically saying that you feel many of the applications for genetic science that we have now allowed to be patented have probably fallen into that category of being things we would find on the way? If we were doing this over again—if we were looking back over this and we were doing this with the benefit of hindsight—we would not patent some of the things that we have patented in this area of science?

Prof. Christie—I think I am saying that and something else. On that one we would possibly recognise that the inventive step threshold was not applied at the appropriate level. Therefore, some of the things to which we granted 20-year monopolies would have evolved without a spark of ingenuity. We therefore do not have to reward or incentivise with a grant of a patent. On the utility side I would also say that I think some of the patents that have been granted in the past did not require the patentee sufficiently to specify, 'What is the use of this?' What practical application are you telling society that you have given to it through this invention? I think both utility and inventive step, either not applied at the right level or not set at the right level in the first instance, would mean that in retrospect the early gene patents are ones that we would prefer not to have, for social and economic reasons.

Senator HUMPHRIES—Is one of the reasons for that—I am having a go at people in the back at the room—that we do not have the level of expertise in our patent system for people to be able to sit down and read a complex document and understand its potential for utility? With the best will in the world you cannot have a genetic scientist with 20 years experience sitting in the Patents Office to read the next patent that comes through in that area.

Prof. Christie—Let me answer that question in two phases—firstly, specifically as it relates to utility and then more generally. On utility I think the main problem is that we do not require them to examine for utilities, so it is a problem in the law and not in their inherent ability to do so. More generally, what do I think about the inherent ability of the office in Australia or elsewhere to do that job? Inherently I think it is high. I do not have the view that we are lacking in appropriately qualified people in this area or other areas.

We are not asking them to be the scientist who has created the invention and we are not asking them to be inventive; we are simply asking them to judge, in light of what we know from prior published documents, how this appears to sit in relation to newness and inventive step. I do not have a concern that we do not have sufficient expertise in the office. However, I have a concern that the things we ask the office to do either are not set at the right level or are not set at all. At the moment I do not think we ask them to examine for you utility but we should. We ask them to examine for inventive step and I think the office is developing its understanding of how to apply that appropriately.

Senator BOYCE—I think you are suggesting that some of the patents in this area that have been granted in the past are too broad, which corresponds to the evidence that we took yesterday. What is the remedy for that, if any?

Prof. Christie—The way to rectify that situation retrospectively would be to challenge the grant and to seek to have it revoked. We have mechanisms in our law. More generally, nobody gets anything right. I do not get everything right; I wish I did but I do not. I make mistakes,

patent offices make mistakes, inventors make mistakes and everybody else makes mistakes. We need to put in place mechanisms to rectify egregious mistakes and preferably all mistakes.

In retrospect if the Patent Office wrongly granted a patent post acceptance and prior to grant we would give third parties an opportunity to oppose. Post grant anybody has an opportunity to oppose—to go to court and to seek to have that patent revoked. Many patents are revoked. On average, patent litigation tends to work out so that roughly half are revoked and roughly half are passed. The ones that are revoked are so unclear that you need a court to resolve them.

Senator HUMPHRIES—That is a very expensive process though, is it not?

Prof. Christie—Unfortunately it is extremely expensive.

Senator HUMPHRIES—Should there be some kind of public interest mechanism to allow that to be done when public interest demands it rather than because some competitor or someone else thinks that he or she should take the patent holder to court?

Prof. Christie—I think that would be preferable. One of the comments that came out in the public hearings I was conducting in another capacity for the Advisory Council intellectual properties review of the patentable subject matter test was along those lines. I must admit that that made an impact on me. Unfortunately I think we have left too much to the private sector. Essentially we need a wealthy competitor to say, 'That has been wrongly granted.' We cannot expect you, me, or even non-governmental organisations to stump up the big cash. I think it would be good in principle to see whether we cannot get the public interest back into this a bit more.

Senator HUMPHRIES—You made a good point. Can you give me an example of a patent—and I am being quite specific here—that you do not think discloses a specific, substantial and incredible use of the invention but that nonetheless has been granted in Australia?

Prof. Christie—I do not have a specific one in front of me but I will give you one that I think would map to a few. I have no doubt that Senator Heffernan has a few that would rather look like this. In general terms if such patents had been granted with a claim, say, to the genetic sequence, that is simply not enough. I will offer an analogy that might or might not work here. It works for me as I keep trying this analogy on myself. I have heard Senator Heffernan, including last night, expressing well his concern about the fact that subject matter that is in the body simply should not be patentable. One could ask the same question about subject matter outside the body. Take, for example, electromagnetic radiation. It exists and it is there. If somebody said, 'I would like to have exclusive rights to this frequency and he or she claimed it for a patent we would say no.

Why? You have selected something that exists and you have taken this frequency—maybe the analogy is, 'I have taken this sequence'—but you have not told us what you intend to do with it. You have not delivered anything to us as a community so why should we give you 20 years monopoly over it? That person might then state, 'I would like to have exclusive rights to this frequency or this amplitude because I found out that I can transmit a certain type of information much more effectively this way and I will tell you how to do it in my patent specification. In return for that, I have made an invention. Please give me 20 years.'

Undoubtedly there we would say through the patent system, 'Yes, you have. You have disclosed a practical application. So long as it is new and not disclosed by others and so long as it is not an obvious development—it is non-obvious and it is inventive—and you have done the utility side with your practical application, we would. Senator Heffernan, I have a different view to you about this. I do not think the fact that it is inside your body makes an ounce of difference because I think the same issue applies to things outside the body to anything naturally occurring. We have to ask the question, 'Have you done enough to warrant 20 years monopoly?' I think the answer is, 'Yes, if you can give us a practical application and if that practical application is new and it would not have occurred in the ordinary course of events, that is, it occurred only because of your invention.'

Senator HEFFERNAN—You are happy to lock up for 20 years the exclusivity of the isolated gene from all other users because they have a use for it?

Prof. Christie—No, I am happy to let them lock up that use of it.

Senator HEFFERNAN—They are locking up not the use of the gene but the access to the gene.

Prof. Christie—Access in an experimental sense or generally? I am not quite sure whether I follow your question.

Senator HEFFERNAN—The experience we have is that the so-called research access has been locked up.

Prof. Christie—Yes.

Senator HEFFERNAN—Allegedly it cannot be. The people who said that it could not be locked up then said, 'It is a vague area that needs to be defined.'

Prof. Christie—We could deal with that.

Senator HEFFERNAN—My interpretation of who owns your body is a broad and colourful expression because the mob out in the street does not get all the language that is in these documents. We are exclusively locking up access to a gene which, in effect, stops better and further research.

Prof. Christie—I think we are in vigorous agreement. I do not want to have a patent system that allowed someone to say, 'Here is the sequence. Here is the utility for it. By the way, I will have all uses of that sequence and not just the ones that I have disclosed.' If someone said, 'Here is the sequence and here is the use' that is the locking up that we should give. We may disagree on that but I agree with you that we should not allow them to lock up all uses just because they found one.

Senator HEFFERNAN—These patents lock up uses for things that they hope they will discover, not that they have discovered.

Prof. Christie—We are in agreement. I do not think it is appropriate. If we examine for utility and apply a proper test we would not have that. That is where you should be.

Senator HEFFERNAN—In other words this thing should be chucked out.

CHAIR—Senator Humphries, have you finished? Senator Adams and Senator Moore have questions.

Senator HUMPHRIES—I have one more question. You mentioned a solution to the ownership of patents in the area of genetic science, for example, with respect to testing. If people cannot afford the tests the appropriate government response to that is that they should move in and subsidise the tests in the same way as they subsidise medicines. Of course, that was recommended by ACIP in 2004-05 and I think it was also recommended by ALRC.

Prof. Christie—I cannot be certain whether the ALRC made that recommendation. I do not think ACIP has made such a recommendation but I think it is a fairly logical way of doing it. As you well understand by granting this monopoly, which we hope is an incentive for inventions to occur in the first place, we create market exclusivity. Market exclusivity has the main effect of driving up prices. That is how they determine their reward. If we conclude that this is not appropriate for other reasons we need to drive down the price. In Australia where at least pharmaceuticals are patented we drive down the price through a monopsony. We become a sole purchaser.

Senator HUMPHRIES—What did you say?

Prof. Christie—I think the economic term is a monopsony. A monopoly is a sole supplier and a monopsony is a sole purchaser. Effectively, the government of Australia says, 'We will be the sole purchaser of pharmaceuticals for Australia, we will set the price and you drive it down.' That is one way in which we do not appropriately deal with the second order effective patents that can raise prices unduly highly. The other way is simply to step in and require a rise.

We have means to do that through Crown use and we have means to do that through compulsory licensing. However, those tools may not be perfect and if they are not let us improve them. They are there to be used. We should not overlook that and say, 'We cannot get access to breast cancer diagnostic tests, which is bad'—and it is bad—'so let us not grant gene patents.' That is just not right. What we should be saying is, 'We have this problem in other areas. We have dealt with it in second order ways and they seem to be much more appropriate.'

Senator HEFFERNAN—When BRC adopted the patent they patented the isolated gene. Should they have done so?

Prof. Christie—I do not think so, no. If they cannot give us a utility for it we are in agreement.

Senator HUMPHRIES—Do you think that the reason that has not happened yet is that a large cost will be associated with it?

Prof. Christie—Firstly, I suspect that there could well be a large cost associated with that, although I have not done the assessments. Secondly, I suspect that you are right. One of the reasons we have not done that is that we would have to commit to a very substantial cost. But that may be the way to go; I just do not know. Another way may be to do it selectively rather than doing it basically for all pharmaceuticals or all tests. I know it is not quite the case but let us say for all pharmaceuticals. In the most egregious situation we have the tools to deal with it.

The Americans might deny it but they will do that. I was in the United States when the September 11 events occurred. Thereafter we had anthrax being sent through the mail and there was great hysteria. The United States government had no compulsion whatsoever in saying that it would use compulsory licensing and Crown use—their equivalent provisions—to acquire sparfloxacin for wide use by the United States population in the event that this was going to have a major effect. In such an egregious situation we should take advantage of our flexibilities in international documents. They are there—do not let anyone tell you that we do not have them because we do—and we should use them.

We could have a broad-ranging scheme, a PBS style approach, if that is appropriate. We could do it on a case-by-case basis if that is appropriate, but we do have the tools. We need to improve them slightly. I have made a point about Crown use in my submission, but the tools are there. The answer is not to stop it upstream—no patents—the answer is to deal with it when the problem arises at the next layer.

Senator HUMPHRIES—Thank you very much.

Senator ADAMS—I would like to ask questions about inquiries with the ALRC and ACIP and about the recommendations. Have you made any inquiries about why those recommendations have not been taken forward?

Prof. Christie—No, I have not made any inquiries. I can offer a supposition, and it is probably multifaceted; usually there is not just one conspiracy reason behind it. I suspect, first, that it is very complicated and complex for policymakers and governments to understand and, second, it is in an area that has been and that will continue to be contentious. Maybe there is a bit of resistance to change when government policymakers are not completely sure that this is right. At least in IP there is policy reform overload. There is reform fatigue amongst all the stakeholders. We are trying to get so much right that I think it is easy to say there is probably also a bit of a blocking.

I suspect that the reasons they have not been implemented are not because they are not inherently good but because there has been uncertainty, a bit of fear and overload. Other things take their place. There always seems to be something that comes up that is more important. Should they have been? I vigorously believe that they should have, not because the position would now be perfect, but because the position would be better. If we had implemented some of these recommendations we would be able to give persuasive responses to at least some of the concerns that are being expressed.

Senator ADAMS—Are the recommendations that were brought up in 2004 still current or do they need changing?

Prof. Christie—I believe that they are equally as valid now as they were then. I believe that the ALRC's recommendations in relation to utility are equally as valid now as they were then. In fact, I am delighted to see that in the last month or so IP Australia, in its own reform processes, recognised that and essentially put forward that those recommendations on utility be adopted. A number of bodies have finally said, 'Yes, this is the way to go.' I believe that the thrust of almost all the recommendations of the ALRC are as valid now as they were then. I have not gone back and reviewed all 29 versions of them, but I have looked at a number of them for this inquiry. Yes, I think they are valid.

Senator ADAMS—So it is a way forward?

Prof. Christie—Yes, it is a way forward. The other day I was looking at a United States inquiry document which is extremely thick and they said, 'All round the world people have reviewed this issue.' It is to do with gene patents and licensing. They said, 'The most comprehensive review ever was undertaken by the ALRC.' They were very complementary of it. It is not just me who is complementary of it; we have had external validation of it. I think it would be very unfortunate if we did not put all that good work to use.

Senator ADAMS—So we should get it off the shelf and dust it off. Thank you.

CHAIR—You are making suggestions beyond that though are you not—beyond the recommendations in the ALRC report?

Prof. Christie—Yes. In particular I do in relation to that final issue of the social and moral objections. The ALRC's response to that was to recommend that there be an inquiry, that is, the inquiry on which I have the privilege of chairing the working group.

CHAIR—Yes.

Prof. Christie—That fourth point in my submission states that I think it would be very appropriate for the Senate to take account of what that inquiry finds and to consider it. If it is in agreement it should adopt it.

Senator MOORE—Give it weight, consider it and if in agreement adopt it. I love that.

Prof. Christie—Obviously I will not tell you to adopt something with which you are not in agreement.

CHAIR—People do tell us.

Prof. Christie—That is why I am accelerating the hardworking secretariat members as much as possible. My idea would be to make sure that our final report goes to the minister in roughly the same timeframe as you wrap up yours on the last sitting day. It is unclear whether or not we can make that because so much is happening. I am not a slave driver, Senator Heffernan. I cannot make those people work 24 hours every day. What I can tell you is that we will release our options paper which will clearly specify options.

We have done the issues paper and we have quite firm options that I am confident will be released this month. Over the next month or so we will seek further submissions on that and we would very much like to be in a position to get a report to the minister by the end of the year, if at all possible. If it is of any assistance I am happy to sketch what the options look like—not because I am telling you something that is secret—

CHAIR—I was wondering whether you would be able to do that.

Prof. Christie—The council had a meeting in Adelaide in late June, and before that we had a public forum because we need to have public forums. I spoke at that public forum. If anyone had a tape recorder there he or she would be able to play it back to you now to give you a sketch of the thinking of the working group and the council, because the council approves the framework of the options the next day. It goes like this: the test for invention or patentable subject matter plays two roles. It plays the economic role and it plays the non-economic—the social and moral role.

There will be stakeholders—I have heard them—who will say, 'Morals have nothing to do with the patent system. Just ignore it; this is all economic.' Many submissions make the case that you cannot do that. No law is immune from what is socially desirable and moral. It does not matter whether it is criminal law, tort law, or whatever. Patent law is the same. A patentable subject matter test has to embrace that. On the economic side the options that will be put out in the options paper are, firstly, to do nothing. You would do nothing if what we have is perfect. If it is not perfect we cannot identify something that looks reasonably better.

Some of our submitters say that it is either perfect or you cannot get anything better. We will see. I would be surprised if it was perfect but we have to recognise that as an option. Other options are to clarify the language. Instead of using language from 1623 my suggestion is that we use language from 1959 or 1952. But the idea is to re-express the same concept. The concept is right but the language in which it is expressed is not. The concept that is most supported is from the High Court's decision in the case of the National Research and Development Corporation.

The sketch is that something is patentable if it is an artificially created state of affairs in a field of economic endeavour. It is not just claiming that which exists; it is taking it and giving it a practical application in a field that we want to give the economic incentives to innovate. That is an option. The third option is to replace the test and to do something that may result in our economic tests being done better. The most likely one that has been suggested to us is to use international language of inner field of technology—only patent in a field of technology.

The fourth option is to have no test whatsoever economically so that all the work done economically is done by novelty, inventive step and utility. Anything whatsoever that is new and inventive and that has a practical application should be patentable. Those are the four key options for the economic component. But, of course, they do not touch the social component. If people have visceral and inherent objection to certain types of subject matter ever being patented we need to be able to deal with that in the patent legislation.

The options here are again to do nothing and to retain the current exceptions, which include humans. You cannot patent humans and the biological process of their production. We cannot

patent things that the commissioner in her discretion considers to be contrary to law, and there are a few very minor ones. Also, arguably, we cannot patent things that are generally inconvenient. However, that is not written; that is the unwritten law.

An alternative is to add specific exceptions if, in its wisdom, the government believes that if you can define it properly genes should not be patentable. You could then exclude that. I do not think that would be successful or that it would be the right way to go. But again, the government might think that you should expressly exclude near discoveries. We all agree—I am in vigorous agreement with you—that near discoveries should not be patented.

A third option on the social side would be to introduce a generalised test to capture social concerns. We cannot write specifically but we have to write something such as the international language of contrary to 'ordre public' or 'morality'. 'Ordre public' is the French for that saying. Even in the English language version it is in French because we cannot get the wording right in English. I am not trying to be smart: it is called 'ordre public' in English. 'Public order' may be public policy, good for the public, and that is that.

Those are the options which range from doing nothing through to updating the test, changing it, deleting it, and adding specific or general exceptions to social concerns. That is the framework of the options paper that will be released this month. We are keen to see what the stakeholders say in relation to those options.

Senator HUMPHRIES—Will you settle on one of those options when you bring down your report at the end of the year?

Prof. Christie—Yes. It is possible that the stakeholders will come back and say, 'There is yet another option.' There are a few specifics that I have not mentioned. However, if that is the right one we will go with that. I think all our deliberations to date take into account written and oral presentations that suggest the best options lie in that group.

Senator HEFFERNAN—At the moment is not the fundamental problem—as we have done in all these bloody documents—that we have locked up access to the isolated gene? Whether that is an invention these days is questionable. Someone buried in a laboratory somewhere who comes up with a super new test cannot market that test because someone has the patent. Is that not a serious and fundamental flaw?

Prof. Christie—I am not sure whether that is. If I have understood that suggestion correctly, I am not sure whether that is. I think that is a serious fundamental principle of the patent system. Let us now assume that this subject matter is the right subject matter; it has satisfied all the right tests and the experimentation has happened. We are now talking about further experimentation that has produced a competing and advanced product. If that advanced product draws on the first invention, our patent law says you cannot market that without the licence of this person.

