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SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Reference: Gene patents

THURSDAY, 20 AUGUST 2009

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SENATE COMMUNITY AFFAIRS

REFERENCES COMMITTEE

Thursday, 20 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, 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.

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Committee met at 3.47 pm**MOIR, Dr Hazel Veronica Jane, Private capacity**

CHAIR (Senator Siewert)—Welcome. The Senate Community Affairs Reference Committee is continuing its inquiry into gene patents. I understand that information on protection of witnesses and parliamentary privilege has been provided to you. Do you have any comments to make on the capacity in which you appear?

Dr Moir—I have done research on the patent system over the last four years.

CHAIR—Thank you. I invite you to make an opening statement and then we will ask you a series of questions.

Dr Moir—I would like to start by saying that I am an economist and a public policy analyst, so that when I look at the patent system I look at it always from the perspective of the impact on public wellbeing in Australia. I would just like to make a few points in my opening statement. The first is about whether knowledge itself can be patented. A lot of people will have talked to you about the distinction between a discovery and an invention, and that is part of the issue. But traditionally the patent system has never allowed knowledge in itself to be patented; it has only ever allowed the patenting of a specific use of knowledge in an artefact. The artefact might be something you can touch or it might be a process or a method. But over time and in different jurisdictions courts have rejected the idea that anyone can fully appropriate knowledge to themselves. I think this is important in looking at the discovery/invention issue in regard to the patenting of genetic information in itself. Yes, the distinction between a discovery and an invention can be very fine. It does not appear to be fine in this case; it merely seems to be a matter of spin. If you add the words ‘isolated’ and ‘purified’ then information that is no different to information occurring in nature suddenly shifts from being a discovery to an invention.

The problem with allowing patents on discoveries was set out, I think, extremely well by the committee that reviewed intellectual property legislation under the competition reviews principle. That committee said it was very important not to allow patenting of discoveries because that allowed a big intervention in competition. When you allow the grant of a patent over the information in a gene, that prevents anyone else using that information in any commercial manner, which means that it prevents them using that same information to develop alternative treatments, cheaper treatments or better treatments. So I think that a lot of what the committee is looking at has to come on this question: do the words ‘isolated’ and ‘purified’ suddenly convert the information that exists in the gene that is there in nature from a discovery into an invention? I would argue that they do not.

Further, I would argue that, because it is a discovery and not an invention, Australia’s patent laws actually require that such patents not be granted—that there is actually no need for change to the legislation to prevent such patents but that the legislation should simply be implemented as it is written, that patents are granted only for inventions. This means that a lot of the material provided in the submissions by the Department of Innovation, Industry, Science and Research and IP Australia is, in a sense, irrelevant. When their submission says, ‘Australia’s current patents law does not give IP Australia any basis in law to refuse to patent genes, nucleic acid or protein sequences,’ that is wrong. Nothing in our law allows the patenting of discoveries. One

does not need to turn to the TRIPS exclusions of methods of medical treatment in order to say that patents on genes should not be granted.

The other thing that I would like to raise with you is the question of data. I am very attracted by the Competition Principles Agreement because it says that, whenever anyone wants to interfere in a market with the effect of reducing competition, they should make a good case for it. They should actually make a case that the benefits of their intervention exceed the costs. No such data, I believe, has been put in front of this committee in regard to patenting genes. There has been a claim that there is no evidence of any harm, but that is a completely different thing from demonstrating that there is any good.

And, in relation to the fact that there is no evidence of any harm, I actually cannot find substantial evidence that anyone has gone out to look for the data, to ask the questions, to actually map what the area of medical delivery of science is that is covered by the patents that have been granted and to ask who owns them, at what price do they put those products in the market, and what is the impact on the health consumer, what is the impact on the taxpayer, and what is the impact on other research organisations or other biotechnology companies of the fact that that particular knowledge is monopolised? Nobody appears to have gone out and asked for any of that data, and I do not see any evidence that any of that data has been put in front of you.

We simply do not know, and I do not believe IP Australia can tell you, what patent monopolies are being enforced. They can tell you the ones where the fees have been paid, but they cannot tell you how many are being used, in what way or with what effect. I think that creates a real difficulty for the committee in addressing its terms of reference. We do not know, for example, what the costs are to companies on that very small number of patent monopolies that have gone all the way through the court system to a court decision. There is a big research project that the people at the University of Melbourne, the IPRIA people, who have given evidence to you, have done about those patent judgments. There is no data in that on the cost to the losing party, which is quite important in looking at the overall impact.

There was a very recent case that the committee might like to look at that is not about a gene patent but is about a pharmaceutical and shows the kinds of costs. It was a judgment delivered on 3 June 2009 in regard to Sigma Pharmaceuticals v Wyeth. Sigma had permission from the TGA to produce a generic version of an antidepressant. On the day it announced that, it discovered that Wyeth held a patent. It had not discovered Wyeth's patent, despite the fact that it had searched for it. It was criticised by the court because it had subcontracted the searching, but nonetheless it had searched and it had not found that particular patent. The court was satisfied that there was a prima facie case that the invention was obvious, and the court was satisfied that there was a prima facie case that there was no new manner of manufacture. Nonetheless, it granted the injunction, so Wyeth had to stop the plans it had in hand to produce a cheaper generic version of a patented pharmaceutical. I would like to know what the cost was to the Australian health consumer and the cost to the Australian taxpayer, but we cannot get answers to that. We will probably never know those costs.

I would simply say that it is not good enough to say that there is no evidence of harm; we actually have to look at what the evidence of the impact is and, where we know that there is evidence, we should require that that data be provided to the committee so that in answering these very tight terms of reference you could have some real facts in front of you. Thank you.

CHAIR—Thank you.

Senator HEFFERNAN—Under the Patents Act, in division I, ‘Validity’, at section 18, ‘Patentable inventions’, it says:

Patentable inventions for the purposes of a standard patent

(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies ...

Clearly, it would be your view that, as you say, the ‘spin’ of isolating the gene is not a manufacturing process. Would that be a fair assumption?

Dr Moir—Yes. Well, ‘manner of manufacture’ has become very loaded over the 400-odd years since it came in, but it simply originally meant something new. In fact, that section of the Statute of Monopolies went on to say that it also should not be contrary to the law. At that time, ‘contrary to the law’ meant an improvement, because there is a common-law right to carry on a trade, and if someone gets a monopoly over something and it prevents you carrying on a trade it should not. But it has developed since then. It has been used in different ways. But still there is a fundamental distinction between whether it is something that has been made or it is something that is simply there. I would say that, yes, the method to extract the information in the gene requires isolation and purification, but the gene product patent itself is neither isolated nor purified, and my scientific colleagues tell me it cannot be because, if it is, it changes and then you cannot use it to develop a method of medical treatment.

Senator HEFFERNAN—Further down, the section says:

(2) Human beings, and the biological processes for their generation, are not patentable inventions.

Certain inventions not patentable inventions for the purposes of an innovation patent

(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

It gets a bit complicated. Is the act trying to tell us there that what naturally occurs in the body, even in an isolated form, is not patentable?

Dr Moir—Could I step back from that and talk about the history of that particular part of that particular act? The Patents Act 1990 resulted from a review of the patents act that was commissioned by the Fraser government and reported to the Hawke government. The Intellectual Property Advisory Committee put forward this report, which had a number of recommendations in it. There was a split recommendation as to whether chemical products should be patented. The majority felt that they should and the minority felt not. The committee recommended against patenting software but it also recommended against adopting a European type system that listed exclusions—things that could not be patented. When the act was brought to parliament, initially in 1989, it was then amended a bit and it came back in 1990. But at no point in the parliamentary debate was there any disagreement between the major parties over the legislation that the government brought, and the legislation the government brought specified no exclusions. They accepted the recommendation of the committee that it was not useful to go down the European track and list the exclusions. However, you know what happens in the Senate sometimes, and the Democrats put up an amendment that was much broader than that. Senator

Harradine, from Tasmania, was involved in the negotiations and the limitation that you see was the result of bargaining in the Senate. So it has a very specific history.

Going forward from that, the effect of it has been most interesting. Since then the courts have felt free to take the view that the parliament of Australia does not wish anything else to be excluded from patentability. So although the two major parties, in putting forward the 1990 patent bill, did not exclude software, it was clearly their intent that it be excluded. They accepted the whole recommendation of the report. After that the court said, 'Oh, no, we can do that.' It had also been long-standing practice that methods of medical treatment were never patentable, but the courts, in determining to change that long-standing tradition of the combination of common law and statute law that is the patent system, said: 'But parliament did not introduce it; it had the opportunity to do so.' I think that is a very, very poor understanding of the parliamentary process, and it has operated to the disadvantage of Australians.

Senator HEFFERNAN—Given the dilemma and the debate that is occurring that we have been addressing concerning when a patent genuinely become a patent, if in its wisdom the committee was to move a motion of amendment to that particular part of the act along the following lines:

The following are not patentable inventions -

... ..

(b) biological materials, including but not limited to their component parts or derivatives, whether isolated or purified or not and regardless of their state and processes used in their production, which are identical or substantially identical to those that exist in nature;

Would that cover it?

Dr Moir—I think that would be extremely useful. I think the courts would also continue to say, 'Well, anything else goes.' If the committee were to recommend tightening that exemption they might also want to recommend that other things that courts have decided should be patentable, but which government and parliament has not, should be included as specific exemptions. It might also be useful to write an objective into the Patent Act, because there is no objective at present. I understand that lawyers are very much divided as to whether or not they think it is useful to write objectives into a statute. But it is not surprising that when there is not a stated objective the courts can misinterpret the parliamentary intent. The intent is clearly to encourage invention.

It is also clearly not parliament's intent to make Australia worse off as a result of the patent system. So it is clearly also parliament's intent that in granting a patent there should be a probability that the benefit exceeds the cost. I think it would be very useful to put those things in because it would be very hard to demonstrate that the benefit to Australia of patenting, of having a monopoly over, genetic information in any way exceeded the cost to Australia of handing out such a monopoly. When I say that the benefit exceeded the cost, I am talking about Australia. The best spelling out of that was in the state of Massachusetts in 1641, where they said:

... there shall be no monopolies granted or allowed among us but of such new inventions as are profitable to the country, and that for a short time.

That of course is very close to the time of section 6 of the Statute of Monopolies, and the emphasis is on 'We give a monopoly because we expect a country to be better off as a result.' That is not happening now.

Senator HEFFERNAN—Should we, to give further clarification, also consider a further amendment to the act along the lines of: 'For the purposes of this act an invention that includes or makes use of a biological material as a component will be taken to involve an inventive step when compared with the prior art base unless the incorporation and use of that biological material, regardless of whether it was known or unknown in the manner claimed in the invention, would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed anywhere in the world before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection 3'? That is a pretty big mouthful and I will table it for the committee. That is too big a mouthful to think about today, but we will table it and give consideration to it.

CHAIR—Are you asking for that to be taken on notice?

Dr Moir—I would appreciate it if I could. It is very detailed.

CHAIR—Are you able and willing to do that?

Dr Moir—I am willing to take a look at it and provide a view, yes.

Senator HEFFERNAN—I would like to take you to the present act. The problem that this committee also has to grapple with is what we do about some of the patents that were issued as late as 18 months ago that are clearly on an isolated gene and therefore, as you have correctly pointed out, prevent any research on a cheaper or better invention, as would come out of an accessible discovery. Section 20 of the act, 'Validity of patent not guaranteed', reads:

Nothing done under this Act or the PCT guarantees the granting of a patent, or that a patent is valid, in Australia or anywhere else.

So the act sets out that just because you have been granted a patent that does not mean to say it is valid.

Dr Moir—That is right.

Senator HEFFERNAN—Section 20 goes on to say:

The Commonwealth, the Commissioner, a Deputy Commissioner, or an employee, is not liable because of, or in connection with, doing any act under this Act or the PCT, or any proceedings consequent on doing any such act.

I am a farmer and wool classer. That is what I really call Senator Humphries's comfort zone. That is lawyer language. In plain language, doesn't that say that there is a way out?

Dr Moir—Yes, indeed. No application which the Patent Office accepts can be assumed to be valid until it has been tested. Indeed, a patent can be tested again. When somebody is sued for infringing somebody's patent monopoly they typically countersue and say, 'But your patent's not valid,' and the courts often look at both things. I read a very interesting article about a UK case where the person sued for infringement lost and had to pay damages. Subsequently another party was sued but won and the patent was declared to be not valid, but the original person still had to pay the damages. So there are some very strange things that go on. But there is absolutely no reason why the committee cannot clarify that the information in genes is a discovery, not an invention, and should not be being granted patents and that none of the patents that have been granted of that type is actually valid in Australia. There is nothing in the law to prevent that happening.

Senator HUMPHRIES—On page 35 of your submission you say:

Gene and related "inventions" can be found in IPC classes—

and then you mention two category numbers. You provide on the next page a table for the first of those two categories. I assume that if we had a table for the second category it would be much the same as that for the first.

Dr Moir—Smaller.

Senator HUMPHRIES—But I assume that the trend that table 2 demonstrates, of a rise in gene related patent applications, would grow throughout the late 1990s, peak at about 2000, 2001 and start to decline after that.

Dr Moir—It may. I did not have time to look at that one as well.

Senator HUMPHRIES—I just wanted to see whether what is in table 2 is typical of what is happening in this area.

Dr Moir—One has to be careful because the data are always several years out of phase because of the international arrangements. The international arrangements effectively allow an inventor to take out an option on patenting in other countries. As you would know, 92 per cent of patents in Australia are owned by foreign entities. A lot of those patents come in through this international route. That means that it can be years after the filing date before you actually know if it has entered into your country or not. When I am trying to analyse data for research and academic publishing purposes, I often cut out the last six or seven years, because it takes six to seven years for a whole set of applications to get through the patent office.

