COMMONWEALTH OF AUSTRALIA

Proof Committee Hansard

SENATE

LEGAL AND CONSTITUTIONAL AFFAIRS LEGISLATION COMMITTEE

Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2]

(Public)

FRIDAY, 29 APRIL 2011

CANBERRA

CONDITIONS OF DISTRIBUTION

This is an uncorrected proof of evidence taken before the committee.
It is made available under the condition that it is recognised as such.

BY AUTHORITY OF THE SENATE

[PROOF COPY]

TO EXPEDITE DELIVERY, THIS TRANSCRIPT HAS NOT BEEN SUBEDITED

INTERNET

Hansard transcripts of public hearings are made available on the internet when authorised by the committee.

The internet address is:

http://www.aph.gov.au/hansard

To search the parliamentary database, go to:

http://parlinfo.aph.gov.au

SENATE

LEGAL AND CONSTITUTIONAL AFFAIRS LEGISLATION COMMITTEE

Friday, 29 April 2011

Senators in attendance: Senators Crossin, Heffernan, Humphries, Pratt, Trood, Xenophon

Terms of reference for the inquiry:

To inquire into and report on:

Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2]

WITNESSES

BEATTIE, Mrs Fatima, Deputy Director-General, IP Australia 33

CHRISTIE, Professor Andrew, Private capacity 27

COSSEY, Mr Matthew, Chief Executive Officer, CropLife Australia Ltd 2

HALTON, Ms Jane, Secretary, Department of Health and Ageing 33

LAVELLE, Dr Anna, Chief Executive Officer, AusBiotech Ltd 2

LUNN, Mr Peter, Manager, Pharmaceuticals and Health Technologies Section, Department of Innovation, Industry, Science and Research 33

McDONALD, Ms Mary, First Assistant Secretary, Regulatory Policy and Governance Division, Department of Health and Ageing 33

MOORE, Ms Terry, Director, Domestic Policy, IP Australia 33

PALOMBI, Dr Luigi, Private capacity 14

PETERS, Dr Kirrily, Manager, Pharmaceuticals Industry Strategy and Environment Section, Department of Innovation, Industry, Science and Research 33

PRESS, Ms Lexie, Examiner of Patents, IP Australia 33

QUINN, Mr Daniel, Policy Manager, Biotechnology, and Policy Manager, Minor Use, CropLife Australia Ltd 2

REID, Mr Alexander Christie Arnaud (Chris), General Counsel, Department of Health and Ageing 33

Committee met at 08:47

CHAIR (Senator Crossin): I declare open this public hearing of the Senate Legal and Constitutional Affairs Legislation Committee inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2]. This inquiry was referred by the Senate to the committee on 26 November 2010 for inquiry and report by 16 June 2011. We have received 112 submissions to the inquiry. Public submissions that have been authorised for publication have been made available on the committee's website.

I remind witnesses that in giving evidence to the committee they are protected by parliamentary privilege. It is unlawful for anyone to threaten or disadvantage a witness on account of evidence given to a committee, and such action may be treated by the Senate as a contempt. It is also a contempt to give false or misleading evidence to the committee. We prefer all evidence to be given in public, but under the Senate's resolutions witnesses can ask to be heard in private session, or in camera. If you want to do that you just need to advise us and we will facilitate that happening.

[08:49]

COSSEY, Mr Matthew, Chief Executive Officer, CropLife Australia Ltd

LAVELLE, Dr Anna, Chief Executive Officer, AusBiotech Ltd

QUINN, Mr Daniel, Policy Manager, Biotechnology, and Policy Manager, Minor Use, CropLife Australia Ltd

CHAIR: I now formally welcome our first representatives and witnesses this morning from AusBiotech and CropLife Australia. AusBiotech has lodged a submission with us. We have numbered it 97 for our purposes. CropLife Australia's submission has been numbered 65. I assume that there are no alterations or amendments to be made to those submissions? I therefore invite you to make an opening statement and then we will go to questions.

Dr Lavelle: Thank you, Madam Chair, and good morning, senators. I appreciate the opportunity to appear before the committee today on behalf of Australia's biotechnology industry to discuss an issue of vital importance to the public's access to new treatments, diagnostics and technologies; to Australia's biotechnology industry; and to continued growth of investment in innovation in Australia. AusBiotech is Australia's national biotechnology industry association, which represents over 3,000 members, encompassing medicines, medical devices and diagnostics and agricultural, environmental and industrial sectors of biotechnology. I will focus on human health today, and my colleague Mr Cossey will comment on impacts in the agriculture industry.

AusBiotech shares the genuine concerns raised by the community and others. They are that clinicians and scientific researchers should be free to conduct research on or use biological materials that may be the subject of patents, that public access to innovation and beneficial tests and therapeutics should be improved and that the thresholds for patentability should be properly set and rigorously applied. AusBiotech believes that the proposed bill fails completely to address any of these valid concerns and should therefore be rejected. The bill does not serve the interests of patients, clinicians or industry; in fact, the bill threatens the foundation of scientific research and development of biological materials which are built on patents. If this bill becomes law, it is likely to have far-reaching and serious consequences. In this view, AusBiotech is aligned with an overwhelming two-thirds majority of submissions made to the Senate inquiry.

While we believe the architects of the bill are well intentioned—and that is my sincere belief—AusBiotech and many others feel that the bill was drafted with little regard to the consequences and that the bill actually places at risk the timely access of Australians to life-changing medicines and diagnostics, the ability of clinicians and researchers to conduct medical and agricultural research in this country and the future of the Australian biotechnology and medicines industries. The absence of patents for biological materials will extinguish the promise of future returns and therefore halt investment in innovation based on biological materials. Since investment will no longer be available, it will be impossible to translate novel biological discoveries through the critical R&D processes to regulatory approval. Consequently, Australians will have access to fewer new medicines, tests and technologies and not more, as is claimed by the bill's proponents.

Further, AusBiotech believes that the interests of all sectors of the Australian community would be better served by parliament focusing on amendments to the Australian Patents Act that do not discriminate between technologies, including those involving genes and other biological materials and, importantly, those future technologies yet to be developed. AusBiotech strongly supports patentability thresholds that are properly set and rigorously applied; a research use exemption enshrined in law; safeguards that are readily accessible and adequate in their reach to ensure all Australians have access to beneficial technologies and are protected against a patent owner in the course of exercising their patent right who may act unethically or unreasonably in granting a licence to a medicine, test or technology; and the establishment of an additional safeguard in the form of a tribunal-like model and/or the appointment of a patents ombudsman to whom the public, clinicians, researchers and industry could turn in the first instance with a grievance.

AusBiotech is in favour of the government's raising-the-bar bill of 2011 which, when taken together with the erudite recommendations from the Australian Reform Law Commission report, the Senate inquiry into gene

patents of 2010 and the Advisory Council on Intellectual Property 2010 review, will deliver the solutions to address the issues identified by clinicians, researchers, industry and members of the community. Thank you for that, and I am happy to take questions later.

CHAIR: Thanks, Dr Lavelle.

Mr Cossey: Chair and senators, good morning. By way of background and for the record, CropLife Australia is the peak industry organisation representing the agricultural, chemical and biotechnology sector in Australia, otherwise referred to as the plant science industry. CropLife represents the innovators, developers, manufacturers, formulators and registrants of crop protection and agrobiotechnology products. The plant science industry provides products and services that are key to the nation's agricultural productivity, sustainability and food security. All of the commercially available genetically modified crop technology in Australia is provided by our member companies, as are the vast majority of crop protection products.

CropLife Australia note that the many inquiries on patent law over the last decade have not specifically referenced agricultural biotechnology, hence we have not publicly been active on this issue until now. However, the bill that is before this committee raises serious difficulties for the plant science industry. CropLife understand that this bill is being driven by concerns over patient access to certain genetic tests, and that intent is not one which we oppose in any way. However, on our assessment, the bill will not prevent patents being granted on diagnostic tests, hence not achieving the publicly stated purpose of the bill, and at the same time it has the potential to have devastating effect on the development of a range of agricultural technologies.

It is our genuine assessment, following extensive consultation with our member companies, that the passing of the bill would threaten private investment in both GM crops and newer pesticide chemistries that aim to imitate naturally occurring compounds. These newer pesticide chemistries are typically softer, safer pesticides that are compatible with the integrated pest management approaches of the nation. Private investment in these fields is vital because the costs of bringing a new chemical or crop technology to market are high, in part because of the extensive regulation of both industries. Our member companies spend on average eight to 10 years and $80 million to $100 million to develop a new GM crop product to the commercialisation stage. This is about 10 times the investment in time and money that is required to bring a non-GM crop to market. It is even more expensive to develop a new crop protection tool. On average, globally it takes almost 10 years and costs over $250 million to bring a single product to market. If the intellectual property associated with these significant investments cannot be properly protected, investors will stop financing these projects locally. Consequently, Australian farmers would not have access to many new, safe and innovative farming tools. This has obvious implications for their international competitiveness.

CropLife believes that the current bill's effect may also extend to other new technologies. This is because it effectively introduces discrimination in the patents system towards certain classes of technology. This is a complex area of law and we do not claim to be experts in this field. Fortunately, we do not have to be. The experts have already reviewed this issue several times in the last decade, and none of those reviews have recommended the banning of specific classes of patents. Instead, they recommend more general changes to ensure that all patents are only granted when a sufficiently inventive application has been developed. CropLife strongly supports efforts to implement these recommendations and notes the release of the IP Australia raising-the-bar bill that seeks to do just that. We believe the raising-the-bar bill will be a more comprehensive and more successful way to address the concerns that have led to this private member's bill. Importantly, it will achieve this without the potential disastrous side-effects that CropLife has identified with the Patent Amendment (Human Genes and Biological Materials) Bill. Thank you.

CHAIR: Thank you very much. Mr Quinn, do you want to add anything?

Mr Quinn: No, thank you.

CHAIR: We will go to questions.

Senator HUMPHRIES: Thank you, witnesses, for those opening statements. I will go first of all to the AusBiotech submission. In it, you make a comment about litigation arising out of the enactment of this new legislation and you say:

> AusBiotech predicts a frenzy of legal activity will be necessary to interpret the language of the Bill and that parties will be tied up in the courts for what could amount to years of legal debate and cost.

The proponents of the bill, or some of the supporters of the bill, have argued that phrases used in the legislation—phrases like 'substantially identical' and things like that—are already known to the law. Do you think that the law is settled enough in this area to allow people who produce products there to know what is, for example,

'substantially identical' to what is in nature so as to avoid that kind of litigation, or do you believe that there is in fact a likelihood that these issues will need to be defined by courts?

Dr Lavelle: We do not amend the comment in our submission. We do believe that there will be debate. In fact, we have seen that debate take place since 24 November last year, when this bill was presented in the Senate. It has been a very assertive debate that has taken place between people who have drawn different conclusions. That in itself tells you that people come at this with various impressions.

The other thing that I would like to say is that the bill will not benefit anyone except one professional group, and that is the lawyers. They will benefit directly by being paid to attend court sessions to debate with each other the definitions and parameters and to talk at length about what the interpretations are in particular case-by-case situations. Frankly, I would prefer to see that effort and resource applied to innovation and to developing new medicines for the community rather than increasing lawyers' income levels.

Senator HUMPHRIES: I will try to take offence as a lawyer myself to those comments! You also say that the bill will be responsible for serious delays in research progress. Would you explain what you mean by that.

Dr Lavelle: One thing that is overlooked by the proponents of the bill is that one of the great benefits of the patent system is that it requires mandatory disclosure. That disclosure takes place at the time of filing for a patent, not at the granting of it, so it means that academics worldwide can keep an eye on their area of expertise and know what is happening in other countries and other institutions.

Senator HEFFERNAN: Can I just say that some patents that are granted are for unknown methods.

CHAIR: Senator Heffernan, Senator Humphries has call.

Senator HEFFERNAN: I have asked Senator Humphries.

CHAIR: But I am the chair, so you might want to ask me if it is all right for you to interrupt.

Dr Lavelle: To conclude, my point is that in fact what the bill encourages is trade secrets. If people are not disclosing their inventions and innovations, that is really going to hinder the exchange of information across continents and so on. We cannot really see that that is going to be beneficial.

Senator HEFFERNAN: Can I explain once again, through you, Madam Chair, that some patents that are now granted which would be a lawyers' feast—forget about the future—are for methods unknown, with no disclosure. They are in the patent claims; I can give them to you.

Dr Lavelle: We do not want to see an increase in that situation.

Senator HUMPHRIES: So you are saying that you believe there would be an increase in people dealing with their research basically through trading secretly in these things rather than putting them on the record through patents because of the difficulty associated with that?

Dr Lavelle: Indeed. There would be no benefit in them disclosing. At the moment they must disclose if they are seeking a patent.

Mr Cossey: It is certainly not our position to advocate that the current system is perfect by any means. That is why our industry specifically is enthusiastically engaging in the issue of IP Australia raising bar. We believe a vast array of improvements could be brought to patent law in this country, simply commencing with most of the recommendations of the ALRC's 2004 report. It is not that we are arguing that the current system is without fault or is perfect in any way; we believe a vast array of improvement is required and we would encourage that and seek to play a constructive role in that. It is specifically about how it addresses this issue, and introducing a technology specific differentiation is a principle that would not serve the nation well.

Senator HEFFERNAN: Raising the bar only deals with the methods and not with the biological materials—do you agree?

Mr Cossey: Our position is that it could be a very dangerous precedent if you start setting a technology specific legal structure around patents for a number of reasons. Firstly, technology will always move on quickly, so your legislation can date very quickly and not actually be future-proof. Secondly, for more than half a century, starting back at the High Court decision of 1959, there has been recognition that it is very hard in statute to define to the point of differentiations on a specific level between innovation and discovery. Hence, the decision should be made on the guiding principles of having clear parameters, principles and a guiding framework. That is the best way to have patent law to (1) address all the issues properly (2) ensure patents are not applied to things that they should not be applied to and (3) evolve as technology evolves.

Senator HUMPHRIES: You say further on that same page, Dr Lavelle, 'Vaccines are at risk of exclusion from patentable subject matter,' under your reading of the bill. My understanding of a vaccine—and this is from

my high school science—is that you take a small amount of a disease and you inject it into a body in order to stimulate the immune system of that body to prepare for larger encounters with that disease or illness. I take it from your comment today that in your industry people are producing vaccines which are essentially synthetic in nature, which mimic the effect of those diseases as they occur naturally. Are you saying that you feel that the legislation would make it difficult to patent those synthetic vaccines because they mimic what occurs in nature?

Dr Lavelle: It is a complex response. Firstly, we have an Australian inventor of a vaccine, Ian Frazer, who is on the record and in print as saying that he has a concern that the bill as it is currently put may well have prevented him from developing his vaccine, Gardasil, which is a vaccine that prevents women from dying from cervical cancer. I think that is a fairly powerful statement.

The other thing is that medicines traditionally have been based on chemistry and a lot of the medicines that we are familiar with are chemical compositions such as aspirins. In the modern world, the new age of medicines will be based on biologics and that is what makes this bill so potentially dangerous in terms of thwarting new medicines, therapies and technologies that are coming through, and that is based on the last 30-odd years of genetic and biological research.

In terms of biological therapies, very often the biologic is the therapy. That is what is concerning for people when they look at the wording of the bill and they say, 'What will this mean in terms of our ability to protect our intellectual property such that we can guarantee a period of time to get return on that considerable investment?' The thing that is missed at times in these conversations is that the inventor has to pass a series of power tests in order to be eligible for patentability. Furthermore, once you are eligible, it does not guarantee anything. You can easily be challenged and lose that patent.

We are saying that we want a technology neutral solution. We want to see a world-class intellectual property management system in Australia. We want to see a package of reform which is going to be more comprehensive than what we are seeing through the private member's bill. So, yes, there are some concerns that therapies such as vaccines could be negatively impacted.

Senator HUMPHRIES: There is an equivalent comment in CropLife submission:

> The Bill, in its current form, will have a devastating effect not only on the agricultural biotechnology industry, but also on newer chemistries in pesticide science that aim to imitate naturally occurring compounds.

Can you describe one of those sorts of pesticides and illustrate how it would be affected by this legislation?

Mr Cossey: Certainly, and that perhaps is one of the best examples of how, while a bill might seek to address an issue in one specific area, the technology evolves so quickly into other areas that it might have unintended consequences of capturing there. Aside from the GM activity that we do, which is obviously core in this patent area, the traditional crop protection side of our industry spend a lot of time researching softer, newer, safer pesticides. They seek to look to the genius that is in nature to do that by replicating naturally occurring compounds in a synthetic or chemical formula. That is where we expect a whole new era of crop protection products will come on line. On page 9 of our submission is a table that seeks to touch on just a few of them. It is by no means an exhaustive list, but you have already a range of synthetic pyrethroids, glyphosate ammonium, bacillus in the animal health area, mectins—there is quite a vast array of new chemistry that seeks at its core in technology to duplicate biology. At this stage, I must say, the information we are getting from members is that they believe that, if this bill were to be law, it would capture those issues, and that would give them a significant problem.

On the issue of a lot of time being spent on lawyers, we already know that, just with the bill being debated, we have member companies spending a lot of time with lawyers already. So that is a new area we think it would capture, and if it occurs in our industry we can see that it must occur in other industries as well. It goes beyond straight biological material. As it stands, we believe it captures anything that even looks to replicate that synthetically or on a chemistry basis. If you like, I am more than happy to provide on notice a more comprehensive list of those new products that are either on the market now and would not be if this bill were law or that are on their way, both in Australia and globally.

CHAIR: Before I go to Senator Xenophon, I have a few questions to ask you. Dr Lavelle, I just want to go to this issue of the appointment of the patents ombudsman that you have suggested grievances could be made to. Can you outline for me what role you think an ombudsman would take. Do you think it would provide an assurance to government and the public that the patent system is actually working, or do you see it like the Commonwealth Ombudsman, in that it would handle complaints about the patent system?

Dr Lavelle: There was some discussion that members of the community, patient groups and so on may be intimidated by the current court system and feel alienated, unable to have a grievance heard. Therefore the idea of

a Commonwealth ombudsman arose as a way of having a non-threatening environment which is also not costly to enable members of the community or patient advocacy groups and the like to take a grievance and have it heard by an expert panel. That may well give an increase in comfort to the community that they are able to go to a safe environment and get an expert view about whether or not their grievance is legitimate.

CHAIR: Would you see their functions as being able to investigate complaints as well as initiate investigations and reviews?

Dr Lavelle: Receipt of grievances and also investigating and giving some feedback to the complainant about the perceived status of their complaint. They may well then need to go on to a court process, but we feel that some of the minor issues may well be dealt with efficiently in that way.

CHAIR: Would you see them as also being able to initiate their own review into particular areas?

Dr Lavelle: Sorry, their own view?

CHAIR: Their own review of a particular area—or would it be more about complaints resolutions in grievance handling?

Dr Lavelle: We saw it more in terms of complaints resolution and grievance handling, but it would be obviously up to people such as you, the Senate and the parliament as to how you see it best serving the interests of the community.