Senator HEFFERNAN—Let us say, and this can be the case, that you might want to combine an isolated gene with another gene, or do whatever you want to do with it. However, if you do something that is completely different but it is tremendously important and is not related to the other one, because they have a patent on access to the gene you are dead.

Prof. Christie—If I have understood the question rightly—and I am not sure whether I have and forgive me for that—

Senator HEFFERNAN—I can understand why you have not.

Prof. Christie—When you say it is fundamentally different but they have access to it, I am not sure whether you mean access to get to it or exclusive rights over it.

Senator HEFFERNAN—Lawful rights. Let me try to clarify it. If in these documents there is a series of isolated ageing genes—Eliza Hall has it—there is exclusive access to the genes. You cannot go anywhere near any work on the genes because they have exclusive rights to access them.

Prof. Christie—Subject to having an experimental research exemption, we should have that.

Senator HEFFERNAN—That is a vagary.

Prof. Christie—But we should have it. This committee should consider it.

Senator HEFFERNAN—We have not got it at the moment though; that is a vagary.

Prof. Christie—I agree, but we want it.

Senator HEFFERNAN—Subject to this pile of documents, at present they have exclusive access to the isolated gene. I, or anyone else who wants to have a crack at that gene, for whatever purpose, would be breaching the patent.

Prof. Christie—If by 'access' you mean the ability to work on it the answer is we should make it clear that there is the ability to work on it. Nothing bad is done by allowing experimentation on inventions. That is how we get new inventions. If, however, you mean that, having done all that work, which we should allow in our law, a new product, a new process, a new test or a new treatment comes out that still draws on the first invention, the reality is that our patent law stops that. If that is what you mean by access—

Senator HEFFERNAN—No.

Prof. Christie—No, okay.

Senator HEFFERNAN—I am saying that I have received evidence from people who want to do work on a particular gene. They do not want to come here and they have not done so because they do not want to blow the whistle, as it were, on their work. These people, who tucked away in laboratories, have not been here and will not come here because they are intimidated. I think it is a bloody disgrace.

Prof. Christie—I agree. I would strongly encourage the committee to consider making a recommendation in relation to a clear and express exception for experimental and research purposes.

Senator HUMPHRIES—Senator Heffernan referred to particular patents on a number of occasions. Professor Christie, you have already explained to us that you are a busy man but I wonder whether it is possible for you to look at the patents to which Senator Heffernan referred to see whether they are examples of the kind of exceeded authority to which you have referred—patents that should not have been granted. It would be great to know whether there are those sorts of examples—examples that you have said already exist in our patent law.

Prof. Christie—I would be happy and pleased to do that. Thank you for the opportunity.

Senator HUMPHRIES—Thank you.

CHAIR—We are over time. Senator Moore has one question about the interest in your work.

Senator MOORE—I am trying to find out how many people are interested in all this stuff. I am worried that it has not got out, apart from the publicity. When your public fora are linked to these processes and you call for submissions, do you get a lot of submissions?

Prof. Christie—We never get anywhere near what we would like to get. We would like to have hundreds but maybe thousands would be too much. I have been involved with many ACIP inquiries and the like. This inquiry is one of the more contributed to inquiries, because of the importance and topicality of the subject matter. We had in the vicinity of 40 or so written submissions, which I know is a very small number.

Senator MOORE—That is very good.

Prof. Christie—When we compare that with some of them that get only nine—the nine patent attorney organisations and one government department, or whatever it is—that is good. The public consultations were well supported. We ended up having about 100 people across four locations. Again I know that that is not ideal. People were coming during the day and I was encouraged. There was also good representation. In fact, the least represented sector in our submissions was government, about which I was delighted. There was roughly equal representation of the professions, that is, lawyers and attorneys, what I call the research sector—medical research in particular—and what I call NGO civil society, including individuals. There was roughly equal representation across those three. The numbers are not big but they are better than they are for some inquiries and at least the representation is spread, if I can put it that way.

Senator MOORE—We have had a couple of submissions from people who represent consumers that are caught up in giving their own genetic material for testing and so on. Do you have submissions from those people or have they expressed an interest?

Prof. Christie—I do not believe we have received a submission from an individual who has given his or her material in that situation. I do not believe we have.

Senator MOORE—I think that those voices are getting louder than they used to be. Thank you.

CHAIR—Thank you. You have some homework to do—we call it questions on notice. Thank you very much for your evidence and for the time that you have given to us today. It is much appreciated.

Prof. Christie—You are welcome.

Proceedings suspended from 12.35 pm to 1.32 pm

HAMER, Mr Richard, Member, Business Law Section, Law Council of Australia

JARVIS, Mr Richard, Member, Intellectual Property Committee, Law Council of Australia

CHAIR—I welcome members of the Law Council of Australia. I understand that information on parliamentary privilege and the protection of witnesses has been given to you. We have your submission. I invite you to make an opening statement and we will then ask you some questions.

Mr Hamer—I have been practising in the area of intellectual property law for about 25 years. Prior to that, I qualified in genetics. However, I am appearing on behalf of the IPC. The IPC is a group of leading barristers, solicitors and academic lawyers in the field of IP law. Their role is to evaluate and provide commentary on proposed legislation.

Mr Jarvis—I think Richard Hamer will make a statement for both of us. I would only be saying that I agreed with that statement.

CHAIR—Okay, that is fine.

Mr Hamer—I was saying a bit about the IPC to explain its role. The members of the IPC represent lawyers in a lot of areas of intellectual property practice reflecting people with a variety of clients and interests. The endeavour of the IPC is to provide objective opinions in the public interest and that is why we are here. The IPC is concerned with the proposal, as it has been put forward at this stage, to remove gene technology from the Patents Act. It considers—

Senator HEFFERNAN—Where is that in the documents?

Mr Hamer—It was in the terms of reference, apart from anything else. I do not have the terms of reference in front of me, but it was one of them. Maybe I do. Paragraph (iv) (c) of the terms of reference states:

(c) whether the Patents Act 1990 should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

CHAIR—It is a question rather than a proposal.

Senator HEFFERNAN—It is not a proposal. You just said it was a proposal.

Mr Hamer—Okay.

Senator HEFFERNAN—You are the lawyer.

Mr Hamer—To the extent that that is proposed we disagree with it. We would like to convey that view. The reasons are that having exceptions or special treatment of particular forms of intellectual property is unsatisfactory. It creates disputes, it results in people trying to find loopholes, it creates inconsistencies and it is unfair. Despite the fact that as lawyers you might say we like disputes, in this capacity we are trying to avoid it. We also think it would be contrary

to international treaty, almost certainly under TRIPS, to have a blanket prohibition of patenting of gene technology.

Therefore, the question is whether there is any good reason for doing it. We can see no good reason for doing it. The purpose of patents is to provide an incentive and reward to patentees to innovate. It is to promote the disclosure of inventions to the public and it does that by making that mandatory—if you get a patent you have to disclose your invention to the public—and it provides a protective period that enables people to expend the capital required to get an invention to market. In that context of the order, typically, of 99 per cent of the cost of getting a new product to market is the development, and only one per cent the actual invention, in particular, in the area of pharmaceutical inventions where people have to pay for clinical trials and other developments.

Some of the submissions that I saw were concerned about the fact that people were able easily to obtain patents for things that were not regarded as inventions—for example, references to patenting of isolated gene sequences. We think it would be highly undesirable to treat the technology differently because of that issue. If there is an issue with what is patentable that should be dealt with generally by looking at the test for inventive step, for example, as a whole and not looking at it in the context of gene patents separately.

I was having discussions before this but I think a lot of the issue is one of hindsight. I think people who now look at some inventions that were filed 10 or 20 years ago say, 'That was a terribly obvious thing to do.' If you are looking at it you would not be able to get a patent for that today but you could then because the test is, 'Was it inventive as at the date that it was filed?' I think a lot of this discussion seems to be based upon those hindsight issues.

So far as experimental use is concerned—and that is another issue—the Law Council has strongly supported putting in place a specific exception for experimental use. That has been the subject of a number of inquiries. Currently it is before IP Australia, and the proposal before IP Australia is one that has been supported by the Law Council. We would encourage that to happen to avoid issues that have been raised in relation to experimental use of gene patents. But that should be a general provision relating to all technologies, not just gene patents.

I suppose, ultimately, in relation to gene patents, we think that the issues that are being raised are really based on hindsight and that the position going forward is a different position to the position as it was, and that is because the state of knowledge has changed. What is obvious now is not what was obvious 10 years ago. That is as it should be because that is the way the patent system works. It is based on assessing inventions at the time that they are made. In summary, we can see no good reason for excluding gene patents from the legislation, or having any specific regulations dealing with gene patents.

Senator HEFFERNAN—I refer to the matter of application 1997021439, which relates to the ageing gene. Is it true that one of you blokes comes from Davies Collison Cave?

Mr Jarvis—Yes.

Senator HEFFERNAN—Were you actively involved in that or was that one of your junior partners?

Mr Jarvis—I am a partner in Davies Collison Cave, which is the law firm.

CHAIR—Can I just interrupt? You are appearing here as the Law Council and not on behalf of a law firm. That is correct, is it not?

Mr Jarvis—That is correct.

CHAIR—You do not have to answer any questions that are directed to you in your capacity as representing a law firm.

Senator HEFFERNAN—I was just identifying that it is your law firm.

Mr Jarvis—I understand that and thank you. My answer to the question is no. I was not involved in that application. The reason for that is that I am a partner in the law firm, Davies Collison Cave. If Davies Collison Cave filed that application it was filed by one of the members of the patent attorney firm and not by me.

Senator HEFFERNAN—I apologise. I was really only wanting to know whether your firm was involved just to get the background relating to the resale of the document or the original patent. The Walter and Eliza Hall Institute of Medical Research was the applicant; it was buying the patent. You do not know?

Mr Jarvis—I do not know.

Senator HEFFERNAN—It is our understanding that recently India signed up to a global agreement but Brazil has not. Where does that leave all this work in Brazil? Brazil does not recognise the international patent system that we are dealing with today. Where does that leave it in relation to the rest of the world? If India can do it, why can other countries not recognise the patents on human genes? What is the big deal?

Mr Jarvis—I am not sure whether I understand the question, Senator.

Senator HEFFERNAN—Brazil does not recognise the international patent system through the free trade agreement. None of this has ever been tested at law in Australia and they always settle because the law is very vague. Through the convention we agree with the United States' patent licences and patent system and we allow the licences here. Gene Technologies Australia is a good example of that, with BRCA1 and BRCA2, but Brazil does not recognise the system. The argument that you have put and one that has been put to us generally is that if we alter the way we do this business it will upset the apple cart, as it were.

Mr Jarvis—I am not competent to answer that question.

Mr Hamer—I could have a brief go at it. Australia is already a party to international treaties that include express provisions about discriminating against a particular form of technology.

Senator HEFFERNAN—I understand that.

Mr Hamer—We could exit out of those treaties and I assume that there are mechanisms for that.

Senator HEFFERNAN—We could do that with a stroke of the pen. If we think the public good is at risk, with the law that we have now with a stroke of the pen we could exclude or do away with the patent. The government could have done away with the BRC or the hold that Gene Technologies Australia had on the patent just by a stroke of the pen. That capacity is available now.

Mr Hamer—No. There is an exemption for therapeutic, diagnostic and surgical methods of use, but that does not prevent people patenting, for example, the gene sequence, or the kit.

Senator HEFFERNAN—I do not have those documents with me. Unfortunately I was already $58 overloaded. Let us go to the definition. As a lawyer is an isolated gene different from a naturally occurring gene in the body? What is the difference in the gene?

Mr Hamer—The isolated gene has been isolated and characterised.

Senator HEFFERNAN—But it is the same gene. What is the difference in the gene?

Mr Hamer—It is not. One fundamental difference is that it is not in the body.

Senator HEFFERNAN—But it is the same gene.

Mr Hamer—I do not know that.

Senator HEFFERNAN—Do you agree?

Mr Hamer—If it has been isolated—

Senator HEFFERNAN—You do not think it is the same gene?

CHAIR—Let the witness answer the question.

Senator HEFFERNAN—You do not think it is the same gene?

Mr Hamer—I do not know that but I make my comment.

Senator HEFFERNAN—You are the lawyer.

Mr Hamer—I make my comment and my answer as a lawyer and not as a scientist. I am not practising in this area.

Senator HEFFERNAN—One of the difficulties we face—we heard evidence from Dr Suthers this morning—relates to participation in the decision making on a patent. Obviously some of them are too broad and they have to be dealt with because there has not been a human

science input. There has been plenty of input from lawyers and bureaucrats. Can either of you fellows describe this for me?

Mr Hamer—I am happy to give it a go.

Senator HEFFERNAN—What is the difference between a gene that is in my body and a gene that is isolated? What is the difference? It is the same gene. It is here in this bloody document.

CHAIR—You have made your point, Senator Heffernan.

Mr Hamer—There are two issues here and this is where you need to talk about historical perspective, which is where I started. As a principle you can get a patent for isolating something which has never been isolated before. The isolated compound is something that you can do something with—something that you cannot do when it is in the body. For example, you can use an isolated gene sequence in a test kit. You cannot use it in a test kit when it is in the patient's body. It is capable of uses that are not there in the body and that is because it has been isolated. It is also different chemically because it is separated from the other components.

There is no conceptual issue. The timing issue is a different one. As of a few years ago the entire human genome has been sequenced, it is available, you can look it up on a computer program and you can look at every base pair and run through it. If someone now says, 'I claim this bit of it' there will be real questions about obviousness. You are going to say, 'That is entirely obvious.'

Senator HEFFERNAN—When did that event occur? When did we cross that line and we can no longer say that? When did that occur?

Mr Hamer—I would make a guess that it was early this century. I am not sure of the precise dates because the problem is that the genome, although it was published as being complete, still had gaps in it.

Senator HEFFERNAN—No-one is sure.

Mr Hamer—No. You have to look at a specific case on a case-by-case basis.

Senator HEFFERNAN—Have a guess. When do you think we crossed the line?

CHAIR—You cannot ask the witness to have a guess.

Senator HEFFERNAN—Have a crack at it. Go on, be brave.

CHAIR—What is the point? What does it matter?

Senator HEFFERNAN—The point is that in 2004 we allowed an isolated patent on an isolated gene. I would have thought that was beyond the date of the invention.

CHAIR—Do you think this is after the date or not?

Mr Hamer—Is that its priority date?

Senator HEFFERNAN—Yes.

Mr Hamer—Its priority date is 2004.

Senator HEFFERNAN—Do you want me to find it for you?

Mr Hamer—The priority date might be different to the date on which it might have been patented.

CHAIR—The priority date is—

Mr Hamer—The priority date is the date on which you assess its inventiveness. That is the date on which the provisional application is filed.

Senator HEFFERNAN—The filing date?

CHAIR—Rather than the date on which it is granted?

Mr Hamer—The priority date is the date that you would want. Ordinarily it would be a year before the filing date.

Senator HEFFERNAN—That would make it even worse.

Mr Hamer—So what is the what filing date?

Senator HEFFERNAN—The filing date is 2004. I am just trying to find the pages.

Mr Jarvis—It is probably 2003.

Senator HEFFERNAN—I would not have thought that in 2003 you would describe that as inventive. Would you agree that this is a legal vagary?

Mr Hamer—It is uncertain. We require evidence and we conduct a proper investigation into the facts of each case.

Senator HEFFERNAN—It has never been to court.

CHAIR—Could we just clarify what is uncertain? The uncertainty is the date when the final sequence was—

Mr Hamer—In order to determine whether something, for example, is obvious, which is the primary inquiry here. If it is not new and someone has already published it you cannot get a patent.

CHAIR—Whether or not it is inventive.

Mr Hamer—Whether or not it is inventive is the primary inquiry. That turns on expert evidence. You would get a line up of professors who would say, 'This is what everyone knew, this is what they did not know, and this is how you went about finding these things'. In each case you would have to make that proper investigation in order to come to an ultimate answer. That is how a court would do it. The Patents Office does it by a rule of thumb method. They use their own expertise as examiners of the patent. They see technology coming through in these areas and they make their own assessment of whether they think it is new and inventive. They do searches and so on. There is a preliminary screening by the Patents Office but, ultimately, if it is tested in court it will be tested on the basis of the evidence that I have just mentioned. It is impossible, without knowing the details of the particular case, to answer absolutely one way or the other.

Senator HEFFERNAN—But it is a legal vagary.

Mr Hamer—Of course. The outcome of the case depends on the evidence.

Senator HEFFERNAN—There has never been a legal interpretation. How do we know and how does the mob know when we have crossed the line from a discovery to an invention?

Mr Hamer—They would need to look into the particular cases. They would get advice on it. That is what people do.

Senator HEFFERNAN—But no-one has ever bothered to test this. Should there not be a regulator such as ASIC or someone who says, 'Right, we will go and have a look at this' because there is none at the present time?

Mr Jarvis—The gatekeeper at the moment, if you like, is IP Australia which assesses the particular application according to the criteria for patentability.

Senator HEFFERNAN—According to the rules as they are set but not according to the progress of technology and the outdating of the illustration of the law as it was back 80 years ago. For instance, in the area of irrigation we now have fertigation. The water laws have been messed up and this is a similar outfit. I am not a lawyer but this is a mess because it is not defined. As I said this morning we now have a situation that might give you great glee because you blokes get paid for each discussion. In Europe, because of the interpretation of the courts and various IP equivalents, they have come down in a divided fashion on BRCA1 and the Jewish community now pays four times the cost that the non-Jewish community pays for these tests. Do you think that is fair?

Mr Jarvis—I do not have the details. I do not have a detailed knowledge of the specifics of that case so I cannot comment on that.

Senator HEFFERNAN—But if that were the case do you think it would be unfair?

Mr Jarvis—Do I think what is unfair?

Senator HEFFERNAN—Based on your genetic background the patent for the BRCA1 test, which has never been traded, has been interpreted by everyone from the courts to the intellectual

property mob. After two court tests they have decided that the Jewish members of the community will pay €4,000, or thereabouts, and the non-Jewish members of the community will pay €900 for exactly the same test.

Mr Jarvis—I do not know the basis for that.