Senator HUMPHRIES—If that is true, then the lag from overseas applications would push the peak even further back in time, wouldn't it? It would make it earlier than 2000 or 2001.

Dr Moir—What I would say is: it is too early to see that there has been such a significant drop in applications. The other thing is that people manipulate, I believe. The evidence on this is a bit patchy, but there is some evidence that people carefully craft their words to make sure of where they are going to be assigned in terms of the classifications. That is particularly alleged in

regard to the US. Whether it is as bad an effect in Australia I do not know. But people can, by the way in which they phrase something, make sure that they are classified in a different class.

Senator HUMPHRIES—The patent lawyers who came to speak to the committee in Melbourne asserted that there had been a hump about the turn of the century with these sorts of applications. After the mapping of the human genome and so on, or as that went on, there became fewer applications in relation to human gene patents and patents generally, because it became more apparent that they were really discoveries rather than inventions. At least as far as some witnesses were concerned, the assertion went that it was becoming apparent that, at various points in the past, patents had been granted over genes and gene sequences but that that was contrary to the principles in the Patents Act, and the number of patents granted over genes, because their novelty was no longer there, was reducing and it was a trend that was going to continue. Would you accept that that was likely to be the case?

Dr Moir—It may be the case. The ALRC took that kind of view. Effectively, reading between the lines, they said, ‘This is bad policy, but it is too late.’ They reported in 2004. We can see from this table that there have been a number of patents granted since that period. The other thing about patents is that they are a bit like lottery tickets. Most of them are actually not worth anything, but a few of them are worth billions, and you never know which ones. In terms of the impact on the people of Australia, it is a question of: which ones are operating and what effects do they have? Are the ones that are really operating being used in any way to protect manufacture, to prevent competition, to extract a higher price? What is happening with those? It does not matter how few they are; if you get one or two like the BRCA gene, then you could have a substantial negative effect. It is not the numbers.

Senator HUMPHRIES—IP Australia, in their opening statement for us today, say:

In the case of chemicals the claim to the product is to the chemical molecule or combination of molecules. Gene patents take the same form. In the gene patent a claim to an isolated gene sequence per se for which a practical use is identified is a claim to a chemical molecule, a nucleic acid molecule to be precise.

If we were to take the approach that we should treat gene sequences as not being patentable because they were mere discoveries, would that have an impact on the patenting of chemicals?

Dr Moir—I do not think so. Until relatively recently there was not a general view that chemicals should be patented as products. There was not as much of a problem about the process, so it was very similar. Indeed, until 1978 Italy did not allow patenting of chemical products. As I mentioned before, in the IPAC review in 1984 in Australia the committee was divided: the majority thought we should; a minority thought we should not. Now we have to under TRIPS; there is nothing that one can do about that. But the ‘purified and isolated’ I think has a different meaning in the chemical area. One can imagine, for example, if you are producing a chemical, which is a product, not information, as it is in the gene, that being able to produce it again and again and again to a reliable quality pure standard for use in a health treatment might be a difficult thing and it therefore might be inventive to isolate and purify it.

In the case of gene patents, I cannot see what the evidence is that there has actually been any isolation or that there has been any purification. They have simply extracted the information, and it is that information which people seek to patent. So the phrase is imported from the chemical

industry, but I do not think it is a proper parallel. If I might quote Siva Thambisetty, who is an IP lawyer who works at the London School of Economic, she says that this importation of the chemical analogy into biotechnology:

“... is credited with a number of oddities in the way in which genes are now treated in the patent system, including the reliance on structural elements rather than the essential function or ‘information’ nature of gene sequences.”

I quote that on page 30 of my submission. So I think that patent offices have been led astray. When they first were faced with these new technologies and did not have necessarily a great deal of expertise in dealing with them, they imported reasoning from another technology field, and I think that now we can see the sad effects of that.

Senator HUMPHRIES—Okay. Thank you.

Senator ADAMS—Dr Moir, we are running out of time, but you have commented about the narrowness of the terms of reference for the committee’s inquiry so, just as a brief help for us, what recommendations do you think that we could make to improve the operation of the system in relation to genes and genetic sequences?

Dr Moir—I think the emphasis on discovery and the fact that discoveries are not so hard in all circumstances to identify is important. I think that the research exemption is something you might look at. IP Australia recently circulated their discussion paper on the research exemption and they framed it quite narrowly. They said the exemption should apply where the sole purpose was research. But purposes are very rarely sole. For example, a university undertaking research might also be undertaking education, and I can tell you that a patent lawyer would say, ‘Well, that means that it is not solely for research and therefore you cannot claim the exemption.’ So I would look very closely at propositions in regard to the long-awaited research exemption and make sure it is very tight and very broad, because it is that cumulative research that is very important.

Another thing that bothers me is that, where a method of medical treatment resulting from biotechnology is patented—and I have no problem with that—and where the patent owner requires that the test be done in his or her laboratory, then that patent owner gains access to ongoing genetic material which gives them an unfair research advantage. I am not sure how you would do this—though I am sure you have access to people who could advise you on it—but the patent right should not include the right to say where a test should be done. And that, I think, was part of the fuss with BRCA—that the big research hospitals, which were doing the BRCA test, were getting that genetic material, which allowed their researchers to look at other possibilities around and about.

Plus I do think that it is important to emphasise the section 6 definition of what is patentable subject matter because it is a long phrase, an old phrase, and it does include language that the courts will not use about the benefit to Australia. The courts systematically avoid using that, and it would be useful to draw that part of the definition to their attention so that, in determining a patent, they look at the benefit to Australia as part of the definition of patentable subject matter.

Senator ADAMS—That is good. Thank you.

Senator HEFFERNAN—I would like to ask a question after Senator Williams.

CHAIR—I must be very short.

Senator WILLIAMS—Were you saying, earlier on, that the Senate passed a bill, and that there was an assumption that this was how it would be and this was what it would mean, but that when the courts tested it they came out with a different decision from what was assumed by the Senate, back in the Harradine days et cetera?

Dr Moir—That is my interpretation. The courts have quite frequently said, in the period since 1990, that, because parliament did not say you could not, then you could. It is my understanding that parliament did not say you could not because parliament had accepted the recommendation that said, ‘We will not go down the European route.’ Parliament did not say that they wanted to throw out long-standing presumptions that you cannot patent maths and you cannot patent methods of medical treatment. But our courts have done that.

Senator WILLIAMS—So that is obviously something that the parliamentary process must have to address if that is what the courts are ruling.

Dr Moir—It does seem to me that the biggest area of judge-made law is patent law, and I for one would be delighted if parliament decided to take a look at that and make sure that parliamentary intent was properly reflected in the drafting so that the courts interpreted that intent properly.

Senator WILLIAMS—Thank you.

CHAIR—Senator Heffernan, you can ask a short question.

Senator HEFFERNAN—We have been told that the patents generally that have been issued are not actually on the gene, and that that is some sort of myth, because people can get access. Then, of course, we received evidence that was the complete opposite of that. Could I just take you to the diagnostic for the patent—I will not read the number of it but it is the epilepsy patent. The title is, ‘A diagnostic method for epilepsy,’ which, I have to say, sounds like an invention. And then, when you go into the four inches of paperwork to the claims, you see that it claims that the invention is ‘a method for determining the likelihood that a patient suspected of SMEI does or does not have SMEI’. Then it sets out a claim, testing a patient sample. It does not define the boundaries of the test. So, as in the patent document—I can table these documents in due course—it appears to me that this particular patent is a very broad patent because it actually takes a patent on any method of testing, which means—and I am not a lawyer—that it could say that any other testing is excluded. Then, further into the patent—

CHAIR—This is supposed to be a short question.

Senator HEFFERNAN—Yes, I know. It actually sets out the isolated genes that it also claims. Isn’t this a typical—

Senator WILLIAMS—Misleading?

Senator HEFFERNAN—It is a very broad document. Page 2 talks about not only the test but a method for the diagnosis of SMEI epilepsy which absolutely locks everyone else out of the field. Does that encompass what you see as the legal minefield that people enter into?

Dr Moir—I cannot comment on that particular patent, but I would draw your attention to *Patent Failure* by Bessen and Muerer, which does talk about those kinds of things and about the fact that patent monopolies have very indistinct boundaries. Nobody knows where the boundary of the patent monopoly is, which means that it is very easy to trespass.

Senator HEFFERNAN—That also means that, if this were tested at law, it would be a lawyer's feast.

Dr Moir—That is right.

Senator HEFFERNAN—The haemophilia patent actually claims the methods and compositions for use in gene therapy for the treatment of haemophilia. As we know, there is not a successful patent for that. This is a patent in anticipation of success and, according to the document, it prevents all other work until 2018. Isn't that the problem we face? Here we have a patent that claims methods and compositions—and it also includes the isolation bit—which anticipates success that is not there.

Dr Moir—The National Innovation Review has made some useful recommendations here—in particular, with regard to the clarity with which a patent monopoly is claimed. They have recommended to the government that there be a significant raising of the inventive step and action to improve clarity. One of the problems with some of those claims, as you have said, is that they are very long, very repetitive and claim property that the inventor probably has not invented.

Senator HEFFERNAN—That is right; that is exactly what they do.

Dr Moir—We have that example in haemophilia, and there are plenty of examples in other fields. But, yes, claim construction is a real problem. That might be another thing the committee might want to look at, particularly in relation to the *Venturousaustralia* recommendation.

CHAIR—Thank you, Dr Moir. You have got some homework! We very much appreciate the time you have given us. As with all the witnesses that we have had, we could have kept going for a significantly longer period. But thank you very much.

Dr Moir—You are welcome.

[4.27 pm]

DRAHOS, Professor Peter, Private capacity

RIMMER, Dr Matthew Rhys, Private capacity

CHAIR—Welcome. Would you like to comment on the capacity in which you appear before the committee day?

Dr Rimmer—I am a senior lecturer at the Australian National University College of Law and I am appearing in a personal capacity.

Prof. Drahos—I am a professor at the Australian National University and I am appearing in a personal capacity.

CHAIR—I understand you have both been given information on parliamentary privilege and the protection of witnesses. I now invite you to make an opening statement and then we will ask you questions.

Dr Rimmer—Our submissions are separate. I have read extensively on intellectual property and biotechnology. I have both written a book and edited a collection on patentable biological inventions. I have written about 17 other papers as part of an ARC discovery project on gene patents in Australia in relation to options for reform. The research I have done has been quite systematic in looking at the various dynamics of gene patents and charting the way in which the patents system has expanded to accommodate microorganisms, plants, animals, human gene patents, stem cell patents and a dazzling array of new technologies such as proteomics, nanotechnology, bioinformatics and synthetic biology.

In terms of the particular approach that I have taken on the topic, patent law in theory is technology neutral. But there are quite nuanced impacts in relation to the operation of patent law in particular contexts, depending on the nature of the technology.

In my opening statement I would like to do a couple of things. First of all, I would like to augment some of the evidence you have already received in relation to Genetic Technologies Ltd and the controversy over their particular patents. I have an article called the ‘Alchemy of junk,’ which, I think, helpfully complements some of the evidence that you have received already about some of the recent controversies in Australia over Genetic Technologies Ltd. Then I would like to make some suggestions in terms of what you might like to think about patent reform.

Regarding the controversy over Genetic Technologies Ltd and their patents in relation to non-coding DNA and genomic mapping, some submissions made the point that Genetic Technologies Ltd is just an isolated case, an exceptional case. In my particular view, the dispute over Genetic Technologies Ltd has a lot of resonance with some of the other fights that have been happening with biotechnology patents but also some of the battles in relation, for instance, information technology patents and clean technology patents. I guess there has always been a fundamental concern about the validity of the patents both in relation to the non-coding DNA patent, which is

US patent 5612179, and the genomic mapping patent, which is 5851762. It is interesting to see that there has been a score of pieces of litigation in the United States, and New Zealand in particular, in which questions have been raised about the validity of those particular patents.

Genetic Technologies Ltd in the United States was involved in litigation with Myriad Genetics and Nuvelo, Covance, Labcorp and Applera. In New Zealand, they had a battle with the Auckland District Health Board. They have also had battles with Monsanto and General Electric Healthcare. One of the very interesting things that have emerged out of some of those battles has been the question about whether those patents are novel and inventive, according to a person skilled in the art. The evidence presented by Applera in their initial litigation with Genetic Technologies Ltd was interesting. They pointed to an array of prior art relating to research in respect of non-coding DNA and genomic mapping, which questioned the validity of the patents. There has also been evidence from a range of researchers, including Professor Little from the University of New South Wales and from John Sulston, John Mattock, Francis Collins and Joe Sambrook, all questioning whether those particular patents were novel and inventive at the time that they were filed.

The great tragedy in relation to the saga of Genetic Technologies Ltd has been that the validity of those particular patents has not been properly tested yet, and those particular patents are coming to the end of their duration. Apparently the United States Patent and Trademark Office recently said that it was going to re-examine one of the patents in terms of the validity of its claims. That will be problematic given the wide-ranging impact of those particular patents and the way in which Genetic Technologies Ltd have used those quite weakly based patents to licence fees from a range of commercial companies, research institutions and universities, but also very recently from departments of health, especially in New Zealand, and some of the clinics in Australia who have been providing certain assistance and help.

I think the story of Genetic Technologies Ltd is a very important one because it really shows what a powerful impact a certain kind of family of patents can have once they are granted not only upon research and access to health care and the ability of people to get access to genetic tests; they also have quite a critical impact on agriculture in terms of some of the licences in relation to plant and animal genetics.