CHAIR: So you would see the minister as making the appointment?

Dr Lavelle: Yes.

CHAIR: And I am assuming you would expect them to have expert knowledge of the IP system?

Dr Lavelle: Yes indeed.

CHAIR: So how would you see a patents ombudsman interacting with the current process?

Dr Lavelle: We would see that it would enable people who currently, as I say, feel alienated from the core process to have a place to go to have a discussion with legally trained professionals—people who understand IP law, and also scientists and perhaps others as well—to be able to get some feedback as to whether or not the perceived grievance is in fact material. We have the view that there are a number of perceptions that may be based on fear rather than fact and that the ombudsman process would help to allay those fears.

CHAIR: At the moment, though, disputes and grievances have to go to the courts; they have no other place to go, essentially.

Dr Lavelle: That is right.

CHAIR: So would you see the ombudsman perhaps as trying to resolve some grievances or issues to avoid that costly court process?

Dr Lavelle: Yes. That is what we would see. But we also understand that probably big pharmaceutical companies, for example, would not use that process. We are seeing that it would be more user friendly for people who feel disempowered by the current process.

CHAIR: But if it were not resolved with the ombudsman you could still, of course, go to the courts?

Dr Lavelle: Of course.

CHAIR: Or you could choose not to use the ombudsman and still go straight to the court process?

Dr Lavelle: Of course.

CHAIR: That is how the ombudsman may or may not interact with the court system?

Dr Lavelle: That is how I would see it—as an addition rather than a replacement.

Senator XENOPHON: Further to the chair's final questioning: realistically, though—and I think you have acknowledged it—the concept of a patents ombudsman would, in reality, not be used that often if there is a substantial commercial dispute. We heard from the Generic Medicines Industry Association that when they are involved in a dispute it is $2 million or $3 million in costs. It is a high-stakes game. It can take prolonged litigation. But that is because there would be literally tens of millions, if not more, at stake. So the ombudsman, apart from very minor disputes, is unlikely to be useful. How would they empower people? If there is a lot of money at stake, and one party does not want to play ball, you are really stuck, aren't you?

Dr Lavelle: A lot of the aetiology for this whole inquiry came from clinicians, researchers and from patients, not from big business. So the idea of the ombudsman was directed to that cohort—not to resolving serious commercial disputes but talking to people who feel that there may be an issue and clarifying whether or not there is , indeed, an issue.

Senator XENOPHON: So almost like a preparatory step, in a sense?

Dr Lavelle: Yes.

Senator XENOPHON: Mr Cossey, the organisations you represent would include Monsanto, obviously.

Mr Cossey: Yes.

Senator XENOPHON: And Monsanto has a notorious reputation for aggressively pursuing its intellectual property rights around the world—is that a fair thing to say?

Mr Cossey: I would not say they are notorious; I will not endorse that adjective.

Senator XENOPHON: But they do aggressively—

Mr Cossey: They seek to protect the research and innovation which they deliver, yes.

Senator XENOPHON: They litigate. They bankrupt a lot of farmers in the US through using intellectual property law—are you aware of that?

Mr Cossey: No. I am not too sure I can agree with that. They seek to protect their interests, as do all our members, and as does industry across the board when their IP needs protection.

Senator XENOPHON: Even in cases of accidental contamination of other farmers' crops—the Percy Schmeiser case quite famously?

Mr Cossey: I will just correct that. It is not correct to describe it as an accident. That is actually an issue not about them pursuing somebody who had an accidental GM crop but about pursuing somebody who sought to take the technology without paying for it. I think that is now generally accepted.

CHAIR: I want to draw people's attention back to the content of the bill.

Senator XENOPHON: I am sorry, but Monsanto always just raises my blood pressure.

CHAIR: Time is short. So let us concentrate on the bill today.

Senator XENOPHON: Yes. Monsanto always provoke a response from me, even though I was the one who raised them. I put it to you, Dr Lavelle, Mr Cossey and Mr Quinn: do you acknowledge that the bill does not prohibit the patenting of inventive products, processes and methods that use biological materials for medical applications? I will just repeat that—maybe I said it too quickly. This bill does not prohibit the patenting of inventive products, processes and methods that use biological materials for medical applications—it does not stop that, does it?

Mr Cossey: Obviously, from the medical perspective, that is a separate industry; but we see it as impacting on us in that I think there is a differentiation between what the intention of the bill is and what its consequences may be. This goes to the core issue of the difficulty in providing parameters in statute around separating 'discovery' and 'innovation'—ever since the High Court, in 1959, identified the problem. It is why we argue that any patent bill that seeks to make a technology based differentiation will only end up undermining the IP system and the benefits that it is meant to protect.

Senator XENOPHON: The bill does not touch on inventive products, processes and methods, though, does it?

Dr Lavelle: I cannot agree with you, because this is a case-by-case discussion and general application or general comment is very difficult in this situation. That is why you are better off having a robust, world-class system that is technology neutral and applies the same bar to all technologies, and leaving it to the examiners to use the rules to determine on a case-by-case basis whether or not something is in fact novel, inventive or of use to practice.

Senator XENOPHON: But isn't that the problem now, in that it invites litigation? It invites $2 million to $3 million court cases. You are saying this will make it worse, but we already have a system where people cannot assert their rights; they are completely disempowered under the current system because of the nature of the litigation, particular when they are dealing with medical research.

Mr Cossey: As I said earlier, we are not in any way suggesting that the current IP legislative framework does not need improving. We enthusiastically encourage its improvement, but it is a very complex area. It is why we argue that it should be done in a comprehensive, non-technology-specific manner to achieve the benefits that you seek. That is the best way, we believe, for them to occur. So our belief that this is not the right way to address it is specific to this bill; it is not that I disagree with what you seek as an outcome.

Senator XENOPHON: Well, let us look at global common-law trends. Aren't other regions trending away from the patentability of certain biological materials? This is something that the Generic Medicines Industry

Association gave evidence on in the EU and US: those regions have not felt it necessary to legislate the change. In June 2010, the Court of Justice of the European Union issued its first decision under the EU biotech directive, in the Monsanto case—my friends Monsanto!—and the effect of that decision is that claims to DNA sequences will likely be limited to a particular function, and it may not be sufficient that a function of the DNA is simply known and mentioned in the patent specification, in order to enable the sequence to be validly patented. They may be limited to the disclosed function and there may be no protection for the DNA sequence per se. Now, isn't that what this bill is trying to achieve? It is consistent with that common-law trend.

Dr Lavelle: No. It will not achieve that, Senator. You talked about DNA sequences; this bill talks about all biological materials.

Senator XENOPHON: So what is your attitude to DNA sequences? Should they be patentable?

Dr Lavelle: At the moment, if we are talking about human DNA sequences, just a sequence in isolation cannot be patented. You have to clear those other hurdles—

Senator Heffernan interjecting—

CHAIR: Dr Lavelle has the right to answer Senator Xenophon's question uninterrupted.

Dr Lavelle: It has to be novel, it has to be inventive and it has to have some use. Currently, the patents that are often spoken about are old. We are talking about examinations that took place many years ago. Examinations now have changed, because it is no longer novel to isolate DNA in the same way that it was once novel. The patent system rewards the pioneers and not the latecomers, and that is how it should be. So nobody is arguing now that you should or would get a patent on a stand-alone human DNA sequence.

Senator XENOPHON: I think Senator Heffernan may have some issues about flea heads and patenting—

Senator HEFFERNAN: I would say so, as of last year. That is garbage.

CHAIR: Senator Xenophon, could you finish your questioning, and then we might go to other senators.

Senator XENOPHON: I am trying to concertina my questioning. I am just trying to be helpful—as always.

Mr Cossey: That EU decision is very specific to what it was regarding. I think Mr Quinn is well placed to put on the record exactly what that matter was with respect to.

Mr Quinn: I understand that that case related to a specific trade—namely, herbicide tolerance—in a commodity that was exported from a country that had a very poor knowledge of property protection.

Senator XENOPHON: Which country was that?

Mr Quinn: I would have to take that on notice.

Senator XENOPHON: Sure.

Mr Quinn: It was in South American. My understanding is that the company tried to enforce its intellectual property when they arrived in Europe, where it did have intellectual property protection for that patent on that trade. However, the court found that, because the herbicide tolerance was no longer relevant to the food, that patent was not actually applicable to that commodity. If that crop was to be planted in the EU, I believe that that would be a discussion that the court would have about the applicability of that patent sequence. I think that is a very specific example. I do not think it represents a general trend towards getting rid of these types of patents in the EU.

Senator XENOPHON: I will go to a US decision. Judge Dyk, in his decision in Intervet v Merial in August 2010, said that serious questions were raised as to whether isolated nucleic acid claims represented a patentable subject matter under the US Code. He said that it must be qualitatively different from the product occurring in nature, with 'markedly different characteristics from any found in nature' and that 'it is far from clear that an isolated DNA sequence is qualitatively different from the product occurring in nature'. Does that not indicate a judicial trend towards essentially what this bill is trying to achieve?

Dr Lavelle: Again, Senator, it does not mention biologics.

Mr Quinn: I would also note that the district court decision on that particular case was contrary to around 30 years of American case or common law.

Senator XENOPHON: But it gives us a turning point, though, doesn't it?

Mr Quinn: The decision will go through the usual processes of appeal. If the Supreme Court affirms the judgment of the district court, that would represent a turning point.

Senator XENOPHON: We are a few months away from that, aren't we?

Dr Lavelle: Yes.

Mr Quinn: Some time, yes.

Senator PRATT: I want to ask a question with respect to the current system. There has been a bit of a critique about looking to the government's bill to solve some of the issues that have beset us. Is there anything wrong with how we currently operate with respect to discovery versus novel and innovative steps? I think you reflected that some of those things are being corrected by historical decisions in terms of such things no longer being patented in the same way because they are no longer novel and innovative. I just want to go back to looking at how those kinds of issues might be corrected in the future in a more sophisticated and less blunt instrument.

Dr Lavelle: We support the raising the bar bill, the government bill, because it constitutes a comprehensive reform package. Industry is not in any way trying to argue that the current IP management system in Australia is optimal. After two years IP Australia have put together a comprehensive reform package which we think ought to be looked at seriously. There may well be a few changes that people would like to suggest, but the intention is good and it will raise the bar, as the title indicates, in terms of making it more difficult to secure a patent in Australia and harmonise the law with the legal situation in other jurisdictions with whom we have trading partners. So we see it as a positive step. We also believe that by adopting the package that IP Australia has developed the parliament will guarantee an improvement in current IP management in this country. That will guarantee a better situation. We cannot say that about the private member's bill. In fact, what we would say is that it is a high risk strategy that is highly likely to have unintended negative consequences.

Senator PRATT: With respect to discovery versus novel and innovative, to what extent will the new bill look at and resolve those issues? To what extent will it tweak those particular factors?

Dr Lavelle: The new bill, as I understand it—and I am not legally trained—will make it more difficult to prove novelty, inventive step and utility. They are all good things.

Senator PRATT: With respect to human genome material versus biological material more broadly, is there any differentiation in your views on those two things? The human genome has now been mapped. There is probably less novelty in much of the discovery taking place. Do you have a view on how that might differ from other biological materials?

Dr Lavelle: You are precisely correct. The human genome was mapped in 2004. That is one of the key reasons why it is unlikely—and I would say impossible—now in Australia and other places to get a patent on a standalone human sequence without passing those other tests. That will not occur. In the biologics area, there is far more scope for inventiveness and far more scope for appropriately claiming a patent for innovation. You are correct in pointing to the fact that the human genome DNA sequence is one that is well known and can be seen differently to the 'all biologics' claim in the bill.

Senator PRATT: We really need a patents section that is able to differentiate between different types of biological material and the level of research and innovation that has taken place.

Dr Lavelle: My colleague has stated several times today—and I know that others feel the same way—that we would prefer to have a technology neutral situation. That is the gold standard or the best practice currently. We would like the emphasis to go to providing Australia with a best quality IP system rather than to looking at particular pieces of technology.

Senator TROOD: Clearly, you are not in favour of this piece of legislation. Do you think that anything can be done to amend the legislation that would make it acceptable to you?

Dr Lavelle: I have not seen any suggestions of amendments that would make it acceptable, no.

Mr Cossey: From the perspective of our industry, the principle problem is that it seeks to start differentiating patent law on a technology basis. That, I believe, is fundamentally flawed and not the way to approach it. In the short, medium and long term that will more broadly undermine the IP system in Australia.

Senator TROOD: So, as long as the bill persists with that principle, you would find it unacceptable?

Mr Cossey: Yes.

Senator HEFFERNAN: Could you outline how it looks to differentiate on technology? You just said it did.

Mr Cossey: That is right.

Senator HEFFERNAN: How does it do so?

Mr Cossey: You are seeking to specifically target biological research.

Senator HEFFERNAN: No. This is about allowing access for everyone to the biological material. I will take you through this. You did say, Ms Lavelle, that it would be impossible these days to get a patent without passing

the downstream tests on method et cetera. That is right. But as of last year they were still including biological materials. Why do you need to include the biological material at all in the patent?

Dr Lavelle: I do not understand your concern.

Senator HEFFERNAN: I will take you to Monsanto in a minute, but if I want to compete against you I want access—which the raising the bar bill will do on methods but not on the biological material, will protect the method—I want access to the gene, which they say will do with an exemption, but then if I want to commercialise my inventive work I am still beholden to the person who holds the patent on the gene. Do you or do you not agree that biological naturally occurring materials are not patentable?

Dr Lavelle: I agree that the human genome sequence is not patentable. I agree with that.

Senator HEFFERNAN: Righto. Do you agree that, in isolation, it is not materially different from in situ?

Dr Lavelle: No, I do not agree.

Senator HEFFERNAN: So you think that isolated genes ought to be patentable.

Dr Lavelle: The analogy I would attempt to use, at the risk of being long-winded, is that if we take the analogy of a novel and see that as the genetic code, and we take out a phrase randomly from that novel, what the scientist is asking is: what is the meaning of that phrase? They do not know what has gone before, what is coming after, what the story is, and that may take years of investigation to determine. So what potentially you are seeking to do is to negate that work. And that is what we are objecting to.

Senator HEFFERNAN: No. What we are saying is that you should not be able to lock up, under licence, naturally occurring gene material—biological material. Could I just pass you for a second and go back to this crop stuff, because man, I am into crop stuff. Are you familiar with the Gladiator versus Roundup blue?

Mr Cossey: Not the detailed specifics.

Senator HEFFERNAN: Are you familiar with it at all?

Mr Cossey: Roughly.

Senator HEFFERNAN: Tell me what you know about it. Please do not try to bluff your way through. You either know about it or you do not.

CHAIR: Senator Heffernan, do you have a question about the bill?

Senator HEFFERNAN: This is certainly about the bill.

CHAIR: Let's ask some questions about the bill then and the legislation before us.

Senator HEFFERNAN: This relates to what he was talking about a minute ago.

Mr Cossey: Senator, the reason that we are approaching this bill in this manner is that obviously—

Senator HEFFERNAN: I ask you: do you know what the trouble was which was about—

CHAIR: Senator Heffernan, order! Mr Cossey is providing you with an answer.

Senator HEFFERNAN: No, he is not answering. I want to know: does he know the details around Monsanto's problem with Roundup versus Gladiator?

Mr Cossey: Senator, can I be clear. I am here to represent the entire crop—

Senator HEFFERNAN: I am asking you: do you or do you not know. If you do not know, just say no.

Mr Cossey: It depends on what level of detail you wish to get into, Senator—

Senator HEFFERNAN: Any detail. Tell me what you know about it.

Mr Cossey: They are matters that we are aware of generally, but—

Senator HEFFERNAN: You have got no idea!

Mr Cossey: If you would like a comprehensive answer, specifically how it relates to this bill—

Senator HEFFERNAN: No, no. Are you familiar with—

Mr Cossey: I will happy provide it.

CHAIR: Senator Heffernan, order! I will bring you to order.

Senator HEFFERNAN: Righto.

CHAIR: No, I am not giving you permission to go further until you allow this witness to complete his answer—without badgering the witness.

Senator HEFFERNAN: All right, so I take it you do not know, otherwise you would have said something--

CHAIR: Senator Heffernan—

Senator HEFFERNAN: Well, I will tell you.

CHAIR: Senator Heffernan, I am about to call on the next witness and finish the questioning here. So you either allow this witness to complete his answer in full without interruption or I will terminate these witnesses and we will go to the next one.

Senator HEFFERNAN: Away you go, mate.

Mr Cossey: I simply make the offer that if there are specifics relevant to that matter that you would like provided as to how this bill has impact on it, or how it has impact on this bill, we will happily look to provide a very detailed answer for you. I should point out, though, that if that are specific issues that you wish to address to Monsanto, they should be done to Monsanto.

Senator HEFFERNAN: What that was all about, just for those who do not know—and you obviously do not—was that the generic Gladiator, which is glyphosate—

CHAIR: Senator, I am going to ask you to withdraw that comment about the witness.

Senator HEFFERNAN: I withdraw. Gladiator is the Chinese product which halved the cost of Roundup in Australia. Monsanto discovered in their Roundup ready crops that if you used the Chinese equivalent it was actually not tolerant. So they did a deal on Gladiator, which was to monopolise the market and of course the price went vertical straight after they did it.

Dr Lavelle: The uncomfortable truth is that the private member's bill will have no impact on Monsanto or companies like it.

Senator HEFFERNAN: I intend to look at the crop side of this in a different forum—back in agriculture. Don't worry; it is coming. One of the problems with seed supply—whether it is potato growers or wheat growers—is of course the monopolisation of seed markets. One of the problems there is that Syngenta and Monsanto and these people are looking to patent the genes in plants—and I can name the plants if you want them—that give the plants salt tolerance, drought tolerance et cetera, which then allows them to do research that the Wagga Agricultural Research Station cannot do, under those arrangements, to come up with a cheaper variety, because it is all cartelised. That is the difficulty.

Dr Lavelle: Wagga will have no hope of working with partners overseas, will they, because they will not be able to patent their discoveries. The reality is that we have a small economy here with a small number of people and we are a very innovative country—

Senator HEFFERNAN: This is a multinational company—

Dr Lavelle: and the bill will not have an impact on Bayer, Monsanto and Syngenta but it will have an impact on indigenous Australian inventors, because it will be Australian law only.

Mr Cossey: The inventions you are referring to are actually public research matters. There is no restriction on that. In fact they are good examples of public research working very successfully.

Senator HEFFERNAN: I have no objection, because the world is not going to feed itself unless we successfully do GM production. I am fully in favour of GM, but I am fully in favour of not cartelising the industry with a monopoly on naturally occurring genes. There are companies now up in the Kimberleys looking to monopolise with patents some of the naturally occurring native genes up there; it is the same thing, which is to corner the market.

Dr Lavelle, you said 'without passing tests'. Again, clearly a patent is available under the monopolies act for an inventor's step—useful et cetera.

Dr Lavelle: that is correct.

Senator HEFFERNAN: Why do you need to include the biological material?