Senator HEFFERNAN—But if it were—

Mr Jarvis—I cannot answer that.

CHAIR—A patent was given for the genetic mutation of those—

Senator HEFFERNAN—That is the outcome.

CHAIR—That is the outcome.

Senator HEFFERNAN—It is crazy.

CHAIR—The decision was taken to grant a patent over genetic mutations for those of Jewish ancestry. That has therefore resulted in a cost four times the amount paid by others for having that test done.

Senator BOYCE—That is because it was a different test. It was the test needed for non-Jewish people.

Mr Hamer—And that was because of the genetic predispositions of that condition in the Jewish population.

Mr Jarvis—If it was a result of the genetic predisposition I would not have any trouble with that.

Senator HEFFERNAN—With great respect to all of you it is based on the BRCA1 patent. That is the interpretation of the BRCA1 patent. By the way, the BRCA1 patent requires Westmead hospital in Sydney to surrender all its research. Do you go along with that?

Mr Jarvis—I do not have any trouble with there being a patent over that particular gene or the company making a charge for that particular test.

Senator HEFFERNAN—But they were doing further tests. You are probably not familiar with it. You ought to go there and become more familiar with it. Since 1990 they have been taking samples from cancer families. When the new research comes along they go back and do another test. Every now and then they achieve success. They have been asked by Gene Technologies Australia to desist or to face litigation.

Mr Jarvis—Senator Heffernan, I am not familiar with the details of that but I am certainly familiar with the fact that there is this particular test. My wife has breast cancer so I am aware of this. I still do not find any difficulty in there being a patent over that particular test kit.

Senator HEFFERNAN—Nor do I. The problem I have relates to the patent and to access to the gene, which precludes other people from having a crack at it. Do you have a problem with that? There are four patents in BRCA1 and BRCA2. Three permit access to the gene and one is a follow on from that. In all these patents, including a series of medical patents that are here, they have blocked access to the gene. They take the patent, even though it is described differently at the front of the patent document, and they block access to the isolated gene. Do you think that is right and fair?

Mr Jarvis—I am happy with the idea of somebody having a patent and being able to exclude others from operating in that area. That is what the patent is intended to do.

Senator HEFFERNAN—All right. As a lawyer you are happy making a living out of this business. You are happy with a particular mob getting an isolated gene that is no longer inventive—these are discoveries. You are happy to exclude all other research. Under the present arrangements you are happy to exclude other people having a crack at the gene.

Mr Hamer—Could I have a go at this? One point that we have made clear and that the Law Council supports is having a specific and express experimental use exception in the law. That is something that we have supported for years and it is us now finally coming through the process. It is arguable that there is already such an implied right and maybe these demands are unjustified. Nevertheless, we think it should be made clear that experimental use is acceptable.

Senator HEFFERNAN—I agree with that. We have received evidence that it was an understanding—but it is only an understanding—that other experimental work could occur. But it is not in the law; it is an understanding.

CHAIR—It is an assumption. People put it as an assumption.

Mr Hamer—I would accept that.

Senator HEFFERNAN—Which is a problem. We have evidence of it being a problem.

Mr Hamer—Certainly from our point of view we support the fact that there should be an experimental use exception, but we are of the view that that general exception should apply to all technologies. Exactly the same issues apply whatever you are talking about.

Senator HEFFERNAN—Let us extrapolate that further. Given that, would you concede that other people could have access to the gene, which is prevented at law in these patents? If a test were performed on the same gene for a different purpose, for example, a person was involved not only in the present BRC arrangement but also he or she could have the gene and the downstream test but for a different purpose, would you agree that that person could then go off and commercialise the gene and not have to report back to the person who had the BRC patent?

Mr Hamer—To get a patent?

Senator HEFFERNAN—Sorry, they had a patent on the—

Mr Hamer—They could get a patent on the new technology. They may or may not be able to exploit that without the licence of the first person. So there may be circumstances—

Senator HEFFERNAN—There is a difficulty. They have the patent on access to the gene—not the ownership of the gene but access to the gene. In effect, they have control of everything that flows from that. When they come back for the licence they might then discover a new use for the isolated gene.

Mr Hamer—It is very common to see situations where people have developed improvements of other people's inventions and they file a patent on the improvement. In order to market it they need to get a licence from the first person.

Senator HEFFERNAN—So you create a monopoly with this. Do you agree that these are monopolies?

Mr Hamer—Yes.

Senator HEFFERNAN—That is the very essence of it. How do we, representing the people of Australia with a limited health budget, restrict the cost of the fixed administrative overhang of the patent system? Last year Canada was able to put up the cost of the test by 400 per cent because it had the monopoly rights to it. How do you prevent greed in the system? How do you prevent these financial instruments, which are tradable, eventually ending up in the hands of lawyers and bankers—people well removed from researchers? That is what is happening with water licences. People on the Gold Coast are buying up all the water licences.

Mr Hamer—I will answer the last question for you as that is straightforward, but you have asked a few questions. So far as patents ending up in the hands of lawyers and bankers, on the whole that is most unlikely. The way you make money out of a patent is by selling the product or by licensing it. Normally you make money selling the product. That is your aim. A banker will not be very good at making gene sequences, kits or pharmaceutical products.

Senator HEFFERNAN—With great respect I alert you to the fact that part of the appreciation of the value of the asset is the capital appreciation of the monopoly value of the asset, which is what happens with water. Senators might laugh, but people have said to me—

Senator BOYCE—It is not commercial reality, Senator Heffernan.

CHAIR—While I have the floor, this is your last question because we have only 15 more minutes and other people have questions.

Senator HEFFERNAN—All right. I will get off now.

Senator HUMPHRIES—I am not aware of any case, other than perhaps for a short period arising out of an insolvency, where a bank owns any patents.

Senator HEFFERNAN—Not a bank.

Senator HUMPHRIES—Or a lawyer.

Senator HEFFERNAN—They become tradable. They are tradable financial instruments. Do you agree with that?

Mr Hamer—They are tradable instruments.

Senator HEFFERNAN—I am saying that they might end up in the tradable financial market rather than in the medical wellbeing market. That is what I am saying.

Mr Hamer—It is just that I am not aware of any cases where that has happened.

CHAIR—I know that Senator Humphries and Senator Boyce have questions.

Senator HUMPHRIES—You dispute the assertion that the inventive threshold is too low for the maintaining of patents and you state:

The Committee notes that it has been contended in public debate that some granted gene technology patents have not met the required level of inventiveness or novelty. They have been too broad and not useful.

However, you then state:

There have in fact been very few challenges to the validity of granted gene patents.

Is it not possible that there have not been very many challenges to the validity of granted gene patents because to do so is quite expensive? It entails a challenge through a court and that process is unlikely to be taken up by anybody other than a rival patent holder or someone with a commercial interest already in there who wishes to use litigation to gain some commercial advantage over the upholder of the original patent? Can we read much into the fact that there are not many successful challenges other than the fact that it is very expensive to challenge a granted patent?

Mr Jarvis—I was going to observe that there have been no court challenges, or very few court challenges, involving these sorts of inventions but there has certainly been lots of opposition before the Patents Office which has resulted in modification of claims that have been arrived at as a result of a contest between the patent applicant and an opponent.

Senator HUMPHRIES—Before lunch Professor Andrew Christie said that in about 50 per cent of cases the patent is not backed or reduced in scope because of those sorts of objections, and in about 50 per cent of cases they do not. Would that not suggest that some patents, as sought originally, are quite wide in their ambit and potentially overstate the level of novelty or inventiveness in the patents?

Mr Jarvis—I think that there is a timing issue here, as Richard mentioned before. It may depend on the particular time at which the patent was applied for. If it was early in the piece—20 or 25 years ago—perhaps, yes. But it may well be less likely now, where technology has advanced.

Senator HUMPHRIES—Those patents that were granted, say, 10 years ago can still be commercially exploited in the marketplace to exclude others from using that knowledge to proceed to apply that patent's value in a particular sense, such as testing.

Mr Jarvis—I am sure that Richard has a view about this. I have great difficulty in answering that question because I would have to look at the particular patent in question to make that assessment. I find great difficulty in generalising.

Senator HUMPHRIES—With respect, you generalise in your submission. You question the assumption that there have been lots of cases where there is too low a threshold for inventiveness or novelty.

Mr Hamer—I can answer that point, starting back where you began. It is not a correct assumption that this technology is not commercially valuable. It may be that there are cases where you have a—

Senator HUMPHRIES—I did not assert that it was. You must have misunderstood my question.

Mr Hamer—Sorry, that there is no incentive for someone to contest the validity of a patent. I understood you to say that it was going to be expensive.

Senator HUMPHRIES—No, I did not say that either. I said that it is very expensive for somebody to do that and it is unlikely that Joe Bloggs out in the street who happens to have an interest in the area is going to go to the court to challenge the width of a patent that has been granted. That person's success in the court does not enrich him at all and he suffers the real risk that he might lose and have costs awarded against him. For the most part it will only be rival commercial interests that will take a patent holder to court, will it not?

Mr Hamer—Yes. We see this commonly and it occurs whenever you have a generic company that wants to bring out a generic product which is what is going on here. They are constantly taking pharmaceutical companies, to court in relation to pharmaceutical products if they think there is any weakness in the patent. Their commercial interest obviously is getting their product on the market and getting onto the market first, so they are very aggressive about it. That is part of the system and that works.

There are aspects of gene technology where all those things are relevant, that is, where the product is subject to Therapeutic Goods Act registration and where there is easy registration for generic products. All those cases can happen with gene technology. There are many cases where there is lots of money at stake which would justify competitors coming in and yet, for whatever reason, they have not. That is part of the point. I agree with that you if you are an individual small laboratory you will not take on a patent. But there have been cases—I have been involved in some of them—where the industry association might do that. If you have an association of people who are concerned they might fund the action on behalf of all the people.

Senator HUMPHRIES—There have not been many cases like that though have there?

Mr Hamer—There have been cases. I have done cases myself for industry associations.

Senator HUMPHRIES—But not on genetic?

Mr Hamer—Not on genetic but on other technologies.

Senator HUMPHRIES—Could I put this question another way? As I understand it with your company laws, ASIC has the power to accept an application from almost anybody who claims that a company that is registered with ASIC that is defunct or no longer has any operation should be de-listed as a company in ASIC's books. There is no need to take them to court; you can simply bring the matter to the attention of ASIC and they will examine the facts and, if necessary, remove that company from the list. Is there not a public interest to be served? If people in the general community claim that a patent should be removed—granted some years ago in different circumstances there might have been an exaggerated sense of the inventiveness or novelty of that patent—that patent should be removed at the initiative of a citizen but on the assessment of the Patents Office against the current test about what is inventive or novel? People should not be put to the expense of having to take the matter to court.

Mr Hamer—There is exactly such a procedure which is called re-examination. Any person can write into the Patents Office, provide information and ask the Patents Office to re-examine a patent. The existing procedure is very cheap.

Mr Jarvis—The assessment will be based on whatever the state of the art was as at the priority date, not what it is now.

Senator HUMPHRIES—My question stands. Should it not be capable of being reassessed on the basis of current knowledge rather than what happened at the priority date? If we determine now, with the benefit of hindsight, that this particular patent is not novel and it did not involve inventiveness to the degree that would have warranted that being granted if it were sought today, that patent should be withdrawn.

Mr Hamer—The whole principle of assessing inventiveness is not to use hindsight; it is to assess it at the time that the invention is made.

Senator HUMPHRIES—I appreciate that that is what the law says, but we are capable of changing the law. I am putting it to you that, given this concern in the publics mind and in the minds of a number of stakeholders that we have had as witnesses, patents have been granted too freely over genetic processes and there are adverse consequences of that. We can debate what they are but obviously many people believe that there are such consequences. Our previous witness, Professor Christie, who has worked in this area for 25 years, said that he believes there are a number of cases where patents have been granted too freely over processes that are really not, when you bore down into it, inventive or novel, or they do not have that manner of manufacture that would warrant them being regarded as inventions rather than discoveries. Should there not be a capability of going back with hindsight, assessing those patents and saying, 'They are really not a patent. They should not be granted patent status and we will withdraw that patent.'

Mr Hamer—I think that is what the re-examination process does. It is true that it looks at date at which the patent was filed but it also re-examines it and asks whether further information has turned up that was relevant at the time.

Senator HUMPHRIES—At the time of the priorities?

Mr Hamer—Yes.

Senator HUMPHRIES—That is not what I am arguing. I am arguing that it be assessed at the time that the application is made.

Mr Hamer—I do not think Professor Christie would have suggested that approach.

Senator HUMPHRIES—No, he did not, but I am asking you whether that should be the case.

Mr Jarvis—I do not think it should be either. I think there would be great confusion. That would engender great confusion and greater litigation.

Senator BOYCE—I want to follow up on the comments you made about the fact that there have not been a lot of court cases, as Senator Humphries pointed out. We have had some evidence—unfortunately most of it is anecdotal—to suggest that there is a degree of secrecy within the research and clinical sector because of its concerns about how owners of patents relating to reagents and other gene testing materials would be treated. Are aware of any such cases where hospitals and laboratories that operate without holding a patent have been stopped from going ahead with either testing or research by the patent holders?

Mr Jarvis—Not that I am aware of, but I would have thought that this experimental use exception to the act would be appropriate.

Mr Hamer—I think Senator Boyce's was not about experimental use so much as actually therapeutic or clinical testing.

Senator BOYCE—Yes. Perhaps new testing or changes to tests and things like that which might be undertaken within the research and the clinical community.

Mr Hamer—I am not aware of any cases, Senator.

Mr Jarvis—I am not aware of anything either.

Senator BOYCE—As Senator Heffernan pointed out, not many people from the industry have come to speak to us on this topic. I am trying to get a sense of the industry's view, as you might understand it, and the Law Council's view on the proper use of patented bodies of information in this area.

Mr Jarvis—If there is a patent and it is commercial use there needs to be some sort of licensing arrangement. If it is experimental use then, arguably, it is not infringement. Hopefully if the changes have been suggested to the act to codify this, if you like, that will be even clearer.

Senator BOYCE—The other point you touched on when you were talking to Senator Heffernan is that it is perfectly possible to go about testing by somehow overlapping a patent on a particular thing as long as you are prepared to look at paying a royalty when that intersection occurs. Is that the case?

Mr Hamer—You can negotiate a royalty with the patent holder.

Senator BOYCE—Yes.

Mr Hamer—Often you can do what they want, which is to send it to their laboratory to do the testing, and pay for it. In the event that the test is not being provided at all, for example, you can enforce compulsory licensing provisions.

Senator BOYCE—But they have never been enforced?

Mr Hamer—This morning I was talking with someone about this issue. They are not enforced in the sense that there have not been cases on it. In a sense this is partly in answer to the other questions. There have not been cases on it but it does not mean that you do not quite often write letters to people saying, 'If you do not give us a licence we will enforce these provisions.'

Senator BOYCE—We will get out the big stick.

Mr Hamer—The fact that there has been no decision on it does not mean that the law is not being thought about.

Senator BOYCE—Within your knowledge there are times when it has been used as the potential next negotiating step and that has led to an agreement about the product being used?

Mr Hamer—Yes.

Senator BOYCE—I am coming to what appears to be a fear of waking up the sleeping giant owners of patents by research and clinical communities. This is something that has come across several times and it would appear as though there is no crossover between clinical and commercial understanding. All I can ask from you people is your sense of how industry feels about this. I will use as an example if a patent owner finds out that a particular test could be done only for a gene for which he or she had some sort of patent rights. If that owner finds out that someone is working in that area, he or she might take it off the owner, stop the owner and charge $1 million. This is the sort of anecdotal evidence that we are getting at the moment. Can you respond to those anecdotes?

Mr Hamer—I can respond only in this way. There have been some isolated cases but on the whole I am not aware whether major IP owners pursue research institutions. Generally they want to have good relations with them because they are the key opinion leaders who then help them to promote their products and to sell them in due course. Generally they do not want to antagonise those key opinion leaders. On the whole, they try to preserve good relations. That would be my general observation.

Mr Jarvis—I would agree. I do not think anybody sets out to become involved in major patent litigation these days and incur the cost of that without having very good reason to do so.

Senator BOYCE—Do either of you have any thoughts about where this fear comes from which, from what you are saying, is unfounded?

Mr Hamer—I am trying to work out where the fear is. Having looked at the submissions—and I have not gone through every submission you have had as you have had quite a number and that is your job and not mine—most of the research institutes generally seem to be keen to ensure that they are able to patent.

Senator BOYCE—There has probably been more anecdotal evidence given to us by our witnesses. A level of concern has certainly been expressed. Senator Moore just pointed out that a paediatrician who gave evidence yesterday spoke about the fear of being caught out by the big owner of the patent material, or the patent. From what we are hearing—and as you quite rightly said, Mr Hamer, after looking at the submissions—there is a whole underworld that we are not accessing in our evidence. I am asking you, as representatives of the Law Council, whether you have any sense of this other world?

Mr Hamer—I can merely state that quite a lot that goes on is intentionally or otherwise ignored. It is not commercially worth it for people to pursue a patent infringement, even though they think one might be one going on. That certainly happens. Despite the comments, patent litigation is still expensive to the patentee and you never know who you might attack. For example, some people have insurance, or they have a backer, and you think that you are attacking someone who might have no ability to defend the litigation and you find out that they do.

Senator HEFFERNAN—There is lawyers-minded work there!

Mr Hamer—The point is that you cannot just assume that some litigation will go away or that it will be quick and easy. Even when you think you have a simple and straightforward case you can end up in litigation that goes on for a long time.

Senator BOYCE—If someone writes to someone else and says, 'Excuse me, but I think you are breaching my patent', often that is not the first step of litigation per se. It might well be the first step of negotiation. Is that correct?

Mr Hamer—Indeed. Conventionally you could write a letter of demand but then say to them, 'If you want to negotiate we will,' or you could even write to them inviting them to take the licence in the first place.

Mr Jarvis—That is certainly my experience as well.