In terms of the recommendations that I am really making in terms of my overall submission, I guess I make a number of recommendations. My great fear in terms of the way the committee might approach the topic of gene patents is that you are receiving sometimes quite extreme submissions on either side, from patent loyalists who say you should not change anything with the patent system and the patent system is working wonderfully on the one hand, and on the other hand the patent abolitionists who say you should prohibit patents in relation to genes and an array of other biotechnological inventions. My great concern is that, faced with such extremes, there will be a terrible temptation to do little or do nothing and avoid the controversy.

Senator HEFFERNAN—Don't you believe it.

Dr Rimmer—I think one of the really productive things in terms of this inquiry has been a great consensus between a number of the submissions, both by IP Australia the department of industry and some of the academic submissions, about the need for modernisation and reform of the patent regime. I would like to emphasise that this is a very mainstream concern. Barack

Obama when he was running for president was emphasising the need for a reform of the patents system in the United States and the need for:

... a system that produces timely, high-quality patents is essential for global competitiveness in the 21st century

There is certainly consensus that there needs to be something done in relation to patent quality first of all. I was very interested to read the submission of IP Australia and the department of industry saying there was a problem in Australia in terms of the thresholds of novelty and inventive step being set lower than some of our counterparts. I think a number of things can be done to address some of the issues in relation to novelty and inventive step. The approach of the United States Supreme Court in the case of *KSR versus Teleflex* has been very interesting in terms of raising the standard of novelty and inventive step in applying a slightly higher threshold in terms of what is required. That is being applied in terms of biotechnological inventions in the case of *in re Kubin* by the Court of Appeals of the Federal Circuit. I think that has been a very productive approach and I prefer that sort of approach to perhaps the one presented by IP Australia. A lot of commentators have also emphasised the role of a person skilled in the art. A great problem in terms of the judgments in relation to novelty and inventive step has been that a person skilled in the art is credited too little creativity. Some commentators like Richard Gold and Mark Lemley argue that the reasonable person test, the person skilled in the art, you must attribute a greater level of creativity to them.

The other very important thing on questions of patent quality is introducing the US standards in relation to utility, for there to be a substantial specific and credible utility. There is a big biotechnology case in the United States in *re Fisher* dealing with the patentability of expressed sequence tags in relation to maize. The Court of Appeals for the Federal Circuit rejected the particular patent application by Monsanto out on the grounds of utility. I concur with the Australian Law Reform Commission and IP Australia that we need to do something about the question of utility. That would be my submission in relation to patent quality.

On the question of defences, it has been a great pity in Australia that it has taken so many inquiries to really implement a proper defence of experimental use in Australia. Justice Story in the US invented the defence of experimental use back in the early 1800s but in Australia there is still a lack of clarity about whether or not we have a defence of experimental use and what its scope should be. The United States has defined the defence of experimental use very narrowly and has confined to strictly philosophical inquiry. The European Union has considered much more broadly in saying the defence of experimental use can operate in relation to research on a patent invention. I think the best proposal in relation to experimental use was from the Australian Law Reform Commission. I share the last speaker's concerns about the very narrow way in which IP Australia has put forward their proposal in relation to a defence of experimental use. The sole purpose test I think is used in the Netherlands and has not proved to be a very effective way of dealing with that scope.

Thirdly, in terms of compulsory licensing and Crown use, I would point to the submission of Charles Lawson, who emphasises the great problems with the current compulsory licensing regime in Australia. I would also note that the Joint Standing Committee on Treaties said two years ago that it would modernise the compulsory licensing regime in line with TRIPS to deal with the issues in relation to access to essential medicines, especially in relation to the export of essential medicines. I think it is very important that our compulsory licensing regime adequately

deals with concerns about competition and public non-commercial use, but also about health concerns and health crises, which can cross over into the field of gene patents, because there was a big race to patent the SARS virus.

I have a couple more recommendations. I think Australia should follow the leadership of the Supreme Court of the United States in relation to remedies. In the eBay versus MercExchange case, they emphasised the need to be very flexible in the use of remedies, particularly to deal with the problem of patent trolls—companies who hold patents and then try to pick-off research and development companies.

Finally, I would note that there has been a very interesting discussion about the relationship between patent law, informed consent and benefit sharing in a number of different contexts, particularly in relation to genetic testing. In the case of Greenberg versus the Miami Children's Hospital, research participants were particularly upset that the research hospital tried to patent genetic research in relation to Canavan disease. The UNESCO declaration on bioethics and human rights in 2005 emphasised the importance of informed consent and benefit sharing. There are ongoing discussions in relation to biomedical research and access to genetic resources and traditional knowledge about the interaction between those concepts.

Prof. Drahos—My submission relates most strongly to term of reference (b): 'identifying measures that would ameliorate any adverse impacts'. What I am about to say is based on a study I have conducted—as an academic would inevitably say—of the patent offices in 45 countries. This was a project funded by the Australian Research Council, and IP Australia was a partner in this project. I looked at a lot of issues in that study, but the issue that I think is probably most relevant to this committee is the issue of patent quality. I asked all 45 offices what they understood by patent quality, what they were doing about it and whether it an issue they were concerned about. The answer was that, in all the developed and developing countries—and I spoke to all the major patent offices in all the major countries, including Brazil, India, China, the United States, Korea, the European patent office, the Japanese patent office and so on—patent quality is a major issue. However, it is true that quality issues concern some patent offices much more than others. In Europe, in particular, I would say that patent quality issues are taken more seriously than in other countries.

If I have one message for the committee it is that thinking about improving patent quality, whether it is in the area of biotechnology or any other area, requires an integrated strategy. You do not fix the problem of tax evasion with a single amendment to the Tax Act, and you are not going to fix the problem of patent quality with a single amendment to the Patents Act. The analogy is with water quality. We all want to drink pure water. If you have a water filter that has one screen, it follows that you are going to miss a lot of impurities. If you have a water filter that has many screens, you will get your water. So how does this principle of having multiple screens relate to the patent system?

In the submission I outline some proposed reforms, and I will just mention two of them here. One is the idea of audits. In most areas of regulation that I have studied—and I have studied a lot of different areas of regulation—the idea of independent audits is kind of important. It is certainly important in financial regulation. What is remarkable is my finding that no patent offices that I came across are really the subject of independent, quality audits. This creates a lot

of problems, and one of them is that legislatures, parliaments, do not have independent information about what is going on in patent offices; this is very important.

So one of my proposals is that we should think about creating an external patent audit committee. I hasten to add this committee would not have formal powers, it would not be a formal regulator; rather, it would be an information gathering body. It would be staffed by scientists of considerable stature, of independence, of integrity, who were concerned about the public interest dimensions of patents in particular areas. They would, on perhaps a yearly or biannual basis, with the assistance of members of the profession perhaps or legal expertise at any rate, conduct an independent audit of a selection of patents. So one year they could target nanotechnology patents; another year they could look at patents in the area of agriculture—whatever was thought to be important at the time. They would essentially conduct an independent audit of the quality of patents that were being granted in that area and then they would report to whatever body was thought suitable. That would be one way in which we would have independent information about what was going on in patent offices.

The second idea that I propose is what I call a transparency register. This is based on a registration system that exists in relation to pharmaceuticals in the United States—it does not work very well there. Essentially, the intuitive idea is that a company would be forced to disclose all the patent holdings that it had in a particular area. One could declare, for example, a transparency register around climate change technologies or in the area of agricultural biotechnology, if it were thought that there were problems with patents in those areas, and companies would be forced to disclose these patents to the register, and if they did not do so then they would not be able to enforce those patents. The idea behind this—it is a simple device—is to create more transparency within the system.

So there are two simple, low-cost ideas that would, as it were, act as filters to improve the quality of the system. Thank you.

CHAIR—Senator Heffernan.

Senator HEFFERNAN—Thanks, Professor. So you agree—and I presume, Dr Rimmer, that you also agree—that patent law needs to be tidied up?

Prof. Drahos—My finding is, as I said, that not only is there a need; most countries—or rather all countries—are concerned about patent quality. The concerns are the greatest in Europe at the moment, but there are also concerns in China and India. One can see patent reform processes taking place in all countries. It would be surprising if that were not also true of Australia—that patent quality needed to be, in your terms, ‘tidied up’.

Dr Rimmer—Absolutely, Senator Heffernan. I think the big difference between, say, Australia and the United States is perhaps that the Supreme Court of the United States has started to take quite significant action to try to deal with questions about patent quality, especially in the KSR decision but also in the eBay case. By contrast, the Australian High Court has not taken such a role thus far—and I think that have been somewhat problematic for IP Australia, for instance. They think that there really needs to be a modernisation of the patent regime as well, because they are kind of frustrated with a number of inflexibilities within the system at the moment.

Senator HEFFERNAN—Have we ever tested the validity of a patent at law to work out how the law would interpret some of these very broad patents? I mean: while the broadness is in the act, is it a waste of time going to court?

Prof. Drahos—Well, it is never a waste of time—

Senator HEFFERNAN—It is not a waste of time for the lawyers.

Prof. Drahos—No. My basic point here would be that I think it is important to remember that very few patents are ever litigated. The litigation rates in the United States are less than two per cent; that is the most active litigation system in the world. In most other countries, it is less than one per cent. So relying on courts to reform the patent system is fairly futile, actually.

Senator HEFFERNAN—Dr Rimmer, do you have something to say?

Dr Rimmer—I do not think that has been particularly a problem in the case of Genetic Technologies Limited, because we have had this cat-and-mouse chase with Genetic Technologies Limited and these various other parties.

Senator HEFFERNAN—We have.

Dr Rimmer—Part of the evidence that was given by Dr Charles Cantor, the chief scientific officer of Sequenom, noted:

The amount of pressure they put on us to come to a conclusion one way or another was ... blackmail.

He said on the *Four Corners* report that they said to him:

“We’re going to take you to court and it’s going to cost you so much money to defend yourself that you’re better off just paying us what we’re asking for and we’ll go away and you’ll never hear from us again.”

I think that is the great problem in terms of the patent regime at the moment.

Senator HEFFERNAN—That is the dilemma, yes.

Dr Rimmer—Once the patent is granted, it then becomes very difficult to challenge the validity of the patent in terms of the costs and expenses associated with that. The United States regime has been making much greater use of re-examination of patents once they are granted. The Public Patent Foundation, which is a civil society organisation, has been particularly good of late in bringing re-examination requests against critically important patents such as, for instance, the BRCA1 and BRCA2 patents and some of the Wisconsin Alumni Research Foundation’s stem cell patents. So some are keen on re-examination as a less expensive means of assessing the validity of patents. Some are interested in postgrant opposition proceedings in relation to the validity of patents. It is a big problem at the moment, because the current environment really allows patent trolls to flourish, because parties in most instances will be willing to pay a licence fee rather than necessarily take legal action.

Senator HEFFERNAN—Yes, take on the trouble. So what if we wanted to clean out the cupboard, as it were, of what you would call ‘junk patents’? Under the patent law act, which says that just because you have granted one it is not necessarily valid, what would be the most cost-effective way to get rid of junk patents and patents that are considered too broad?

Dr Rimmer—I think that there really needs to be a judgment as to the validity of those particular patents. Maybe the quickest means at the moment would be the ex parte re-examination taking place in the United States Patent and Trademark Office. I guess the great dilemma is that these key patents are really coming to the end of their lives, so in some ways it is—

Senator HEFFERNAN—Yes, but there are a lot that are just starting. I have one down in my office that I cannot find—I have that much stuff down there—which was only struck 18 months ago. My learned friend here, Senator Humphries, might want to follow up that question. Do you, my learned friend?

Senator HUMPHRIES—You said ‘a judgment’. Do you mean a court judgment?

Dr Rimmer—I think there has been so much disputation over the patents that a court judgment would be best, but failing that I think that the re-examination proceedings underway in the United States Patent and Trademark Office might help to properly evaluate the patents. It is amazing to look at some of the discussions in relation to that particular family of patents. Apart from Mervyn Jacobson, who was in charge of Genetic Technologies Limited, there is very little in the way of independent scientific support for those particular patents being breakthrough inventions. Even the inventor, Malcolm Simons, has suggested that perhaps the patents are not as broad as Mervyn Jacobson would suggest.

Senator HEFFERNAN—And interpreted them to be.

Dr Rimmer—For instance, compared to a leading researcher in Australia on non-coding DNA, Professor John Mattick, whose work has been cited hundreds and hundreds of times, by contrast Malcolm Simons’s work has really been hardly cited as relatively insignificant in terms of these scientific fields. Hence the great anguish in the scientific community between scientific judgments that have been made about his particular research and the way that these particular patents have given this company such strong exclusive rights in relation to a very wide range of fields of research.

Senator HEFFERNAN—Jump in there, Professor.

Prof. Drahos—I do not think you can do anything about the patents that have been granted. They are granted patents so they are vested property rights. The re-examination procedure that Dr Rimmer refers to has not worked in the United States. The number of re-examinations are extremely low—we are talking hundreds—and there are huge procedural problems with re-examination, as it works in the united system, which is—

Senator HEFFERNAN—All right; that is a simple answer.

Prof. Drahos—I think you will have to wear the patents that are granted. One can always contest the validity of a patent if one is sued for infringement of the patent. I think one has to be forward looking in this area.

Senator HEFFERNAN—So, grandfather—

Prof. Drahos—In any set of reforms involving patents, generally speaking, if it confers a benefit on the patent owner one might use a transitional clause in legislation to confer the benefit of that advantage. If you are reducing rights, as it were, the patents that have been granted have to have those clauses.

Senator HEFFERNAN—In regard to the present interpretation of the Patents Act and in particular the BRCA 1 and BRCA2 and Genetic Technologies anguish, which was printed after the Melbourne hearing—I thought it was a page of gold; it reinforced the case about the river of gold, not the river of lead—where they complained, and fair enough too, that they were missing out on \$50 million or something in licence fees, would it be fair to say that the present system is unnecessarily loading up medical research with costs and reducing competition? Is Ian Fraser, the cervical cancer vaccine man, right when he said in the *Australian* the other day that this is such an important question that this committee may well be inquiring into the most important Senate inquiry that has ever been conducted into human wellbeing.