Dr Lavelle: Because you may have spent five years and a goodly sum of money getting to the point where you are able to demonstrate inventiveness and novelty.

Senator HEFFERNAN: But biological material is not patentable.

Dr Lavelle: It is taken as a package.

Senator HEFFERNAN: I think this is a very useful exercise because it has everyone like you in the landscape lit up on the issue. Otherwise everyone would have been quietly sleeping. But if you really want to know the reason the government has the 'raising the bar' bill it is that—

Mr Cossey: As we said before, we are not advocating that the current system is perfect and does not need reform—

Senator HEFFERNAN: It is because Medicines Australia went to the government and said, 'Oh my God, they are raising this stuff in the Senate. What are you going to do about it,' which made the government start to do something about it, because they slept on every report in the past.

Mr Cossey: We are going back to crops, Senator, we agree with you.

Senator HEFFERNAN: I hear what you are saying and I am glad to hear that.

Dr Lavelle: We are happy to see progress here.

Senator HEFFERNAN: It is nice to hear you say it and thank you very much for that evidence.

Mr Cossey: Since the ALRC report in 2004—

Senator HEFFERNAN: Sorry but we have to move on. With regard to, as you say, the pesticides, there is absolutely no reason under this proposition that a pesticide that has a combination—and I am very familiar with it because I won the crop competition in our area of New South Wales for the last two years—

Mr Cossey: We Cootamundra boys are very familiar with Junee boys' farming!

Senator HEFFERNAN: Well we did Cootamundra over! But they would still be patentable, because it is the combination.

Mr Cossey: I might want further clarification in light of some of your questions, because our approach to this is that the impact on the agro-biotechnology sector was unintended. The bill, and some of your questioning, seems to indicate to me that you actually are trying to capture it using a different stalking horse.

Senator HEFFERNAN: This is a serious issue for the local—

Mr Cossey: We would be addressing this matter entirely differently if we thought that in fact the publicly stated intent of this bill was not its genuine intent. We are not for one moment suggesting, and it is not necessarily that we disagree with the intent of what you are trying to achieve, that straight genes are patentable. But this is a very complicated area. As Dr Lavelle sought to identify the gene will not be patentable but the entire processes that go around the innovation need to be protected.

Senator HEFFERNAN: I surrender. I absolutely agree with you—

CHAIR: Senator Heffernan, your time is up.

Senator HEFFERNAN: For God's sake I just need a couple more minutes.

CHAIR: It will eat into your next key witness's time.

Senator HEFFERNAN: Do you agree that the biological mix would still be patentable because of the application. It is the same for biological material that you tweak and turn up a purpose for. You can absolutely patent that. But on the original form, what I have gotten from you to date through Dr Lavelle is that you think that biological material that is isolated should be patentable, as opposed to in situ.

Dr Lavelle: Correct.

Senator HEFFERNAN: That is your evidence today, which is a bit of a change.

Mr Cossey: I think the problem is that your bill actually refers to anything substantially identical. We are beginning to go well beyond biologics. We are talking about proteins. We are talking about chemicals compounds that seek to replicate biologics. That is the point we are here to argue.

Senator HEFFERNAN: You have read the—

Mr Cossey: We understand you might have a view—

Senator HEFFERNAN: It certainly refers to biological materials.

Mr Cossey: That is not a matter that is before us.

Senator HEFFERNAN: What do you think about it?

Mr Cossey: I would argue that if we are at the stage where in the midst of an inquiry we are already beginning to drop different amendments to your bill that highlight—

Senator HEFFERNAN: Part of the process of the Senate is to have amendments.

Mr Cossey: It perhaps goes to the point of our argument—what has caused it or not I leave for you to debate—that IP Australia and the 'raising the bar' bill now look to comprehensively address a range of issues in the current intellectual property market. I do acknowledge that there has perhaps not been enough action since, particularly, 2004, when the ALRC report came out and made a number of recommendations that have led to this.

Senator HEFFERNAN: I will give you some comfort. We will re-visit this in another forum where I will be the chair.

Dr Lavelle: Am I right in assuming that you have abandoned the bill that we are talking about today?

Senator HEFFERNAN: Amending a bill does not abandon the bill.

Dr Lavelle: So you are amending the amendment.

Senator HEFFERNAN: The amended amendment is there because we have listed to the criticisms—certainly, everyone swam into the water and took the bait on it—and it is to tighten it up. This tightens it up remarkably. But it is not going to help you because you think that isolated genetic material should be patentable. That is your view. You are incorrect.

CHAIR: There was an exchange here between you, Mr Cossey, and Senator Heffernan about governments sitting on reports and not taking any action. But the ALRC report came down in 2004. That is correct?

Mr Cossey: That is correct.

CHAIR: So there was no action under the previous government prior to the 2007 election in response to that report?

Mr Cossey: That is correct and that is why we encouraged it as a good thing that the incorporation of all the recommendations from that ALRC report in 2004 be addressed.

CHAIR: Senator Ken Carr, as minister, has now taken up those reports. How long has the consultation process for this new IP bill been going on under this government.

Dr Lavelle: I believe that for at least two years there have been efforts of the Senate and the inquiries of IP Australia. We responded in 2009 to an inquiry from IP Australia consulting over the research use exemption clause, for example. So it seems that a considerable amount of work has been put into it.

CHAIR: Thank you for your submissions and for your evidence today. I will leave Senator Heffernan to make his own apologies. The committee distances itself from his constant interruptions.

Senator HEFFERNAN: I wish you badly in your attempts to cartelise the local seed supply. I hope you fail, because we have got to feed the world. You are as independent as the person who pays you.

Mr Cossey: I can assure you, Senator, that we are not seeking to cartelise, and feeding the world is something that our industry is dedicated to.

Senator HEFFERNAN: Tying up the genetics of naturally occurring plants is cartelising. We will continue this somewhere else.

Mr Cossey: We look forward to it.

[09:50]

PALOMBI, Dr Luigi, Private capacity

CHAIR: Welcome. You have lodged a submission with us which we have numbered 103. I take it that there are no amendments or alterations to that submission.

Dr Palombi: No, there are not.

CHAIR: I invite you to make an opening statement, then we will go to questions.

Dr Palombi: Let me begin by refuting the assertion made at this hearing yesterday that the recent judicial trend in the United States and elsewhere favours the intent of the bill. This is wrong. The truth is that the judicial decisions going back more than 150 years support the intent of the bill. As I am about to explain once more, patent law and the judicial interpretation of patent law in the United States, the United Kingdom and Australia is that you cannot patent a composition of matter or substance if that substance is a natural phenomenon. It matters not how that substance is made; it matters not what that substance does. If that substance is identical to a natural phenomenon then, regardless of how much time, sweat, blood and money it has taken to make it or develop a process of making it, the substance itself cannot be the subject of a valid patent monopoly.

These things are not technologies or products of humankind. They are products of nature. It is for this reason that Lord Hoffmann, who wrote the unanimous decision of the House of Lords in the Amgen erythropoietin case in 2004, said that, while Amgen had invented a perfectly good process for making synthetic erythropoietin, the claims to the protein itself were invalid. Therefore, biological materials that are identical or substantially identical to those that exist in nature cannot be the subject of a valid patent monopoly. That is different of course from being the subject of a granted patent. The Amgen erythropoietin patent stood for nearly 20 years before Lord Hoffmann delivered their Lordships' decision invalidating the claims to synthetic erythropoietin. In 1989 the UK Court of Appeals did the very same thing, applying the very same principles, when it invalidated Genentech's patent over human tissue plasminogen activator in its entirety. For full details of this decision I refer the committee to pages 233 to 238 of my book entitled *Gene Cartels*. A copy of this book is available in the Parliamentary Library. So the idea that this bill is taking Australia into unknown territory is a complete fabrication. It is unfortunately a deliberately misleading statement made by those who seek to illegally profit by the grant of inappropriate patents.

As you were correctly informed yesterday by Dr Cross, a granted patent is not necessarily a valid one. Indeed, the Australian Patents Act goes so far as to expressly provide in section 20(1) that there is no guarantee of validity. In other words, the grant of a patent by IP Australia does not necessarily reflect the true state of the law. So patent law is what the courts say it is, not what patent offices do with it. Accordingly, when the Australian Patent Office adopted here in Australia the policy first adopted by the United States Patent and Trademark Office in 1988—namely, that isolated biological materials, even though they are identical to what exists in nature, are patentable subject matter under US patent law—that did not mean that the policy was a true reflection of the state of patent law in either the United States or Australia. Now that the US patent office policy is being judicially scrutinised in the United States, the US government has made it clear that it, too, on reflection, agrees that it was not. The US government's position was expressed in the amicus brief of the US Department of Justice filed in the Myriad appeal in October last year. This is what the US government said:

> PTO stated that, if the specification of a patent discloses a particular use for a gene—e.g., that the specified gene expresses a useful protein—then "an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it." Id. at 1093. PTO stated that a DNA molecule that has been "isolated" in this way is not a product of nature "because that DNA molecule does not occur in that isolated form in nature. "
>
> … … …
>
> 3. Until this case, no court had previously addressed whether such an isolated DNA molecule is patentable subject matter under 35 U.S.C. § 101. Cf. Intervet, Inc. v. Merial Ltd., 617 F.3d 1282, 1293 (Fed. Cir. 2010) (Dyk, J., concurring in part) (observing that "thus far the question has evaded judicial review"). Nor has the United States previously expressed its view on that question in litigation.
>
> … … …
>
> Methods of identifying, isolating, and using such DNA molecules may be patented, as may any new and useful alteration of those molecules through human intervention. Genomic DNA itself, however, is a product of nature that is ineligible for patent protection, whether or not claimed in "isolated" form.

> We acknowledge that this conclusion is contrary to the longstanding practice of the Patent and Trademark Office, as well as the practice of the National Institutes of Health and other government agencies that have in the past sought and obtained patents for isolated genomic DNA. The district court's judgment in this case, however, prompted the United States to reevaluate the relationship between such patents and the settled principle under Supreme Court precedent that the patent laws do not extend to products of nature. For the reasons below, the United States has concluded that isolated but otherwise unaltered genomic DNA is not patent-eligible subject matter …

I wish to add that the fact that the subject of that brief was genomic DNA does not mean that the US government accepts that it is not possible to extend that principle to other biological materials. DNA is merely a subset of biological materials. The point is that if it is naturally occurring it is not a product of humankind.

While I accept that the Myriad appeal will not be concluded until all avenues of appeal have been exhausted—not likely until the US Supreme Court has made a ruling—I nevertheless invite you, for the reasons I am about to give and for the reasons expressed by the US government in its brief to which I have just referred, to accept the premise that the policy which has permitted the patenting of isolated biological materials that are identical to what exists in nature is not now nor has ever been a valid application of either US or Australian patent law.

First, it is a longstanding US Supreme Court precedent going back more than 150 years that natural phenomena is one category of subject matter that is excluded from patentability—period. This is not because there is no inventive step involved in their elucidation. This is because compositions of matter that are identical to what exists in nature, regardless of how they are made, are not patentable subject matter under US patent law. That is also true in Australia under current Australian patent law but not as the law is applied by IP Australia, and that is the dilemma that we are in. In both Australia and the United States the first and primary threshold of patentability is patentable subject matter. This is a separate and distinct threshold of patentability from the secondary thresholds of novelty, inventive step and industrial application. Unless the subject matter of a patent—that is, an invention—meets all four patentability thresholds, it is not the subject of a valid patent monopoly.

What I have stated is not controversial; it is the recognised position at law. The government's raising the bar bill has nothing to do with patentable subject matter. It has nothing to do with patents of the kind which concern this inquiry. This was made clear by IP Australia when the exposure draft of the raising the bar bill was first circulated in December last year. This is what IP Australia said at the time:

> Please note that the draft Bill does not deal with gene specific issues, rather it seeks to raise patentability standards across all technologies. Gene specific issues are being considered separately by the Senate Legal and Constitutional Affairs Legislation Committee, and by the Government in its response to the Senate Community Affairs Committee's Gene Patents report—

both of which are due to report back in early-mid 2011. So we must travel back to 1623, when the Statute of Monopolies was passed, to understand why the bill that is before this committee is so necessary. I want to explain the law and how it came to be. Prior to 1623, English kings and queens had used letters patent to create monopolies over all manner of things—like playing cards, salt, coal and other commodities—to raise revenue for their personal treasuries. However, by the turn of the 17th century the English courts had begun asserting their authority by striking down patent monopolies, even those granted by the queen. In the famous case of Edward Darcy Esquire v Thomas Allin of London Haberdasher (1599) 74 English Reports 1131, the patent monopoly granted by the queen to Edward Darcy, a member of her court, over all playing cards imported to or made in England was struck down by the queen's bench because of its anti-competitive effects. The man who was her attorney-general and who defended her letters patent in that case was Sir Edward Coke. This is an irony, because 23 years later as a privy councillor to King James I and a member of the English parliament he drafted the Statute of Monopolies and saw to it that it was passed into law.

Indeed, the passage of this law was not straightforward. Along the way, Sir Edward was arrested on the order of the king and spent nine months in the Tower of London. He was 70 years of age. This is not something that just happened miraculously, ladies and gentlemen. Four hundred years of hard earned precedent is at stake in terms of this bill. Imprisonment was not enough to stop Sir Edward, who was a brave and determined politician. Why did he risk his liberty and even his life? Because the king's patent monopolies were a threat to the English economy and to its national security. You must understand that within five years of the passage of the Statute of Monopolies the English parliament asserted its authority over the king and put into place many of the civil liberties that today protect us from draconian and capricious laws.

The development of laws that supported free competition and provided citizens with certain civil liberties were essential steps towards today's modern liberal economic system. I want you to understand that the patent system is about the creation of today's economic system. But it has to be balanced against the anti-competitive effects. The basic premise of our economic system is free competition and we only allow exceptions to that in very limited circumstances. Section 1 of the Statute of Monopolies provided:

... all Monopolies, and all Commissions, Grants, Licences, Charters and Letters Patents heretofore made or granted, or hereafter to be made or granted, to any Person or Persons, Bodies Politick or Corporate whatsoever, of or for the sole Buying, Selling, Making, Working or Using of any Thing within this Realm ... are ... utterly void and of none Effect ...

That was the effect of the Statute of Monopolies.

An exception was made in section 6. This is germane because our law still refers to section 6, and that is why I am taking you back to this particular piece of legislation. It said:

Any declaration before mentioned shall not extend to any letters patents (b) and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm (c) to the true and first inventor (d) and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use (e), so as also they be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient ...

While the United States was to go down a different political path and eventually pass the Patents Act 1790 under its own constitution, section 6 of the Statute of Monopolies gave birth to the Anglo-American patent systems. It is for this reason that patents must only be granted over things that are truly inventions and natural phenomena, even when isolated from their natural environments, are not and never will be inventions. Thus, the grant of a patent monopoly over something that is not an invention not only contravenes hundreds of years of settled patent law but undermines the very foundation upon which are economic and political systems depend: free competition and the right to share information. We must jealously guard that foundation. The erosion of that foundation by the grant of patents over isolated biological materials that are identical to those that exist in nature must be stopped, and by express legislation if necessary. And it is necessary. After more than 20 years since the adoption of the policy which has permitted the grant of such patents, the time has come for decisive legal action. This is what the bill seeks to do, first by restoring the full import of section 6 of the Statute of Monopolies as this parliament intended not just in 1990 but from the very beginning with the first Patents Act in 1903. The second aim is to protect our economic system by applying the law to strike down the specific policy so that it cannot be allowed to do any more damage to the fabric of our modern liberal economy, in other words to stop, as Professor Olver said yesterday, the ticking time bomb. Patents are not some benign legal instrument; their abuse or misuse has economic and social ramifications that may not always be immediately or readily apparent. That is why, regardless of the reasons given to this committee to justify the continuance of the current practice, this parliament must act now.

The US Supreme Court recently said this: the relevant principle of law "exclude[s] from … patent protection … laws of nature, natural phenomena, and abstract ideas." This principle finds its roots both in English and American law. The justification for this principle does not lie in any claim that the laws of nature are obvious or that their discovery is easy or that they are not useful. To the contrary, research into such matters may be costly and time-consuming. Monetary incentives may matter and the fruits of those incentives and the research may prove of great benefit to the human race. Rather the reason for the exclusion is that sometimes too much patent protection can impede rather than promote the progress of science and useful arts, the constitutional objective of patent and copyright protection. The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements and by raising the costs of using the patented information, sometimes prohibitively so.

Patent law seeks to avoid the dangers of overprotection. Just as surely it seeks to avoid the diminishing incentive to invent that underprotection can threaten. One way in which patent law seeks to sail between these opposing and risky shoals is through rules that bring certain types of invention and discovery within the scope of patentability while excluding others. Its doing so reflects a basic judgment that protection in such cases, despite its potentially positive incentive effects, would too often severely interfere with or discourage development and the further spread of useful knowledge itself.

You have been told that patents of the kind being considered here are on the wane, but this is not true. Even a few days ago I discovered many granted Australian patents that contain claims that are to no more than isolated biological materials found in nature, such as Australian patents 200035719 entitled 'Schizophrenia associated genes, proteins and biallelic markers', which consists of some 729 pages of which 431 contain the genetic code for these human genes. You can see there has been a lot of inventive work there. This patent was granted in 2004, some four years after the complete human genome was decoded and published. I hope we can now put to bed any suggestion that the publication of the human genome has put an end to those patents. This is just one example I found without any difficulty whatsoever.

So much for the novelty and inventive step being an effective measure to stop the patenting of what are human genes associated with a human mental disorder. Another is Australian patent 20023433671 entitled 'Type II cytokine receptor and nucleic acids encoding the same'; as if the title does not tell you what it is about. This patent is 127 pages. It was granted in 2009. A cytokine is not an invention, it is a naturally occurring protein. According to Wikipedia the term 'cytokine' encompasses a large and diverse family. It is a whole family of biological materials, of regulators produced throughout the body by cells of diverse embryological origin. As you can see, again, there is lots of invention going on here.

In case you believe, as you have been told erroneously, that the invention is to a novel or inventive use or application of these materials let me take you to claim 1. This is the invention as is defined for the purposes of determining infringement. It reads, 'An isolated polypeptide consisting of an amino acid sequence at least 85 per cent homologous to amino acids 21-230 sequence ID No: 2.' I can tell you that that is not something that these people invented. It is a claim to a protein or to a segment of the protein. Not only that but it is claiming anything that comes within 85 per cent of it. That is the legal boundary of the patent monopoly. The patentee has the exclusive right over that very material regardless of how it is made and regardless of what anyone does with it until 12 November 2022.

There is no qualification whatsoever going to its inventive step or application in something that might be medically useful either as a diagnostic medicine or therapeutic. Yet this claim empowers the patentee to be able to stop anyone coming after it doing anything with the defined substance which might be useful as a diagnostic medicine or therapeutic. Moreover not only does it claim the isolated cytokine protein as it exists in nature but anything that comes within 85 per cent of it. It is for this reason, and I know you have heard lots of people criticising the term 'substantially identical', that the term is included in the current bill. 'Substantially identical' is needed in order to avoid the wordplay that patent attorneys constantly apply to these sorts of claims. You must understand that the patent system is a bit like the tax system in reverse. Until there were general anti-avoidance provisions inserted into the tax act it was fair game to basically game the tax system. There are no anti-avoidance provisions in the patents act and it is fair game to game the patents system and it is being done quite liberally and easily.