Senator MOORE—I want to follow up on that question. What is your awareness of the knowledge in the community of patent law? We have been hearing that people have been locked away in a laboratory who have no idea that they are breaching a patent and they suddenly find out that they are. My understanding is that the larger institutions are meticulous in checking patents before they go for research. In NHMRC and ARC grants that is one of the things they ask about specifically in that process. I am wondering whether you are aware from your knowledge whether there are pockets of genuine ignorance that could be surprised by where they find themselves?

Mr Hamer—It is certainly my experience that research scientists are generally well-informed on patents. They know exactly how they work and it is part of their business to produce their

records in a way that supports patents. Equally they know that there is no point in, for example, developing some technologies that they will not be able to use because of a patent, so they conduct searches before they engage in their research to ensure that they are not reinventing the wheel and to ensure that there is freedom to operate. That is all standard.

Senator MOORE—That is not to say that people might not deliberately ignore that. It has worried me that there has been some indication that people would be punished when they have not known what is going on.

Mr Hamer—I think there probably is a boundary area and it probably comes not in the people who are engaged in core scientific research. Basically, I think the people engaged in gene technology, for example, are in the area of core scientists who would understand patents very well. Earlier you mentioned dieticians, people who were not in the mainstream scientific community or even medical practitioners who sometimes have not come through a scientific training who might never have picked up those elements. Maybe that is where you are getting some of those comments.

Mr Jarvis—I agree. There may be some small pockets, but the freedom to operate advice is a constant thing that patent attorney firms and lawyers get when there is an assessment of the constraints on working in a particular area. That happens all the time.

Senator MOORE—My other question is to do with people changing their minds. My understanding of what happened with the recent case in Australia is that there was an agreement that charges would not be laid for a patent for people to operate within a particular field. The person who owned that patent changed his or her mind and decided to impose charges. That is different; that is another process.

Mr Hamer—Was it a contract or an agreement?

Senator MOORE—I think it was verbal.

Senator HEFFERNAN—It made it to the stock exchange.

Senator MOORE—It was a question that I asked yesterday. Is there any limitation on people's usage of their patent? They might let it lie dormant for a long time and then suddenly, in a period of 20 years, they might decide to invoke it. Is there any limitation on that?

Mr Hamer—There is the ordinary limitation period, that is, essentially six years from the infringing act as a general rule.

Senator MOORE—Okay.

Mr Hamer—It is three years after the patent is granted. If for some reason the grant of the patent is delayed you can still sue for that period.

Senator HEFFERNAN—The licence is acquired from the patent that was granted. This was the licence acquired in Australia from the Myriad group. When does it begin—six years from the acquisition of the licence or the implementation of the—

Mr Hamer—I am not sure.

Mr Jarvis—If there is a licence you do not infringe. What Richard was talking about was—

Senator HEFFERNAN—Hang on, let us define this.

CHAIR—We are crossing over now. In the case to which Senator Heffernan referred it was the licensee and not the original owner of the patent who decided to change his or her mind and to invoke the licence rather than letting it go.

Mr Hamer—The rights of the licensee can never be any greater than the rights of the patent owner. If the patentee does not have the rights to sue someone for infringement, neither does the licensee.

CHAIR—So there are time limits. Senator Adams has a question.

Senator ADAMS—I would like to ask you about the recommendations that were made by the ALRC report and the ACIP report. How do you feel about those recommendations? Do you think that if they had been brought forward we might not be in the situation that we are in at the moment?

Mr Jarvis—Are we talking about the experimental use exception or just generally?

Senator ADAMS—Generally—just the general recommendations that have come forward. Nothing seems to have happened. I am just wondering why.

Mr Hamer—I think something has happened in the sense that I think we were talking about the fact that IP Australia is now going through a lot of those recommendations and putting proposals which I assume will lead to legislation being drafted. In fact I think we were just told that they are expecting—

Senator HEFFERNAN—That happened only after the event of the BRC gene technology thing. That was the trigger. Nothing was happening until then.

Mr Hamer—I think IP Australia put out a number of papers and some of them are for different reasons. One of the major proposals—you may have heard from them—is changing the obviousness principles to align it with international standards. That has advantages when you are examining patents as you do not have to examine them separately for Australia; you can simply have an international standard of examination. So there are principles like that that have nothing to do with BRC.

Mr Jarvis—I think the ALRC also made some recommendations relating to what is meant by 'useful'. I think—

Mr Hamer—We support them.

Mr Jarvis—The Law Council supports those recommendations.

Senator ADAMS—I was worried about the fact that the ALRC report came out in 2004 and we are now in 2009. We might have been able to avoid some of these things. Anyway, thank you.

Senator HEFFERNAN—The genome was plotted in 2000. Is that fair enough? When was the completion of the plotting of the human genome?

Mr Hamer—I am sorry?

Senator HEFFERNAN—When was the completion of the genome plotting?

Mr Jarvis—I do not know.

Senator HEFFERNAN—In 2000?

Mr Jarvis—I do not know. It might have been announced as being completed in a particular time.

Senator HEFFERNAN—Anyhow, it was around then. I refer to the epilepsy patent, which is here, and to a company called Bionomics Limited. Are you familiar with them?

Mr Jarvis—No.

Senator HEFFERNAN—They have applied and the title for their application is 'A diagnostic method for epilepsy.' The date of filing was 10 March 2004 and the date of priority was 27 March the year before. You are right; there was about a year's difference. They set out their patent in 2003, which is well beyond the plotting of the genome. If you go to this document you find that it states, 'This is a diagnostic method for epilepsy.' It sounds like a bloody good idea. The abstract refers to 'a method for the diagnosis of the SME-1 gene'. It is a method for determining whether a patient suspected of SME-1 does or does not have the gene. The claim includes the testing, so any method of testing, which cuts out all other testing. It includes the actual genes, or the isolated genes.

As it says at the start, this is a test for 'a method for diagnosis'. It goes further in the claims. It goes from diagnosis to methods for the diagnosis and treatment of epilepsy. My understanding is that this is a valid patent with a very broad scope. My understanding is they have the patent on the access to the gene; they have the diagnosis complete; but there is no treatment, even though they have claimed the treatment. They have locked up the treatment legally in this document. How can that be when there is no treatment? Earlier this morning we heard from lawyers that part of the obligation of a patent is that you have to publicly define what the innovation is within 18 months. If when the 18 months is up there is no treatment is this a valid patent?

Mr Jarvis—I do not know; it is outside my area of expertise.

Senator HEFFERNAN—That is the answer the lawyers always give. How do we test this? Is this a perfect example for an ASIC type body that oversees this patent world? Certainly the average punter cannot get his or her head around this stuff.

Mr Jarvis—I presume that the patent would have been granted after examination by IP Australia.

Senator HEFFERNAN—But IP Australia does not have to go into the bit that we do not examine.

Senator BOYCE—Utility.

Senator HEFFERNAN—Utility?

Senator HUMPHRIES—Utility is the word.

Senator HEFFERNAN—They do not look at that. If they did, they would have to say, 'What is this cure that you are looking at?' But they do not have to and it therefore escapes.

Mr Hamer—One of the existing proposals that has been put up by IP Australia is specifically to include a provision that they examine on utility. That is something that we support. That is something that should apply to all patents; it is not specific to gene patents.

Senator HEFFERNAN—With great respect, this is a sham.

Mr Hamer—No, I am not saying that at all. I do not know anything about the circumstances of that case.

Senator HEFFERNAN—The third leg has not been described. It has not been put under scrutiny and it does not exist, yet this patent binds—

Mr Hamer—I do not know the case and I have not got the document. It certainly may be right.

CHAIR—It is Senator Heffernan's opinion and you have not seen the patent so we cannot expect you to have an opinion on the patent. I will not ask whether there are any final questions as we are way over time. I have allowed questioning of these witnesses to go over time firstly because it is useful and secondly because our next witness is waiting patiently but the witness after that is not coming, so we had a bit of extra time. Thank you very much; it is much appreciated.

Mr Hamer—Thank you.

[2.32 pm]

COYTE, Dr Belinda, General Practitioner

WEST, Mrs Jennifer Anne, Director and Secretary, Australian Marfan Foundation

Evidence was taken from Dr Coyte via teleconference—

CHAIR—I welcome Mrs West from the Australian Marfan Foundation, and Dr Belinda Coyte via teleconference from Adelaide. I understand that you have been given information on parliamentary privilege and the protection of witnesses. I invite one or both of you to make an opening statement and we will then ask you some questions.

Dr Coyte—I am the mother of a child who has been tested for long QT gene testing as well as other gene testing.

Senator HEFFERNAN—Belinda, I congratulate you on coming forward in the way that you have.

Dr Coyte—Thank you.

CHAIR—Mrs West, would you like to commence?

Mrs West—Thank you for the opportunity to speak on behalf of the Australian Marfan Foundation to this important inquiry. As I stated, I am a director and secretary of the Australian Marfan Foundation. It is a recently established not-for-profit organisation. The aims of the foundation are to provide support for subjects with Marfan syndrome, to stimulate research into Marfan syndrome, to increase community awareness of Marfan syndrome and its complications by the development of educational tools for patients, schools and medical practitioners.

Marfan syndrome is an inherited disorder affecting one in 3,000 to 5,000 in the community and that is referenced in the Oxford Desk Reference Clinical Genetics 2005. It is caused by a mutation in the DNA sequence of the fibrillin gene—a gene involved in ensuring the integrity or strengthening of connective tissue in the body. The main risk of Marfan syndrome is development of aortic aneurysm with potential for rupture or dissection. Other physical problems include problems with the eyes, the skeletal system, skin and respiratory abnormalities as you would expect in any defect that affects connective tissue.

My background is as a registered nurse and I have coordinated a multidisciplinary diagnostic and follow-up Marfan syndrome clinic at the Prince Charles hospital in Brisbane for the past 15 years. Prince Charles is the main hospital in Queensland that deals with Marfan syndrome and cardiac surgery. I have been a member offer the Queensland Marfan Association for 18 years and act as an almanac for them. I have a significant background in dealing with Marfan syndrome subjects and multiple clinical problems. Together with my husband and other colleagues around Australia we established the Australian Marfan Foundation this very year.

The diagnosis of Marfan syndrome is difficult. Up to the present the diagnosis has been based on satisfying the clinical criteria which was determined at an international conference in Belgium in 1996. However, it has been found that not all subjects with Marfan syndrome fully satisfy the criteria. DNA testing for mutation sites in the fibrillin gene is now the gold standard. Unfortunately, since each family has a different mutation, mutation testing is not simple. Multiple sites in a very large gene need to be assessed. DNA testing is thus complex and not readily available. There is no patented test for Marfan syndrome. DNA testing is carried out by both not-for-profit and commercial organisations.

There is no government support for Marfan syndrome genetic analysis. It is possible that a surrogate DNA test using hapla types will be developed but there is no such test available at present. The issues for consideration that we have identified, although there are several others, are that the DNA gene sequences are not inventions and should be available to anyone; that diagnostic or treatment innovation is not more likely to occur if a gene sequence is patented; that the proposed new laws regarding patents for genes should involve geneticists, scientists and the public as well as legal practitioners.

The law regarding patentability of genes needs to be reviewed although the ALRC report of 2004 disagrees with that. Gene testing should be regulated, accessible and benefits and limitations publicised. Would you like me to go further on each of those points?

CHAIR—How much more do you have?

Mrs West—I can expand on any of the issues to which we have referred.

CHAIR—Perhaps that will come up in questions. I think we are happy to go to Dr Coyte. If we do not cover the topics you have that you want to expand later, I will ask you at the end to add anything.

Mrs West—I have a bit of information on the benefits and costs of DNA testing to these subjects.

Senator MOORE—Mrs West, can you table what you have in front of you? Can you leave that with the committee?

Mrs West—I could send it to you electronically if you would like me to do that.

CHAIR—We will go to questions and we will also get a copy of what you have there. Dr Coyte?

Mrs West—Thank you.

Dr Coyte—I have had problems with my son having three different cardiac problems. The gene testing is very expensive and it means that people with conditions cannot afford the tests. If it were patented it would be worse. Basically, we still have not got the result of a test that was conducted in 2005 because the person died in New Zealand, it then got lost in Denmark and the geneticists in my state said they did not want to send an email to Denmark because it could

embarrass New Zealand. I was not able to find out until years later that it had gone missing and it was never tested in Denmark, or where it was in Scandinavia.

We are still waiting for the result of the test that was then sent to Melbourne in June last year. It is still not available. If future decisions are made about gene testing I would be interested in being one of the consumer people on a committee because I found out from my own research that a lot of the tests can be done for the same price within six to eight weeks instead of waiting a year longer in Australia. The blood is sent to America and it is much the same price. If this were available as quickly in Australia of course that would be equally as good.

I spent over $10,000 this year when I was told that my son would probably need a heart transplant for dilated cardiomyopathy. I was told that probably no cardiologist in Australia would work out the diagnosis. When I have tried to speak with geneticists I have often been told that there are none available, that they are away on meetings or holidays, and those that are interstate are on long service leave and are not available, even in the major cities.

From my own research I found out when I was told my son could have Marfans, Ehlers-Danlos or Loeys-Dietz, that that probably explained why he has a sunken-in chest and a dilated proximal aorta that could have ruptured over the past four years. I was told to pay $8,000 because the geneticist said he did not have 90 per cent of one of the conditions so the hospital would not help pay for it.

I was told that the test for Ehlers-Danlos would be $5,000 in Australia. From my own research this year I found out that the vascular type of Ehlers-Danlos is the only one that really causes significant problems to people as regards their heart—cardiomyopathy and dilated aortic roots. This one itself costs just over $1,000 to test. I found out from my own research what we are not told by geneticists. That would save people that are told they need to have a test for a condition.

My son's sister was diagnosed clinically with Ehlers-Danlos by the geneticists this year, but the hospital did not want to spend the money to confirm it with any gene testing. I said that the only one that matters is the vascular one. So I have actually sent his blood to America. It had to be re-sent again due to some problem. But we have got back the Marfans, and it was negative. His other problem is dilated cardiomyopathy. They tested the genes that they already had a few of and they have come back negative. But it is $10,000, and I didn't know what else needed to be spent. We do not have a house to live in; we are renting. When you are on a disability pension for your own heart you do not really get help with gene testing.

The hospital where my son attends paid $800 for Loeys Dietz, but they were going to wait a year if that came back negative. They were then going to send the same blood for Marfans, which is $1,600 in Australia. Then if that came back negative a year later they were going to send it for Ehlers-Danlos, which they said was more expensive. When they said they did not know how long he had to live, I thought it was preferable to send the blood to America. But we are still waiting on the Loeys-Dietz, which was sent in January to be tested in Australia.

But I think people should have the right to know where the quickest testing is and how much it is. I think people should be able at least to have a tax deduction or have more availability of help when they say the person could die from the condition. If people had a close relative die who had, for example, Marfans or something that is serious, they should have some way of being able

to afford to get the gene testing. I do not feel I was told enough by the geneticists about what was available and what was the quickest way of getting it tested.

As a consumer, when I rang different laboratories in Australia—I found out later that I had to pay for the ones in Australia—I was told they were research laboratories and it takes so long in Australia because there is not much money and not many people doing it. When I asked how many hours it takes to look for Marfans, Ehlers-Danlos, Loeys-Dietz or long QT, none of the laboratories could give me any idea or how many times they would have to look at any one of those genes or why each one costs over $1,000 for work done by research people in Australia. It is hard as a consumer, but I think people should have the right to be tested for conditions that could affect someone's lifespan and save their life.

Another thing that I worked out from being a doctor myself is that with cardiomyopathy there are some reversible causes that are just an enzyme deficiency which can be found in a gene test. So I thought it was important that people be told which ones are the reversible ones. If an enzyme was already available to treat something, it would mean someone would not need a heart transplant. When I have asked geneticists which are the metabolic or neurological conditions that we have an easier test for and are reversible, rather than having a heart transplant, no-one seems to know which they are. People should know what is available, which are reversible causes that we already have treatment for and also, when someone is not told how long they have to live there should be at least some assistance with getting certain tests done if they think there is a chance that it could be useful, or especially if someone else in the family has an important condition.

As I said, my research has found that ones such as Ehlers-Danlos have at least five different types. But type IV vascular is the only one that really causes the problems. Doing that research saves money by not having to test the other ones that do not really have any significant problems. As I said, I have found out some things myself from having done research on the internet and talking with people around Australia. But I feel that if patents were also enforced, it would be a lot worse for people who even now cannot afford testing.

When you have conditions that have not been diagnosed, sometimes your whole family can turn against you and leave you out of inheritances and family gatherings. As far as they are concerned, if nothing has been diagnosed there is nothing wrong. Yet, when you never know if your child is going to come home from school and they could have the long QT, it seems not right that you can wait four years without the results of a test which should normally take a few weeks.

The cardiologist said he needed to know if my son has Marfans to see if the dilated aortic root matters and then I was told I would have to pay thousands of dollars by the hospital. As I said, I cannot afford it. I tried to borrow money. I asked Variety if they could put money towards it. I asked all my relatives to lend me money before I sold my house, but no-one would help. I could not live with knowing that I had not done tests that could have helped work out what was wrong. There are quite a lot of issues for families when you cannot afford gene testing and when you have to wait a long time for any result. When people need things that can help their life it is important at least to get some help from the government and not to have patents.

Senator HEFFERNAN—Thank you, Belinda. That is a very telling story. When you first wrote to me about it I found it hard to believe. It certainly brings home the impact of the money side of the monopolisation of the gene world. Thank you very much for that evidence.

Dr Coyte—I was very impressed with places in Australia like the Victor Chang Institute that are doing research and other people who are doing research to look for causes of other diseases involving gene defects. I know it is an important area, but there does need to be some improvement for people who cannot afford to find out if their children have a serious condition like a close relative has or if it looks like a gene test would solve the problem and help save their life.

Senator MOORE—Mrs West or Dr Coyte, I am trying to get this clear. It was a very crackly line and I did not hear everything as clearly as I would have liked to. It sounds like you have had an extraordinarily difficult process with both your children and their medical conditions and trying to get support. I am trying to find out in your story where the issue of patents came up. You talked about the difficulty of getting blood testing and blood test results. Your story about how long it took is horrific. I was not really clear about where you believe the issue of patents impacted on your experience.