Prof. Drahos—We know from research that the patent system has increasingly generated tremendous amounts of uncertainty. That is simply because of the sheer volume. The major offices are each getting over 400,000 applications per year. We are talking about almost one million patents granted per year when you add up the number of patents that are now within the system and are having an effect. Even patent applications, let alone granted patents, can create uncertainty. The medical profession is, amongst other professions, simply responding to the massive amount of uncertainty in this area. The problem is that they do not have deep pockets in order to remedy that uncertainty.

Senator HEFFERNAN—That is exactly right.

Prof. Drahos—The costs for them are very high so they play it safe—they become risk averse. The one thing you do not want in Australia or in the United States or anywhere is a risk averse medical research culture, which is why this issue has become so important, both in the United States and in Europe. Patent offices that I spoke to in Europe are very concerned about these impacts. They worry particularly about US patents landing in Europe having these kinds of effects, which is why offices like the German patent office, which is really the gold standard in terms of quality, will not accept a situation of mutual recognition of patent examination. It wants sovereignty over patent examination because, fundamentally, it does not trust the quality of many other patent offices' work. So the issues are very high here.

Dr Rimmer—Particularly in the Metabolite case, which went to the Supreme Court of the United States. There was a lot of debate about the impact of medical patents on the medical profession. In his dissent, Justice Breyer said:

Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health

care to the legal task of searching patent files for similar simple correlations; they may raise the cost of healthcare while inhibiting its effective delivery.

So in that particular dissenting judgment there was great concern about the expansion of the patent regime to cover, amongst other things, methods of human treatment.

Senator HEFFERNAN—Could it be possible—with your indulgence, Madam Chair—that, with the overload in processing the proliferation of patents, the situation with the supervisory authorities, such as IP Australia, is similar to that of the people that deliver the junk mail in your mailbox? Sometimes they just take the junk mail to the tip and dump it rather than deliver it because there is just too much. Do you think there is that much stuff being processed, they are so overloaded, that a lot of the processing is less than optimal in its scrutiny of the patent?

Prof. Drahos—Again, this was an issue that I discussed with all 45 patent offices that I spoke to. There is no doubt that, in the offices with large backlogs, examiners are facing considerable stress. Even in the European Patent Office, which my study found is probably the most highly regarded patent office in the world for quality, there is little doubt that examiners face enormous pressures because of the backlog. It is well known—this is such an opaque area one cannot say anything is well known in this area; nevertheless, it is clear—from various studies, including my own, that the processing time for a patent application is between 10 and 20 hours. It may be a little more in some cases and a little less in others. In developing countries it is a lot less than that because they are essentially just rubber-stamping decisions that are coming out of the USPTO or the EPO. So there are very deep issues facing patent offices. I do not envy them the task of managing these workloads, and there are going to be compromises in terms of quality. That is inevitable.

Senator HEFFERNAN—I would like to put one more proposition to you—if we were able to send you some amendments to the act, could you give them some consideration?

Dr Rimmer—Senator, if I may, I would just like to pick up your earlier question about section 18(2) of the Patents Act and give you a little bit about its history and some of the battles over the question of patentable subject matter. Section 18(2) has been quite controversial. It was a Brian Harradine amendment in relation to human beings and biological processes for their production not being patentable subject matter. It has been the subject of a couple of matters at the Australian patent office in terms of its interpretation in the context of stem cell research. I have done a few papers in relation to the question of patenting stem cells, but there seems to be a little bit of slippage between the wording of Harradine's provisions and the approach taken by the Australian patent office, which is very much focused on following the approach of the UK patent office and drawing a distinction between pluripotent stem cells, which it thinks are patentable, and totipotent stem cells, which it thinks are not. That provision is really the last taboo—that one cannot patent human beings.

The question in relation to patentability of genes has been much more hotly contested. I think Senator Natasha Stott Despoja and Senator Coulter during the 1990s made some efforts to try to get a moratorium on gene patents but were unsuccessful in that. In the United States congress, there was an effort by representatives Weldon and Becerra to have a perspective moratorium on gene patents. The problem is, I guess, that the dominant approach to patentable subject matter in the patent offices, the courts and the parliaments has been very broad.

In the United States there is a kind of antinomian tradition saying that you should take a narrower approach to the question of patentable subject matter, but the dominant approach has been very much that anything under the sun made by man is patentable subject matter. For instance, that would make the challenge by the American Civil Liberties Union and the Public Patent Foundation against the Myriad Genetics BRCA1 and BRCA2 patents very difficult, because, looking at the *Metabolite* case, the Supreme Court of the United States has taken a very broad view of patentable subject matter and it is going to be very difficult to challenge that status quo.

The only place I can really think of is Canada. For a brief moment the Supreme Court of Canada in the *Harvard oncomouse* case ruled that higher life forms were not patentable. But then the numbers changed and they qualified that decision in a subsequent case dealing with GM crops and Percy Schmeiser. There was a lot of debate around the question: what is a higher life form anyway? How do you draw a distinction between a lower life form and a higher life form?

I know there are a number of submissions which are calling very strongly for a prohibition against gene patents, but the pragmatic part of me wonders what support amongst the main political parties there would be for such an exclusion. I would say that it would be much more worthwhile thinking about some of the issues in relation to manner of manufacture that need clarification, like stem cell patent. Also I think that the *Metabolite Laboratories* case and the Australian case of *Grant* against the Commissioner of Patents shows that there are certain areas that do need clarification, particularly distinguishing between scientific discoveries and inventions and the scope of abstract ideas and products of nature. So I think there is a kind of in between position between the extremes of ‘anything under the sun is patentable’ and ‘we should have broad prohibitions or exclusions of patentable subject matter’.

Senator HUMPHRIES—I just have two questions. You made the point, Professor Drahos, that for the patents already granted it is very hard to undo the effect of having a patent granted which is too wide or a patent granted over something for which a patent ought not to have been granted. If you accept that the law needs to be changed to clarify that patents over genes or gene sequences ought not to occur then that implies some means of clarifying or tightening the wording of the law. Senator Heffernan used some words before that may or may not achieve that. Do you think there is a formula that could be used to clarify the intention of the law so that the principle that discoveries are not patentable but inventions are could be made clearer in the operation of the Patents Act?

Prof. Drahos—Oddly enough, before I became an academic I was a drafter of Commonwealth legislation so I speak with some technical expertise in this area. Unfortunately, I think it is unlikely that you will ever achieve very clear statutory language. The reason for that is that if you look at the effect of exclusions in the European Patent Convention you see that there are a number of exclusions to do with, for example, the patentability of computer programs, the patentability of plant varieties and so on. I can show you in the European Patent Office many thousands of patents—probably tens or hundreds of thousands of patents—on computer programs and on plant varieties.

Most patent attorneys will tell you that there is not an exclusion they cannot draft around. So essentially the patent attorney profession you should think of as a bunch of tax evaders. Tax evaders always think of new ways to get around our tax laws. So we should learn from the tax

authorities around the world. When they draft tax laws they have rules. So I am not saying to you that you cannot find a form of words that will attempt to achieve a public purpose. I am not arguing against that. When I am saying to you, as a drafter and as someone who has studied this area for a long time, is that it is going to be difficult. Relying on the words of the statute alone probably will not be enough.

When we look at tax acts, what else do they contain? They contain provisions that encourage courts to look at the substance of the particular tax scheme. Is it really a tax minimisation scheme or is it an anti-avoidance scheme? So what we need in our statute is language that encourages courts to look beyond the claiming format, because what we have to remember is that patent offices accept particular claiming formats. They do not look to the effects; they just say, 'We will accept this Jepsom claim. We will accept this Markush claim. We will accept this kind of claim, that kind of claim and this kind of signalling claim.'

What they are worried about is the form of the words. They do not worry about effects. That is fair enough. That is basically their job, but we as the public worry about the effects. So, in terms of drafting, it is simple. We have rules but we also understand that there will be attempts to evade the consequences of those rules so we need other forms of regulation, such as transparency registers and an external patent audit committee along with things like anti-avoidance principles that we learn from the tax act are extremely important.

Senator HUMPHRIES—What was the audit committee that you mentioned?

Prof. Drahos—The external patent audit committee, which is one of the proposals in my paper—the idea that you would have an independent audit committee looking at the quality of patents granted by the patent office that would report, say, to parliament.

Senator HUMPHRIES—Are you saying that fixing up the quality of patents granted would substantially solve this problem about granting patents over genes and gene sequences?

Prof. Drahos—Yes, I think it would, particularly if, for example, a decision were made in Australia to try to match the quality standards of, say, the German Patent Office. That is a decision for any particular office to make: 'How much as an office do I care about patent quality?' If, for example, it were decided in Australia to raise the threshold of the inventive step and if a number of other decisions were taken to try to improve patent quality then the sorts of things that I am talking about would be complementary. It would help the patent office.

Dr Rimmer—I think it is also worthwhile thinking about that once patents are granted there will be some patents—for instance, the BRCA 1 patent—which might still be valid in some form but that you might think have some negative consequences in terms of its social impact. If you really want to better control the behaviour of patent holders, it is very important to have a strong, modern and efficient compulsory licensing regime. Compulsory licensing is when you override the permission requirement, so you gain access to the patent invention in return for reasonable remuneration. That device is very important in a range of different contexts—biotechnology patents for pharmaceutical drugs, especially in the context of access to essential medicines. Interesting enough, in relation to clean technologies as well at the moment there is a great deal of debate in the lead-up to Copenhagen.

Also, the Australian Law Reform Commission is very much of the view that there should be greater regulation by competition authorities of intellectual property. In the United States, the Federal Trade Commission has done a number of studies on the patent regime. In Australia there was the Ergas and McKeough report on intellectual property and competition policy under the Howard government. I think it would be useful to have a regulator who had a greater purview of some of the impacts of some applications of certain patents. Interestingly enough, in relation to non-coding DNA patents, Myriad Genetics accused GTG of anti-competitive conduct in their initial skirmish before they reached a settlement.

Senator HUMPHRIES—Do you think—and I am sure that the answer will be yes or no—that the free trade agreement with the United States or the TRIPS Agreement would effectively be a barrier to us reforming our patent law in this area?

Dr Rimmer—I read the submissions by IP Australia and the department of industry and I would disagree with the interpretation that they place upon article 27 of the TRIPS Agreement. There has been one big WTO decision on the interpretation of article 27, which is the Canadian patent pharmaceutical case. That says that one cannot discriminate against technologies but one can differentiate between technologies. IP Australia and the department of industry may speculate on the scope of the exemptions under articles 27(2) and 27(3), but I do not necessarily share their conclusions. I think article 27(2) could be read quite broadly to include gene patents as a kind of exclusion of genes from the scope of patentable subject matter. Indeed, the Canadian position in not allowing patents on higher life forms suggests that that is a possibility with the regime.

Senator HUMPHRIES—So that is a ‘no’, is it?

Dr Rimmer—There has not been a WTO decision on the scope of those provisions, so it is really kind of speculative. I would note though that during the Australia-United States Free Trade Agreement the United States trade representative made some very outlandish claims about the operation of article 27 in the context of the evergreening provisions, which I think also lacked substance. Having exclusions under articles (2) and (3) are permissible in terms of a possible approach, but you should really talk to Peter because he is the big expert on the TRIPS Agreement.

Prof. Drahos—No.

Senator HUMPHRIES—Thank you.

Prof. Drahos—I should also add that it has not stopped countries like India, for example, from inserting specific exclusions in relation to the patenting of pharmaceutical compounds. The answer is no, and it certainly has not stopped other countries.

Senator ADAMS—My question is on the ALRC 2004 report. They made some recommendations which we have been discussing at each of our hearings. I would like both of you to comment on whether those recommendations are outdated or will help. What do you think about them?

Dr Rimmer—I have mixed views about the Australian Law Reform Commission report. Although it is a rather longwinded report, I think its key recommendations are rather minimalist in terms of legislative reform. Their key recommendations from memory are the defence of experimental use, which I support; revisions in relation to utility, which I also support; and revisions in relation to compulsory licensing and Crown use. I think they need to go further and pick up the requirements under the TRIPS Agreement to adequately have domestic and export mechanisms to deal with essential medicines. They also had some recommendations in relation to the operation of the competition regime.

I think there are a couple of weaknesses in the Australian Law Reform Commission report. The key weakness is that they do not adequately address the question of patent quality. I think IP Australia and the department of industry have really emphasised that that is a key concern for them. I think it is definitely a key concern for me. I think addressing novelty and inventive step is fundamentally important.

The second observation I would make about the Australian Law Reform Commission report is that it was a little bit hamstrung by its terms of reference in that it focused very much purely upon gene patents and the impact upon health care. I take a much more holistic view and say that gene patents also have very significant impacts upon agriculture, healthcare research, innovation, clean technologies and the environment. For instance, J Craig Venter, who did shotgun sequencing of the human genome, is now applying that same technology to shotgun sequencing the world's micro-organisms in the oceans under the Sorcerer II Expedition. His synthetic genomics project is very much focused on developing novel minimal genomes to address certain concerns about biofuels, partly funded by the department of energy.

I think the problem with the Australian Law Reform Commission report is that it does not adequately acknowledge the broad-ranging array of material covered by biotechnology.

Prof. Drahos—I think Dr Rimmer has more or less said it all. I agree with him that the ALRC probably did not, or perhaps the patent quality issues have become more pressing since the ALRC reported. We need to understand that even patent offices are becoming quite radical about improving patent quality. The United States patents office is experimenting with patent wikis, in which it will post applications and encourage submissions of prior art from the public. When patent offices are experimenting with wikis, it suggests that patent quality issues are pressing. It is not the kind of thing that the ALRC was thinking about.