I want to make it clear to you that I do not agree that the proposed amended bill tabled with the committee yesterday adequately neutralises the effect of the current policy. I could go on but I think these two examples together with the flea head nucleic acid and the prostate stem cell antigen patents mentioned yesterday make the point that these kinds of patents remain a serious problem. They are not on the wane and I can provide you with more examples by way of a further submission if the committee so requests.

The committee has been told that the bill will prevent the patenting of genetically modified genes or structurally modified proteins. This is not so. The bill is specifically focused on those that are identical or substantially identical to those that exist in nature. The term 'substantially identical' is based upon the approach taken by the US Supreme Court in Diamond v Chakrabarty decided in 1980. In that seminal case the US Supreme Court held that a genetically modified bacterium that was capable of degrading crude oil, a function that was not something any naturally occurring biological material could do, was patentable subject matter. What drove the court to that conclusion was that the modified bacterium displayed markedly different characteristics from any found in nature and I want you to understand that. 'Markedly different characteristics from any found in nature' is the phrase of the US Supreme Court; I did not invent it. Therefore, if a biological material has been modified so that it performs a function that is different to what it does in nature then it is not substantially identical. For instance, the protein at the heart of the Gardasil vaccine patent would not be prevented from being patented because the protein has been modified specifically so that it can elicit an immune response that the natural protein does not. The same is true for the modified biological materials that are at the heart of Herceptin, an anti-cancer drug used for the treatment of breast cancer. This too does not exist in nature—it consists of both rodent and human proteins and it is a monoclonal antibody—a thing that does not exist in nature. The ALRC and ACIP reviews that have taken place to date have been unduly influenced by vested interests or those that have vested interests as clients—details I have provided to the committee in my second submission, the relevant parts of which have been redacted. I am now happy to answer any questions.

CHAIR: Thank you, Dr Palombi. We have only half an hour left of your time with us. Senator Heffernan, I will go to you first.

Senator HEFFERNAN: We just heard, Dr Palombi, from the guy who is representing the plant people—sadly, he has only worked with them for two months, coming out of the military. He said that a whole lot of pesticides—I intend to look at this in a separate forum; I think it is appropriate to look at this as a separate issue from what we have today—would be excluded from the patent system. That is not so, is it?

Dr Palombi: No. I think that certain submissions have been put forward because they clearly just want to defeat this bill. If you look at the submissions that have been put forward to the committee by those that are opposing this bill, you will see a very similar approach, and that approach has been coordinated; there is no question about that. It is a coordination not necessarily with everyone meeting in the same room but in terms of meeting the vested interests that they wish to protect.

The fact of the matter is that the bill is focused very narrowly on stopping the patenting of biological materials that exist in nature, and really those that have been modified for immaterial purposes. If you modify something dramatically, even if it is just one amino acid substitution—which has been done with human insulin; Novo Nordisk have a version of insulin that is different to natural human insulin by only one amino acid, but in doing that one thing that human insulin is much faster acting—there is no way that a court would consider that to be substantially identical, because the function has been vastly improved. It is more efficacious.

I think we have to give the courts a little bit of credit here in terms of the way they are going to interpret legislation. If we were always worried about what the courts are doing to do, we would not pass any legislation. Let us face it: it is part of the system. Parliament passes a law; then the courts interpret it. That is just the way of things. But to suggest that the parliament should not pass law because we do not know what the courts are going to do is just plain ridiculous.

Senator HEFFERNAN: Dr—as she likes to be called—Anna Lavelle, a previous witness—

CHAIR: That is her title, Senator Heffernan.

Senator HEFFERNAN: But she corrected me, because I think I called her 'Ms'.

CHAIR: That is right. Correct. That is her title.

Senator HEFFERNAN: So it is a doctor of dust, not medicine. She actually went somewhere where a lot of them have been and gone away from; she has gone back to it. She actually said on the record a few minutes ago that her view was not only that this is wasting a lot of research time—having to respond to all this—but that an isolated gene ought to be patentable even if it is just isolated and there is no material difference to in situ. Would you like to respond to that?

Dr Palombi: I have news for Dr Lavelle: the game is over. The US government is now focusing its torchlight on this issue, because for nearly 30 years it has been basically asleep at the wheel. The reason why it has been asleep at the wheel is that there has been no litigation to highlight the issue, and it was only highlighted when the American Civil Liberties Union, a not-for-profit organisation—which really shows you how inefficient and ineffective the patent system is in dealing with issues of public policy—brought this matter to the court's attention. And what did the court do? The first moment it got its hands on that patent, it knocked it out. Yet it was sitting there quite happily—nobody was going to say a thing—for all these years, and Myriad have been basically creaming the market in the United States all this time, much to the cost of the American taxpayers.

By the way, most of the work in identifying the gene that was linked to breast cancer was done by Professor Mary-Claire King at the University of California, San Francisco. It took her 16 years. It was not done by Myriad; it was Professor Mary-Claire King, with public money, at a public university. She did not patent the gene or the chromosome, by the way; she did her work because she basically wanted to find a way of helping women. Sixteen years it took. Then Myriad came along and went, 'Bang'. How did they do it? They came from the University of Utah. Where did they get the data which helped them identify where on that chromosome were the specific gene mutations that they say were linked to breast and ovarian cancer? It came from the goodwill of many Mormon families in Utah who keep fantastic family records. It was the combination of the work of Mary-Claire King and the people of Utah, with the University of Utah, that ultimately led to the identification of the specific genes. The fact that Myriad came along just meant that they were able to monopolise them.

Senator HEFFERNAN: There was the monopolisation of that particular gene and the erratic behaviour of Genetic Technologies Australia—gifting the thing to the people of Australia, taking it back because they were going broke, and then putting all the laboratories on notice. Can you describe to us the rise in costs due to the monopoly patent on the test in the United States?

Dr Palombi: The problems in the United States are more than just the cost. There are two problems. There is the cost problem. The patent has been there all this time and the cost has been going up. Instead of the price of the test coming down, which you would expect over a period of time, the price has actually risen. It has now risen from US$3,000 to US$4,000 a test. But that is only part of the problem. The other part of the problem is the accuracy of the test. Because there has been no competition in terms of developing alternative tests, the Myriad test is actually not the gold standard. That is one of the big complaints that has been made in the American litigation—that there are in fact women out there who want to get a second opinion and they are being denied the

ability to get that second opinion. If you are a young woman of pre-marriage age and you have been told that you have the BRCA1 gene mutation, I think you would like to have a second opinion before you go and have a radical mastectomy and perhaps have your ovaries removed. But that is actually prohibited as a result of the way the patent system is working at the moment in the United States.

Senator HEFFERNAN: So in terms of a broad brush of patents that have been granted, as late as last year, which include the biological material, the commercialisation of the work on that genetic material would still stand if the genetic material were moved from the patent, wouldn't it?

Dr Palombi: Yes. That is a very real point, a point that has been made by a number of submissions, including that of Dr Lavelle. I accept that this is not the complete answer. This bill does not deal with the issue of providing equity of access to genetic testing. The point was again made by Dr Graeme Suthers for the royal college. Other measures are going to have to be put into place in order to overcome those sorts of issues. Whether it is compulsory licensing or whether it is some other form of licensing I do not know, but this bill certainly will not deal with that particular problem.

Senator HEFFERNAN: My final question—

CHAIR: Yes, because we need to go to Senator Humphries.

Senator HEFFERNAN: Could you just explain to the committee what is happening in the Kimberleys with native plants and the future of seed supply?

Dr Palombi: It is not just native plants; there are companies going around the world that are taking out patent applications on genetic traits which they believe will be useful in developing crops that will be resistant to climate change effects, so high-salinity, low-water, low-nutrient requirements et cetera. The problem is that they are not actually developing new plants; they are simply patenting the genetic traits, and they are then using the patents in order to effectively negotiate—

Senator HEFFERNAN: It is like taking up exploration rights.

Dr Palombi: Yes, but the problem is they did not invent anything.

Senator HEFFERNAN: No. I realise that.

Dr Palombi: The other problem is that, with an exploration right, at least your claim is limited to the area of land in which the claim is effective, but with a patent your claim is universal. If you have a patent in America, if the plant genetic trait exists in America, your patent will capture and control that in the United States and anywhere there is a patent on it.

Senator HEFFERNAN: I am very interested in that with the global food supply.

Senator HUMPHRIES: Can I come first of all to the question that I am sure you heard me debating yesterday with Professor Olver about the text of the bill itself—your bill. You refer to it here as your bill, so my illusions that Senator Heffernan had sat down one night and drafted this have been shattered.

Dr Palombi: It was a collective effort.

Senator HEFFERNAN: I cannot read or write. How could it have been me?

Senator HUMPHRIES: Indeed.

Dr Palombi: It was a collective effort.

Senator HUMPHRIES: My reading of your bill is that the new paragraphs 18(1) and 18(1)(a) are designed to reinforce that law that you described—the 400-year-old law which says that you cannot patent a discovery; you can only patent an invention. That is the effect, as I understand it, of those first two paragraphs. But then subsection 18(2) imposes a general prohibition that, notwithstanding what comes before, there are two things that are not patentable at all, under any circumstances. One is human beings and the biological processes for their generation and the second is—I am reading it as it is now amended:

... biological materials ... whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

Am I right in saying that, even if something qualifies as being sufficiently inventive to be an invention under the Statute of Monopolies, which on the face of it would qualify to be patentable, if it falls foul of subsection 18(2), notwithstanding that general patentability it would in fact not be capable of being patented under your legislation?

Dr Palombi: Senator, I think you need to understand that there are four filters of patentability. We all know that. The very first one is patentable subject matter. It is not inventive step and it is not novelty. So if whatever it is that you are trying to patent does not pass through that filter that is the end of the game.

Senator HUMPHRIES: Yes, but I am talking about things that do pass through that filter, that are considered inventive, that do qualify under general patent law but then come up against subsection 18(2).

Dr Palombi: Can you give me an example?

Senator HUMPHRIES: Yes, I can: the example that was given in the submission yesterday from Professor Nicol from the University of Tasmania. I quoted it.

Dr Palombi: Would you be able to remind me of that?

Senator HUMPHRIES: Yes, I will find it for you again.

Dr Palombi: I think it is always easier to talk in specifics.

Senator HUMPHRIES: I agree. She gave the example of something which was published by Professor Brennan in the *Age*. It says:

A hypothetical R&D team is employed by a private company which invests heavily in developing anti-cancer drugs. The team identifies for the first time an enzyme produced naturally in a plant. It uses standard techniques to put the plant enzyme into an isolated form. It identifies the gene that encodes for the enzyme, isolates that gene, and uses the gene to genetically engineer a synthetic form of the enzyme. The team undertakes complex and lengthy testing of the enzyme. It makes the surprising finding that the enzyme has powerful anti-cancer properties. The enzyme comprises a breakthrough in treatment of leukaemia by chemotherapy.

What Professor Nicol seems to be saying, as I understand it, is that that qualifies under the usual test of a patent as being novel, as being practical—having all the qualifications of something which is patentable and which at the present time would be patentable under the laws as applied by IP Australia. It would absolutely be patentable. But under your test you have also got to throw in 18(2), which throws in a blanket barrier to patentability if it qualifies as a biological material.

Dr Palombi: I understand where you are coming from. The difficulties with examples like Professor Nicol's is that you actually have to look at the claim. Unfortunately Professor Nicol is not a patent lawyer; she is an academic. I have both been an academic and practised as a patent lawyer. One of the things you learn as a patent lawyer is that, no matter what you are talking about, you have to look at the claim language, and the claim language—

Senator HUMPHRIES: Let us assume that this claim is for—

Dr Palombi: The claim language is critical, Senator. The claim will say something like this: 'I claim the following as my invention.' If the claim is, 'I claim an isolated protein'—which in this instance would be the plant enzyme—'comprising of amino acid sequences blah-blah-blah as contained in sequence ID No. 1', then that would be excluded.

Senator HUMPHRIES: Therefore that patent that she has referred to—

Dr Palombi: No, no. I am going to continue. That claim would be excluded. But if the claim reads, 'I claim as my invention (1) a pharmaceutical composition containing within it the following, including this enzyme, for the purposes of achieving an anti-chemotherapeutic effect,' that would be acceptable, because that is a claim to a medicine, not to the biological material per se.

Senator HUMPHRIES: But it is the enzyme which is the breakthrough, that is the basis on which this anti-cancer treatment would be established—

Dr Palombi: It might be, Senator. But the patent law is: you get a patent over the invention. The breakthrough might be the discovery—

Senator HUMPHRIES: At the moment, as you admitted, you can get a patent over the enzyme.

Dr Palombi: No, no. I am saying the Australian patent office certainly have a practice of doing that, but that is not the law.

Senator HUMPHRIES: Let us put that question to one side for a minute. The fact is that the enzyme that she refers to in this example could, under the present practice—you have already told us—be patented by IP Australia.

Dr Palombi: Yes. I accept that.

Senator HUMPHRIES: And there is a great deal of invention in that, isn't there?

Dr Palombi: No, there is not. The invention is not the enzyme. The invention is in actually making the association, if there is that, between the enzyme and the fact that it can be useful as a chemotherapeutic drug. But you have then got to convert that idea into a product. You have actually got to produce a pharmaceutical that will achieve that—

Senator HUMPHRIES: But that is another process.

Dr Palombi: No, it is not—

Senator HUMPHRIES: That may not be necessarily very difficult. Discovering that the enzyme is useful could itself be, if you use existing patterns to apply to a medicine and administered to people –

Dr Palombi: But Senator, there is a difference between a claim on the enzyme itself and the product which includes the enzyme to achieve a particular medical advance. The patent system is there to reward the latter, not the former.

CHAIR: Could I ask though: would not the process of isolating the enzyme be patentable?

Dr Palombi: If you have developed a particularly fantastic technique in helping you isolate that particular enzyme—

Senator HUMPHRIES: But you may not. You may still find the enzyme using somebody else's existing technology.

Dr Palombi: Generally speaking that is what happens. There is usually no novelty or inventiveness in isolation. These days particularly it is almost stock standard stuff. Assuming this was a particularly difficult enzyme to isolate and you developed a new technique which does not already exist, yes, you could probably get a patent on the methodology that you used to isolate that particular enzyme. But that still would not give you the right to claim the enzyme itself in an isolated form as an invention.

CHAIR: No, but could I interrupt you for a minute. That in itself, Dr Palombi: isn't that the problem with diagram 2 in your submission? What you say is that the inventiveness only starts when you get that enzyme or that gene. Your diagram 2 does not acknowledge the technology that could possibly and does exist around isolating that gene or isolating that product. Your diagram on page 2 of your submission says that something is only patentable once you have got that biological product. You failed to recognise in your diagram that you can patent obtaining that biological product. Isn't that the main issue that most of the people who are opposed to this legislation have been highlighting to us over the last 24 hours?

Dr Palombi: No, the bill does not prevent the patenting of a new methodology of isolation.

CHAIR: But your diagram says that.

Dr Palombi: No, it does not.

CHAIR: Yes, it does: it has 'non-inventive/inventive' and then it talks about 'not patentable', 'not patentable' and 'patentable' and 'patentable'.

Dr Palombi: I am sorry; I do not actually have a copy of my submission in front of me.

Senator HUMPHRIES: This is figure 1, not figure 2?

CHAIR: Yes, this is figure 1.

Senator HUMPHRIES: I thought you said figure 2.

CHAIR: No, the first diagram on page 2.

Dr Palombi: Okay. That is because, when we were creating this, we were just focusing our particular minds on biological materials; we were not thinking about explaining the patentability of methodologies. It was not meant to suggest that you cannot claim new techniques or methodologies in isolation, if you can do that, as an invention. That is not what this diagram is supposed to do. It is simply looking at the biological materials and saying that, if you have a gene or a gene product such as a protein, those per se are not inventive, but the use of those materials in, say, a new product—a new vaccine—

CHAIR: Yes, I understand what you are saying. I am sorry to cut into you, but I think this is a crucial element in the guts of this legislation. So, under your interpretation of the words in the bill, can you identify which part of this diagram would be patentable in relation to the legislation before us?

Dr Palombi: The part that says 'APPLICATION eg: Diagnostic Test' and 'APPLICATION eg: Vaccine'. So a new and inventive application, whether it is a product, a method or a process, that uses these materials or contains them as a component in the materials would be patentable subject matter—no question. Have I still misunderstood you?

CHAIR: I really want to explore this, so we might come back to it, because I am cutting into your time; I am sorry.

Dr Palombi: If I have misunderstood you, I am sorry.

CHAIR: No, you have not.

Senator HUMPHRIES: I think you have raised a good issue, so I am happy to come back to that.

CHAIR: We need to explore your answer further.

Dr Palombi: Sure, I am happy to.

Senator HUMPHRIES: I have to press my original question: does not proposed section 18(2) impose a freestanding test on patentability which is separate from all the other usual elements of making up a patent? So, even if a patent could be found to be inventive and so on, to be novel, to be practical et cetera, you could still discover that, because it was essentially the patenting of biological materials or of human beings and their biological processes, it would not in fact be patentable.

Dr Palombi: No, it does not do that. It simply clarifies the existing law: you cannot get a patent on a natural phenomenon. That is really—

Senator HUMPHRIES: With respect, this is not a question about science; it is a question about law.

Dr Palombi: Yes, but how do you tell the science from the law? You cannot separate the science, because the science—

Senator HUMPHRIES: You can.

Dr Palombi: No, you cannot, because the science is actually the factual basis upon which the law is interpreted. If, as a matter of science, an isolated biological material is practically no different to what exists in nature—I am not trying to be argumentative—then it is artificial to try and separate them. The two are critical.

Senator HUMPHRIES: Your point about the science is—I am happy to argue another point; I am taking a reading of your legislation—

Dr Palombi: Okay.

Senator HUMPHRIES: Let me give this example: a person may apply for a driver's licence. They are required to produce a certificate from a doctor showing that their eyesight is adequate. They must demonstrate that they have undertaken a training course to be able to drive a car. Subsection (3) says no person under the age of 18 may apply for a driver's licence. Notwithstanding that a person satisfies subsection (1) and subsection (2)—they have their certificate and they have done their training course—subsection (3) is an absolute prohibition. Nothing that they satisfy in the first two subsections helps them get over the third one, which is an absolute prohibition. That is the quality of your proposed section 18(2). Notwithstanding that a thing might be inventive, it still cannot fall foul of what is in 18(2) and be patentable.

Dr Palombi: Sorry, Senator: it cannot both be inventive and fall within the proposed subsection, because if it falls within the proposed subsection then by definition it is not an invention. I am sorry: there is nothing inventive in isolating a biological material that exists in nature. Sorry: there just is not.