Dr Coyte—Some of the patents are on the genes but they are not being enforced. If they start getting enforced then all the expenses will be even more than they are now. So people will be even less likely to get the test done because the costs will be even more.

Senator MOORE—Has it been explained to you about how much it would rise for the kinds of very specialised tests that you are seeking for both of your children, but in particular your son? Have you had that explained to you—how much tests would cost?

Dr Coyte—Yes, I have been told how much they would cost. I have also been told by the geneticists that if it was patented that it would cost more.

Senator MOORE—So the geneticists told you that?

Dr Coyte—And scientists have as well.

Senator MOORE—Okay. Thank you for that. I just could not get it clear. Mrs West, I refer to your work with your organisation. One of your issues is about research. Have you had the same information from the people working in the field; that is, that the patent process could increase the costs for your people?

Mrs West—We do have a research department at the University of Queensland which I am involved in and we have been looking at aneurysm diseases for a long time. One of the issues is not necessarily the patenting of a gene as such but the patents on the pharmaceutical or gene testing drugs that are used. That is really where the costs come in. For instance, we send samples to places in Sydney and New Zealand, and sometimes America or England, for gene mutation testing for Marfan syndrome. The gene is enormous and the mutation does not always occur at the same part of the gene. The mutation that affects people can occur anywhere along the gene. It is a very long and complex gene. The kits and things that are being used are costly.

Senator MOORE—Very high cost.

Mrs West—The thing is that even if you subject a patient to a gene test or mutation screen for Marfan syndrome it might cost them $2,000 for the index case but it may still not be found. They still have to bear that cost, even if they cannot find the mutation.

Senator MOORE—So that could be a false negative.

Mrs West—They will not give you an indication that yes you have it unless you can actually pinpoint the loci of that particular family. If you can do that then you can test all other members of the family, which cuts down the costs to them in the foreseeable future by reducing their having to come back and have all the expensive tests and to be monitored, which really is the only way you can do that at the moment. But the costs at the moment are really high. I suppose the private laboratories have to charge to keep themselves going. It is really the chemicals that are used.

Senator MOORE—And the tests that you are doing are under patent?

Mrs West—I would not be able to clearly answer that question. I could come back to you with the answer.

Senator MOORE—That would be very useful to find out. It sounds to me that the condition and the testing is so complex and you have to do it maybe a few times. That would explain the delay. But I am still at a loss, Doctor, as to why you provided blood in 2005 and you have not received the results of those tests yet. I just do not understand.

Dr Coyte—The one that was sent to Scandinavia got lost. We do not know what happened. So we had to re-send blood in June last year to Melbourne. That result has not come back. But from what I have been told, quite a lot of the tests are patented but the patents are not being enforced. So it is best if they do not even get patents. If the existing patents are not enforced that is something. But I have been told that they need more money for the hospitals and researchers to do gene testing, and maybe some commercial ones as long as they are not causing problems for the hospitals and for people as regards the prices. It would have been nice to know how much the hospital has to put towards gene testing. I know that some patients are allowed $55,000 a year for cancer treatments. If you are told that your child could die or need a heart transplant and the hospital will not spend $800 when they think there could be a certain gene test, it makes you wonder. It would be good to have some idea of whether you have certain rights to something towards helping a child's life.

Senator MOORE—Doctor, are you in New South Wales?

Dr Coyte—I am in South Australia.

Senator MOORE—So your children are being treated at the Women's and Children's Hospital in South Australia.

Dr Coyte—Yes, they have been under a geneticist for quite a few years. It could be Marfans as well. As I said, my son has the collapse, but he also has dilated aortic roots, which they said

could rupture. Now they have found a very dilated heart and they still do not know the cause of that. But basically we just have to live with it. I am on a disability pension and I was told to pay $8,000 to find which connective tissue he has for the gene testing.

As I said, from my own research I worked out how to save a whole lot. Ehlers-Danlos is one of the three connective tissue ones—Marfans, Ehlers-Danlos and Loeys-Dietz. I worked out myself from research that only one of Ehlers-Danlos ones really needs testing because the others do not really cause any serious problems for the patients. If you speak to the geneticists they do not tell you that. So, instead of having to pay $8,000 it would have been pretty well half with that information.

Senator MOORE—Thank you.

Senator HUMPHRIES—Perhaps I can direct a question to Mrs West. There is a very important role obviously for patents in the provision of health care in Australia and every other country in the world at the moment. For example, almost all the medicines that we use are or have been under patent at some stage. The existence of patents helps to create those medicines in the first place. They would not be created if the manufacturers or inventors did not have a financial incentive to get them to the stage where they can be manufactured.

A point was made by a witness earlier today that the issue with genetic testing particularly should not be who owns the patent over the creation of that particular medical remedy but how society pays for people's access to that remedy. For example, if you find a wonder drug that cures a particular illness and it is very expensive to produce we do not say that we will take that patent away or we will not grant a patent for that because people will get the drug for free.

We say instead that the person who has developed the drug is entitled to the patent, but the community subsidises access to that drug by a mechanism—in this case the PBS—to give them that access at an affordable price. The witness earlier today suggested that that is what we should be doing in this area as well. That is, genetic testing should be more accessible through a system of public subsidy for those for whom a test is available and clinically appropriate but who cannot afford it because of the high cost which the patent owner reasonably charges for access to a piece of technology that has been expensive to produce. Because of that they have to charge a lot to access it without public support. Do you think there should be a scheme of that kind to provide access to those sorts of genetic tests?

Mrs West—It would be ideal, especially in the case of people with Marfan syndrome, because there is not such availability for them at the moment, unless we get funding. Up until this point some of our funding has been through research moneys that we have had to apply for. You may have a PhD student who is doing a project that involves mutation screening for something in particular, but you might just get one or two of those in a family, but there are too many families out there that need it.

I believe that the cost could be got back, if you like, from that sort of PBS-type system that you are suggesting by the fact that you would no longer have to have the expensive screening of all patients in a family that are suspected of having the syndrome. At the moment, if they have dilated aortic roots and we have expensive tests and keep them going and keep monitoring them on a yearly or half-yearly basis then they may need to go on to surgical intervention.

If we are screening up to 300 subjects—which we have in the case of a large Aboriginal family with Marfan syndrome—now that our laboratory has found the mutation for them we can then cut out the 50 per cent of them who do not have it. That means that we are not flying them down from remote parts of Queensland. We are lucky that we have a situation like we have in Queensland where there is a multidisciplinary clinic to diagnose the problem in the first place. I think a lot of the costs would come back to health care in general in that type of system if there was fairer way of testing.

The majority of the things that Belinda has been alluding to come from different genes. It is huge; it is large. The genome project has been wonderful, but we still need to look at things that are not quite in the public eye like we have with this. If you have good funding for research in this arena then you can look at other things, other diseases if you like, or problems or mutations that will impact on this. But I would gladly welcome a system where people with Marfan syndrome, suspected Marfan syndrome or a known history of Marfan syndrome had access to that genetic screening like they do for other genetic abnormalities at the moment.

Dr Coyte—Can I just say something about gene patenting? From my knowledge of medical history, not every medicine or invention has to have a patent put on by the inventor. For example, Florey from South Australia invented penicillin, but the patent was put on by America. He wanted to find a cure like the new antibiotic.

From what I have been told, a lot of the genes have already been patented but they are not enforcing the patent. If they enforced it, the cost of the procedure would be a lot higher. The cost now is due to the time that the researchers have to put in looking for the different genes. They have to keep looking over months, or weeks in Australia anyway. But they often have to put batches in together and wait for more to get a batch. Apparently it takes a lot of time.

So the cost of it is the time of the people looking for the loci in the gene. Basically it is good in a way for the public if the patents are not put on, but even for some that are put on if they are not enforced. But if they are enforced that usually means that only one place in Australia can then do the testing or it will restrict the places and the cost will go up and it will be a longer wait and more expensive in general and harder to get the test.

Some countries have chosen to try to reduce the number of new patents and also not to enforce the existing patents. They pass legislation that it is not to be enforced in the country. There are some things that can be done. But in my opinion patents make it more likely that people will die of illnesses in Australia because they are not going to pay for them to be tested. A lot of these conditions are fatal—people can die from them because people are not paying for the testing.

There will be more and more in the future and it will be getting more and more expensive if the patents are put on or if they are enforced. But if there is legislation that they not be enforced or not put on that would be better for the public. Of course, there needs to be more money for the researchers and for the hospitals, or even for some private system that has, of course, some of the top people if it is accredited properly and working so there is also quick but not unnecessarily expensive tests.

Senator ADAMS—Mrs West, you suggested on page 2 of your submission that ethicists should be involved in decisions about gene patents. What do you think are the ethical arguments around gene patents?

Mrs West—The arguments in general, Senator?

Senator ADAMS—Yes. It has been raised before. I just want your opinion on it.

Mrs West—I guess we would like to make sure that ethically the development of diagnostic tests and novel treatments or further understanding of a biological phenomenon does not depend on whether the gene sequence itself is patented. There are arguments that patenting limits access to new information. Greater access to information would seem to be more likely to stimulate innovation. We believe that that is the case. We believe that if you do not have the access and research departments things will be put off by it. Ethically I think that is immoral because it does have an impact on what is happening with people with genetic diseases such as Marfan syndrome and some of the others that have been suggested today.

Senator ADAMS—Do you see it bordering on a human right and that these people are being discriminated against?

Mrs West—I would like not to see them discriminated against by too much ownership of natural body rights. Everyone has genes. People like to patent some of the technologies and the novel technologies, but by and large I would like to make sure that patent attorneys did not encourage people to make it restrictive for further novel research and information to get through for the betterment of humankind. I do believe that people should have the right to have full access, yes.

Senator ADAMS—Have you any evidence that other conditions are receiving fairer treatment rather than a more obscure disease such as these two? Dr Coyte, you may be able to answer this as well.

Mrs West—Sometimes you can get that perception. All things like cancer that are really out there with dreadful issues in the community certainly do get a lot of funding because they are large bodies. They have large fundraising bodies and they can link up with larger fundraising bodies. So, yes, it is a little bit tougher for the more obscure ones because raising money for research is harder.

Sometimes you can get a little bit of a perception that some of the National Health and Medical Research Council and Australian Research Council funding is more about the flavour of the month this year—big projects that have proven to be successful in different arenas. It is harder to get people focused on a cardio-vascular problem that requires funding that might get overlooked by some of the larger projects. I do not think I would call it a gripe, but I think that that needs to be looked at and I suppose by more people being involved, from lawyers to ethicists to other people. That might placate that a little bit.

Senator ADAMS—Dr Coyte, do you have any comment?

Dr Coyte—I do not think these conditions are that rare. Even if it is only one in 2,000 or one in 5,000, it is still significant. I was recently told that if either my son or I die then the cardiologists will look into our problem more. They are waiting for one of us to die before they do further investigation.

But a lot of these conditions involve children and relatives of people who have already died, and they do not know if they have the condition themselves. Young children have conditions that will impact their life and their family's, yet the government is putting a lot of money into other areas of treatment or investigation and things like that. I do feel that there does need to be some increase in the amount of money that is put into gene testing.

From what I have heard, if the patents are enforced or new patents are granted it will be more expensive for the government for people who need testing and it will be more out of the reach of people who need to be tested. There should be some rebates or help with the payments. There needs to be more people, such as geneticists, and more money for research so that people who need these tests can have them.

But, as I said, I found out myself ways to save money by finding which of the genes were important, for example, in Ehlers-Danlos. There needs to be a lot of improvement. But if gene patenting was enforced it would be a lot worse for people in Australia and more expensive for the government's health budget as well.

I do not think personally that these are rare things. We are going to be finding more and more genetic problems. People should not be dying because the government or hospitals cannot afford a test that costs $800. If it is patented or the patent on it is being enforced, it will not only be the cost of all the staff time and what is usually involved but also a lot higher costs. It is part of the body.

It is not very nice that companies are patenting things to do with an individual's body. I agree that they should not be patented. They still get a lot of money from all the tests anyway. There definitely needs to be some improvement. Not only would it mean that there is less health dollars if things are not patented and if it is improved, but also people will be more likely to stay alive, including children. I do feel that there needs to be a lot of improvement in the gene testing area. There is a lot of money put into some areas that I think is wasted for the health dollar and not much use at all. Yet children and adults are dying of these conditions where only $1,000 might be needed to sort something out.

Senator ADAMS—I ask again: Was it your doctors who told you that the cost of these tests was going to be increased?

Dr Coyte—The scientists who do the research in the laboratories. I have spoken to Melbourne, Sydney and Adelaide scientists. I have spoken to geneticists interstate and in Adelaide. I was told that some of these conditions have patents but that the patent is not being enforced. It is important if legislation can prevent it being enforced. It will be good if new patents are not granted because that will also keep the price down. It will only go up if patents are applied as well. We do not have to have patents put on them.

Senator HEFFERNAN—I congratulate you, Doctor, on your fortitude, tenacity and commitment because I am sure the carriage of your evidence is helping public debate about the public good on this issue. Scientists, doctors and geneticists have talked to you about the added cost once you go to the patent edge. Obviously there has to be a balance between an incentive and greed.

I refer to the case of the epilepsy patent, which I have in front of hearings and which was filed in 2004 from a priority in 2003 by the Bionomics Ltd. The actual work on isolating the gene was done by academics in Melbourne and Adelaide. They completed the work and, having done so, Bionomics bought their work and turned it into what I call the river of gold. Had it stayed at the university it would obviously have been a much cheaper proposition. But then they got government assistance—they got a government grant—to complete the work of the patent, which has not been completed because the boundaries of the patent for the diagnosis for epilepsy include the cure, as it were—

CHAIR—Senator Heffernan, do you have a question?

Senator HEFFERNAN—This is a demonstration of the inventiveness of the money-makers. Work is done at a university and, having completed the work, they sell it to a trader, as it were, which, with a government grant that they applied for and got, then turns it into a commercial proposition. That encapsulates what your doctors have been telling you. You have patented an outcome that does not exist, but it is bound up in this patent. No-one else can have a crack at the cure. They have the diagnosis, they have isolated the gene—

CHAIR—And the question is?

Senator HEFFERNAN—This was never put as a question; it was always put as reinforcing the added cost and the entrapment of public good by the excesses and the broad scope of the gene patenting world.

Dr Coyte—And there will probably be many more like that if patenting is allowed at much more cost to the Australian government and to the public, and people will not be able to afford to find out the problem if it keeps on happening.

CHAIR—Mrs West, that is the end of our questions. Did we cover everything that you wanted to cover? In your opening statements you mentioned that you could expand on some of the issues. Have you covered everything that you wanted to?

Mrs West—I have, yes.

CHAIR—And you are sending us an electronic version.

Mrs West—Yes, I can send you an electronic version. It is in point form, but there is also some information about Marfan syndrome.

CHAIR—That would be much appreciated.

Mrs West—Thank you very much.

CHAIR—We will break now until 3.30 pm.

Proceedings suspended from 3.18 pm to 3.36 pm

BOWTELL, Professor David Douglas, Director of Research, Peter MacCallum Cancer Centre

FOX, Professor Stephen B, Director of Pathology, Peter MacCallum Cancer Centre

MITCHELL, Dr Gillian, Director, Familial Cancer Centre, Peter MacCallum Cancer Centre

CHAIR—I welcome representatives of the Peter MacCallum Cancer Centre. I understand information on parliamentary privilege and protection of witnesses has been provided to you. We have your submission and I would like to invite any or all of you to make a brief opening statement. I know you were here for at least part of the previous session and you will be aware that we ask questions. You have been in front of Senate inquiries before, so I know that you know the ropes.

Dr Mitchell—Actually, it is my first time in front of an inquiry. It was helpful to see the last 15 minutes. I would like to offer a brief set of remarks summarising the position that we put in our submission to the Senate inquiry. Although this is on behalf of the Peter Mac, I would like to think that we actually speak broadly for the clinical oncology and genetics community as well as the broader genetics research community.

Our position is that we feel that we are on the brink of a revolution in personalised medicine which is going to be driven by understanding the genetic basis of disease. That is genetic basis in two broad areas: hereditary genetics—in other words, the genes that we have inherited from our parents and pass on to our own children—and the genetics of genes that have gone wrong, mutated or faulty or whatever term you would like to use, within various body parts. From the Peter Mac point of view, that is dealing with cancer—that is the genes that can go wrong and cause a cancer. With diabetes it would be the genes that might go wrong in determining the amount of insulin that is made in the body.

I am talking broadly about genetic medicine being the way forward in the future—personalising medicine—so that we actually target our therapies better to people and do not treat people unnecessarily with the wrong treatments and that we focus the usually expensive treatments on people most likely to benefit from them. The starting position is that genetic medicine is a good thing. We want to be able to use genetic medicine for as many of our patients as possible. Research is required for that. We need to discover what these genes are and we need to be able to use them. Certainly, Peter Mac's main focus of research is in translational research; in other words, translating knowledge of genes into the treatment of people and, from our point of view, people with cancer.

The issue as we see it is not so much that patents are bad or evil things. We all see the benefit of patents and there has to be an incentive. I take Senator Humphries' point. They have to be there otherwise there will not be the incentive, certainly for a lot of financial institutions, to put funding into research. The issue is where that patent lies.

From the point of view of our submission, we feel that the patent should lie at the area of innovation, not at the discovery level. The DNA is part of what we are. The basis of our submission is that we cannot understand how we can patent something that is part of us. Just discovering the genetic sequence is not innovative; it is just using technology as we increase our understanding about what that sequence is. What is innovative and what is important is how you then use that information.

It will stifle research, innovation and being able to translate the use of that genetic information into treatment for patients if the patent is put at the gene sequence level. If it is at the gene sequence level then it is very restrictive as to who can use that sequence to do anything else. If the patient is at the innovation, technology or translation level then that allows for competition for people to constantly come up with better ways of trying to test for those genes, to use those genes or to develop better medicines to target those genes. You can then patent the medicine that you make and the technology you use to look at the gene. But the actual sequence itself is there; it is part of us.

Having looked at a number of submissions over the years dealing with why DNA patents can exist and stating that somehow when the DNA is taken out of the human body and becomes a chemical in a test tube, it is no longer human and can now patented—it is now just a chemical that can be patented—I fail to see how once it is in a test tube it is different from the sequence it was when it was in the human body. The basis of our submission is that genetic medicine is important, patents are important and that the level of the patent should not be at the gene sequence but at the downstream innovative point.