Dr Rimmer—I think one of the other things the ALRC perhaps did not pick up on goes to some of the emerging technologies in the field of biotechnology.

Senator ADAMS—Of course, it was five years ago now.

Dr Rimmer—Yes. There are big issues in the areas of copyright protection in relation to genetic databases and patents in relation to bioinformatic software and microarrays. There are also very serious issues arising in relation to nanotechnology and synthetic biology, which have become more apparent over the past five years.

CHAIR—We are seriously overtime. Senator Heffernan, you will have to put your questions on notice.

Senator MOORE—Professor, what is a ‘wiki’?

Prof. Drahos—It is ‘Wikipedia’.

Senator MOORE—Okay. My question follows on from Senator Adams. We heard evidence in Melbourne about an ongoing ACIP review that is being conducted. The evidence we heard was that we should actually consider what they are doing before we make any recommendations. I also raised the issue that this reference took a long time to build up. When we first put it out there, there was very little response, but it has grown and grown; there is now a great deal of interest. I am wondering whether that has interest in itself—that you have to have the discussion first, and we have not had that very much. I am interested specifically in whether in your area—and I am sure you would be involved in that review process—you believe that the ACIP process is addressing the issues that we need to consider.

Dr Rimmer—I guess the great problem in relation to the Advisory Council on Intellectual Property has been that it has had relatively small participation in terms of its inquiries. Its recommendations have not always been implemented in the past. And it has tended to be of a somewhat conservative bent.

Senator MOORE—All of which can be said about Senate committees!

Dr Rimmer—For instance, their recommendation on patent law and experimental use duplicated the Australian Law Reform Commission inquiry that we already had. And they came up with more conservative proposals in relation to the defence of experimental use. I think it is a real problem at the moment that we have had all these inquiries, investigations and discussion papers but there has been very little in the way of legislative action. I think this committee can play a very important role in actually translating all those conversations that have taken place thus far, in a range of different fora, into some sort of legislative response. My great concern is that some of the inquiries that have happened in the past have not actually led to any instrumental action. I think that has been particularly problematic in relation to the defence of experimental use.

IP Australia have been engaging in their own kind of inquiry, too. I have mixed feelings about this. On the one hand I am very glad that IP Australia are very concerned about patent quality and modernisation of the patent system; on the other hand I am a little bit concerned about some of the conservative nature of some of their proposals—for instance, in relation to the defence of experimental use. I think it is slightly awkward, given that IP Australia is partly really the subject of any reformation. They have an important role to play in giving their advice and opinions on how the patent system should be reformed, both procedurally and substantively, but it is unclear to me what will happen through IP Australia holding that discussion process themselves, separate from the Advisory Council on Intellectual Property and the Australian Law Reform Commission. So I am hopeful for legislative action on the key question of patent quality and modernisation of the patent regime.

Senator MOORE—Professor, did you have anything to add?

Prof. Drahos—I would just add that there is an important principle at stake here that will have ramifications for Australian public health, for Australian citizens, so you should press on.

Senator MOORE—I am not saying we should not do our job. I am just looking at the recommendation that was made that there is a professional body already looking at these issues. They value the fact that we are stimulating the interest in getting this involvement, but they still believe—not wanting to verbal them too much—that they are the ones who have the knowledge and perhaps we should see what they come up with before we make any clear recommendations.

Dr Rimmer—The Australian Law Reform Commission report was a highly comprehensive report and I think that provides you with a good basis to deal with the topic and think about the implementation of concerns in this particular area.

Prof. Drahos—I would be worried about the representativeness of the ACIP. My studies suggest that in other countries the patent system does best in terms of public welfare when legislatures take an interest.

CHAIR—Thank you very much for your evidence and for the time you have given us.

[5.28 pm]

BEATTIE, Mrs Fatima, Deputy Director General, IP Australia

HUYNH, Ms Kristina, Policy Officer, IP Australia

McDONALD, Ms Mary, Acting First Assistant Secretary, Regulatory Policy and Governance Division, Department of Health and Ageing

MORRIS, Dr Clive Michael, Deputy Head and General Manager, National Health and Medical Research Council

O'KEEFE, Mr Leo John, Director, Domestic Policy, IP Australia

PRESS, Ms Lexie, Senior Examiner of Patents, IP Australia

REID, Mr Chris, General Counsel, Department of Health and Ageing

CHAIR—I welcome back representatives from IP Australia, the Department of Health and Ageing and the National Health and Medical Research Council.

Senator HEFFERNAN—Dr Morris, are you a doctor of paper or medicine?

Dr Morris—I am a cell biologist.

Senator HEFFERNAN—A soil biologist?

Dr Morris—A cell biologist—biochemistry.

CHAIR—I understand that most of you will be well practised at this, but you have been given information on parliamentary privilege and the protection of witnesses. As departmental officers, you will not be asked to give opinions on matters of policy, though this does not preclude questions asking for explanations of policy or factual questions about when and how policies were developed. The committee has various submissions before it. I am aware that officers have attended the committee's recent hearings and you are pretty conversant with the evidence that we have received. I would like to invite some opening statements, if you wish to give them, and then we will be asking you some questions.

Ms McDonald—Thank you very much for the opportunity for us to come along to this hearing of the committee. When the Department of Health and Ageing and the National Health and Medical Research Council appeared before this committee on 9 March we provided some background information to the committee. Subsequently both the department and the NHMRC have provided submissions to the inquiry, and these submissions address what we see as the key four policy themes relevant to the portfolio. Those themes are: affordable access to health care; research and development; safety and quality; and ethics and privacy. I am able to give the committee more information in relation to those areas but I will leave it there.

CHAIR—Thank you.

Mrs Beattie—Thank you for the opportunity for IP Australia to participate in today's hearings and to observe the hearings held in Melbourne and Sydney. In this opening statement, I would like to clarify and address some of the issues raised during these hearings.

The distinction between invention and discovery continues to be an area of confusion. While both discoveries and inventions add to our store of knowledge, enabling knowledge for a practical use translates a discovery into an invention. Mere knowledge of things is simply a discovery, but being able to do something practical with that knowledge makes it an invention. Whether an invention is patentable depends on whether it meets patentability criteria such as novelty and inventive step.

The confusion around this point is not helped by reports that under Australian patent law a flower picked in the forest would be patentable. If that flower were not previously known then it would be a discovery. If, however, it was determined that an infusion of the flower administered to persons had a beneficial effect on breast cancer, then the substance extracted from the flower by the process of infusion would be an invention, which may be patentable provided it met threshold criteria such as novelty and inventive step. The flower itself would not be patentable.

Patent claims take two primary forms—to the product or method. In the case of chemicals the claim to the product is to the chemical molecule or combination of molecules. Gene patents take the same form. In the gene patent a claim to an isolated gene sequence, per se, for which a practical use is identified is a claim to a chemical molecule; a nucleic acid molecule to be precise. Patents claiming chemical products have been the subject of national sensitivity for hundreds of years as they tend to relate to medicines and food and, until TRIPS, were treated differently by different countries.

Australia unlike many other jurisdictions has provided patents for both chemical products and processes from inception of the federal patent system. In contrast the UK, from where our patent laws are derived, allowed patents claiming chemical methods but not chemical products. This policy position was directed to protection of its indigenous chemical industry and lasted until 1949. In 1995 with the advent of TRIPS this differential treatment of chemical patents was standardised with all member states required to provide patent protection for both products and methods for all technologies.

In this context it is also important to note that Australia's patent system has regarded as inventions substances isolated from nature, both flora and fauna, for which a practical use has been identified. By way of actual examples I provide in evidence: a patent granted in 1920 for substances isolated from Australian flora for use in dyeing wool, cotton et cetera; and a patent granted in 1924 for a substance isolated from mammalian pancreas or glands of fishes and other sources which relieves the cardinal symptoms and signs of diabetes. In both of these examples a patent was granted over the isolated substance and the method of isolation. Neither patent extends to the substance in its natural state, namely the she-oak or the bovine pancreas, from which the substances were derived respectively.

Chemical inventions such as isolated human gene sequences for which a practical use is identified have not been treated differently because they are derived from the human body. IP

Australia has applied over 100 years of patenting practice and precedent to its examination of applications for gene patents.

Concerns about the breadth of patents granted to the first inventor is common in any new area of technology. As the technology develops the scope of patent rights afforded get narrower and narrower and it becomes harder to satisfy the threshold patentability requirements of novelty and inventive step. This is due to the cumulative growth of prior art and skill of persons working in the technology area.

Inventors who are first to isolate a chemical molecule for which a practical use has been identified may claim the isolated molecule, the method of isolation and the methods of use, provided other threshold requirements of novelty and inventive step are satisfied. The BRCA gene was known to be located on chromosome 17, but much work was required to precisely locate and isolate the nucleic acid molecule and determine its chemical sequence for the first time. Identification of the sequence enabled a new and practical diagnostic test that was not obvious or predictable given the technology at the time.

The human genome has been referred to as a blueprint for life, but the blueprint of any organism does not come with a manual detailing the function, interaction and biological significance of the genes and their association with disease. Human ingenuity and invention are necessary to achieve this, especially if society wants these today. Patents augment incentives to identify elusive gene targets. Patents also provide financial security to industry, who invest the millions of dollars to translate basic research into products in a form clinicians and patients can use.

Researchers and industry benefit from information stemming from initial patents, and armed with this knowledge they can, for example, investigate and patent new uses of the BRCA nucleic acid molecule or improvements to its use as a diagnostic or therapeutic. In fact, there are more than 1,000 research publications on downstream BRCA research and at least 15 patent applications claiming BRCA related inventions by a range of public and private applicants from and in different countries. Follow-on inventions are possible and supported by the patent system. However, the system can always be improved and our proposed patent reforms are squarely aimed at making those improvements.

We have also heard varying views about whether we are at the tip or end of the iceberg. IP Australia's data shows the number of patents claiming isolated human nucleic acid molecules steadily declining since the publication of the Human Genome Project. We expect only a small probability of additional such patents. These may arise where the published sequence has a fundamentally significant error or novel and inventive variants of a sequence of clinical or therapeutic significance.

At present there are 202 Australian patents claiming an isolated human nucleic acid molecule in force. Patents granted in other countries are not enforceable in Australia unless also patented in Australia. Conversely, we are seeing a rise in patents claiming downstream uses of isolated human nucleic acid molecules. This indicates to us that basic research and innovation are not being stifled by patents. The evidence so far is that licensing issues are often resolved in the market through commercial negotiations, except for isolated instances like BRCA. The ALRC found that restrictive licensing of gene patents was not pervasive in the Australian biotechnology

industry at that time and, in terms of genetic research, that international empirical studies suggest that the biotechnology sector is capable of developing robust working solutions for dealing with any problems that emerge.

Software, electronics, organic chemistry and pharmaceuticals have all managed to deal with cross-licensing and we see no current evidence to suggest that biotechnology would not work in the same way. If problems do arise, two important safeguards exist within Australia's patents system: Crown use and compulsory licensing. The Crown use provisions provide for the Crown to exploit a patented invention where the exploitation is necessary for the proper provision of services in Australia. Of course, the patentee needs to be remunerated for that exploitation. Secondly, a compulsory license can be sought where the patent holder fails to meet the reasonable requirements of the public or where they engage in anticompetitive conduct. While there have been few applications to the court since 1903 for such licenses, the mere availability of this option lends strength to prospective licensees in private negotiations.

Access and cost issues are not limited to the price individual patients might pay, although that is of course still relevant. Genetic tests and better markers bring about longer term savings to the healthcare system by allowing for more targeted treatments with better responses. These precise and targeted treatments are not simple. They require clinical testing of large patient groups and the investment of significant money to commercialise. Without a strong incentive such as the patent system being available to companies and researchers who wish to use them, there may be no or much slower access to newer and better tests. The patent system is an important element of the total innovation system and one which provides a significant implicit subsidy to Australian innovators, as noted by the IPRIA study of the patent premium, which has been provided to the committee previously.

A US interim report this year found that various factors other than patenting and licensing affect the price of genetic tests, including demand and market size. There is nothing to suggest that the cost of biotechnology inventions will not reduce with maturation of the technology, as has been the case with other technologies. In any changes to how Australia is to treat gene patents we ask that the committee consider all the potential impacts. Excising isolated nucleic acid molecules and proteins from patenting will adversely affect the viability and competitiveness of Australia's biotechnology industry in attracting commercialisation and R&D finance. It may also adversely affect industries other than health care. Inventions based on biologics have huge societal and commercial promise for agriculture and conservation, including bioremediation, water treatment, biofuels et cetera.

A patent system aligned with innovative economies underpins Australian researchers' ability to tap into collaborations with researchers or organisations in those economies. As noted in the Powering Ideas: an Innovation Agenda for the 21st Century, 'Australia has everything to gain' from participating in international R&D networks. A patent system out of step with our major trading partners and prime sources of foreign direct investment may adversely affect Australia's ability to participate in global technology supply chains and our rapid access to new capabilities, with inventors reluctant to transfer technology into jurisdictions with weak or no protection. Australia may not always have the skills, capabilities and/or infrastructure to easily imitate the technologies. Also the costs of IP protection will increase for Australian inventors who need to tailor their patents and enforce these across jurisdictions.

We believe that addressing the BRCA problem by excising isolated nucleic acid molecules from humans or other biologics from patentability, or 'all substances isolated from nature', as suggested by some, has far-reaching consequences. These consequences do not seem to be appreciated on the current evidence presented to the committee. IP Australia is pursuing a number of changes to Australia's patent law that would address some key concerns raised with the committee. The first is an explicit research exemption. The proposal would clarify the current situation and clearly delineate that research on the patented invention is allowed, for example: to determine how the invention works; to seek improvements to the invention; to determine unknown and useful properties of the invention; and to undertake trials for the purposes of obtaining regulatory approval for its exploitation.