Senator HUMPHRIES: I think you are conflating the two issues, but I do not have the time to argue with you about this. I want to ask a question about the diagram that Senator Crossin referred to. The Law Council, in its submission, said that, if your legislation was law today and the situation that arose with BRCA1 diagnostic testing arose tomorrow, this law would not have saved those women from being slurred from that test.

Dr Palombi: Absolutely; I agree. I have no argument with that. This bill is not the panacea to all of the issues that plague the Australian patents system.

Senator HEFFERNAN: Hear, hear!

Dr Palombi: I am getting criticised now because the bill is not going far enough, but—

Senator HUMPHRIES: Not at all.

Dr Palombi: if we were to suggest a bill which actually said, 'You can't get a patent on a method,' all hell would break loose. The fact of the matter is that there are some things that are clearly going to meet the patentable subject matter threshold—and a diagnostic test is one of those things—but whether or not it is ultimately patentable will depend on whether there was an inventive step, whether there is novelty and whether there is some sort of utility in it.

In terms of how the system deals with something as critical as the BRCA1 test, assuming that it is the proper subject matter of an invention, that is going to require other forms of legislation. As various people have already submitted, there are already crown use provisions. I know the Cancer Council wrote to the minister and invited her to invoke the crown use provisions and the minister refused to do so on the grounds that the Commonwealth is merely paying for the service, that it is not actually providing the service, and that it was therefore a matter for the state governments to invoke the provisions of crown use. With all of that sort of political jostling that goes on it is no wonder that, ultimately, the crown use provisions were not invoked.

Senator HUMPHRIES: That is interesting but it is not the issue that I am raising. This whole debate was sparked by the controversy about that testing that was really denying women in Australia. You have had a longstanding beef—as we have read from your PhD thesis—with the way the patents system works. The fact is that this legislation you brought forward deals with your longstanding concern about the patents system.

Dr Palombi: Not just my longstanding beef; the US government seems to agree with me.

Senator HUMPHRIES: All right. But it does not deal with the very issue which this generated this debate and hence this legislation, does it?

Dr Palombi: Excuse me, but I do not believe that this whole issue is going to fall or survive purely on the basis of what happened with the Myriad breast cancer gene case.

Senator HUMPHRIES: Maybe it will not, but—

Dr Palombi: The fact of the matter is that it triggered enough interest that the parliament ultimately stood up and took the decision to inquire into what is going on with the patents system in terms of the patenting of biological materials. This is just one response to what has to be done. The committee that you were on set out a whole series of recommendations in terms of dealing with other issues relating to, for example, access to—

Senator HUMPHRIES: But it did not recommend this sort of bill, though.

Dr Palombi: No, it did not, but it did not preclude it either. One of the other things it did do was that it came down strongly rejecting the argument that isolation was a sufficient point of distinction between a natural occurring biological material and one that is an invention. The American government seems to be falling into line with this view.

I accept that this bill is not going to overcome or make access to genetic tests any more straightforward, but if you at least get rid of these sorts of claims, you enable others to use the biological materials to at least try to produce some sort of competitive response. The competitive response will ultimately lead to litigation and so there will be an argument about whether there is an inventive step that was involved in the methods that were claimed by Myriad to justify the grant of a patent over the genetic test as an invention. But, whilst they have claims of this kind, there is absolutely no incentive for anyone to even go into the diagnostics market. It only even happened in Australia in the way it did because the public laboratories that were performing these tests simply ignored the patent system. For many, many years, until GTG decided to press the hot button, they were getting away with it. The Myriad case is a warning—

CHAIR: Sorry to interrupt you, but we have questions, so I will have to ask you to wrap this up.

Senator HUMPHRIES: The answer I am getting is not the answer to my question, so I wanted to cut him off, if I may. I do not want to be rude.

Dr Palombi: Sorry, Senator.

Senator HUMPHRIES: I had one last thing to ask you, and this is really a political question. We have heard evidence for one and a half days. The fact is that your legislation is not being well received by the very people who would have to administer and deal with this legislation. The pharmaceutical and biotech industries which hold patents are not happy with it. The lawyers and the patent attorneys who would administer it are not happy with it. The key research establishments in Australia do not seem to be happy with it. The academics and even the doctors we have heard from do not give it unqualified support. The regulatory authorities are not going to endorse this. Is it really safe for the parliament to pass legislation of this kind—notwithstanding your view that this is simply stating what the law has been for 400 years—when so many of the stakeholders simply reject what you are trying to do?

Dr Palombi: I think you have to peel the onion and understand why those who are opposing the bill are opposing it. Professor Frazer actually was supportive until he no longer was chair of the Cancer Council Australia. Now he is the CEO, I think, of some $350 million outfit in Queensland.

Senator HUMPHRIES: It is a big call to say all of these people are so bound to their vested interests.

Dr Palombi: I am sorry, but there are at least perceptions of huge sums of money to be made through the patent system. The reality often does not live up to the perception, but the perception is that there are huge sums of money to be made. The perception is that, without patents, the biotechnology industry would come to a grinding halt. You have heard submission after submission say that. It is very easy for these people to make all sorts of unsubstantiated comments of this kind.

Yesterday we gave the example of Brazil. Brazil, for example, already does not allow patents of this kind, but that has not stopped Amgen, the world's biggest biotechnology company, investing. It has not stopped GlaxoSmithKline investing in Brazil. Brazil has a very, very large pharmaceutical market. It produces its own

vaccines; it has an ability to medicate itself in the event of a crisis. If we are not careful in this country, one day when a crisis does happen we are not going to be able to medicate ourselves, because we are going to be relying on imports.

Senator PRATT: I want to go to some questions around why you have sought to create that distinction between biological material and natural phenomena for the purposes of this bill. Why do you think that distinction is necessary? I am unclear as to why legislation in patents should be so technologically specific.

Dr Palombi: What this subsection defines is not a technology.

Senator PRATT: But nor is natural phenomena.

Dr Palombi: That is right.

Senator PRATT: So why should biological natural phenomena be distinguished from something like the discovery of gravity waves? You cannot patent gravity waves but you might be able to patent the technology you used to discover gravity waves.

Dr Palombi: So you are asking the fundamental question going back to 1623 as to why we do not allow patents on anything but only on specific things?

Senator PRATT: No. I understand why we do not allow patents on natural phenomena. What I do not understand is why you are choosing to isolate biological materials for the purposes of this legislation when clearly the problems with patents in terms of inventiveness and the quality of patents are much broader questions.

Dr Palombi: I see; I am sorry. As I said earlier, there are four filters of patentability, and inventive step and novelty apply to something that already is subject matter that passes the very first filter. So if something is patentable subject matter the question is: is that patentable subject matter novel and does it involve an inventive step? But you do not apply those criteria to whether or not it is patentable subject matter in the first place. The way the US and the English systems have dealt with it is that they have simply said that there are certain things that are never going to be patentable subject matter. One of those things is natural phenomena. What the bill tries to do is in a sense define that by way of referring to biological materials that are identical or substantially identical to those that exist in nature. In a sense that is trying to define what natural phenomena is for the purposes of biological materials.

Senator PRATT: But why should that not happen for all natural phenomena? Surely this is a question of whether we need to raise the standard for all technology as opposed to just biological material.

Dr Palombi: I suppose we are responding to a particular need. This is the issue that has been screaming out for attention for 20 years or so. Really, the legislation is aimed at dealing with this particular issue. The reality is, unfortunately, that if the parliament does not pass this bill or a bill along these lines—I am not suggesting for a second that the words that I crafted, together with help from others in the original draft is necessarily the be-all and end-all. It might be that it requires a bit of tinkering and finetuning and working around. Already an alternative version of the bill has come forth and an attempt has been made to neutralise or deal with some of the of the concerns around the ambiguities, they say, of the original language. But, at the end of the day, we do need this bill. Without it IP Australia have said they will continue to grant patents of the kind that are causing the sorts of problems that we are talking about.

Senator PRATT: Does this mean that you believe that each kind of technology, biotechnology being one of them, should have their own patent regulatory system? What are you doing with the universal principles that, I suppose, patents should be technologically neutral? Clearly there are natural phenomenon that are not biological that should be subject to these same kinds of principles of discovery versus inventiveness and novelty.

Dr Palombi: In fact they would be. If someone develops a modified protein, such as the one that Ian Frazer did for the Gardasil vaccine—and he has a patent which says, 'I claim the following modified protein that does a particular thing' as part of his claim as an inventor—then whether or not that claim succeeds in the terms of grant of a valid patent will depend on whether it also meets the criteria of novelty and inventive step and industrial application or utility. Those criteria will continue to apply. This bill does not in any way do anything to impede the existing processes that would apply to things that would be accepted as patentable subject matter.

Senator PRATT: What I am unclear about is why we need a special rule for biology as opposed to other natural processes, because it appears to me the logic is exactly the same and that therefore what we are talking about is a need to raise the standard for patents in overall terms. There is no doubt that the problems that you have outlined are very real, but clearly as you have also acknowledged there are a wide diversity of problems with the patent system, many of which point to the same questions in terms of standards of patents that have arisen in relation to biological phenomenon.

Dr Palombi: I really think your question is a very good one and I want to give it full attention. Would you mind if I take that question on notice and ask you: could you give me an example of precisely what it is that you are concerned about and then I will specifically address that in response? Would that be something that you would be open to do?

Senator PRATT: Most certainly, but it is an in-principle question as opposed to I suppose specifics. I am uncomfortable with carving out one set of natural phenomenon and creating a special category of patents processes for them when the principal issue is of how natural phenomenon should be treated is a universal one.

Dr Palombi: I find that it often helps to talk in more specific terms rather than generalities. If you can do that for me then I would do my very best to give you a very full answer.

Senator PRATT: Okay. I wanted to ask about the NRDC case. You made a supplementary submission that I think takes exception to the recommendation in the ACIP report, which seeks to codify the High Court's decision of that case. Are we correct in assuming that you are taking exception to that interpretation because you believe that it is not ensuring that the only subject matter that has the appropriate level of novelty, usefulness and inventive step is patentable?

Dr Palombi: No, it is not. The High Court decision in NRDC has been misinterpreted by the ACIP report. It is simply saying that if you have something which is artificial and it has some sort of economic value that that is a patentable subject matter. That is not what NRDC stands for at all. It is really quite mischievous for ACIP to have produced a report which puts forward a recommendation for a change in the law consistent with NRDC when in fact it is not consistent with NRDC.

Senator PRATT: Can I ask why you do not believe that the changes to novelty, usefulness and inventive step—and I think this goes a little bit to my earlier question, and clearly I can put some questions on notice about this—as proposed by IP Australia do not adequately address the standards required for a patient to be granted?

Dr Palombi: I will answer it two ways. The first is because it does nothing to deal with defining what is patentable subject matter. That is the first problem. The second problem is that novelty and inventive step are very specific tests. When they talk about raising the bar all they are really saying is, 'We are going to change the scope of the enquiry in terms of the application of those tests from the state of knowledge as it existed in Australia to the state of knowledge as it exists around the world.' That is effectively what the bill really says. If you think that is going to change things, well, you know—I just do not think it is going to make an awful lot of difference. As Professor Peter Drahos said yesterday, he does not think it is going to make an awful lot of difference, either. It is really just window-dressing, unfortunately.

CHAIR: Senator Pratt, I have two questions I wanted to ask and I am keen to finish at 11 o'clock.

Senator PRATT: I will conclude.

CHAIR: I might ask you to put the rest of your questions on notice to Dr Palombi. Is that all right?

Dr Palombi: That is fine.

CHAIR: Dr Palombi, you referred to the friend of the court submission made by the Department of Justice to the US Federal Circuit Court of Appeal in your opening statement. Are you aware of whether this friend of the court brief has led to a change in practice in the US patent office?

Dr Palombi: I was invited to be involved in a telephone conference with the White House in December last year where the White House spokesman announced that this is now US Administration-wide policy. The government has come down with this view, it has been communicated to the courts through the Department of Justice. That is effectively the process that is involved.

CHAIR: Has it led, though, to an actual change in practice in the US patent office?

Dr Palombi: No. The US patent office has not changed its practice.

CHAIR: Finally, based on your opening statement, it is unclear to me whether you are arguing that there should be a patent system that provides incentives for innovators or whether you are opposed to the monopoly over the commercialisation provided by patents. In other words, what is your view on the role of the patent system in providing incentives for innovators?

Dr Palombi: There is a very simple answer. The patent system will reward an invention with the grant of a 20-year monopoly, which gives the inventor the exclusive right to exploit that invention for that period of time. It does not impose any obligation on the inventor to actually work the invention; it simply gives them the exclusive rights to it. That is it, as far as the patent system is concerned. Whether or not that is perceived as creating a financial incentive to do the research will depend on the nature of the invention. If it is a blockbuster medicine, it will produce a lot of money.

CHAIR: So are you opposed to the monopoly with the commercialisation provided by patents?

Dr Palombi: Not at all.

CHAIR: All right. Dr Palombi, thank you for your time today. We probably have a lot more questions; if you do not mind, those of us with follow-up questions will put them on notice to you. We certainly appreciate your attendance at our inquiry and your ability to provide evidence in person today. Thank you very much.

Dr Palombi: Thank you, Senator. I might add that, if the committee just sends me an email with those questions in it, I will endeavour to answer them properly.

CHAIR: All right. Thank you. We will have a short break.

[11:08]

CHRISTIE, Professor Andrew, Private capacity

Evidence was taken via teleconference—

CHAIR: Good morning and hello. Welcome to this public hearing of the Senate Legal and Constitutional Affairs Legislation Committee. You have lodged a submission with us which we have numbered 19 for our purposes. I am going to assume that you do not have any amendments or changes to that.

Prof. Christie: That assumption is correct. I do not have any.

CHAIR: I invite you to make an opening statement or to speak to your submission and then we will go to questions when you have finished.

Prof. Christie: Thank you. I will be brief because I know your time is slipping a little bit. Part of that is because you have accommodated me and I am very grateful for that. I am sure pretty much every submitter to the hearing has told you this but I want to say it as well: I commend the committee on its work. I do not mean that patronisingly or insincerely. I say that because I am passionate about Australian patent law and I am delighted that the parliament, through the Senate committees, has taken on board various concerns and is looking at them appropriately. That is really good.

In general terms, I also share the aspirations of the proponents of the bill. Like them, I want our patent law to be right. I want it to be fixed up and modernised, and make sure that we patent neither too little nor too much. Where I part company with the proponents of the bill, as you will see from my submission, is that I think they have taken the wrong approach to achieving that outcome. I think the idea of trying to specify now particular subject matters that we must exclude from patentability is problematic, and I think the very fact that you have attracted so many submissions that are concerned about that and criticise this particular proposal reflects my view that specific exceptions, while meritorious in principle, are problematic in practice. What you end up with is a fight over meanings of words like 'biological', 'identical', 'substantially identical' and 'nature.' In fact, you end up no better off, and possibly worse off, than before.

My submission suggests that there is a more appropriate way of trying to deal with this fundamental and important issue—that is, we need to get the test right at its general level. We need to learn from 400 years of court considerations about the policy behind patent law. We need to come up with a set of words that is not a formula—where you just take some particular subject matter, plug it into the formula and out will pop a clear and certain answer every time—but that properly captures the concept that our patent law needs to adopt. That concept is one which says, 'We award patents appropriately, subject to novelty and inventive step, where a person has gone into and transformed something from nature.' If they have made a transformation they get to the first point of then being asked to consider whether it is new and inventive. If they have not transformed nature, that is material which we never grant patents for.

I think the concept that has evolved in Australian law, and it reflects concepts in US law as well, is that we need to look for transformation of nature as a key test. I have suggested to you that some of the work that one of the government's advisory bodies has undertaken recently has had that in mind and has suggested a form of words which seeks to do that.

CHAIR: Thanks.

Senator HUMPHRIES: Thank you, Professor Christie, for the submission. You make a point in your submission on page 4 under the heading, 'The bill does too much' and you say:

> It seems to me quite possible for a patent application to claim biological material that is an artificially created state of affairs, but nevertheless is substantially identical to material existing in nature. In such a situation, the Bill would (wrongly) preclude the availability of a patent for that material.

I have been pressing a number of witnesses on this question in the last couple of days. I take it that what you are saying there is that even if a patent would qualify under the normal rules of patentability—having novelty, practical use and so forth—but falls foul of proposed section 18(2) of the legislation, such as being defined as biological material in that subsection, it would still be excluded from patentability even though it was otherwise inventive.

Prof. Christie: Yes, that does capture the essence of my concern. When I was reading some of the submissions I noticed that at least one other party had made this point. It was one of the research institutes and I could not find it a moment ago when I was re-looking. They gave some examples which are exactly on point here. They talked

about proteins that had been transformed so that personkind had transformed a naturally occurring object, but the process of transformation aimed to make it as close as possible to the naturally occurring object but with the slight transformation that gave it changed functionality. It seems to me if the focus is on identicality or lack thereof, as the proposed legislation change does, it is missing the point and runs the risk of precluding the potential for the reward of a patent where it should be granted because transformation has occurred. But it precludes it wrongly because the transformation has changed it so little that a court might say later, 'Well, that is substantially identical.' So if I have understood your concern I share it and I think some of the other submitters have too and they have given particular examples about biological materials which are changed but changed as little as possible to achieve the effect. In principle the change gives them a chance to claim a patent subject to novelty, inventiveness, utility et cetera. But if the test was made one of substantial identicality they would be wrongly taken out of consideration for patentability.

Senator HUMPHRIES: You make the point, I think, that there is some value in a process of better defining the distinction between discovery and invention but that this legislation does not achieve that stated objective. You have been involved yourself recently in an extensive process to look at this very question. Do you believe that the recommendations ACIP made in its recent findings would address this issue, or have you effectively looked at a different issue and the issues raised in this bill would need to be subject to some further round of consultation or analysis to get the answers that seem to be commonly agreed should be found for this dilemma?

Prof. Christie: That is an excellent question and I will probably need to give a fairly full response to that. If I do not address it properly, push me on it, because I think it is absolutely core to what we are concerned about. In one sense I believe the work of ACIP does successfully deal with this particular issue even though its focus was more general. The reason I say that is that the general focus was trying to grapple with the question of what should and should not be patentable and how to tell the difference both now and into the future. It has one eye on the gene patent debate than half of another eye on the software patent debate, and a third eye, if you like, to the future. As I say to quite a few of my colleagues, this issue of worrying about what is and is not patentable is not going to stop once we sort out gene patents. Whether it is next month, next decade or next millennium, there are going to be other subject matters that we do not even know about now that will come out and that will rightly challenge patent offices and courts and public and politicians about whether they should or should not be capable of being granted a patent. So at the risk of sounding rather grand, ACIP in its work was trying to deal with the general issue for now and the future and I believe its approach does at that general level apply very specifically to gene patterns.