Senator HEFFERNAN—Can I invite our witnesses to take a question on notice formally? The Law Council appeared immediately after lunch. They were categorically of the view that an isolated gene was somehow different to an in situ gene. I would like you to see what they had to say and respond formally to it. In the meantime, do you have anything you would like to add now before you formally respond? They put it to us that there was nothing to talk about and that the isolated gene is an invention and not a discovery.

Prof. Bowtell—I feel exactly the same way as Gillian does. The isolated gene is still DNA and it still has the same sequence. The novelty must come in the way that you isolate the gene but not the gene itself. It is just another piece of DNA in a tube.

Senator HUMPHRIES—They and others have argued that the gene itself is not patentable and does not get patented in Australia. It is the isolation of the gene and then its use in some form outside the body.

Prof. Fox—There is no difference between inside the body and outside the body. It is the same stretch of sequence; it is precisely the same.

Dr Mitchell—I thought that the patent is on the actual gene sequence.

Senator HUMPHRIES—We have been told that it is not on the actual gene sequence. We are told you cannot patent the gene sequence; you can patent an isolated gene sequence and it has to be isolated. The three tests given to us by the patent research institute were that it has to be isolated, capable of being synthesised outside the human body and capable of some useful

application in that form. This is not clear to us because we have had different versions of this test. Can you tell us what you understand to be the test of what is a patentable gene?

Dr Mitchell—I do not agree that there can be a patentable gene because the gene is the sequence. Whether or not you can replicate it using PCR-based technology is irrelevant. That is the technology that is used to replicate genes, whether it is in the body or in a test tube. The sequence is the sequence, whether it is in the body or outside.

Senator HUMPHRIES—I would like to follow up with a question to clarify what you are saying. I understand that when insulin was discovered many years ago it was obviously a breakthrough in medical science. For a long time they were using insulin produced by pigs to treat human beings. Someone was able to synthesise human insulin in an artificial way, and that is what subsequently became the commonly used version of insulin. Is that equivalent to what we are talking about here? Obviously it is not a genetic discovery, but it is the taking of a naturally occurring process in the body and working out how to synthesise it outside the body and then using it for the treatment of an illness in inside the body.

Dr Mitchell—You have hit on a very important point. Although we are talking about gene patents here, I have to say that I think it is an issue for all naturally occurring substances in the body. We need to get it right for gene patents because it is going to be important for the downstream bits of the cellular machinery that we are going discover—the various signalling molecules that we are going to discover as well as the proteins. I cannot speak to the specific insulin example, except that I hope that the patent was not on the insulin molecule itself; I hope it was on the procedure to synthesise the insulin molecule. Personally I have no problems with the idea that you can patent the synthetic process. However, I have a problem in saying that you would have a patent on the sequence of amino acids making the protein. I see those as distinct things.

Prof. Bowtell—I agree. I do not know whether an analogy here will help. The first time that someone made an internal combustion engine there was a great deal of novelty in doing that. Presumably there were patents granted for that. To grant a patent every time a combustion engine is made by Holden would be as ludicrous as granting a patent every time someone isolates a gene based on the processes that were worked out in the 1970s that allowed isolation of insulin. It would be a nonsense. There is no novelty in isolating a gene from a human today, whereas there was a great deal of novelty back in the 1970s when insulin and other growth hormones were first isolated.

Prof. Fox—It is going to be the process of generating the insulin rather than the sequence of the insulin itself, because other companies make the insulin.

Senator HUMPHRIES—We still have not really got a clear picture. We agree there has to be an isolation of the gene or gene sequence.

Dr Mitchell—No, I do not think we do agree there has to be an isolation of the gene sequence. I think that what we say is that the process of isolating is in itself—like if I work out a new PCR chemical which might make that isolation more effective, cheaper or more efficient. Then you can patent that particular bit. But it is not patenting the actual sequence, which means

you cannot do anything at all with that gene because to do anything with that gene requires the sequence to base everything on.

Senator HUMPHRIES—My point was that we are told that merely identifying a gene—working out that this is the gene in the body that produces skin colour or whatever—and identifying what it does is not patentable. That is according to the advice we have received. It is the isolation of the gene and its application in some useful way outside the body that makes it—

Dr Mitchell—I think we actually dispute the way that it is somehow defined as being patentable. I actually dispute the fact that you might work out what that gene does. Why does that make it patentable? All you are doing is working out what that gene does. I think the novel thing is how you use it. It is not the fact that the gene is there and then how you use it. It is how you use it and what test you do to use it; it is the medicine you make as a consequence.

That is the how; not just that you have discovered the gene, taken it out, worked out its sequence and worked out what it does. That is still in existence. You have just discovered what makes us absolutely amazing. But what is innovative and what is patentable is what you then do with that information—you make the medicine or you make the test. That is the patent bit, not the discovery of the gene in the first place.

Senator HUMPHRIES—Lawyers have said to us that the principles that allow you to patent isolated gene sequences and their use are exactly the same principles that are applied across the board to all areas of patent law. You can take something which is naturally occurring in nature and if you can isolate it and then find a use for it outside the context of where it falls in nature then it is patentable. There are many examples of patents of that kind. It would be very difficult to somehow excise genetic discoveries and treat them differently from all the other discoveries that we make in nature and to then create a special case just for genes not being patentable whereas other equivalent kinds of scientific discoveries are patentable.

Dr Mitchell—I probably have a number of different problems with that. The first is that something that is human is actually different for a start.

Senator HUMPHRIES—Why?

Dr Mitchell—Because if we say that there is an argument that human life is important and that we are somehow different then I think the argument goes that what makes us is important.

Senator HUMPHRIES—What we discover in nature, say in a pig or a plant, might help save human life. So why should that not have the same treatment as a gene sequence in nature?

Dr Mitchell—I am not sure that I see a distinction.

Prof. Fox—It goes back to innovation. You can still get a sequence from a pig. Just because you take it out does not mean to say that it is different. In fact we share many genes with many different animals.

Senator HUMPHRIES—What I am saying is that the law presently acknowledges that if you can take the gene out of the pig, isolate it outside the pig's body and work out how to use it in some context outside the pig's body that is useful then you have a patentable invention.

Prof. Fox—Are you then patenting the sequence of the gene or the use?

Senator HUMPHRIES—According what we have been told by some people, it is its useful application that is patentable. I must admit that what Senator Heffernan has in front of him are patents which seem to say that what the patent holder is achieving is an isolated gene. That issue is unclear.

Dr Mitchell—Even if it is a pig, even if it is a plant, even if it is a human, if it is just the sequence of what it is—the basic DNA—I still fail to see how that is in itself patentable. I can understand—

Senator HUMPHRIES—I agree.

Dr Mitchell—The law might have generated in that way. I am not a lawyer by any means, but having looked through some documents while we prepared this it seems to me that by default this situation has arisen without any real test. When the first patents were applied for on gene sequences they were sort of given. Then, because they were given, we are now in this position. Just because it is in a human, a pig, or a plant, if that is a naturally occurring gene sequence then that is just a naturally occurring gene sequence.

I would like patents to exist because they are important. They do stimulate innovation, but they have to be put at the right level. It is the innovative bit which is making a test to look at it efficiently, finding a medicine to use it or developing it into an antibody. That is the important innovative bit that should be patented and that is the bit that actually generates competition. It generates the person over here to try to find a better and cheaper way to do it.

Prof. Bowtell—You have obviously been immersed in this. There are other issues, as I understand it, in that you have to demonstrate novelty and inventiveness. Correct? I understand what you are saying in terms of precedent. If you take a plant and you isolate taxol from it—

Senator HEFFERNAN—In the forest?

Prof. Bowtell—Yes. But I guess what Senator Humphries is talking about someone coming along and identifying a natural product in that and it then becomes a pharmaceutical. The pharmaceutical industry is built on that sort of approach. I can see that that creates a precedent that is difficult because then there is a parallel to isolate a gene, put it in a tube and use it. But I think that it then comes back to the question of which one is going to take precedent, the fact that the notion of isolation is sufficient in its own right or the need for inventiveness and novelty. There is nothing inventive or novel about isolating another gene from the genome these days. I would have thought that it would run foul of patent law at that point, or it should.

Senator HUMPHRIES—Unfortunately I am not sure whether it does. I would like to clarify a point. Dr Mitchell, you said that you did not think any naturally occurring process should be patentable per se.

Dr Mitchell—Just because it is there and you might find a way of looking at it because technology has allowed you to do that. The technology that allows you to do that is the inventive bit. You have just discovered something that is there. It is a bit like if you can get a better telescope you can find another star a bit further along. It is that analogy.

Senator HUMPHRIES—Representatives of the Royal College of Pathologists of Australasia appeared today and they did not argue for special treatment of genetic patents. In fact, they argued that there was no distinction between the way that genes or genetic discoveries should be patented and the way that other discoveries are patented. They said the entire area of patent law which allows a small amount of discovery or inventiveness to be grafted onto a discovery was too small a threshold to allow a patent to be created.

They said that across the board—not just in genetic science, but across any area of science—you should change rules so that there needs to be a significant level of human inventiveness applied to that natural phenomenon before it becomes patentable. As I understand it, you are arguing that we should actually isolate the area of the science of genes and give that different treatment. Putting aside the difficulty of trying to excise an area of patent law that is essentially identical to every other area of patent law and give it different treatment, why is your approach better than the one recommended by the pathologists?

Dr Mitchell—That is the first time I have heard about the pathologists' approach. If I take the definition of patentability, which is the innovation and usefulness, the DNA sequence just does not do that. The DNA sequence is just there; it is just a discovery. It is what you do with it that is important. That is the bit—

Senator HUMPHRIES—The lawyers argue that that is what is happening. It is not just discovery of the DNA. No-one has told us that the mere discovery of the DNA is patentable. They say it has to be isolated, synthesised and a use found for that isolated, synthesised version of the patent.

Dr Mitchell—No. It might just be to say that we know that this gene increases the risk of developing breast cancer. That is nothing novel. What is novel is that you find a new test, like in Stephen's laboratory. You find a better way of doing it, more cheaply or more efficiently or you find a drug which alters the fact that that is happening.

Prof. Fox—I suppose the end result of the IPCA opinion is what we are saying; that is, you have to show novelty and innovation once you have your sequence. I suppose that is what we are saying. Just isolating the sequence and having that is not enough, you have to apply something to it.

Senator BOYCE—In your view was it ever innovative or inventive to isolate a gene sequence?

Prof. Fox—Yes.

Senator BOYCE—To isolate and synthesise?

Prof. Bowtell—Yes, in the 1970s it was very innovative to do that. It is now a routine technique that any VSE student—

Prof. Fox—It is the methodology of isolating as opposed to patenting the sequence. I think that is a critical difference.

Dr Mitchell—Yes. It was the methodology, not the sequence, that was innovative.

Senator BOYCE—I think we need to be fairly clear that we are talking about now, not then. As far as I am aware no-one is currently trying to patent, although patents may continue to exist involving gene sequences.

Senator HEFFERNAN—With great respect, access to the isolated gene was patented in 2003 with a 2004 effect, which is in recent times.

Prof. Bowtell—That is still the case. I do not know that particular case and there is continuing to be innovation in the field with the use of technology. But we are talking about what would allow someone to identify another gene. When I was starting out this sort of thing was very difficult to do and stuff that would have taken me a year to do now you can easily do in a day. The technology has moved ahead and there is an enormous difference.

Senator BOYCE—It has existed for 20 years.

Prof. Bowtell—That is right.

Senator BOYCE—There are things which are covered by patent but which can seem fairly routine.

Prof. Bowtell—Right.

Dr Mitchell—To get into that fine distinction between the technology used and the innovation is how one gets to the answer. With the actual gene sequence, the answer there is not the innovation; the innovation is getting to that.

Senator BOYCE—But it always was innovative to do so.

Dr Mitchell—To get to the sequence but not to patent the actual sequence itself.

Prof. Bowtell—That is right. It comes back to Sector Humphries' point about the Royal College of Pathologists. The innovation was huge in the 1970s, but it is now tiny to isolate a gene.

Senator HEFFERNAN—Would it be fair to say that the times have not moved, but as recently as three, four or five years ago we would issue a patent to isolate the gene in a time when the isolation was old fashioned, as it were? We are absolutely tied up in the epilepsy patent—the gene, the tests and the cure, even though there is no cure—so no-one else has access to the gene to find the cure that this mob have not found yet.

Prof. Bowtell—Yes, that is right.

Senator HEFFERNAN—It is bloody stupid.

Prof. Bowtell—Yes, so we are being drawn along by precedents set 30 years ago.

CHAIR—Senator Humphries, are you finished or are you okay if Senator Heffernan jumps in?

Senator HUMPHRIES—I am resigned to it.

Senator HEFFERNAN—I just want to put beyond doubt that the patent system actually patents access to the isolated gene and not the further processing. What was the word you used?

Prof. Bowtell—The synthesis.

Senator HEFFERNAN—Access to the actual gene. I can read them out to you; they are in all the patents: an isolated nuclear acid coating for BRC to polypeptide. It is the gene and the gene access that is isolated from other researchers through this patent.

Prof. Bowtell—Yes.

Senator HEFFERNAN—Which obviously holds up a whole lot of research and intimidates a whole lot of good people.

Prof. Bowtell—Yes, isolation in this case is actually the isolation from the research community, I think. That is the effect of it.

Senator HUMPHRIES—In recommending that we should change the law as it applies to genetic material or genetic discoveries you are inviting us to go against a fairly long line now of reviews in Australia that have recommended against that. There was a report of the Industrial Property Advisory Committee in 1984, which recommended that we maintain the arrangements for genetic discoveries to be patentable.

There was a report of the House of Representatives Standing Committee on Industry, Science and Technology in February 1992, a report of the Intellectual Property and Competition Review Committee in 2000, the report of on the Australian Law Reform Commission in 2004 and there were some hints about what was coming out of the Advisory Council on Intellectual Property earlier today.

They have all certainly said—and in the case of the last one also tending towards saying—that there should not be an amendment of the law to specifically allow for the ending of the patenting of genetic discoveries. You are inviting us to disregard all of that and go down a different path.

Prof. Fox—They are many years old. I do not think people necessarily appreciate the discovery process that is happening at the moment where people are putting together thousands of genes and lots of profiles that are going to be useful and are already available to the medical community. But we do not understand how they are going to be used.

Senator HUMPHRIES—How does that effect the relevance, say, of the Law Reform Commission's report of 2004?

Prof. Fox—Maybe they have not given enough thought to how these things are going to be used for the good of the community. I have not read them.

Senator HUMPHRIES—You have not either. That is not an argument we can use. Why is your position superior to theirs is the question.

Dr Mitchell—Because I think they fail to appreciate what is the difference between something that is innovative and something that is a discovery. I think they fail to see that this is in existence in nature and why that should not be allowed to be patented. I do not think we are saying that there should not be patents. That is just not the right bit of the process to be patented.

Prof. Bowtell—The way forward, and it is something that is very timely to be considering at the moment, is that in the last 10 years the ability to sequence DNA—to look at our sequence and figure out what diseases we might carry—has increased one hundred thousandfold. The technology for this has exploded.

What was very hard back in 2002 and may have affected their decisions should be reconsidered now. The technology has gone ahead enormously in that time. I guess what I would argue is that if the decision is to allow the patenting of genes because of the problems with precedence in other natural products, there should be very careful consideration of what represents innovation in that step. I would think that the majority of new genes that are isolated these days would fail that test of being innovative.

Senator HUMPHRIES—I must admit that Professor Christie who appeared earlier today said that the level of innovation or inventiveness was too small, that it should be amplified before a patent is granted. He is tending in the same direction as that recommendation.

Prof. Bowtell—The second thing is that if for some reason a decision was made to allow the patenting of a particular gene then I think you have to think about how we deal with the consequences of that, because the current monopoly situation does directly translate to impacting on human health. We heard that in the last submission because it is a blocked innovation in making tests faster, cheaper and more accessible.

Gillian can speak to this better than me. But at the moment we have this many tests that are available and that are funded and this many people that you would like to test. So there are a whole lot of people who are being excluded from testing simply because there is not enough money in the system. In a monopoly situation there is no incentive to drive the cost of testing down and to increase its accessibility to people.

Senator HEFFERNAN—I would think that the more testing the cheaper the tests should be. You were not aware when I mentioned earlier that in Canada they put it up 400 per cent. Dr Mitchell, you were?

Dr Mitchell—Only from reading the report 'Myriad Genetics: In the Eye of a Policy Storm'. I do not know whether that has been submitted to the Senate inquiry. It is certainly a very

interesting document about the process. David's point is that we do have many people who might benefit from genetic testing even for the limited number of genes that we have at the moment.

If we were to stay with the one single provider then the test cost is not going to come down and it is going to remain available to a very small number of people. Whereas if there is competition to be allowed to develop new tests using new technologies coming at it from different angles and the innovation that we are discussing, that certainly would be a way of driving things down. This is something that Stephen is working with at the moment.

Prof. Fox—Another aspect of it, just on the quality assurance, you have a single tester who makes sure that they are going through correct laboratory processes. There is a whole underlying theme of who looks at the monopoly, who makes sure that they are doing a good job and that their results are appropriately given to the patients, who makes sure that they are getting genetic counselling and whether they can go direct to the patient. There is a whole lot of underlying things that would be important to consider in a monopoly situation.

Dr Mitchell—I think that was outlined quite well in that 'Myriad Genetics: In the Eye of a Policy Storm' document.

Senator HUMPHRIES—I can see an argument for saying that you should not grant a monopoly over genetic material that comes from the human body. But you seem to be arguing there for the normal rights that flow from a monopoly once granted not to flow in this particular case.

Prof. Fox—No, what I am suggesting is that if you have a gene sequence that you patent, no-one else can test for at that gene sequence. That is fine, they can use their methodology. But our lab might produce another methodology that they would be able to use on that gene sequence, but currently we would not be able to do that.

Senator HEFFERNAN—No-one else can get access. I have said that 50 times. I hope people are listening.