The second includes a number of proposals aimed at increasing the inventive threshold requiring more than the current scintilla of inventiveness and aligning the scope of the patent to what the inventor has actually enabled. These proposals are quite technical but, for example, under the proposed changes for Chiron to obtain the original granted claims to the vaccine for Hep C in the Australian patent, Chiron would have had to provide more extensive experimental results showing that a vaccine had utility and a reproducible method for producing the vaccine. These changes will make it harder to satisfy the patentability thresholds and also limit the patent scope to that which is supported.

We believe that Crown use and compulsory licensing together with the implementation of the proposed reforms provide a more appropriate solution than seeking to excise from patentability isolated nucleic acid molecules and 'substances isolated from nature', which may have far-reaching and unintended consequences. We hope that your findings will lend support to these reforms. My colleagues and I would be happy assist and answer any further questions you may have regarding gene patents.

Senator HUMPHRIES—You will have seen what the ALRC had to say about the way in which patent offices—not just here but around the world—first approached the question of patenting inventions in relation to genes when it first became a new area of science and was beginning to grow. Someone earlier today put it fairly clearly. There was a temptation to rush in and patent things that with hindsight you would not be patenting today. I think the way they put it was that they thought the horse had bolted, that already it was too much through the gate to change the law after those sorts of things had occurred. Do you accept, if I have correctly summarised it, what the ALRC was saying there about too many patents, or patents over too wide an area, having been granted so many years ago and, if the same patents were being examined today, they would not have been granted—or at least as widely as they were granted?

Mrs Beattie—I think that some of the initial patents did have broad claims that may not have been supported as well as they could have been, but patent reforms that we are proposing would limit the scope of those claims to the extent that you would have to demonstrate utility. So we would be examining for specific utility and it would have to be specific, substantial and credible. To that effect you would not be able to say that a particular nucleic acid has a therapeutic effect, full stop. You would have to be very specific about the nature of the therapeutic effect that you expected this to have and provide some support for those claims. So, yes, I think some of the original patents that were broader may have been granted, but that is not to say that they should not have been granted, because they were discoveries.

Senator HUMPHRIES—Senator Heffernan has quoted from a number of patents that have been granted in the last five or six years, however, which do appear from the parts that have been quoted to the committee to be patents over genes per se, or gene sequences per se—isolated, yes, but still patents over genes. You would have heard the references to those patents over a number of hearings ad nauseam, and I would be surprised if you could not recite the passages off by heart by now. Have you looked at the patents that Senator Heffernan has referred to? Would you concede that they do appear to be patents over isolated gene sequences per se?

Mrs Beattie—They are patents over isolated gene sequences per se for which a practical use has been identified, therefore they are an invention.

Senator HUMPHRIES—You would still say that, if they were brought forward today in the light of all the discussion about where gene research is going, that they would still be patentable in the form that they were patented five or six years ago?

Mrs Beattie—If we were to re-examine those patents we have, we would be re-examining them on the basis of the prior art and the knowledge of the skilled worker at that time, and that is what we still do, and I believe that we would still find them to be inventions. If however you are asking me whether those same patents, if they were to be looked at today based on the current prior art and the current knowledge of the skilled worker, then I would say no, because much of the work has already been published.

Senator HUMPHRIES—But at the time they were granted the prior art was not to the extent that it would have prevented them being patented in the form that they were in fact patented?

Mrs Beattie—Sorry, can you repeat that question?

Senator HUMPHRIES—The prior art was obviously at a less advanced state five or six years ago, so putting ourselves back five or six years ago when these patents were granted, you are saying that their level of inventiveness was such that because they applied the patents in an isolated form to a particular use at that time it was a valid use of the power to patent that isolated gene sequence?

Mrs Beattie—An isolated gene sequence for which a practical use has been identified is an invention. That is the first hurdle. Then you need to look at whether it is novel and whether it is inventive. Therefore if we were to look at those same patents now, we would still determine that they were an invention, so it would pass that first hurdle. Then you would be looking at whether it is patentable, whether it meets the threshold of patentability as it currently exists, and because the genome has been published, for example, the gene sequences per se are now published, therefore they would not necessarily pass the novelty requirements.

Senator HUMPHRIES—You talked at the end of your opening statement about some of the reforms that you are proposing to Australian patent law. You say there are:

... a number of proposals aimed at increasing the inventive threshold requiring more than the current scintilla of inventiveness and aligning the scope of the patent to what the inventor has actually enabled.

This might be a hard question to answer but if you applied the kind of test that you are now aiming for to the patents that you granted five or six years ago, would you still have granted them, given the level of what has been described as the 'scintilla of inventiveness', the very small level of inventiveness that was actually involved allegedly with those particular patents?

Ms Press—That would depend on a case-by-case basis. Some patents would in fact still meet a higher inventive step threshold depending on what the art was at the time and its relationship to a disease and a diagnostic or a therapeutic that flowed from that invention. Any increase in the inventive step threshold would be across all technologies and it would be a harder test to meet.

Mrs Beattie—In terms of what we are proposing with the patent reforms some of those patents may have failed. If we were able to, for example, examine on utility, they may have failed on specific, substantial and credible. They may have failed in terms of the extent of enablement that has been provided in those claims or to support those claims. So there are some that may have failed in that regard. They would still be considered inventions and we would be putting them through the test of whether it satisfies the novelty inventive step description et cetera.

Senator HUMPHRIES—But it is possible that if you had a higher threshold of inventiveness, which I think is what you are implying, you are looking at engineering as part of these reforms.

Mrs Beattie—Yes.

Senator HUMPHRIES—It is possible some of these patents, the ones that Senator Heffernan has been referring to, might not have been granted.

Ms Press—Each case would be assessed on its merits in light of the art at the time.

Mrs Beattie—We do not want to seem to be equivocal here but it is very much based on having a look at each and every patent and having a look at each and every claim. You cannot make a broad brush statement that all of these patents would not have passed that threshold. It is very much a case-by-case requirement.

Senator HUMPHRIES—I realise that your proposals for reform are still emerging; they are not firm yet.

Mrs Beattie—They are in public consultation.

Senator HUMPHRIES—It would be useful for us if you were to actually look at the patents here. We want to see whether the tests should be made harder to get patents over processes involving gene sequences. I think that is the way the committee is tending. It would be interesting to know whether you think, in applying the sorts of tests that you are now talking about for high levels of inventiveness to be demonstrated, that patents like these would actually get through. That is a bit of ex post facto application of new rules or new tests. It may be that you are not in a position to do that. If you cannot, then do not worry about it. If you think that your tests are sufficiently robust to be able to do an exercise like that, I would appreciate it.

Mrs Beattie—I think it would be very difficult to do something like that because you do have to take into consideration the sorts of rebuttals that you would get from the Attorney. This is a process where an examiner would raise objections based on the interpretation of the law. The Attorney then has an opportunity to respond to that interpretation and provide additional support or evidence as necessary to support their rebuttal and it goes backwards and forwards. I do not think that would be the sort of process that I would want to undertake.

Senator HUMPHRIES—I understand what you are saying. You make the point in your opening statement about how products isolated from nature have for decades been used because of their isolation and practical application in a way that has allowed them to be patented. You mentioned the substance from the she-oak used for dyeing and the pancreatic secretions used for relieving diabetes. The argument has been made to us that what we are seeing with gene patenting is slightly different in that researchers, when they have gone back to a particular sequence to start doing their own research on that sequence over which someone has obtained a patent for a particular application, have been told: ‘No, you can’t use our patent on this gene sequence because we’ve got the patent on that. It’s ours. You can’t use that gene or that gene sequence.’ But what you are implying here with these examples is that people who went back to that particular fish and took the secretion of that fish and tried to find other uses for it would be able to do so, notwithstanding the patent granted for the relief of diabetes.

Mrs Beattie—No, if they went back to that fish and they extracted that same substance and then tried to apply it, they would not be able to because that substance, that molecule, is part of the product of that patent. Because it is in that isolated form, it is the same product that is patented.

Senator HUMPHRIES—Okay. Obviously that patent has long since expired, but if the patent was granted last year no-one would be able to use the secretions from that fish to invent some other—

Mrs Beattie—They may use it because they may find an alternative use for it. They would have to get a cross-licence in order to be able to exploit it for that alternative use.

Senator HUMPHRIES—They could not exploited, though, without coming to some arrangement with the owner of the patent over that secretion.

Mrs Beattie—That is right. Can I just note also that this issue of patents over the chemical product is an issue that was considered back in 1939, and it was dismissed because it did not make sense, it was highly illogical. That was the Knowles committee. When they were reviewing the Australian Patents Act they had submissions made to them that the Australian law should adopt the same sort of provisions that the English law had in that it precluded patenting of chemical products per se. The response that the committee had was that such an approach would be highly illogical: why should these things be treated differently to any other interventions?

Senator HEFFERNAN—We have got computers now. Things have changed since 1939.

Senator HUMPHRIES—You are saying to us the principles that applied to that granting of the fish gland secretion in 1924 are the same principles that we are using today?

Mrs Beattie—Yes.

Senator HUMPHRIES—We have heard, however, that the advisory committee, ACIP, is looking at changing the definition of what might be patentable.

Mrs Beattie—Yes.

Senator HUMPHRIES—If they can change that definition, how is it that we can still use the same principles that were used to grant those patents in 1924?

Mrs Beattie—They have not changed it yet. They are looking at whether it should be changed.

Senator HUMPHRIES—Sure, but—

Mrs Beattie—This comes back to the definition of invention.

Senator HUMPHRIES—Are you saying that they can change the definition of an invention and still be consistent with the principles in the Patents Act?

Mrs Beattie—My understanding is that they would be actually looking at changing how ‘invention’ is to be defined in the Patents Act, so they are looking at a replacement for the manner of manufacture, which in fact is the invention component within the Patents Act.

Senator HUMPHRIES—You seem to be telling us here that there are consistent principles which are used for all kinds of patents that distinguish between inventions and discoveries. But we have here a particular exercise which is going on in another part of government to have a different definition imposed on what is an invention with respect to a particular kind of patent—that is, patents over products relating to genes and gene sequences. Have I understood that process correctly?

Mrs Beattie—They are not looking at just genes and gene sequences. They are looking at the test of manner of manufacture—the invention test, in fact.

Senator HEFFERNAN—But they are looking at genes and gene sequences as well? You said ‘not just’.

Mrs Beattie—They are looking at the test itself. They are not focusing on the gene sequences as such.

Senator HUMPHRIES—You said that there are in force 202 Australian patents claiming an isolated human nucleic acid molecule. Can we find out a bit about those patents? What would the average age of them be, for example? You might have to take that on notice.

Ms Press—Most of those were granted before the publication of the human genome in 2003, so those 202 are the BRCA-style type of gene patent that claim over the normal or wild-type of gene, which is the reference type of gene, which is not associated with the disease phenotype. So

it would include that and basically all uses of that gene sequence. So the majority of those had been granted before 2003.

Senator HUMPHRIES—Okay. Can you take on notice how many have been granted since 2003 and give us a breakdown of how many in each year since 2003 which claimed an isolated human nucleic acid molecule.

Ms Press—Yes.

Senator HUMPHRIES—Your opening statement refers to 202 Australian patents claiming an isolated human nucleic acid molecule—which I assume is a reference to a patent over a human gene or gene sequence. Is that roughly what we are talking about?

Ms Press—Yes.

Mrs Beattie—It is not over a human gene. It is over the isolated human gene sequence for which a practical use has been identified.

Senator HUMPHRIES—We have had a succession of representatives of research organisations—Cancer Australia and so on—come before us and they have spoken about the fear, confusion and lack of certainty about the capacity to research in these areas at the present time, because of the effect of holders of patents over gene sequences preventing access to certain kinds of research. You have spoken about solutions being available through things like the crown use provisions, compulsory licensing and so on, but it did not sound to us as if any people working in that research sector really knew about those things or understood the effect of those things on their research. Would you accept that it is extremely damaging to the quality and thrust of Australian research if people working in those fields do not understand what they can do and that, to find out what they need to do, they will generally need to patent lawyers and so on, which would be an expense that most research facilities in Australia would not want to divert much of their resources into? Do you think there is a role for IP Australia to go out there and either clarify the way the law stands, in a plain English way, or even to undertake an education program of those researching in Australia about what they can and cannot do with respect to existing patents?

Mrs Beattie—What I heard was that research institutes that do research seem to understand and do not have any fear about the patent system and it does not seem to be restricting them in that regard. The institutes which have research and provide clinical services have the fear, because they are effectively exploiting patents, so it is not pure research; it is also exploitation of the patented invention. Our understanding is that all of those institutes have intellectual property policies in place. IP Australia also does have a public education and awareness program, and we have provided public education and awareness publications, seminars, et cetera. We also had a program into the universities, and we also have a program in terms of small to medium enterprises. If the committee were to suggest that we needed to do something more in relation to the research institutions, obviously IP Australia could have look at that as part of that program of public education and awareness.

Senator HUMPHRIES—Groups like the Peter MacCallum institute do a lot of research work and then try and exploit that for practical application. I am sure it would be a concern to you if

they did not understand where they stood in respect of what they could exploit of their discoveries that built on existing patents.

Ms Press—If you look at our database you will see Peter MacCallum institute has 50 patents applications filed, all of which are not current. So it has a history of knowledge of the patents system, like most research institutes. University institutes now usually have an intellectual property division that disseminates knowledge about patents to researchers.

Senator HUMPHRIES—But you heard them say how uncertain they felt about where they could go. They talked about how clinical trials were being held up because of the need to negotiate licensing arrangements and so on with patent holders.