If we then say, 'Okay, let us take what ACIP has proposed and see how it would apply to this particular debate,' what you would get would be a statement of principle that seems to be consistent with the generalised statements of principle about what patent systems should and should not do. You will get that principle expressed in a way that is relatively comprehensible to everybody; it is not obscure words from the 16th century but relatively comprehensible. It will enable patent offices and courts to be very clear and transparent in the application of that principle. I would expect that some of the grants that have occurred in the past should not have occurred and would not occur once the principle is appropriately expressed clearly, that is to say claims to sequences per se. Those sorts of claims are very contentious ones. When properly understood, the test would say, 'No, that is not a transformation of nature—that is a claim to nature, not a transformation of it.' So I would expect that in fact when properly understood the test would make it clear to patent offices and courts how some of the examples should have played out and should play out in the future.

To be completely honest, though, what I am not saying to you is that that test will be one that everyone can pick up immediately and unthinkingly plonk down on the table and put every example into it and expect a clear and certain answer. It is not possible here because the council believes the work should be done at a higher level of generality than the bill does. It says, 'Don't try and identify particular subject matters every time they arise and then try and define them and then try and exclude them. Keep the one test but keep clarifying it so that when you get a specific subject matter like gene sequences and genetic materials it is clearer what you are supposed to be doing and more likely you will get the right outcome.' So, to summarise: I do believe that the work done by the advisory council is directly relevant to this particular issue. I do believe its recommendations would give the right outcome to the contentious claims. I do not believe further legislative amendment would be required if the council's proposals were adopted. But I am pragmatic enough to recognise that you will still get objections from people saying: 'What does that mean? What does it mean to say, "an artificially created state of affairs in the field of economic endeavour"?' And I do not resile from the fact that some thinking needs to go into what lies behind that concept. It is not an unthinking test. But I do believe it is a better test to apply than: 'What is a biological material? What is identical with nature? What is substantially identical? Do I have one of those here? And, by the way, what about software? And, by the way, what about business method patents? And, by the way, what about

interpersonal relationship claims and all the sort of future claims that are going to come up?' because we do not want Senate committees going on forever trying to resolve all the new subject matters.

Senator HUMPHRIES: You said '16th century'; I assume you meant 17th century?

Prof. Christie: I did indeed.

Senator HUMPHRIES: So is the approach that you are recommending, or that you recommended through ACIP, likely, do you think, to lead to a fresh round of litigation and judicial interpretation to clarify how that new approach would actually play out in terms of individual patent applications?

Prof. Christie: An excellent question; I do not think I can give you an answer that would carry with it the degree of conviction of my other answers because I just do not know exactly what IP Australia and the patent officers that we are concerned with will do in the future. My understanding, from their past submissions, has been that they appear to take the view that an isolated gene sequence crosses the threshold. I do not believe that is the sort of transformation of nature that is required, and, for that matter, I think the proposal of ACIP is very similar to the United States Department of Justice amicus brief in the Myriad case. It seems to say that the right test for US law is very much what I think has become the right test for Australian law. It says that the US PTO has made a mistake in application to certain claims. Personally, I think the same statement could be made about the Australian patent office. So the question really becomes: would the patent office see it differently and, if not, would you have to get a court to make it see it differently? The answer is: if it does not, yes you would. Would the court see it that way? Well, that is our system; we do not control the courts. But I think if we can make very clear what this policy concept is that the act is about, if ACIP's recommendations are adopted, your chances of getting the right outcome should be the highest of all the various options before you.

Senator HUMPHRIES: How far apart do you think the key stakeholders are in the field of patents—let us cover patenting generally in Australia, not just in the area of genetic science—in terms of a common definition of what ought to be patentable and what ought not? Is there a huge gulf which would need to be resolved through some sort of decisive act like legislation, or could parties be brought to some common understanding of what historical precedent led to applying in Australian law—a precedent from which we seem to have drifted?

Prof. Christie: Again, that is an excellent question, and I am honoured that you think I might be able to shed light on it! I will do my best, but I have to confess that this is more speculation than some of the other points that I have been making. I have listened to the numerous stakeholders and read submissions and thought about this, and, in many respects, I do not think they are very far apart at all. I think they almost all agree that our patent system has to treat the grant of exclusive rights as an exception rather than the rule. The rule must be free competition; that has always been the principle and always must be. The exception must be the grant of exclusive rights, including through patents. We must, therefore, be very cautious and very sceptical about people who come forward with new technology wanting exclusive rights. I think all the stakeholders accept that. They do. I think there appears to be more of a gulf than there is. It is not a bad thing that the proposed legislation has done this, because, when you plonk something on the table, people can focus and then start picking it apart. The trouble is that on this particular proposal they are a long way apart. They either say, 'It's absolutely all you can have,' or 'This is disastrous and the world's ceiling will fall on top of us if we have it.' That is because you have given them a particular proposal to focus on, and that proposal is at a very low level of specificity—it is very low down that order, it is very specific and people can and do pick it apart. If you try and discern their thinking at a higher level, a more general level, I think they are in fact very close together.

The second part of your question is: what would happen if nothing happened; what would happen if there were no legislation, no change to anything? Would we end up with the right result? I think in some respects you would. I think the very fact that we have had this series of reviews and inquiries and the like has really focused the attention of everybody. The executive arm of government has had its attention very much focused, and I would be very surprised if in fact you did not see consequential subtle but important change in practice as a result of this if nothing else happened.

So I think the default setting of just the inquiries and no change to the law will produce a positive outcome, but I would like—and I am sure it is the aspiration of just about everybody here—to take this opportunity to say: with all this hard work that everyone has done, we can get better law written into the statute book, so let's do it, because there is a lot of other stuff that the Senate has to move on to in due course. Patents will lose their 15 minutes of fame. We should take this opportunity to get it right.

In short, if no legislative change occurred, I think the very processes we have gone through will lead to better results. I cannot promise it, but that is my intuition. But let us now take advantage of the attention that has been focused and make sure we improve our law so that, with the next challenging subject matter, whatever it is—

claims to interpersonal relationship improvement, whatever—we have the right tools to resolve the challenging question.

Senator HUMPHRIES: Thank you.

Senator HEFFERNAN: Professor Christie, in your recommendation 4, you say that the reforms envisage amending the legislation by replacing the current words in paragraph 1A 'blah blah blah' with the words 'an artificially created state of affairs in the field of economic endeavour'. Do you think that is a lawyers' feast?

Prof. Christie: To a degree. Like every piece of wording in legislation, it invites and requires people to focus and say, 'What does that mean?' In that sense it is a lawyers' feast, like everything is. Where I think it is different from the lawyers' feast that the proposed bill sets up is that we are requiring the feast, the analysis, the argumentation, to occur at a higher level of generality, and more appropriately so. If we want to call it a lawyers' feast, I would rather have it over 'What is the correct concept of patentability for all subject matters?' than 'How does this concept of patentability now apply to this specific exception?' So I agree with you that wording in legislation becomes a lawyers' feast, unfortunately. I think that is right. But where are we going to have that feast? I would rather have it at the higher level of generality.

Senator HEFFERNAN: This morning we took evidence from Dr Anna Lavelle, representing AusBiotech, and she thought that isolated genes with no material difference to in situ genes should be patentable. Did I just hear you recently say that you do not agree with that?

Prof. Christie: You did. I am of the view that the mere isolation, or the isolation and purification, is not enough, whether it is genetic sequences or other stuff, whether it is biological or non-biological material. I am of the view that that does not appear to cross the threshold, which we rightly set at a high level. So, yes, I do not think that saying, 'I've isolated something from nature; now start my analysis for the grant of a patent, please,' is enough. I agree with you.

Senator HEFFERNAN: Thanks for that. This debate, as you know, began a couple of years ago. Medicines Australia have owned up that they approached the government to try and do something about the vagary and inadequacy of what had been happening in the interpretation by IP Australia, which clearly involved including in patents isolated biological materials. They are of the view that the raising the bar legislation, which is a consequence of their approach to the government, would fix the issue, when, as you know, it does not deal with genetic material. If you gave an exemption for research to me, for instance, because you have the patent on the biological material—which I agree with you that you should not have—and then I want to commercialise my research, how is it that I have to go back to the original patent holder to get a further exemption to be able to include the biological material in my patent which I want to commercialise, which may do you out of business? How would all that work? Would an exemption work in practical terms?

Prof. Christie: The last bit of your question cut out because unfortunately I overspoke you, but can I go to what I think you are asking and see if I can address it. You ask, 'How could it be that …' and I take that as slightly rhetorical. I agree with you that that is in fact the case, if I have understood you correctly—that a research exemption will only permit research experimentation; it will not permit subsequent commercialisation. If that is what you are saying, and I believe it is, I agree with you—that is the effect of introducing a research exemption. It only deals with research; it does not deal with subsequent commercialisation. If I take the question, 'How can it be?' as a query about whether that is the right policy, then I think you and I are on the same page as well. I would say, 'Just a minute, hang on. That is not enough.' If all the patentee has done is take from nature rather than transform nature then I do not want them to be able to have exclusive rights to that taking from nature, and a research exemption only carves that back a little bit. More carving back is required. I would suggest that if it is an upstream concern—that is to say, inherently this subject matter should not have been subject to the grant of patent at all—then the solution to that problem is an upstream solution, which is: do not grant patents to that subject matter at all. So I think you and I are very close on that indeed. Where we perhaps differ is as to whether or not the proposal chooses the right test or concept to do that work.

Senator HEFFERNAN: Thank you for that. As I said yesterday, we have lit up the landscape not only in Australia but in other parts of the world with this inquiry. I note with interest in the legal matter in the US that one of the judges that may sit on that appeal to the Supreme Court has been in Australia recently prosecuting a cause to which he is about to sit in judgment. I do not know where that leaves judicial legitimacy on that matter. One of the things we have had to contend with is an old problem and it no longer happens; the interpretation is different, but as late as last year they were still allowing biological materials—in the case that we heard about yesterday, of a flea's head—to be patented. So it is a continuing problem, wouldn't you say?

Prof. Christie: It depends. I do not see the patenting of biological materials per se as a problem, let alone a continuing one. But I do see the patenting of subject matter, be it biological or not, that does not warrant the grant of a patent to be a problem both current and continuing. So we agree at the general level. I think we do not necessarily agree at the specific level whether biological materials as such—and no more just as such—are the problematic subject matter.

Senator HEFFERNAN: I am of the view that we should just take our time not only with this bill—and I presume you may not have seen the amendment to the bill which takes out 'including their components and derivatives' and leaves it strictly as biological material. If this exercise is doing nothing more than getting everyone focused, because clearly there was no focus before this process started, we are on a useful path, wouldn't you think?

Prof. Christie: Yes. I would agree with you on that.

Senator HEFFERNAN: Thank you for that.

Senator PRATT: I wanted to ask about the distinction between biological processes and natural processes more broadly and whether it is justified that this bill should create such a distinction when it appears that there are probably some universal problems with patents in terms of them meeting the innovation and novelty tests.

Prof. Christie: I think that encapsulates well one of the fundamental issues that I have here. As you heard me say to Senator Heffernan a moment ago, where he and I probably do not agree is that we need to expend our energies focusing on biological materials as if that is the only concern and as if that concern also exists. As you heard me say, it is not the only concern. I am also concerned about issues like patenting business methods. I am also concerned about issues like patenting improved methods of interpersonal relating. These claims come through. How people should act towards each other better may well be new, may well be inventive; it is certainly not biological. It is not a biological material—

Senator PRATT: But it may still be a natural process.

Prof. Christie: Exactly. It may still be the sort of thing for which we just want to be able to say upfront: 'You know what, our patent system doesn't apply to that. So whatever you want to do with it, don't come to the Patent Office.' So I agree with your statement.

Senator PRATT: In terms of thresholds about natural processes, is there any reason why biological processes should be distinguished in terms of—

Prof. Christie: I just missed that last bit: 'Is there any reason why biological processes should be distinguished in terms of'—and then I missed it.

Senator PRATT: We should carve them out and create a special category for them, or are there tests required in terms of novelty and inventiveness versus discovery universal?

Prof. Christie: On the latter point, I believe that the test that distinguishes between discovery and invention should be universal. I believe it is in the sense that we can discern a test or a concept that is evolved by the courts, that is universal and that is non-technology. I believe that. The first bit of the second part of your question was: should we distinguish biological materials? We should give them close attention. There is no question about that. They warrant close attention by the Patent Office and by the courts. Why? Because by virtue of being biological they inherently run the risk of having not been sufficiently transformed from nature. But that is not the only sort of subject matter which runs that risk.

There are non-biological things such as electromagnetic spectra. When I spoke to the Senate in Melbourne a couple of years ago, I said that I do not like the claims to gene sequences per se anymore than I would like the claim to a certain band of the electromagnetic spectrum. Someone says, 'I want megahertz 60 to 45 because I have worked out that that does some really good stuff.' We should not grant that patent anymore than we should say, 'I want this gene sequence per se.' Electromagnetic spectrum is not biological, but it raises the same concerns that claims to gene sequences do. Ways of improving interpersonal relationships is not biological—it is psychological—but it raises the same concerns. So I agree with you that we should adopt a concept—and we do have one—that is applicable to all subject matter. It is okay to be very sceptical about biological materials. They warrant that scepticism but it is not desirable to look at them alone and think that the best way to deal with the general problem is to specifically exclude them per se.

Senator PRATT: So rather than saying that patents should not be technology specific—I think some people have used that terminology—we should not be carving up one set of natural phenomenon versus another set of natural phenomenon for the purposes of patenting.

Prof. Christie: That is correct. That is one example in my claim that the legislation would do too little. It would not fix the general problem. If it fixed a problem at all it would be fixing a specific, yet the flex side of the coin is that it does too much. It would not actually fix the specific problem, I fear. I really do fear that. I do not want non- transformed from nature claims, be they to biological or non-biological materials, to be inherently patentable. I do not want that but I am just not sure about your bill. In fact, you have read that I do not believe your bill gets you there and, at the same time, it does not get you where you need to be.

Senator PRATT: Thank you.

CHAIR: Professor Christie, we do not have any other questions. Do you want one more question, Senator Heffernan?

Senator HEFFERNAN: Yes. Professor Christie, would it be fair to say that in your view this legislation is inadequate? If the raising the bar exemption on research is inadequate then at least we are recognising the inadequacy and inappropriateness of some past successful patent applications.

Prof. Christie: In the sense that this focus of energy has done that, I agree. It has not been at all wasted, but I would just caution that I personally do not want you to take the next step and say, 'Let's pass this bill anyway because it can't do too much harm and it at least does some good.' There I part company with you. As patronising as it may sound, I believe the intention is right but the method is wrong. I think we will be worse off with this bill than if nothing at all happened.

Senator HEFFERNAN: Fair enough. So what should we do about the law prospect of a research exemption which leads to nowhere; it cannot lead to commercialisation?

CHAIR: Professor Christie, thank you very much.

Senator HEFFERNAN: You do not have to answer that apparently.

Prof. Christie: Thank you, I appreciate the time to talk to you.

CHAIR: Thank you very much and thank you for your time today.

[11:41]

BEATTIE, Mrs Fatima, Deputy Director-General, IP Australia

HALTON, Ms Jane, Secretary, Department of Health and Ageing

LUNN, Mr Peter, Manager, Pharmaceuticals and Health Technologies Section, Department of Innovation, Industry, Science and Research

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

MOORE, Ms Terry, Director, Domestic Policy, IP Australia

PETERS, Dr Kirrily, Manager, Pharmaceuticals Industry Strategy and Environment Section, Department of Innovation, Industry, Science and Research

PRESS, Ms Lexie, Examiner of Patents, IP Australia

REID, Mr Alexander Christie Arnaud (Chris), General Counsel, Department of Health and Ageing

CHAIR: I welcome officers from IP Australia, the Department of Innovation, Industry, Science and Research and the Department of Health and Ageing. I want to remind senators that the Senate has resolved that an officer of a department of the Commonwealth shall not be asked to give opinions on matters of policy and shall be given reasonable opportunity to refer questions asked of the officer to superior officers or to the minister. This resolution prohibits only questions asking for opinions on matters of policy and does not preclude questions asking for an explanation of a policy or factual questions about when and how policies were adopted. I want to also remind you that any claim that it would be contrary to the public interest to answer a question must be made by a minister and should be accompanied by a statement setting out the basis of that claim.

We have a number of submissions from the Department of Innovation, Industry, Science and Research and IP Australia which we have numbered 94 for our purposes and from the Department of Health and Ageing we have a submission which we have numbered 68. I am going to assume that there are no changes or alterations to those submissions. I will invite you to make an opening statement. I will get the Department of Innovation, Industry, Science and Research to start first or IP Australia.

Mrs Beattie: IP Australia is a prescribed agency within the innovation portfolio and its responsibilities include the assessment and granting of the four registrable intellectual property rights which are patents, trademarks, designs and plant breeders' rights. Both IP Australia and the department have responsibility for policy advice to government on registrable IP rights. Our joint written submission to this inquiry includes information about the importance of the patent system in stimulating innovation and investment, especially in the high-risk and capital-intensive biotechnology and pharmaceutical industries. The submission also provides information about biological materials and products that are currently eligible for consideration of patent protection but which will not qualify if the bill is enacted. The possible negative impacts of the proposed changes are also discussed. Our submissions in 2009 to the gene patents inquiry may also be of interest to the committee.

In accordance with the provisions of the World Trade Organisation agreement on intellectual property, referred to as TRIPS, Australia's patent system is technology neutral. This means that patents are available for inventions in all fields of technology without discrimination. IP Australia therefore assesses all patent applications against

the same patentability criteria. The first patentability criterion is the subject matter eligibility test. In Australia, this is the manner of manufacture test, as prescribed in section 18 of the Patents Act. Biological material as it occurs in its natural state is not eligible for consideration of patent protection because it does not satisfy the manner of manufacture test.

In contrast, biological material derived from a natural source is eligible for consideration of patent protection if two conditions are satisfied. Firstly, the biological material must be the result of human intervention—that is, transformed in some material way by human action. There must be an artificially created state of affairs. Secondly, the transformed material must have a useful, practical purpose. If these two conditions are met then the biological material derived from the natural source is eligible for consideration of patent protection. The material must then satisfy the other patentability criteria that determine whether it is of sufficient standard to be awarded a patent protection. These requirements are that the material is novel and involves an inventive step. A patent must also disclose the invention clearly enough so that a person skilled in the technology can understand and reproduce the invention.

Our submission at paragraphs at 2.3 to 2.6 provides specific examples of patents granted in Australia in the early 1900s over biological materials and micro-organisms useful in industry and medicine. Examples of contemporary patents claiming biological materials are found at paragraphs 4.2 and 4.24. It is clear that the subject matter exclusion proposed in the bill covers a broad range of biological materials and captures a large proportion of inventions in the healthcare, pharmaceutical, biotechnological and agricultural industries, as well as inventions in food and environmental technologies. However, the patent eligibility status of many biological inventions will be difficult to determine with certainty if section 18 is amended as proposed because the language of the bill is unclear. For example, there is no clear extrinsic guidance as to what derivative or identical or substantially identical mean in the context of the proposed amendment.