Dr Mitchell—People are.

Senator BOYCE—Are you saying that you would be able to do it or you would not be able to do it without negotiating an agreement with the people who currently own the patent?

Prof. Bowtell—If it is a monopoly they are going to give permission to generate a test that will undercut their own monopoly. It is unlikely they will.

Senator BOYCE—How do we know that?

Prof. Fox—Myriad.

Dr Mitchell—If you go to the Myriad example, Myriad considers that it holds the gene patents for both BRCA1 and BRCA2 and they have licensed a company, GTG, to perform the

testing here in Australia. If that licence is upheld then the only people who are allowed to do any testing by whatever methodology are GTG.

Senator BOYCE—But for a certain length of time and, again, they have waived their right to those fees.

Dr Mitchell—Absolutely.

Senator BOYCE—I keep hearing people say, 'They won't let us', but in most cases no-one has actually asked. This has been given to us in evidence as an assumption.

Prof. Fox—That is not true.

Senator BOYCE—Could you give me some examples of where you have actually sought to undertake a commercial arrangement with someone who has a patent and been told no?

Prof. Bowtell—Yes, I can.

Senator BOYCE—Good. Thank you.

Prof. Bowtell—It was a research situation. I am the head of the Australian ovarian cancer study. This is a cohort study of about 2,500 women who were recruited with ovarian cancer. We were very interested to know the frequency of the BRCA1 and BRCA2 mutations in an unselected group of women; that is, not women who came forward because of their strong family history of ovarian cancer but who simply had ovarian cancer. For those genes we know the likelihood of developing ovarian cancer if you carry the mutation. But we do not have a really good understanding of the reverse. If you just have ovarian cancer, what is the chance that you carry one of those mutations? It is very important to know that because there was a recent study that suggested that it could be quite high.

If that was the case, it would really change the guidelines for suggesting whether a woman should be offered genetic testing if she just has ovarian cancer and no other family history, for example. Gillian, Stephen and I won two major grants to investigate that. It was a unique opportunity in the world to do it because we had this cohort that no-one else has managed to put together. There was as a major US grant and a major Australian grant from Cancer Australia. We started to go down that track and we decided that Myriad actually would be a good partner to do this with. So we went to Myriad and said, 'Can we do this with you because you will be recognised as being a gold standard because Myriad is recognised internationally for doing the BRC testing?' We could do that as a collaboration. They offered to do it for a fraction of what it would cost commercially to do it. We were about to embark on this.

Dr Mitchell—Very quickly.

Prof. Bowtell—Very quickly, within six months. This was at the start of 2008. We were about to start and then they realised that because of the GTG licence Myriad would be in breach of their agreement GTG by allowing that to occur. We went to GTG and told them this was a research study and it had implications for understanding the frequency of these mutations in the population and could actually could be good for their business in the end. We asked whether we

could go ahead and do this with Myriad. It was an extraordinarily hostile reaction and it shut it down. Myriad was unable to move and that avenue completely collapsed. As a result, we then went to the NCI in the United States, because at that time there was a real cloud—

Senator BOYCE—What is NCI?

Prof. Bowtell—The National Cancer Institute in the United States. There was a real cloud over our ability to do that at Peter Mac because of the position that GTG had taken. We could be a third of the way down the track of doing it at Peter Mac and be completely shut down. We went to the NCI and we spent six months with their core facility trying to get them up to speed and getting them to do testing they had done in the past but they had lost the expertise. As of April this year, that arrangement ceased.

Around that time GTG reversed their position again and was allowing testing. We are now doing testing in Australia. So we are now 100 cases into the 1,000 cases doing it with Stephen in the laboratory, which is 18 months later. We will probably finish the study about two years behind where it could have been done before at probably three times the cost to us than it would have cost before. It had a very significant impact.

CHAIR—Was there an explanation about why they said no?

Prof. Bowtell—They were extremely hostile about the fact that Peter Mac were continuing to do testing in the public domain. They offered to do it collaboratively.

Dr Mitchell—For double price.

Prof. Bowtell—For double price with GTG and on the condition that Peter Mac cease doing any clinical testing.

Senator HEFFERNAN—You would not care to table that correspondence, would you?

Prof. Bowtell—A lot of that was verbal.

Dr Mitchell—The Department of Human Services holds a lot of that correspondence.

Prof. Bowtell—In fact, I think that that aggressive position was something that the people involved in GTG now regret because it really—

Senator HEFFERNAN—Was that in April this year or April last year?

Prof. Bowtell—That was at the start of 2008.

Senator BOYCE—As you quite rightly point out, it has impeded clinical work but it has not stopped it.

Prof. Bowtell—It impeded the research work substantially. It will potentially flow through to changing practice worldwide. The Canadian study was published in late 2007, I think, and that suggested that any woman with ovarian cancer should be offered this sort of testing. But it has

not changed practice in the United States, Europe or Australia because any study like that needs to be replicated. There were some methodological issues with the way it was done. It was generally a very good study, but there were some methodological issues. Our study was in a position to really nail it absolutely once and for all because of the way that the study was constructed. It was a study that could change practice worldwide and it has been set back two years, at least.

Senator BOYCE—Thank you.

Senator HEFFERNAN—Was it April this year or April last year when they said you could go ahead?

Prof. Bowtell—No, it was in April this year that we were given the go-ahead.

Senator HEFFERNAN—That follows being put on notice, the sacking of the board and the chief executive officer that followed from that, and then they changed their mind after all the public pressure, not because of—

Dr Mitchell—I would like to follow up Senator Boyce's point. The research went ahead because GTG backed down. If they had continued to hold their position we would still be in the same position.

Senator HEFFERNAN—The reason they backed down was the public exposure of the whole thing. Had it been kept—

Prof. Fox—I go back to the process as well. BRC testing is a huge core of our laboratory department work. If you were to take that away, there is not a lot left. Training, education and provision of services and other tests become more difficult.

Senator BOYCE—So it threatens the viability of your organisation?

Prof. Bowtell—Not just ours, many.

Dr Mitchell—It will also then limit the ability to offer genetic testing for much more rare genes, which is certainly not cost effective from a large company point of view, because you have expertise that you then piggyback on lesser things. I should say that although we stated in our submission that we felt that the gene sequence was not the right place for the patent, we then move on one step in saying that if it is accepted that that is where it is going to be because there is too much law invested in it already that cannot be changed—it is just a shame that we cannot think to change laws if they are not actually working very well—how do we move on?

The experience that we have had has certainly been very problematic and certainly with the way that the GTG was trying to link our research activities to shut down the thing that was most threatening to them, which was the diagnostic testing in the public arena. How do we then move on and make it accessible so that it is not a monopoly position?

One of the points that we made here is coming back to that licensing. Again I do not want to say that I have any understanding of the legalities of that. But can't we sort out the licensing so

there is some form of greater good within the country to make something accessible? Yes, there might be some payment made to a company that holds the patent, but how can we do that in a way that then makes it accessible?

What we cannot have is this position where someone holds that ability to do a test. Despite the fact that the BRCA testing has been available from Myriad since the mid-1990s, the price has not gone down, it has gone up. That is despite the fact that the cost of reagents has gone down and the fact that we know that when we do those tests in-house they are a fraction of the cost that they were 10 or 15 years ago.

Senator HEFFERNAN—It is what you call the river of gold.

Dr Mitchell—The monopoly position certainly seems to be causing a problem. I basically want access to this information for our patients. It has to be for the greater good and the financial good as well for the country to have treatments targeted to the people who are going to most benefit from them. We know that treatments are expensive. They are getting more expensive as more time and effort is put into developing them. So, we either have to put the patents in a different place or find a better way of dealing with the patent system as it is.

The purist in me thinks we should put it in a different place because of the example that I gave—I do not think a naturally occurring substance, code or whatever should have a patent on it. If not, can we find a better way of actually dealing with the consequences of it?

Senator HEFFERNAN—I presume you are aware that even though it is expensive and GTG tried to exploit their monopoly as they were getting the financial trembles—that is why they called it up—it could have been a lot worse for Australians because it is only that GTG discovered Myriad breaching one of their patents that they came to a legal settlement that allowed the testing to occur in Australia at all? Otherwise it would be over to America with all the tests. It is a bloody nightmare.

Prof. Bowtell—I will make one other comment. I think we have grown up in the last 10 or 15 years thinking about single genes. We think about these devastating mutations like BRCA1 and BRCA2, but we are now into a somewhat different era; that is, to find the genes that are more common in the rest of the population—things that have relatively subtle effects.

I was mentioning before to Senator Heffernan that in the last issue *Nature Genetics*, which is probably the leading genetics journal in the world, there was a slew of papers about new genes that have been found using what are known as genome-wide association studies. It is sort of a new technology. So we are coming into an era where lots of genes are actually being identified that work in concert to actually cause an outcome, like the risk of developing breast cancer, diabetes, stroke or something like that. If the patents for each of those genes are held by different companies then it is going to be extremely difficult to assemble a practical test to test for a particular condition.

What the individual cares about is their risk of developing a particular disorder. They do not want to have to go to this company to have one gene tested for and this company to have another gene tested for and this company for another. They would like a test that basically asks the question, 'Are you carrying any genes that increase your risk of developing breast cancer?'

If we are to go down the road of patenting genes it is important to try to think about conditions that leave open the opportunity for aggregating different genes into single tests. At the moment, if they are held in different companies, it takes a very long time for those companies to get together and figure out all the issues of these different patents that they own to put together something that will work collectively. It is a little technical, but it is very important to realise that the landscape is changing not just in terms of the frequency at which we are isolating these genes but also the number and the need to be able to test multiple genes, maybe even hundreds of genes in the end, to determine risk.

Senator HEFFERNAN—We received evidence earlier from some people—probably lawyers, I cannot remember—that this is not an issue because we are coming to the end of it and there is only a few of these things out there. But we are actually at the start of the journey not the end of the journey.

Prof. Bowtell—Absolutely. It is not going like this; it is going like this. The genes that we found in the first place were the easy mutations. These were the things that had a devastating impact and it was easy to see the track through a family. Those are the minority of people who develop disease. For the rest of us, it is the multiple genes. It is more like being dealt a hand of cards rather than being dealt a joker. That is for the majority of us.

We are just now, because the technology has changed, starting to find all these more common lower risk genes that work in concert and very much in relationship to the environment. With some of these genes, like Huntington's disease, it does not really matter what you do it is completely penetrant; that is, you will develop Huntington's disease if you carry that mutation.

For many of these other diseases, whether you develop breast cancer, cardio-vascular disease or Alzheimer's, it is probably very heavily influenced by the hand that you are dealt and the environment that you live in. That is the kind of thing that we have to prepare for. The number of genes that are important are increasing enormously.

Senator MOORE—You explained the situation you had when you were looking at the ovarian cancer research. Would that have been fixed or helped by having the research exclusion clause that the law reform paper has recommended?

Prof. Bowtell—I do not think it would have actually. It was complicated because there was a commercial relationship between GTG and Myriad. That is what they were concerned about; they were concerned about breaching the commercial relationship that Myriad had with GTG.

Senator MOORE—GTG has the licence from Myriad?

Prof. Bowtell—Yes.

Senator MOORE—Myriad has the world patent and GTG are their licensed providers.

Prof. Bowtell—Yes.

Senator MOORE—Having the preclusion in the patent for research would not have protected you in that sense.

Prof. Bowtell—I do not think so.

Dr Mitchell—There was an added complication because this is important health information and these women were not de-identified as part of the cohort study. It was part of the research application that was approved by the ethics committee. When we identify these mutations we are getting back in touch with the women and letting them know. They still then have to go and have a formal test through a clinical service because research-held samples are not dealt with in the same way as clinical test-type samples.

Senator MOORE—So that did not count as a test in the wider sense; they would have to go back and be personally tested.

Dr Mitchell—That is right, just in case there has been some sort of mishandling along track. We cannot have people making important decisions about removing bits of their bodies or thinking that they are not at risk without being sure. As a lot of these large cohort projects do, you return a result and say we think we have identified something in your family and we advise you to seek formal advice from an appropriate centre. We then communicate with the centre and tell them what we think we have found and they will then do the test in that sort of very highly controlled circumstance. In 99.9 per cent of the cases that is exactly what is found. But because our information was going back, that added to that complexity. I am not sure that even though there is a licensing issue we would have been saved by saying this is a research project because there was going to be some return of information, albeit broad return of information, to the patients about the results.

Senator MOORE—So, at the moment Peter MacCallum does do formal BRCA testing, not just—

Prof. Fox—Yes.

Senator MOORE—And that is a huge part of your business.

Prof. Fox—Absolutely, yes.

Senator MOORE—And you have been doing that for years and years and years. Now you have had the two experiences with—

Prof. Fox—Cease and desist orders on two separate occasions.

Senator MOORE—Senator Heffernan keeps talking about what happened at Westmead. I am interested in terms of the second cease and desist correspondence. Did that actually ask you to provide all your information to them as well, or just to stop testing?

Prof. Fox—My recollection of it is that we were given about two weeks to cease and desist just to complete the testing of patient samples that had already arrived in our laboratory. That was it.

Senator MOORE—No more testing.

Prof. Fox—Anything else had to be sent off to GTG. There was no prior correspondence; it just came out of the blue.

Senator MOORE—And there were no demands about all your previous research going back to them as well?

Prof. Fox—No. We had opinions from the lawyers saying it would be hard for them to do that, to go back.

Senator MOORE—But they had not asked at that stage?

Prof. Fox—No.

Senator HEFFERNAN—In terms of the wellbeing of the patients whose samples you held for some years, if they say you cannot test that anymore and they will do all the testing, would that not mean that you would have to surrender that material?

Prof. Fox—It would be prospective samples. So we would have to send them samples after their cease and desist order. We would have our samples in store.

Senator HEFFERNAN—What would you do with them?

Prof. Bowtell—We keep them in storage. We would not send them off site.

Senator HEFFERNAN—You could not go back if some better technology came along and test them. They are just stored?

Prof. Fox—If the cease and desist order and the legal system upheld their decision then we would not be able to touch that stuff.

Senator HEFFERNAN—So the bank of knowledge that is in your samples that you have stored is wasted?

Prof. Fox—We would not be able to do anything with them.

Senator MOORE—It would be historical knowledge rather than future knowledge.

Prof. Fox—Yes.

Senator MOORE—In terms of the process, what we have been told by the people who work from the legal perspective is that the original correspondence is often a shot across the bow—that was the term that they used. It was designed to attract your attention, which I am sure it did. The expectation was that after that it would lead to a form of negotiation and that was what they said is the standard practice in this field.

Prof. Bowtell—We tried to do that with GTG in terms of the research study. There was a subsequent teleconference involving Myriad, GTG and us after the initial meeting that we had with them and it basically went nowhere.

Prof. Fox—What is more scary from a clinical perspective is that had all the laboratories in Australia ceased and desisted, GTG would not have been able to do the work. They are just not set up to do that volume of tests.

Senator HEFFERNAN—It is all about the money, mate, they are running for cover.

Prof. Fox—Another element is that they rely on public laboratories to train up a lot of their staff. We generate and educate our staff to a level and then suddenly we find they have disappeared. That has happened to about four or five of our molecular scientists.

Senator MOORE—So GTG actually had testing laboratories in a number of places around—

Prof. Fox—They have one testing laboratory in Melbourne.

Senator MOORE—So Melbourne was their centre?

Prof. Fox—Yes.

Senator MOORE—I know we have met with them in different guises, but not this time. But it was all in Melbourne and the understanding was that their plan was to have every test of BRCA1 and BRCA2 done by their laboratory in Melbourne. So people would be sending tests all over the place.

Prof. Fox—With their current configuration they would not be able to handle the tests. In fact, some tests have to be done in a very fast clinical turnaround for patient decisions and they cannot even do those.

Senator MOORE—It would seem that that could have been part of future negotiations, but they withdrew that fairly quickly for whatever reason. They actually sent the letter. But that was enough to actually cause considerable consternation within the laboratory.

Prof. Fox—Reverberations throughout the organisation and into DHS. We spent a huge amount of time—wasted time—involved in this process. It went on for months and months and months.

CHAIR—How long did it take to resolve?

Prof. Fox—A year.

Senator HEFFERNAN—It is not resolved. They can still send you one tomorrow.

CHAIR—From when it started—

Dr Mitchell—The first letters must have gone out in July, because I think they said stop in August and then we finally had some resolution in April.

CHAIR—So how long did you actually have to stop testing for?

Dr Mitchell—We did not stop.

CHAIR—So you kept testing.

Dr Mitchell—We took advice from our local DHS because there are two large laboratories here in Victoria. We both took advice from DHS about what was our position, were we institutionally liable or was it the DHS? The DHS took the view that they were responsible for the service and they took over. And every time letters came to us we referred them to the DHS. So, no, we didn't. They told us to keep testing.

Senator HEFFERNAN—But they could send you a letter tomorrow morning.

Dr Mitchell—They could.

Prof. Bowtell—One thing the committee might be interested in is the issue of the context that this sort of testing occurs in. I am not just trying to advocate for Peter Mac, but the motivation for us doing testing is driven by medicine and not by commercial issues. It is a concern to all of us that if this test is locked up in a commercial sphere then the motivation for testing primarily will be commercial. It is very important that testing is done in an appropriate way. Gillian should jump in here. It must be patient focused, the right kind of information given and the right people receive the testing. There are a lot of implications when you test someone. This is particularly true for these low risk genes that I mentioned before. At the moment we do not know how to handle that information.

We are doing a lot of research on figuring out what to do when someone carries one of those mutations. But at the moment the guidelines would suggest that you do not test and provide that information back because it is more likely to do harm than good. You do not want women who have a 1.3-fold increase in risk suddenly rushing out and having a mastectomy or having their ovaries removed on the basis of something like that. I think it is very important to make the point that this kind of testing has to remain in the public sphere for all these different types of genes to make sure that we are delivering good medicine. That is the first priority, not delivering what will return the biggest yield to the shareholders.

Senator HEFFERNAN—There is no question that in the conversation that I had with the CEO of the company that it was all about the money and their financial plight that they issued those letters.

Senator MOORE—The process that we have been talking about, which is differentiating the gene itself from any kind of technique or model that they use, would not be that effective in this discussion, would it? What they are worried about is the test.