Ms Press—I think they had knowledge of that. There may have been a delay. I think Peter MacCallum's research also involved a preliminary diagnosis which was provided to the women who were donating their samples of tissues or blood. Perhaps that avenue of the research project delayed licensing arrangements.

Mrs Beattie—What I heard in that regard was that in fact the delay did not occur because of a patentee. The patentee was happy to engage with them in that research program. They realised, though, that because there was a degree of exploitation rather than just research they may have been in breach of the license agreement that they had with GTG. That is why the program was then moved out of Australia and undertaken that way.

Senator HEFFERNAN—Would you be able to provide on notice to the committee the logic behind, and the process that you went through in, granting the epilepsy patent, for instance, which was filed on 10 March 2004?

Ms Press—This was comprehensively examined. It went through five—

Senator HEFFERNAN—I would like to see the full paper trail that made you arrive at the decision that it was okay to isolate the gene, just to see how you test the logic. You said you test the logic of the isolation.

Mrs Beattie—All the patent files are publicly available.

Senator HEFFERNAN—But we want to see the work that you do: the decisions, the minutes of the meeting or whatever happens.

Mrs Beattie—Absolutely. That is available to the public, so you can access the examination—

Senator HEFFERNAN—I am asking you to provide it.

CHAIR—Senator Heffernan, let Mrs Beattie finish.

Mrs Beattie—All the examination reports are available. The submissions made by the applicants are available on the file. Any member of the public can request those documents from the Patent Office and they will be provided. There is a concept called 'open for public

inspection' that occurs at 18 months. From the 18-month mark everything that is on that file, including the application, is open to the public.

Senator HEFFERNAN—But we want you to provide it. We do not want to go searching for it. Could I just take you through the logic of what—

CHAIR—Before you go on, Senator Heffernan, to clarify: are you able to provide that information to the committee?

Mrs Beattie—I can provide you the full copies of the files.

CHAIR—Thank you.

Senator HEFFERNAN—I will go to what would have been the process for this particular patent. It says 'the method for determining the likelihood that the patient is suspected' et cetera, and it is very broad in comprising testing a patient's sample for the existence of an alteration in the SCN1A gene of the patient, including a regulatory regime of the gene. The way this claim reads for the epilepsy patent, which was granted in 2003, it appears that any method is covered, which really means that anyone else trying to approach this problem of testing cannot do it.

Ms Press—No, I do not agree with that construction of the claim and the specification at all. There are two arms to this. It does not prevent people from working on the gene, because there is no claim in this patent to the wild type, normal SCN1A gene. That was identified and published in the non-patent literature, in *Nature Genetics*, in 2000. So the sequence is not novel. The claims in this are to mutated variants of that gene of clinical significance both to Dravet's syndrome epilepsy and to other types of epilepsy. This gene is also involved in many other diseases, migraine being one, and this patent does not tie it up. It is not a conventional diagnostic method and in the patent specification there are many pages devoted to the ways that this may be put in place with current methodology. So it does not prevent—

Senator HEFFERNAN—If we provide to you two or three patents and ask you to provide us with the logic that allows you as recently as last year to grant a patent on an isolated gene—

Ms Press—Which patent is that?

Senator HEFFERNAN—I will provide it to you. I have it back in the office. It was 18 months ago, to be accurate, you allowed the patent of an isolated series of genes. I will provide you that. That was a long way from when the human genome was plotted. I want to go to two genes, given that we have the Ageing people here, and the hep C gene. The claim on the virus in pure form, which is claimed in the hep C patent—a purified HCV polynucleotide—is actually the claim on the virus, isn't it?

Ms Press—I thought your question was to Health.

Senator HEFFERNAN—You have a battalion of people with you. Can someone answer it?

Mrs Beattie—Who are you asking the question of?

Ms Press—I thought your question was directed to Health.

Senator HEFFERNAN—No, I am going to come to the Ageing one shortly. The questions will be directed to you.

Ms Press—Sorry, Senator—you might have to repeat the question. Which claim?

Senator HEFFERNAN—The HCVC DNA.

Ms Press—And which claim? The claims define the monopoly.

Senator HEFFERNAN—Claim No. 1 is on a purified HCV polynucleotide.

Ms Press—Those claims have not been part of the granted monopoly for the last 11 years.

Senator HEFFERNAN—That is right—they have expired.

Ms Press—The patent expired in 2008. The claim set was amended in 1997, so for the last 11 years of the patent these claims were not part of the granted monopoly.

Senator HEFFERNAN—But the patent included a vaccine.

Ms Press—The granted patent for eight years included a claim to a vaccine.

Senator HEFFERNAN—We are just trying to get our heads around this. It is pretty technical. So this patent, when it was granted, included a vaccine. You will agree with that?

Ms Press—That is right, because there was support in the patent for immunological—

Senator HEFFERNAN—Yes, all right.

Mrs Beattie—Senator, could she answer the question that you asked, please.

Ms Press—There is experimental support in the patent that many of these polypeptides were immunogenic and it was reasonable to extrapolate from the art of the time that a vaccine would have been possible to produce, and we know that researchers need upstream protection.

Senator HEFFERNAN—So, for all the life of the patent, they had a claim over the vaccine?

Ms Press—No, they did not, because the claims were amended and there has been no claim to a vaccine for the last 11 years.

Senator HEFFERNAN—But how do you grant a patent on something that does not exist?

Ms Press—Because it is reasonable to extrapolate. An inventor does not actually have to have the vaccine, if there is a reasonable scientific basis to extrapolate from the experimental data provided.

Senator HEFFERNAN—So, if I and my learned friend here are both working on something—in this case, a hep C virus—and I claim the vaccine, does that prevent my learned friend here from doing work that might also arrive at the same vaccine—he wins and I don't?

Ms Press—No, he is not prevented from research. People working in the art and hepatitis C vaccine would know that there was not a vaccine available. They would know that there was not a commercially available vaccine. So they have an incentive to go and research further.

Senator HEFFERNAN—We have heard from a range of people—except for the Eliza Hall mob, who are in the business of being in the business—even including the lawyers down in Melbourne, that there is a certain level of uncertainty in what you can and cannot do under the present arrangements. That is fair enough. You do not think there is uncertainty. Why are they wrong and you are right?

Mrs Beattie—Organisations that I have spoken to that do pure research do not have concerns about whether or not they might be infringing a patent, because they believe there is a common-law exclusion—

Senator HEFFERNAN—But even the patent lawyers were uncertain.

Mrs Beattie—I am conveying to you what I have been told by researchers. However, they all acknowledge that it is not a statutory exclusion that is available and that they would not mind having a statutory exclusion available.

Senator HEFFERNAN—That is very bureaucratic.

Mrs Beattie—Sorry, I am having difficulty hearing.

CHAIR—That is good. Senator Heffernan, you need to speak up and not make under-your-breath comments.

Senator HEFFERNAN—Do you think, then, that there is no uncertainty?

Mrs Beattie—Uncertainty in relation to what, Senator?

Senator HEFFERNAN—We just talked about it. We have had evidence from umpteen people saying there is uncertainty on the boundaries of what you can and cannot do, including from people like Peter MacCallum and a bunch of lawyers. You do not think they are right? Do you only hear from the people who say that is not right?

Mrs Beattie—There is a product called a 'Freedom to Operate' search that anyone can have commissioned to be done. That provides people with a clear understanding of where they can undertake work in order not to infringe the patents that are in that area. I have not heard any of the providers of the Freedom to Operate searches telling me that they cannot do those searches, that there is uncertainty.

Senator HEFFERNAN—That is not my question. We have had a series of witnesses—clinical, legal and professional—say that this is an area of uncertainty. My question is: are they wrong?

Mrs Beattie—I am not sure that I understand where the cause of the uncertainty lies.

Senator HEFFERNAN—Maybe Senator Humphries could help me out.

Mrs Beattie—Is it because there are patents out there and they are uncertain what they can and cannot do? I am saying that there is this product called the Freedom to Operate search that you can commission, and that tells you where your freedom to operate is.

Senator HUMPHRIES—My recollection of the evidence was that they expressed a lack of certainty about how the research exemption operated and how the ‘Crown use’ provisions operated. It is in their evidence. I think it would be useful if you went back and had a look at what the Walter and Eliza Hall Institute and the patent attorneys said about it. I recall that they made comments about the need for clarification.

Mrs Beattie—There is no clear statutory exemption for research at present. That is what we are trying to—

Senator HUMPHRIES—Can I cut in, though. That is not the issue that is being raised by Senator Heffernan. He is not asking what the law is; he is asking whether people seem to understand what the law is as they go about using it. Those witnesses expressed concern about the lack of certainty of what the law said about that.

Mrs Beattie—If they are uncertain about the law, there are legal advisors from whom they can get that understanding—or they can access the IP Australia website.

CHAIR—We have to finish this in 10 minutes so can I just clarify. People understood the law. The law is uncertain itself, and you have said so in terms of, ‘there is no exemption for research.’ It is the interpretation of the lack of exemption that people are concerned about. They do not need advice on the law because they know that the exemption does not exist. There is assumption of the exemption. That is what people are having problems with. I thought we were at that point about five minutes ago when you said that people are saying that they want the law clarified.

Mrs Beattie—I am supportive of the view that the law needs to be clarified, but I am also conscious that there are some research organisations out there that believe that there is a common law exemption for research, and that is why they continue to research it.

CHAIR—Senator Heffernan, is that now clear or is there something else you would like?

Senator HEFFERNAN—I think we are going to have another go maybe at some other time.

CHAIR—Maybe you could take the time to look at the evidence and you may want to elaborate further on what we have just discussed. Could you take that on notice for us?

Mrs Beattie—In relation to the research?

CHAIR—Yes.

Senator HEFFERNAN—This year you have called for several reviews. How many?

Mrs Beattie—We have a patent reform process underway that is being undertaken in the context of the innovation review the government initiated late last year.

Senator HEFFERNAN—Is that since the BRCA thing hit the airwaves?

Mrs Beattie—No, sir, it is not as a result of that.

Senator HEFFERNAN—That was not the question. Is it since it has hit the airwaves?

Mrs Beattie—Which BRCA? The one this year?

Senator HEFFERNAN—You were putting everyone on notice last year. It happened in July. The legal letters went out.

Mrs Beattie—The patent reform was not instigated as a result of the BRCA issue.

Senator HEFFERNAN—That is not my question because you could ‘lawyer’ that any way you like.

Mrs Beattie—I am not a lawyer, sir.

Senator HEFFERNAN—Has it happened since the laboratories were put on notice?

CHAIR—When did you start the process? That is the easiest way to ask the question.

Mrs Beattie—I did have a brief that told me. I am sorry, I cannot put my finger on a timetable that I had. The closing time for the first paper was on 30 June so it would have been probably April-May when the first public consultation paper was issued. As you know, there is a whole lot of process that goes before that in terms of drafting those papers and in terms of getting ministerial approval. It would have been at least 12 months before that we would have been starting to do that work.

Senator HEFFERNAN—That is in 2008?

Mrs Beattie—Yes.

Senator HEFFERNAN—I have here—which I am not authorised to table yet—a complaint about the process that says, in effect—and it may not be right: ‘While I am pleased that IP recognises the need for IP law reform, particularly with respect to the patent system, it is respectfully unfair and unhelpful of IP Australia to have released seven consultation papers since March.’

Mrs Beattie—The first two papers were released—and I cannot recall the exact date—but the responses were due by 30 June and then they were extended to, I think, by another period.

Senator HEFFERNAN—When were they released?

Mrs Beattie—I am not sure.

Senator HEFFERNAN—Can you take that on notice?

Mrs Beattie—I think, Senator, that that particular complaint has been responded to directly to the complainant.

Senator HEFFERNAN—But not to this committee.

Mrs Beattie—Is this committee having a concern about the process? Is that what you are telling me?

Senator HEFFERNAN—No. We are trying to gather all the information we can. You may not like it, but we are trying to gather all the information we can to form a view, so we would like you to respond to us on the details of whether you have released seven consultation papers since March, on top of another review of patentable subject matter. We just want to know what sort of a crowded program you have created for people that take an interest in this. You can take that on notice.

CHAIR—Perhaps we could have a time line.

Mrs Beattie—I am happy to do that.

Senator HEFFERNAN—In the case of the ageing gene—

Ms Press—What serial number is that?

Senator HEFFERNAN—It is 728863. In claim 1, they claim the isolated gene. You would agree with that?

Ms Press—Yes.

Senator HEFFERNAN—And that produces the anti-ageing protein?

Ms Press—Anti-apoptosis, yes.

Senator HEFFERNAN—Is that novel, inventive and a discovery?

Ms Press—It is novel and inventive. It was granted in 2001.

Senator HEFFERNAN—Could we see the paperwork that allowed you to go through that process?

Ms Press—You want a copy of the file?

Senator HEFFERNAN—Yes. They claim an antibody, in claim 22.

Ms Press—That is right.

Senator HEFFERNAN—If the body creates the antibody, how can you claim it as a patent?

Ms Press—Our bodies do create antibodies, but not to our genes.

Senator HEFFERNAN—But this is part of the human body.

Ms Press—No, it is not. With respect, Senator, it is a claim to an engineered antibody. That is a derivative that is genetically engineered and related to that gene sequence. Healthy bodies do not normally create antibodies to our genes.

Senator HEFFERNAN—Are you saying that an antibody specific to the polypeptide is not part of the human body?

Ms Press—That is right. It would be an isolated and engineered antibody. It made a monoclonal polyclonal.

Senator HEFFERNAN—Is it in any different form than it would appear in the body?

Ms Press—No, because it does not appear in the body. We make antibodies if we are infected with swine flu, but we do not make antibodies to that isolated nucleotide.

CHAIR—I am really conscious of the time, and Senator Humphries has some more questions.

Senator HEFFERNAN—Fair enough.