Table 1 in our submission identifies categories of inventions that are presently patent eligible but would clearly be denied patent protection if the bill is enacted. Examples of inventions whose patent eligibility status would be difficult to determine are also provided in the table. The subsequent amendments proposed in supplementary submissions by the Cancer Council and Dr Palombi do not resolve this uncertainty. Any uncertainty regarding what biological material qualifies for patent protection will reduce confidence in the patent system and is not in the best interests of the public innovators and investors.

If the bill is enacted, Australia will be out of step with patenting activities in all the developed and most developing countries, including the US, United Kingdom, European Union, Japan, Korea and China. All these countries do not prohibit patents over isolated biological material for which a practical use has been identified. In Europe, the eligibility of biological material for patent protection is codified in article 3.2 of European Union biotechnology directive 98/44, where it is stated that biological material which is isolated from its natural environment or produced by means a technical process may be the subject of an invention even if it previously occurred in nature. Articles 5.1 to 5.3 of EU directive specifically mandate that elements isolated from the human body such as isolated genetic material are patent eligible if an industrial use of the material is disclosed in the patent application.

Maintaining harmonisation with the global intellectual property environment is important to ensure that Australia remains internationally competitive and Australians continue to have access to the latest innovations such as new drugs and vaccines and healthcare services, non-toxic chemicals, green technologies and new plant varieties. If Australia is not aligned with international law, we risk reducing international investment in Australian research and business and reducing opportunities for researchers to participate in international collaborations.

We believe that a strong patent system that permits patents over biological material is not inherently in conflict with Australia's access to healthcare products and services. To that end, providing an explicit research exemption and requiring higher internationally comparable standards for demonstrating novelty, inventive step and usefulness are what is required. The higher standards applied uniformly to all technologies would deal directly with overly broad and speculative patents without adversely affecting the patent incentive for creating and making available valuable innovations which can improve Australia's productivity, prosperity and public health.

To this end the government is progressing a number of changes to the Patents Act through the IP Laws Amendment (Raising the Bar) Bill 2011. These changes have been the subject of extensive public consultation over a two-year period, including the release of an exposure draft of the bill. We hope the raising-the-bar bill will be introduced into the lower house in the coming winter session. We note that many of the submissions to this inquiry express strong support for the express research exemption and the other reforms in the raising-the-bar bill. Many stakeholders consider that enacting the raising-the-bar bill will address general concerns about patent

quality in a desirable technology-neutral fashion, and this will go a long way to relieving many concerns related to the patenting of biological material.

The safeguard measures that already exist in the Patents Act—namely the Crown use, compulsory licensing and Crown acquisition provisions—are also alternatives for ensuring the public has ready access to patented products and services. Our submission to the gene patents inquiry, at 9.1 and 9.2, provides detail about the Crown use and compulsory licensing provisions and the circumstances governing when these provisions can be used. While these provisions are rarely used, their existence does assist reasonable commercial arrangements being reached with patent holders.

Our joint submission also notes that previous inquiries and parliamentary debates in Australia have considered patent subject matter eligibility in general and also the availability of patents for certain biological material, in particular genetic material. These reviews and considerations did not result in recommendations to exclude material other than human beings and biological processes for their generation from patent eligibility. We do not think that contemporary concerns around the patenting of biological materials raise any new issues.

The changes proposed by the bill will capture a broad category of biological materials, adversely impacting development and availability of a broad range of products and services for the public good. Furthermore, such exclusion fails to acknowledge that biological materials have been and will continue to be a significant source of human health inventions.

My colleagues and I are happy to answer any questions you may have regarding the innovation system and the patenting of biological material. We are also happy to provide more detailed information on the reform proposals in the raising-the-bar bill. Thank you.

CHAIR: Thanks very much, Mrs Beattie. Mr Reid or Ms McDonald, I take it that that is a joint opening statement between IP Australia and the department?

Mrs Beattie: No, the innovation department.

CHAIR: Yes, that is right. The Department of Innovation, Industry, Science and Research—is that right? Yes, okay. Ms Halton, do you have an opening statement from the Department of Health and Ageing?

Ms Halton: We do. Thank you for the opportunity. We just have a few brief things we would like to put on the record before welcoming any questions from the committee. It goes without saying that genes are the physical and functional unit of inheritance and collectively contain all of the information necessary to build and maintain a living example of an organism. Free access to genetic material including normal genes and their mutations, as well as information relating to the association of genes with a disease, is essential, in our view, to promote the continued innovation in the prevention, diagnosis, prognosis and treatment of disease.

The key policy objective for the Department of Health and Ageing is to ensure affordable access to appropriate and high-quality health care while supporting and maintaining the biomedical research and innovation activities that are necessary to continue to improve health outcomes. Advances in medical research and commercialisation of inventions are time-consuming, expensive and risky ventures. Patent protection provides for a time limited monopoly to exploit an invention and is a key government mechanism to allow investors and industry to recoup the costs of innovation and translate basic biomedical research into products and/or treatments for the community's benefit. To maintain investment in scientific research and to support the equitable provision of effective health care, a balance, in our view, is required between encouraging the publication and use of information on natural phenomena to promote continued scientific discovery and allowing the patenting of scientific inventions to reward technological innovation. The policy and technical issues relating to patentable subject matter are complex. Clarity regarding the scope of eligible patentable subject matter is necessary to provide certainty for industry and also to promote competition and further innovation. Patents over naturally occurring genes, in our view, restrict competition and place upward pressure on healthcare costs for both government and the community.

The department supports the patenting of inventive products and novel methods for applying genetic information as a mechanism to allow investors and industry to recoup the costs of innovation and translate basic biomedical research into products and/or treatments for the community's benefit—that is, genes that are structurally and/or functionally engineered or novel diagnostic or therapeutic biotechnologies are rightly considered patentable subject matter. Isolated and/or purified genes, or portions of genes, that are identical to those that are naturally occurring are not inventions and hence should not be considered patentable subject matter. The intrinsic nature and function of a gene is not altered when it is isolated, purified or cleaved to remove the regions that do not code for the formation of proteins.

The department supports the intention of the private member's bill to the extent that it seeks to clarify the distinction between discovery and invention as it applies to genes and biological materials, including isolated and purified materials, whether normal or mutant, that are identical to those that occur in nature. As presently worded, however, the department believes this bill may apply more broadly than genes and biological materials with naturally occurring homologues, with potentially significant consequences on Australia's biotechnology research and development sector. We have made that view known to a number of people.

I also understand that there has been a reference to the failure of the Commonwealth to use the Crown use provisions in 2004. Before we go on I will just ask my colleague Chris Reid, the General Counsel, to explain why that was the case in 2004.

Mr Reid: I am relying on my recollections here of something that happened a few years ago, but the essential problem as I understand it with the Crown use provisions in the Patents Act are that they can be used by the Crown in right of the Commonwealth or by the Crown in right of the states where either the Crown in right of the Commonwealth or the Crown in right of the states is actually using patents. The problem that arose in relation to BRCA1 and BRCA2 arose in a context where BRCA1 and BRCA2 were being used by laboratories that were either individual companies or parts of states. Accordingly, the Crown right provision was not something that could be used by the Commonwealth in that context.

Ms Halton: Hence the suggestion that if it were to be used the states might in certain circumstances be able to use it, but we were unable to use it.

Senator XENOPHON: I ask this of any of the witnesses. Some evidence has been given in the course of this inquiry that the 'raising the bar' bill is inadequate to deal with the issues. Ms Halton, you identified that concern in terms of research. They feel that the 'raising the bar' bill will not necessarily address those issues. Mrs Beattie, you may like to comment on that.

We heard that the patent on a fleas head was granted on 8 September 2008; it is an example of the sort of patents that have been sought or approved. Could you respond to that in terms of whether the proposed 'raising the bar' bill would deal with the mischief, if you like, that is the subject of this bill.

Mrs Beattie: What I would really appreciate is for someone to actually explain what the mischief is. In all of this debate I have not really had a clear understanding of the problem that the bill seeks to fix. If we could really understand the problem that it is sought to fix then maybe we could respond. The raising the bar bill is not about what is or is not eligible for a patent; it is about whether it is worthy of being granted a patent. The raising the bar bill is raising the standards required to meet those requirements for being awarded a patent. So the raising the bar bill is increasing the requirement for describing the invention, for the inventive step that is required, for the common general knowledge that is to be applied and for the citations that are to be applied. In effect, it is raising the standard for granting a patent. It is not about whether or not something is an invention and therefore eligible for a patent.

Senator XENOPHON: I do not want to continue to debate with you, Mrs Beattie. I guess the concerns that led to the bill being introduced were, I think, fairly well expressed in the second reading speech of Senator Heffernan and in the explanatory memoranda, which have been tabled.

Mrs Beattie: Some of that discussion is around access by researchers to the material. A solution to that is the research exemption.

Senator XENOPHON: So taking the instance raised about the Myriad case, you think that would be dealt with in the raising the bar bill.

Mrs Beattie: The issue around the Myriad case will not be resolved by the private member's bill. The issue around the Myriad case will not be solved by the IP reform bill. What will be resolved will be the standards required to grant a patent. They will be different. They will be higher. Whether or not that patent, if it were filed now, would satisfy the requirements of patentability is something that I would have to take advice on.

Senator XENOPHON: The bill is not directed to all biological issues, only those that are identical to or substantially identical to those found in nature. That has been the concern that has been expressed to us and that is what has instigated this bill being introduced.

Mrs Beattie: The debate that I have heard to date and the evidence that you have received have the notion that an invention is something that can only be created by something that is constructed. All the evidence that you have received to date says that a new invention is something that you have to construct. It fails to recognise that you can actually create a new invention by deconstructing. In other words, you can take a large molecule and you can create a new invention out of that large molecule by deconstructing it, by creating a smaller molecule which has a different functionality, a different structure and a different application from that large molecule.

Senator XENOPHON: It is being said that it is broader than that, isn't it? It is said that some of the patents that have been granted actually go beyond the way that you have characterised it and that while that might be the case for some instances it is a bit broader.

Mrs Beattie: Isolated gene sequences are, in fact, molecules that have been created by deconstructing a larger molecule. An isolated gene sequence is created by breaking covalent bonds from a larger molecule and finding a practical use for that molecule. That is what makes them eligible for consideration of a patent grant. Whether or not that then satisfies the patentability criteria—so is it of a sufficient standard to warrant being given a patent?—is about novelty, inventive step and utility.

Senator XENOPHON: You might want to take this on notice. Can you comment on—in shorthand—the flea's head patent granted on 8 September 2008? I am very happy for you to take that on notice.

Mrs Beattie: I would be happy to answer it.

Senator XENOPHON: It has been referred to in the last couple of days.

Mrs Beattie: Yes. I have it in front of me. The claims are to isolate nucleic molecules. They are not as to a flea's head. As for the priority date of this patent, it is a divisional patent so it has a parent that was filed and it also has a priority date of 1999. In examination, we are obliged to look at the prior art, to assess its novelty and inventive step based on that date. It is about the knowledge and the art in 1999 and also, while I am at it, the schizophrenia patent, which was mentioned earlier this morning, also has a priority date of 1999.

Senator XENOPHON: Okay.

Mrs Beattie: And that is before publication of the genome.

Senator XENOPHON: That is the key date from your perspective?

Mrs Beattie: The prior art that we have to assess it against is 1999, not 2011, and in 1999 the genome was not published.

Senator XENOPHON: But there is a concern that it could stymie research, though, isn't there? You can understand that concern amongst some researchers.

Mrs Beattie: In the evidence that has been presented to date and in the submissions, no-one is claiming that gene patents are stymieing research.

Senator XENOPHON: The Generic Medicines Industry Association have said so in their submission, for instance.

Mrs Beattie: I am not aware of—

CHAIR: But they rely on patents being expired for their business to flourish.

Senator XENOPHON: They see that this bill would enhance research.

CHAIR: Or their business. It will certainly enhance their business and their profitability, I would have thought, as well.

Senator XENOPHON: I think that is one of the issues here, Chair, about profitability for various parties—

CHAIR: Correct.

Senator XENOPHON: not these parties but various parties—that have made submissions. Thank you.

Ms Moore: That is also part of the objective of the raising-the-bar bill, to introduce the research exemption and so to give greater certainty to researchers who would like to work in these areas that they will not run into problems with infringement of existing patents.

Senator XENOPHON: Finally, before I miss my flight: is there a concern generally about the costs of litigation? We heard from the Generic Medicines Industry Association—and I am sure this would apply to others involved in this—that sometimes litigation costs $2 million or $3 million if it is protracted. Is that a concern?

Mrs Beattie: There is a concern in the community about the cost of litigation. Can I add, however, that the patent system is a very transparent system. There are multiple opportunities for third parties to engage with the examination of the patent application. During the examination, third parties can submit evidence which they believe would go against the granting of the patent, so the examiner would have to consider that information. There is also a period of three months in which third parties may lodge an opposition, which is heard before the office. The office procedures are not expensive. And then of course there is also re-examination, which can occur post grant. So, if people have an issue with the patent and they believe that it has been granted erroneously, they can make submissions in relation to having it re-examined.

Under the IP reform bill, we are actually seeking to strengthen the re-examination provisions by expanding the criteria for re-examination. Currently it is only on novelty and inventive step. The IP reform bill is seeking to include all the examination criteria to be considered also under re-examination.

Senator XENOPHON: But you can see that, when disputes arise, you need very deep pockets to fight some of these cases.

Mrs Beattie: But that is no different to any other technology, and it is an issue that the government has been seeking to address through various reviews of post-grant enforcement.

Senator XENOPHON: I guess, as a lawyer who did not act in this field but who acted for plaintiffs in complex injury matters where sometimes the cost of litigation stopped people from exercising their rights because of the risks involved in litigation, that is something that I think is an issue.

Mrs Beattie: And that is why the government has provisions like re-examination and pre-grant opposition that parties can engage in.

Senator XENOPHON: I look forward to the Senate inquiry in relation to the raise-the-bar bill. Thank you.

Senator HUMPHRIES: I just want to follow up the questions of Senator Xenophon to clarify what exactly the view of IP Australia is about the patenting of gene sequences or proteins or other naturally occurring substances. You mentioned that the prior art, for example, for that schizophrenia patent was based on the 1999 patent granted—did you say in Australia or in the United States?

Mrs Beattie: No, that is an Australian patent.

Senator HUMPHRIES: That is an Australian patent?

Mrs Beattie: Yes.

Senator HUMPHRIES: So are you saying that IP Australia is bound by the terms of the patent that was granted in 1999 as to how it determines the outcome of a patent application based on that prior art in 2008?

Mrs Beattie: It was not granted in 1999; that was its priority date. That is the date that is considered for examination, and you apply the state of the knowledge, the state of the prior art, the state of the technical person's knowledge in that art, at that time. So the examiner has to put themselves into that time frame when they are examining the application. They might be examining the application in, let us say, 2002 or 2003, but they have to refer to the prior art as it existed in 1999.

Senator HUMPHRIES: I recall you explained this during the previous inquiry, but can you refresh our memories as to why they are doing that? Why are they basing this on the knowledge as in 1999 and not the knowledge as in the year in which the decision is actually being made?

Mrs Beattie: Because that is the state of the art that existed at that time, and that is the state of knowledge in the art. That is when it is filed. That is when you are supposed to be assessing whether or not it is inventive.

Senator HUMPHRIES: So why the delay between 1999 and 2008 in the case of that particular patent?

Mrs Beattie: There are various reasons. There are various clocks within the patent system. Some of those clocks are initiated by the Commissioner of Patents. Some of those clocks are initiated by the legislation and available to the applicant to initiate. So, for example, you can file a provisional application to get your priority date. Within 12 months of that provisional application you have to file your full application. Then you would be asked to have that examined. Once the first report for examination is issued, the applicant then has 21 months in which to get their application in order for acceptance. Then, once it is accepted, there is a three-month period for pre-grant oppositions before it can actually be granted. So there are a number of those sorts of clocks in the system that determine how fast an application might be examined.

Senator HUMPHRIES: Is there a resources issue there for IP Australia that would explain part of that delay?

Mrs Beattie: Part of that delay can be explained by resources issues in IP Australia. But, as I said, part of that is also the legislative time frames that are available to the applicant.

Senator HUMPHRIES: So if you have an application for which the prior art date is 1999, and it is not considered, for those reasons you mentioned, until 2008, but in the meantime the science has moved on so that the things being claimed as of 1999 no longer really satisfy the various tests—novelty, inventiveness and so on—can the patent still be granted, notwithstanding that, in effect, those elements would not be satisfied today but would have been satisfied in 1999?

Ms Press: Well, that is what we do. We assess—and I must point out that this is a divisional, so its parent application was actually accepted in 2004. These claims from the flea are two isolated nucleic acid molecules, and there have been several molecules claimed, so the applicant is obliged to divide out, and the opportunity exists for

them to do that. But when you assess the novelty, your prior art base—what you are basing the assessment on—is 1999. I think the first examination report on this went out. But, as Mrs Beattie said, there are 21 months for the applicant to respond to that.

Senator HUMPHRIES: Let us go to the fundamental question of how much is being patented, which is, in effect, the patenting of naturally occurring genes or gene sequences or proteins or whatever. I think that on the previous occasion we interrogated you about this, or on one of the previous occasions, you conceded that, with the better knowledge we have, for example, of genetics, some patents granted some years ago probably would not have been granted in similar circumstances today, given the better state of knowledge—that there were in effect errors made, or errors with the benefit of hindsight. Is that still your view?

Mrs Beattie: No, they were not errors made. What we are saying is that the knowledge in the art increases, and progressively, over time, it becomes harder to satisfy the inventive step and novelty requirements because there is so much of that knowledge in the public domain. That is what commonly happens with technologies as they mature. It is not the errors made; it is simply that the prior art available to the examiner to use to examine the application against is that much greater, and therefore the inventor is required to produce more in terms of inventiveness to satisfy those patentability requirements. It is a natural progression within the patent system, based on the maturity of the technology.

Senator HUMPHRIES: In her opening statement, Ms Halton said that the isolation of a gene from nature was not, per se, patentable—I think that is what you said. Is that the case? Is mere isolation of a gene, a sequence or a protein patentable or not?

Mrs Beattie: Let me go back. Is it patent eligible—that is, is it considered an invention? In our view, it is, because the isolated gene sequence with a practical use does not exist in that form in nature.

Ms Halton: And I said we did not support that, not that it was not possible. I said we did not support it.

Senator HUMPHRIES: Okay.

Mrs Beattie: That is why I tried to explain that an invention can be created not simply by construction but also by deconstruction. You can create a new invention by deconstructing an existing, big molecule because the new, smaller molecule has different properties, a different structure and a different utility. That is why it is considered an invention. Then you look at the criteria in terms of: is it worthy of a patent? For example, today an isolated gene sequence would still be eligible for a patent because it would be considered an invention. However, the requirements for an 'inventive step' and novelty are much harder to satisfy now because of the maturity of the art and the amount of prior art that is available now to the examiner when they are examining the application.

Senator HUMPHRIES: So the department of health are saying they think that test is essentially too low and that, in an ideal world, we would require more to satisfy patentability than is currently required?