Prof. Fox—They have the sequence of the gene patented.

Senator MOORE—Yes.

Prof. Fox—So we are not allowed to test that using any methodology. If they had a patented methodology and we came up with a better methodology, it would give them an incentive to improve their methodology.

Senator MOORE—Do you know whether you use the same methodology as they do?

Prof. Fox—We do currently, but we are looking at other methodologies. In the instance of BRC, further research is occasionally done even in a monopoly situation. It was discovered that the Myriad test for BRCA1 was not adequate. So they had to redevelop their test based on other information.

Senator MOORE—So they did redevelop. A previous witness talked about the fact that the Myriad test did not cover—

Prof. Fox—Absolutely.

Senator MOORE—I will not even pretend to understand, but it was said it did not do the full job. So they developed a new test, which they could do because they owned the patent. I just wanted to get it clear.

CHAIR—Can I clarify that? They therefore used other people's IP to develop that?

Dr Mitchell—Yes.

Prof. Fox—Yes.

CHAIR—I just wanted to clarify that.

Prof. Fox—They cherry pick all the bits out that people are doing for the public good and commercialise it but do not allow anyone else to use it.

CHAIR—Because it is based on the sequence.

Prof. Fox—Yes, because they have the sequence.

Dr Mitchell—All tests are based on the sequence.

Senator HEFFERNAN—In America there was a legal argument because the United States is on their patent as part of the settlement of the legal argument between the various universities. For them it is about the money, too.

Senator MOORE—I want to clarify something. The reason you could use the NCI when you looked at that alternative was that the testing was being done in America.

Prof. Bowtell—Yes, because we were not then breaching the arrangement between GTG and Myriad.

Senator MOORE—Because you were sending samples to America.

Prof. Bowtell—Because it was being sent to the States. The concern from Myriad's point of view was that if they tested Australian samples they would be breaching the exclusive arrangement they had with GTG.

Senator MOORE—And the proposal that GTG gave you was not only at double the cost. That is a commercial thing and they owned the process, but they actually added the threat of cease and desist all the testing you are doing.

Prof. Fox—That was the condition of the offer.

Dr Mitchell—And also that we had to publicly state that we were in collaboration with them.

Prof. Fox—But they could not match the timeline of Myriad either, so they were not even matching the Myriad offer in any way.

Senator MOORE—They would get the good PR.

CHAIR—That is clever.

Senator MOORE—In previous evidence it was said that the process that your lawyers gave you just to keep on going seems to have been replicated in at least three other countries where Myriad has been trying to do things. So, despite the fact that they have legal threat and probably legal right, people just ignore them and keep on going.

Dr Mitchell—That is the case in most of Europe.

Senator MOORE—And Canada, I think. They said the Canadian hospital system is going ahead. I just wanted to make sure that was your understanding as well—that they have put the process in place but it has not changed anything, except instilling more fear of what could happen to people doing—

Dr Mitchell—It is more the example that this has given. It was felt, certainly here in Australia, that we were given the advice to go ahead and test because of the precedent that was set when GTG originally gifted this to the Australian and New Zealand public. If that had not happened I am not sure that the DHS would have given quite the same view. Anyway, for whatever reason, they did advise us to continue on.

Senator MOORE—It was actually the state government that stepped in to give you the strength. Thank you.

Senator ADAMS—I would like to talk about the recommendations made in the 2004 ALRC report. Some of them included changes to competition law, compulsory licensing and Crown use

of gene patents. If these recommendations were implemented, would that address some of your concerns regarding gene patents? Are you aware of what I am talking about?

Dr Mitchell—Vaguely, but we are not lawyers. This is what I was trying to say earlier on. If we move away from saying where patents should lie and it is decided that the patent law will remain as it is and genes are patented, we have to find a better way of managing them so that they can be accessible to the public in a way that is affordable. If those recommendations are a way of doing that that is going to work to achieve that then I think we would be in agreement with that. But not actually understanding the finer points of the legality of those arguments, it is very hard to comment.

Prof. Fox—I think the devil would be in the detail. If it is an unrestricted licence that will enable us to do research, develop new tests and do as we would normally do then that would be fine. But if they are highly restrictive, we would have to use a one-platform test copying what they are doing and not being able develop. There would be no innovation or anything. That would not be very optimal.

Senator ADAMS—Most of the witnesses that we have had before us have been in favour of these recommendations because they will free things up a little bit more. But because nothing has happened—or a little has happened—we probably could have been a lot further down the track and possibly not be having the problems that we are having at the moment. That is just my very basic reading into it from the evidence we have heard.

Dr Mitchell—I suspect that part of the difficulty was that when that came out in the early 2000s there was not the understanding of the potential use of genetic medicine in the way that we have now in 2009. There also was not the understanding in the general public about genetics in quite the same way. I think there is also still a lot of ignorance in terms of the general public both about science generally and this very specific area. That is partly our fault. We should be getting out there and spreading our message better and telling people that genetics is not a scary thing. But I think we are in a different position where there is greater knowledge and greater public awareness.

Certainly, when this GTG issue occurred last year there was an awful lot of public outcry in support of being able to use genetic medicine to help people's health. We certainly heard that very eloquently with the submission before. Yes, it would have been great if things had moved on more quickly. I think that at the time when that came out there was neither the public interest nor the general knowledge to move things on. I think we are in a different position now and I agree with Stephen that the devil will be in the detail.

If we accept that the patents will remain as they are—unchanged—and it is too difficult to change patent law then we have to find a way of dealing with them better than we do at the moment. If that is the way that it works and it works well and it is then accessible and we can use it, we can innovate and it is more cost effective and more widely available, then great.

Senator ADAMS—It has to focus on the public good, and I think that is probably one of the results of this inquiry anyway. That is coming out very strongly. Hopefully we will get some results.

Senator HUMPHRIES—You said before, Professor Bowtell, that Peter Mac's motivation was medicine rather than profit. I understand that Peter MacCallum Cancer Centre actually owns a number of biotechnology patents. What does it do with those patents? What is the purpose of holding those patents?

Prof. Bowtell—The purpose is to commercialise them. But the intention is to develop them for medical purposes. I can give you an example which is very familiar to me because it has come out of my own lab. At the moment we are co-developing with a pathology company a test for cancers of unknown primary. That is being developed because we really want that test to be out there and available to people to try to better diagnose those cancers. But the motivation for us is to get it out there and make sure it is accessible to the public. The money that will be generated from it is relatively minor compared to peer review grants.

Sure, they are patented because, as Gillian said earlier, that is necessary to partner in that case with a commercial provider to get them to feel that they have some security around that to take it forward and to develop it as a test. But the purpose of our patenting in that case is driven by getting it out there. The patenting is important as part of that process rather than the money that it is going to generate.

Prof. Fox—The test is based on a pattern. Another person could look for another pattern and come up with the same answer. We are not patenting the gene sequence; it is the pattern of genes.

Prof. Bowtell—In that case it is the algorithm mainly. It is the maths behind it.

Senator HUMPHRIES—So some of these are patents over genetic applications.

Prof. Bowtell—Applications of the genetic information rather than the genes.

Dr Mitchell—We have not patented the gene sequence itself.

Prof. Bowtell—No, we have not. We are finding other genes in ovarian cancer that fall into the same sort of category and we have not attempted to patent those.

Senator HUMPHRIES—Have you ever had occasion to have to deny someone the right to work in the same area because they have infringed on your patent?

Prof. Bowtell—Not in terms of genetic information. I cannot go into the details, but there is a challenge that we have with a company in the States at the moment around some technologies associated with stem cells. It is not to refuse them to do it, but to recognise our intellectual property in that space and to pay us a licence as a result of it. I cannot recall any case where we have stopped people from doing something as a result of holding IP.

Dr Mitchell—Again, that is all to do with process; that is not about the genetic sequence that is patented. It is about a technology that has been developed.

Senator HUMPHRIES—Sure. Can you explain to me why your sort of action to defend your intellectual property in that particular non-gene related patent is any different to the situation of,

say, GTG defending its intellectual property rights over its testing process and demanding that it not be done without proper payment or whatever it might be that they want?

Dr Mitchell—I make the point that our argument about GTG was the fact that we do not agree that they should be holding the patent on the gene sequence.

Senator HUMPHRIES—I agree with that. But the law has granted them a patent, they have a patent and they are exercising their rights in respect of the patent. Is there any difference between their exercising of their right having been granted it in respect of your use of their material and your action against the people in the United States?

Prof. Bowtell—They were exercising their rights as they saw them. What Gillian says is correct. We feel personally that that was a right that should not have been given, but they were exercising their right. All we can point out is the consequences of them exercising their right. That is what we are presenting today—the consequences for research and the consequences in a clinical setting. But what would we do if the shoe was on the other foot? I guess that is what I am trying to say in this example involving a company in the States. The approach there has not been to block the activity or to block innovation on the development. It is really asking them to recognise our intellectual property in that space and to provide a commercial return.

Senator HUMPHRIES—So you have asked for money for their right to work in the space that your patent covers.

Prof. Bowtell—That is right.

Senator HUMPHRIES—Is that not what GTG was doing?

Dr Mitchell—No, they just wanted to do it all. They wanted us to pay them to do it.

Senator HUMPHRIES—They wanted to utilise the commercial value of the patent that they owned. Their way of doing that was different from the way that you have chosen to exercise your right over your patent. Essentially you both wanted to garner the commercial advantage or commercial value of your patent. Is that not really the same thing?

Prof. Bowtell—The consequences are different.

Prof. Fox—From a legal perspective that may be the case. But our thesis is that perhaps gene sequences should not have been patentable. Now that they are, we are in a sticky situation that needs unravelling.

Dr Mitchell—Another point about the GTG situation is that we thought that we were able to do it because the sequence was a granted to the Australian public. That is why all the state governments have put money into the public laboratories, which are based on the backbone of the BCKA testing, because that is the largest bit of what we do.

All that money was invested. Although you say that they have the patent and that they want to exercise that, there was a kerfuffle early in the 2000s and they granted the patent and then as a consequence of that the public laboratories were able to be developed. Then we had the cease

and desist order. It has brought the whole question back up again about the ability of a gene patent.

Senator HEFFERNAN—It was the creation of a serious monopoly of the test and the cost—

Senator HUMPHRIES—Monopoly has formed in both camps. You have a monopoly as well and you want to exercise that monopoly in a way which does not stop people from using it but demands a commercial return.

Senator BOYCE—The extent of the monopoly seems to me to be different.

Prof. Bowtell—A patent is a patent. We said right at the very outset that we were not anti-patents. We see the need to patent various parts of the process. I think that what we have been talking about today is whether there is anything innovative in patenting a human gene. I cannot see that.

Senator HEFFERNAN—Do we need a regulator like a Australian Securities and Investments Commission-type regulator in the industry? The people down the back there are from IP Australia. Their process does not include a lot of medical input; it is just a dry argument on the law surrounding the patent. Do we need a regulator given that we are at the tip of the iceberg?

Dr Mitchell—I think a lot of the argument has been based on laws that are in existence and patents that have been in existence. So either we accept that that is what they are and move on, or we go back and look and think.

Senator HEFFERNAN—Do we draw a line?

Dr Mitchell—That is my question: Do we draw a line and except it, or do we go back and re-address it and change laws? If you draw a line and address it, how do we move on? If we are going to draw a line and move on, and we are going to then look at different ways as the Law Reform Commission suggested of actually managing the consequences of those patents, can I please put a big hand up for people delivering the service being part of the process?

Senator HEFFERNAN—Hear! hear!

Dr Mitchell—Because right now, policies are made all across the health sector without people who are actually delivering the service being involved.

CHAIR—I want to finish. You have been very indulgent with us. You have gone beyond the time that we had originally set. We originally asked for an hour and I have let it go on because we have the time and also because it has been so useful and interesting. We have 10 minutes and then we have to finish. I have asked very few questions and I have one I want to ask at the end.

Senator HUMPHRIES—With regard to that last issue, we heard from Professor Christie today about the consultation process on what should be patented in Australia. Have you been part of that consultation process?

Dr Mitchell—No.

Senator HUMPHRIES—That is the next major way in which this issue will be resolved. What should be patented and what should not? You have just asked for people who deliver services to be involved, but you are not involved in the most important process, other than perhaps this committee, for determining what is patentable in the future.

Dr Mitchell—You can see we feel very strongly about it and we would love to be part of the process.

Senator HUMPHRIES—Okay. You had better get in touch with Professor Christie. Professor Christie says that we are probably patenting too much in the area of genetic discovery, but he does not say that we should not have patenting of genetic discovery. He says that we need to facilitate access to the benefits of those discoveries, particularly testing, in the same way that we facilitate access to discoveries in pharmaceuticals by subsidising people's access to them. Companies, rightly or wrongly, develop the particular process, put it out in the marketplace and it is the government's responsibility to buy some of that access in the same way that they buy medicines. Do you think that would be an effective scheme within the Australian context?

Dr Mitchell—It is a possibility. The problem I would have with that is that if you still have that patent at that level it will still stifle the ability to eventually drive costs down. All you are doing then is accepting the status quo and you have to buy that particular test until the patent runs out.

Prof. Fox—An analogy is that you have a target on a tumour cell and you have a drug against that target. The drug is presumably patented, but the target is not. Another pharmaceutical company might come along and target the same thing and they patent it. There is internal competition between the two, three or four drugs, which is good. If you have patented the target, there is no development or innovation. I suppose that is the analogy we are using. The sequence itself is the target, if you like, and that is the monopoly.

Prof. Bowtell—I guess what you are asking is whether the problem would have been solved if there was a large pool of money that was paid to GTG. Would everyone have been happy in terms of the outcome? I think the answer to that is no. Because you are then reliant on one organisation to do all the innovation. There is very significant innovation occurring in the public sector. What will drive the costs down with this?

Senator HEFFERNAN—Optus did it with Telstra.

Prof. Bowtell—You have GTG over there in Collingwood providing testing to all sorts of places all around the country. One of the really powerful things about having testing in a public setting is that there is a very dynamic interaction between the people who are actually in the pathology lab doing testing and the people who are using the testing and counselling patients at the end. These two interact all the time in that sense.

Prof. Fox—A lot of these things are not simple transactional tests—positive or negative. There is a lot of greyness in there. Having a monopoly there is no incentive to look at the grey areas, which are probably very important, because it is just too hard and too expensive. That is what the public sector provides; it provides an opinion about the grey areas in consultation with the clinics so they can give valuable information back to the patients.

Dr Mitchell—And you continue to do work on those grey areas.

Prof. Fox—We work on the grey areas all the time at great cost.

Prof. Bowtell—If all that funding had gone to GTG and the testing had gone out of Peter Mac another consequence would have been that a big part of what the molecular pathology lab does would have disappeared. That would have meant that scientists would have left and the opportunities to use the infrastructure that that sort of turnkey testing creates to develop new tests would go. For example, the path lab has recently introduced a new test that helps guide whether a patient should get a molecular therapeutic for colorectal cancer. That kind of expertise would disappear if all of it went off to GTG.

Senator HUMPHRIES—It would not disappear; it would go to GTG.

Prof. Bowtell—Not necessarily. They would not necessarily develop those tests.

Senator HUMPHRIES—Why not?

Prof. Bowtell—Because a lot of those things happen first in a research setting before they are actually proved to be commercially viable. Some of those tests are actually never going to be commercially viable because they are for a very small market. The drivers are different for us.

Senator HEFFERNAN—Can I address that exact point? Can you explain to the committee the multiplier effect for the public good when a public laboratory or a university develops something and it gets commercialised?

Prof. Bowtell—I was thinking about this when you were talking in the previous session about the epilepsy case and the Bionomics development. That was probably funded by Australian Research Council or the National Health and Medical Research Council, which are both federally funded. It then went, as you described it, to a company that got federal assistance to develop the commercialisation of it. Then I guess the federal government would pay again for the testing at the end.

Prof. Fox—The university is also federally funded.

Prof. Bowtell—It is probably paying four times over.

CHAIR—You used an example earlier and we have been talking about the BRCA example. We have been given evidence that people are not patenting gene sequences anymore because it is not innovative. Have you had any experience where in fact that is still happening? We are being told that we do not need to worry because they have learnt now.

Prof. Bowtell—I can think of some of the newer tests which are based on not just a single gene but multiple genes. So, for example, oncotype DX is a test to determine whether women are at risk of developing metastatic breast cancer even though they have only very early stage breast cancer. That has been developed by Genomic Health in the United States. It is based on 21 genes and it is a profile of those genes. That is a good example of how things have moved from

an individual gene to multiple genes. That is looking at the activity of 21 genes in a tumour cell. But the next thing will be a profile of 16 genes—

Prof. Fox—The MammaPrint is 70 genes.

CHAIR—So the patent has been taken over. Earlier we were talking about the process rather than genes themselves.

Prof. Fox—It is now a profile.

CHAIR—Has the patent taken over the profile rather than the process?

Prof. Bowtell—The profile.

CHAIR—That is very recent?

Prof. Fox—It is the combination of the genes rather than sequences themselves.

CHAIR—But it is still genes, not the process of identifying them?

Prof. Fox—It is the combination of genes.

Prof. Bowtell—I think it is still going on.

CHAIR—Okay, thank you very much.

Senator MOORE—Professor Fox, when you develop your new test, which is going to be better than the other one, are you going to patent it?

Prof. Fox—No, it is already published. We cannot patent it.

Dr Mitchell—It is the methodology.

Prof. Fox—The methodology is established.

Senator MOORE—So when you develop something that is different, better and wider, you still cannot go with that, even with negotiating the original?

Prof. Fox—No, it is like open source software—it is just out there.

Senator HUMPHRIES—It is already in use.

Senator MOORE—That is what I wanted to get on the record.

CHAIR—Thank you very much. If I do not bring the proceedings to an end now, we will still be going at 7.00 pm. Thank you for the generous amount of time you have given to the committee. It is very much appreciated.

Prof. Bowtell—It is a very important issue. We thank all of you for taking such an interest in what is a very critical issue.

CHAIR—The hearing is adjourned until 9.00 am tomorrow in Sydney.

Committee adjourned at 4.57 pm