CHAIR—To go to the point on that one: that was a purely synthetic antibody that the body would never have generated.

Ms Press—I would need scientific evidence to show that the normal body creates antibodies to our genes.

Senator HEFFERNAN—And we have got a long way to go.

Senator HUMPHRIES—I think you were here and heard Dr Rimmer and Professor Drahos say that they did not think that the TRIPS agreement or the free trade agreement with the United States were couched in such a way as would prevent us from modifying our law with respect to the patenting of gene sequences. Do you agree with them? If not, why not?

Mrs Beattie—The TRIPS agreement is a treaty which sets the minimum standards. TRIPS does not actually have a definition of invention, therefore the interpretation could be that you could define invention in whatever way you wished to do so.

Senator HUMPHRIES—So we could modify gene-patenting law without being inconsistent with TRIPS.

Ms Huynh—With the qualification that you cannot discriminate against a field of technology if you are going on a non-invention basis.

Senator HUMPHRIES—Would the exemption in TRIPS for diagnostic, therapeutic and surgical treatment of humans also be a way in which we could approach human-gene-patenting processes which lead to remedies for human illnesses? Would that be a way of dealing with that consistent with the TRIPS agreement?

Mrs Beattie—That particular exclusion relates to the methods of treatment, not the products as such. So, if you were seeking to exclude the patenting of a nucleic acid type, that is a product, not a method, therefore you would not be able to exclude patents for isolated nucleic acid molecules. A method of treatment you can exclude. My understanding from the evidence is that that is not what people want.

Senator HUMPHRIES—So is Senator Heffernan's diagnostic treatment for epilepsy caught by that exemption or not?

Mrs Beattie—The method of treatment—it might be that the actual method claims would be able to be excluded from this.

Senator HEFFERNAN—'Might' or do we need to clarify?

Mrs Beattie—This talks about methods of diagnosis—therapeutic methods, surgical methods. So if the claim is to a method then that patent could be excluded. If, however, the patent is for the product then this exclusion would not work.

Senator HEFFERNAN—No wonder there are so many lawyers in the world!

Senator MOORE—I am interested, certainly with the department's submission, first of all about the affordable access to health care and the research and development. We have had differing evidence. Under 'Affordable access to health care' your submissions states:

... found little evidence that gene patents and licensing practices with respect to genetic testing and clinical research and development have had any significant impact on the cost of health care in Australia.

Certainly we have been aware that there have not been too many cases to date. You do talk about BRCA 1 and 2. I would really like to have on record exactly what the department's role was in working through that. State and federal governments came forward in that area and we have had evidence that says that is the type of thing that is going to continue to happen. It is almost like this is a test case of what could happen if we do get into this situation of increasingly looking at research and treatment dollars being affected by gene patents. I take the point and I think all the evidence has shown that there has been little evidence to date that says there has been a huge impact. I am sure you have read the submissions. A number of people have said we are at the start of something that is going to get bigger and bigger. I would like to get some comment from the department about that point. In particular, what did you have to do as departments of health

to step in when the threat was being given that the gene testing for breast and ovarian cancer could have been under threat by a gene process?

Ms McDonald—My understanding is that you have really got two questions there. One is about the current situation in relation to affordability and the other is in relation to the BRCA gene. At the moment we are at the beginning of working through what will happen. We have had, as you are aware, some approvals for funding for various genetic tests, and a number of those are covered under the MBS. They go through the standard MBS approval processes. I think we also mentioned in our submission that we are doing a review at the moment in relation to health technology assessments, which is really responding to the changing technologies that are coming forward and our assessment processes and approvals and how in the future they will enable us to ensure that we do have appropriate health technologies able to be approved through our mechanisms. So that review is underway at the moment. In relation to the issue of the BRCA genes, I think Chris Reid has a bit of a background in relation to that.

Mr Reid—I do. The BRCA gene problem came to the attention of the department of health through a state-Commonwealth committee which discusses things of this nature from time to time.

Senator MOORE—Mr Reid, does that have a special name?

Mr Reid—It does, but I am struggling to remember what it is.

Senator MOORE—Take it on notice. I am sure it does.

Mr Reid—The Commonwealth was made aware that this issue had arisen. We got a copy of the letter from GTL. There were some discussions about that. One outcome of that was that we initiated discussions with the ACCC because it seemed to us that what was being done by GTL might conceivably breach the Trade Practices Act. Those discussions led to the ACCC making a decision to investigate and there were some investigations. I cannot tell you a lot about those investigations because I was not involved in them.

The process of discussion involved looking at various options for what, if anything, needed to be done about what GTL was doing. That was a problem that needed to be dealt with at a state or a Commonwealth level. It involved exclusively state laboratories, which were being told to discontinue testing, so it was not something that directly affected the Commonwealth; it was something that was susceptible to being dealt with at a state level. For example, the crown use provisions of the Patents Act could be activated by state governments if they chose to do, so there was some discussion about whether that was a way to approach it. There was some discussion about getting advice, particularly amongst the states, about the validity of the GTL patents, although to my knowledge that advice was never obtained. In the event, the matter was resolved by GTL effectively withdrawing the ultimatum that they had initially given. Whether that was a result of the ACCC investigation I have no idea, but that is possibly what generated GTL's decision to withdraw their ultimatum.

Senator MOORE—That is the second time this company has withdrawn—

Mr Reid—It is.

Senator MOORE—which could mean that at any time in the future it could come back into play—is that how, as a lawyer, you see it?

Mr Reid—As a matter of practical possibility they could do that again.

Senator HEFFERNAN—No trouble at all.

Senator MOORE—The issue I am trying to get on record is that this could have an impact on our Australian health system, and that has not been fleshed out very much in the evidence to date. We have had evidence from research facilities in Melbourne and Sydney. In Melbourne we heard about a particular program of research that was delayed significantly because of discussions around one particular patent and the licence—because there are two things involved: the American patent and the Australian licence. I forget the timing, but it was a very long period in a research project in which very important research was delayed because of that ongoing action.

We heard in Sydney from a couple of hospitals, and doctors from those hospitals, that it was only through the support that their state governments gave them—they said that they would be behind them if they were subject to any kind of action—that they were able to continue with their day-to-day work with their clients, all of whom were particularly needy and had another level of stress placed on them, in an already stressful environment, by this process going on. As yet we have not really had put on record what this kind of thing could potentially do to our health program.

Mr Reid—I suppose the concern of the Department of Health and Ageing was essentially about whether this testing was going to continue to be made available—

Senator HEFFERNAN—And at what price.

Mr Reid—and at what price. In fact, GTL were saying not that they were going to stop the testing but that they would do all the testing.

Senator MOORE—That is right; it was the cost aspect.

Mr Reid—So, in a sense, if the testing got done then that would not be a big problem for us, but cost could be a problem. In terms of the cost that GTL were proposing to charge for the testing, my understanding is that it was pretty much on par with what was being charged by state laboratories to do the testing. My recollection of the demands that were made was that that price was going to be held stable over a period of time. There did not appear to be an immediate threat that the price would be pushed up to a level where it would effectively stop testing happening. I guess that whole context generated our thinking about it. Had it reached the point where testing was going to stop or where it was going to become so expensive that it would effectively prevent access to testing then we would have become much more concerned than we had been.

Senator MOORE—That would have stimulated further involvement. So it was about seeing what the impact was and getting involved to the extent that you needed to at the time.

Mr Reid—That is right, yes.

Senator MOORE—And is it the case that only the Commonwealth has been involved up to now?

Mr Reid—That is the only one that I am aware of. It may have happened in the more distant past, but my understanding is that that is the only one.

Senator HEFFERNAN—Can I continue?

CHAIR—One question.

Senator HEFFERNAN—A couple. You would be well aware that the BRCA is actually four different patents. BRCA1 expires in 2015 and BRCA2 expires in 2016. The BRCA1 and 2 patents define the primary invention to be the isolated nucleic acid—that is, DNA that has been removed from the human body. So there is no question that they have patented the actual gene in its isolated form.

Mr Reid—I think that is probably a question that I should refer to my colleagues at IP Australia.

Senator HEFFERNAN—The BRCA1 patent, 691331, defines the primary invention to be any method of detecting in a human being the DNA or a biological derivative of the human gene that codes for the mutant protein BRCA1. There is the discovery in there, as part of the four patents, but the invention is in there as well. We heard evidence in Melbourne, from the Peter MacCallum Cancer Centre, that if they had lost their testing work they would have lost their critical mass as a laboratory, doing what they do. That would be pretty serious, wouldn't it?

Mr Reid—That would be of concern, yes.

Senator HEFFERNAN—That is the evidence we received. Suppose Genetic Technologies Ltd happened to go broke because they were in a shaky financial position—and I wish them well. I asked this question of the since resigned CEO and of officers from the department. They told me that they would be sold up and they would sell their goods and chattels. Part of their goods and chattels would be the patents—the financial tradable instruments. One of the fears that the clinicians have is that this eventually becomes just another river of gold, as it were, for lawyers and bankers. The clinicians who tire away with a vocation for better health become a side-effect of all of that. It would be possible, wouldn't it, that, if a company like Genetic Technologies went broke, any person who bid the highest money for the patents could buy them, like an exploration licence?

Mr Reid—As a general proposition, that is correct.

Senator HEFFERNAN—So a bloke who lives on the Gold Coast and launders drug money could own the patents?

CHAIR—We do not need to draw that analogy.

Senator HEFFERNAN—But I mean absolutely anybody as far removed as possible from the clinical side. We have seen the evidence in Canada. Once they got the monopoly in place, up she went—the cost of the test—by 250 per cent. That could happen here.

Mr Reid—It could not happen, as I understand the position, with Genetic Technologies because they have a licence to use the patent in Australia. They do not own the patent itself.

Senator HEFFERNAN—But they can charge as they see fit here, I presume?

Mr Reid—To exercise the patent themselves?

Senator HEFFERNAN—Yes. The service for the test. Myriad Genetics, in America, are trying to get broad screening, which the scientists have told some doctors you do not need to do. But they are trying to get a broader community screening program just to get the money in. Hopefully, that will not happen here. But the point is that if, after having their lawyers travel through the feast hall, they won and everything was surrendered to their lab in Victoria, they would be the monopoly holder in Australia.

Mr Reid—They would be the monopoly holder of the licence to use the gene in Australia.

Senator HEFFERNAN—If they cared to they could exploit the fact that ‘you will do all your testing here’.

Mr Reid—They could, but subject to a couple of things. One is the accessing of somebody who wanted to use the patent under the compulsory licensing provisions of the Patents Act or, conceivably, use of the Crown use provisions in the Patents Act.

Senator HEFFERNAN—Yes, I appreciate that.

CHAIR—Senator Heffernan, we are way over time.

Senator HEFFERNAN—Okay. We will come back another time.

CHAIR—Dr Morris, you have been very quiet and patient. Do you have any concerns about the existing arrangements, particularly in light of the evidence we have received?

Dr Morris—The NHMRC, in its submissions to the Australian Law Reform Commission in 2003 and, I think, subsequently to this committee, has spoken about the researchers’ exemption and the need for clarity which researchers have expressed. We have said recently that we support the position of the Advisory Council on Intellectual Property that this should be made more clear in legislation.

CHAIR—In view of the late hour, perhaps Mrs Beattie you could take these two questions on notice. There is one on the issues of patent quality. You were here when we were receiving evidence earlier from Professor Drahos.

Mrs Beattie—I would like to answer that, if I may, rather than take it on notice. Patent quality has two dimensions to it. One is patent quality in terms of the patentability threshold and that is

about what the legislation defines as the requirements to obtain a patent. Some of the discussion you may have heard in evidence today relates to that dimension of patent quality. The patent reform provisions are looking to address that element. The other dimension of patent quality is in relation to what I call applied quality and that is around how the patent examiner interprets the requirements of the legislation and applies it to the applications. In terms of the applied quality, IP Australia has a number of quality mechanisms in place, including an external auditing arrangement under the ISO 9001 quality standard. We have external auditors who come in to check our quality system, to ensure that all our procedures are in place and that the examiners who use those procedures understand them and are applying them. On top of that we also have what we call product quality checks, which are done by our senior examiners—random samples of patents which have been progressed are examined, looked at by senior examiners to determine that the examiners have applied the appropriate interpretations of the law.

We are currently also putting in place an improvement on that particular product quality regime. That will be rolled out over the next 12 months. There are two elements and the legislative element is the one being addressed through the patent reform, and of course we have our internal elements. In terms of our internal element, the applied quality, we also do benchmarking exercises with other patent offices. We have patent examiners from other offices looking at the work we have done. We compare notes to see whether we have all interpreted the legislation in the same way and that the principles have been applied in the same way.

CHAIR—The other comment made was that some of the recommendations from the ALRC report are now outdated. Do you have a comment on that?

Mrs Beattie—I am not sure which recommendations the other witnesses refer to as being outdated. I think it would be appropriate to get some understanding of which ones they think are outdated.

CHAIR—Perhaps you could look at today's *Hansard* when it becomes available and give us some feedback.

Mrs Beattie—I did not hear them mention a specific recommendation being outdated. I am concerned that it might be a bit vague. I am happy to take it on notice and have a look to see whether a specific recommendation was referred to as being outdated.

CHAIR—That would be appreciated.

Senator HUMPHRIES—I think we should clarify Dr Morris' status. Dr Morris, you are a real doctor—that is, you have a doctoral degree from a university.

Dr Morris—I have a PhD from the University of Queensland.

Senator HUMPHRIES—Right. It is not a courtesy title; it is a real title.

Senator MOORE—Which is a very good place to have one from, Dr Morris.

Senator HEFFERNAN—It is paper one, but not a medical one.

Senator HUMPHRIES—He is a real doctor!

CHAIR—Thank you very much.

Committee adjourned at 6.50 pm