Ms Halton: In our view—and our view is very clear—we do not agree on this. We do not accept the logic that says that, if you divide something that occurs in nature, then a subcomponent of what occurred can then be patented. We accept that you should be able to patent techniques and we accept that you should be able to patent all those things around it but not something that is actually a natural thing—in this particular case, a gene, a protein or what have you. And we do not accept the extension of a logic that says, from chemistry, for example, that, if you have a large molecule and you divide that molecule, it becomes something new and therefore it is an invention. We do not accept that this is an invention.

Mrs Beattie: I would like to add to that, if I may. What we have had for the last 100 years are molecules isolated from nature, plants and animals, for which a therapeutic use has been determined. That isolation, the creation of that smaller molecule and the identification of that therapeutic use have been considered to be sufficient creative genius to be regarded as an invention, and it has had access to the patent incentive. Now we are able to isolate molecules from the human body. Although we are able to supplement those molecules, fix those molecules and improve those molecules to do what they do in the body—which, I would suggest, is in fact the holy grail of human medicine—we are saying that that is not worthy of a patent incentive; that is not sufficient creative genius to warrant being considered an invention. That is what the argument is about, in my view.

CHAIR: Can I ask something and it goes back to the diagram that is on page 2 of the submission to us, which we were having a discussion about this morning. In my mind this bill splits non-inventive and then, suddenly, inventive. What you are saying, Ms Halton, is that a naturally occurring biological product should not be patented. I do not hear IP Australia disagreeing with you about that. What should be patented though, maybe, is the process that is able to isolate.

Ms Halton: I would disagree with you, actually.

Ms Beattie: Yes.

Ms Halton: We are disagreeing. They are saying it should be able to be patented and I am saying it should not.

CHAIR: Yes, but, what I am hearing is that the process in which that germ, that molecule or that enzyme is isolated—

Ms Halton: We have no problem with that.

CHAIR: That is right. It is not the enzyme or the finding of that enzyme; it is the process by which it can be isolated and reused that is patentable. Is that right?

Ms Beattie: We are saying that the molecule itself is the invention because you have created that.

CHAIR: By deconstructing.

Ms Beattie: By deconstructing or by constructing as you can also construct a new molecule, but the examples that you have received are simply examples of construction not the constructed.

CHAIR: I understand.

Ms Beattie: What we are saying is that that molecule is an invention because it does not exist in nature. It is an artificially created state of affairs. If you identify some practical use for it in a field of economic endeavour, then it satisfies, in our view, the manner of manufacture requirements as they currently exist.

CHAIR: So the patent system should be able to move with technology.

Ms Beattie: Yes, absolutely. That is why I have used the example of because we are able to do the same thing that we have done before in terms of molecules from plants and animals, and now that we are actually to isolate them from human beings and do all these wonderful things to them, we are saying that that is insufficient creative genius to warrant the patent incentives.

Senator PRATT: I want to ask a question about the construction and deconstruction of molecules, if now is an appropriate time.

CHAIR: I will just get Senator Humphries to finish his questioning and then I will come to you.

Senator PRATT: Thank you.

Senator HUMPHRIES: You would say, Ms Beattie, I assume that the test, as you have applied it, is the test that most of the world applies?

Ms Beattie: That is exactly the test that is applied by the US, the UK et cetera and it is the test that has been applied since 1903 in Australia. Many therapeutics are isolated from natural products and you get that isolated molecule. That is the key patent that the inventors want; that is the patent that sits at the centre. It is the heart of a portfolio of claims and patents, and this bill would actually take that centre out and make it hollow. The centre is the molecule that has been isolated, that has been created. Then you would also then put claims around the method of isolation, for example, or the method of creation, the formulation. What you then do is take that molecule. That is the new chemical entity or the active molecule in pharmaceuticals. That is the centre. Then you create these formulations and you might get a patent for the formulation as well. If you take out that centre, the creators are saying in the submission that you have received, we collapse. We would not bother doing this other stuff around it.

Ms Halton: Can we make a comment around that.

CHAIR: Sure.

Mr Reid: There are couple of different situations which arise when you patent a molecule. In the gene context what you do is isolate a molecule, a gene or a sequence and the fact that you have been able to isolate it and that you can contribute the piece into that genetic sequence is an indicator, say, for schizophrenia or whatever. That is regarded as being patentable and that, I think, we see as problematic. There is another context in which you isolate genes or molecules or whatever and what you have isolated is something that is a true invention in the sense that it does something. That is to say that this molecule, if you inject it into somebody, may have a beneficial effect in relation to a certain condition.

Ms Halton: A drug molecule, for example.

Mr Reid: Those clearly are full inventions in the true sense because you have gone through a process and you have produced something which performs a particular function. The difference with patenting genes is that you have isolated something which in a bottle is of absolutely no utility at all. It is the knowledge that attaches to it

that is of utility. It is the fact that you can identify that same gene sequence in another person and say, 'This is a marker of a particular condition' and use it for diagnostic purposes. That, to us, is the problematic part.

Ms Halton: I can give you a particular example of this. Say someone discovers a gene for Alzheimer's. Under these circumstances that gene would be patentable and then the owner of that patent might or might not be able to exploit it. It might be the case that you are able to have a research exemption, but unless you were the owner of that gene and under licence you would not be able to do anything else with it. So, effectively, while the life of that gene occurs, the owner and people licensed by the owner have control of it. You actually stifle the competition that comes from other people. We all know that with Alzheimer's all manner of things are being explored, but the patenting of that gene controls it. The gene itself delivers you no therapy—nothing. It simply says, 'Guess what could happen to you.' Let us be clear: the life of a patent would mean that if any person sitting around this table in the next 20 years ends up, regrettably, in that position, unless the owner of that patent on that gene enables licences or themselves come up with the answer to the problem, they will have to wait until the patent expires. That is the point. That gene does not give you the answer, whereas in pharmaceuticals the chemical itself has utility.

CHAIR: Is that a likely scenario, Ms Moore?

Ms Moore: I guess there is one thing that I would like to clarify. I do not like to complicate the matter further, but there are circumstances where a gene on its own actually is a pharmaceutical or a drug. There are technologies out there that are actually manifested by introducing a piece of DNA into a person. That is the first issue. The second issue is that part of the incentive of the patent system is that it provides the opportunity for some sort of economic reward for the work that you have done to get a patent. The fact that you own a patent over a gene and that others might want to get commercial advantage—I am distinguishing that from using it for research—is part of the incentive that is provided by the patent system. When there are issues with access, when that access is blocked, then, yes, that is a situation where problems can occur. But I guess that does not mean that there is a problem with actually allowing patents. It might suggest that there needs to be attention given to how people might access those patented materials, and in that way you might better balance the incentive that the patent system provides to invest in research and to get some economic reward with the ability of Australians to get access to that technology because of the way that it is licensed or because of the way—

CHAIR: In that instance, can't the minister intervene? Could people not make a call to the minister to intervene under the IP Act?

Ms Moore: There are Crown use provisions.

Mrs Beattie: There are Crown use provisions. There are compulsory licensing provisions as well. There are also industry solutions. For example, a patent pool is being created in the US for diagnostic multiplex testing. There is also an IP exchange being launched in the US which is about providing more ready access to patentable inventions as, for example, in buying shares. There is an initiative to develop an IP exchange where you would go and buy unitary licence rights to various patentable inventions. So there are various mechanisms available.

Ms Halton: Senator, to be clear, our view is that regarding Crown use and compulsory license mechanisms, which as we understand it are meant for infrequent individual cases of patent monopoly abuse, if you are having to resort to a whole series of other mechanisms to effectively get around the arrangements, that suggests there is some problem with them.

Senator TROOD: Just in relation to Ms Moore's proposition about economic incentive—I understood you, Ms Halton, in your opening remarks to acknowledge the importance of economic incentive. Is that right?

Ms Halton: That is correct and, to be absolutely clear, hence my comment about techniques, approaches to the isolation—all of those things which we absolutely agree should be the subject of patents, if appropriate. It is what the item is which we do not accept is an invention.

Senator TROOD: I understood that. I have further questions, but I am happy to let Senator Pratt proceed.

CHAIR: Senator Humphries, have you finished?

Senator HUMPHRIES: I have not, actually, but go to Senator Pratt. I am happy to come back.

Senator PRATT: Can we return to the debate about the construction versus the deconstruction of molecules. As I would have understood it in the logic that has been outlined to me, you could construct or deconstruct the molecule, but you could not just attach or remove things from it unless it actually did something innovative or novel to it. It would not allow you just to patent that molecule having arbitrarily just altered it—it having retained its original function—just so you could patent it.

Mrs Beattie: In effect, to be an invention you have to demonstrate that it is new—that you have done something artificial—and that it has some practical use, before it gets over the hurdle of, 'Is it or isn't it an invention?' So it does have to have a practical use identified. What you are getting—

Senator PRATT: Would it be the same use as in nature, or does it have to be a new and novel use?

Mrs Beattie: It has to be a use that was not previously known.

Senator PRATT: So if it is—

Mrs Beattie: There has been, I think, a little confusion around what happens then when you structure a patent application. What you are getting is Dr Palombi quoting to you claims where the claim is to the molecule itself. The eligibility test requires you to identify the function—the practical use—for that molecule. That use has to be in the description. You can then claim the molecule, you can claim the use, you can claim the method that you have used to isolate it, and you claim those separately. You will not find a claim to the molecule that says 'I'm claiming this molecule, and it's for this use', because that would then limit that molecule to only that use.

Senator HUMPHRIES: So why claim the molecule at all in that circumstance? Why not just claim the other uses of it and so forth?

Mrs Beattie: Sorry?

Senator HUMPHRIES: Why claim the molecule in those circumstances? Why not just claim the other things and exclude the molecule?

Mrs Beattie: Because the molecule is the heart; it is the molecule that you want. For example, this is a device that when fitted to an engine gives you fuel efficiency—20 percent. This is patentable; you get a patent for this device for the various uses that you have described in the application and claimed—so all engines. Inventor No. 2 comes along and determines that this device when worn alleviates arthritis and reduces pharmaceutical consumption in relation to arthritis. That second inventor, because that is an unexpected use that was not identified by anyone else before, gets a patent for that second use. They do not get it for the device, because it is the invention of the first inventor; it has already been invented. You can apply the same logic to a molecule.

Senator HUMPHRIES: Why would you get a patent, though, if it had already been subject to another patent or was natural—

Mrs Beattie: You get the patent to the use, so you can then use that device for treatment of arthritis.

Senator HUMPHRIES: But you do not need the patent over the device; you only need the patent over its use.

Mrs Beattie: You cannot get the patent over the device. What you have to do, though, is, if the patent by the first inventor for this item is still in force, you actually have to go and get a cross license to use that device for your arthritis use. That is how a patent works.

Senator HUMPHRIES: But the question is: should it? Sorry, I am interrupting.

Senator PRATT: I would like to continue with that flow of questioning. Where does the distinction between the invention and nature actually kick in as it relates to its purpose and use?

Mrs Beattie: It is in that first test: the manner of manufacture test. Is this an invention? Is it eligible for a patent? That is when that distinction has to be identified.

Senator PRATT: So you should not just be able to patent something because, in a sense, you have altered the molecule and therefore you can patent what is a typical natural function in any case, unless you have a novel use for it, which might be, for example, to inject it and create a therapy, and therefore you have created the novelty without substantially changing it? That is the patentable part of it—use and not its function?

Mrs Beattie: You have to have transformed the molecule in some way. You have to have created an artificial state.

Senator PRATT: I understand. You have transformed it and created something artificial. What I want to know is whether it is possible, I suppose, just to arbitrarily create something artificial even though what you are seeking to do is really to duplicate its natural function. That would not seem novel to me. Clearly molecules change in their function if they have bits attached sometimes but, in other instances, they may not. They may retain their natural function, but you have nevertheless deconstructed it.

Mrs Beattie: But if you did not know what its natural function was in the first place then you have actually created and enabled that function.

Senator PRATT: But if you always knew what its natural function was but you really just altered it arbitrarily for the purposes of patenting it?

Mrs Beattie: You would not be able to—

Ms Press: It may fail on the inventive step test. You have a new product. It is not identical, but it does not have a surprising function, so in some instances that would fail. It would still be eligible to be considered for a patent, but it would fail, most likely, an inventive step test. So if it were a trivial tinkering of a molecule for no surprising, unappreciated, previously unknown benefit, it would fail an inventive step test.

Senator PRATT: Thank you. With respect to the history of these debates, clearly we have a bill before us but we also have the raising-the-bar bill before us. It is not before this committee, but clearly they are being debated in context. Can I ask about the history of some of the issues that have arisen, which have motivated the bill before us, and how those issues are being sought to be dealt with within the raising-the-bar bill, because I think implicit even in its name is a sense that clearly there are things that have been patented in the past that perhaps should not have been.

Mrs Beattie: I think the key one would be the research exemption. I think the bill before you claims to be seeking to provide improved access for researchers. I think the IP reform bill does that by the research exemption. I think the issue around whether something has been patented that should not have been is the nub of the debate about whether or not what has been patented is an invention. We claim that it is an invention—it is an artificially created state of affairs in a field of economic endeavour. The IP reform bill does not address the eligibility for a patent; what it does is increase the standards required to be granted a patent.

Senator PRATT: I do not know if you were here for the previous witness discussion—because I am not in the room I am unclear whether you were there or not—about how inventiveness is defined and the history of IP debates about natural processes versus discovery versus inventiveness. Clearly we have a bill before us that tries to carve out biological phenomena separately; whereas, I would have thought that IP law overall would have to deal with natural phenomena holistically. The question whether you have altered nature to do something novel or inventive is universal. I would like to ask you about how we set that bar within the raising the bar reforms. How do we deal with that question of discovery versus inventiveness and novelty?

Ms Moore: The raising the bar bill makes some changes to the way that 'inventive step' is assessed under the Australian patent system. We have a couple of anomalies in the way the inventive step tests are applied that place our standards a bit lower than standards in places such as the US, the UK and Europe. The raising the bar bill removes those anomalies so that the way that inventive step is assessed in Australia is more aligned with elsewhere and does it to a higher standard. That is one of the main ways in which it raises standards but it also ensures that there is a full description of inventions in the patent specification so the public has access to all the knowledge about the invention and how they might repeat it.

Senator PRATT: Does any of that go to the question of discovery of natural phenomena versus inventiveness and novelty?

Ms Moore: It does not go to the question of discovery versus invention. As Ms Beattie said previously, the particular issue of what is eligible for a patent, and what is not, is not addressed by the bill; rather, the bill seeks to raise the threshold that you have to reach to be granted a patent.

Senator PRATT: Are they legitimate questions? For example, if you discover gravity waves—we all know gravity waves exist but they have not yet been discovered—I would have thought the method of discovery is something that would be patentable but clearly a gravity wave in and of itself would not be. These are questions that would be the same for the biological world as for the broader environment questions.

Ms Moore: I am afraid I am not an expert on gravity waves so I will shy away from that example. I could go back to genetic material and use that as an example. Although the raising the bar bill does not look at the eligibility of that sort of material, it does make sure that if somebody seeks to claim a gene sequence in a patent it is sufficiently inventive and is new. One of the things we have seen as time has gone on, particularly with the widespread publication of things such as the human genome, it is a lot harder to get a patent for a gene sequence and you need to have surpassed a higher inventive threshold. The bill will make sure that if you did get a patent for a gene sequence—and that sequence was eligible because it met the requirements that Ms Beattie has mentioned, such as being isolated and having a practical use—that it was also significantly different from anything that had been done or suggested before and so was truly inventive.

Senator PRATT: In terms of what has been done or invented before, how do you define what has been done before versus what has been done before in nature by nature itself?

Ms Moore: We do not distinguish between what has been done in nature and what has been done artificially when assessing novelty and inventive step. We look at what information is publicly available: what has been published and what a worker in that particular field would know. So when they assess patent claims, if there was

information about how something happens in nature that had been published then they would take that into account in deciding whether a claimed invention was novel and inventive. Similarly, if they had access to information about what had been done artificially they would take that into account.

Senator PRATT: Okay, thank you.

Senator TROOD: I must say, Mrs Beattie, if your proposition to us is that a patent can be gathered because someone can isolate some part of something that we know to exist and all they can do is to affirm that the part exists—

Mrs Beattie: With respect, no-one knew that the BRCA gene existed. They isolated that molecule—

Senator TROOD: Perhaps I misunderstood.

Mrs Beattie: They isolated a molecule. They created a new molecule and they subjected it to a whole range of testing and experimentation before they determined—

Senator TROOD: But it turns out to be part of the whole, so it exists as part of the whole.

Mrs Beattie: Not as that molecule. Those atoms in that order exist in this other bigger molecule. The isolated gene sequence itself does not exist in that form in the body.

Senator TROOD: That was something I was struggling to come to terms with because it seems to put you at odds with the department of health's position on this matter which is at least, of interest, perhaps it is even of concern. I just wanted to ask you a couple of questions about the raising the bar bill because you put that into evidence. Firstly, has the exposure draft been subject to widespread consultation prior to it being produced or are you hoping that as a result of it being published it will now be subject to scrutiny?

Mrs Beattie: There was substantial consultation in relation to papers dealing with the changes that were being proposed. The bill is a culmination of those consultations and all that feedback that has been gathered over the two-year period. The bill now is available for people to see the end result of that consultation.

Senator TROOD: Thank you for that. Do I take it from that response that it is designed to address concerns that IP Australia identified in relation to the patent process and it is not necessarily responsible to the things that are identified by this bill?

Mrs Beattie: This bill deals with the eligibility issue. The eligibility issue was the subject of the ACIP review, the Australian Council on Intellectual Property did a review of the manner of manufacture test. That too was the subject of extensive public consultation and that report has been published. The government is now considering that report in terms of how it might respond to those recommendations.

Senator TROOD: The raising the bar bill is responsive to a series of concerns which have been long standing.

Mrs Beattie: It comes from the ALRC 2004 issues, it comes from various stakeholder issues that have been raised over time. It also deals with matters that IP Australia identified through the things that we saw where a patent could not be granted, for example, in the US but we would have to grant it in terms of those claims and we felt that that was inequitable for the Australian economy.

Senator TROOD: Presumably the Senate will deal with that in due course. Ms Halton, was your department involved in the preparation of the raising the bar bill at all?

Ms Halton: We were consulted.

Senator TROOD: I see. Do the provisions of that bill meet the concerns or the observations you have made about the process of isolation?

Ms Halton: No.

Senator TROOD: It does not?

Ms Halton: We still think there is a fundamental blurring between the notion of discovery and invention.

Senator TROOD: I see. So this bill is not going to address your concerns?

Ms Halton: No, it is not.

Senator TROOD: Thank you.

CHAIR: Is there also not, Ms Halton, a blurring between intellectual property rights and physical property rights here?

Ms Halton: You are beyond my area of competence. I will ask my general counsel.

Mr Reid: I am not sure whether I understand the question, but it may relate to what I was trying to say earlier on. If it does not, please help me. It seems to me that you could distinguish between two states of affairs, one

where you isolate part of a genetic sequence and can identify a function which that isolated genetic sequence can perform like any other invention and the other is the situation where you identify a genetic sequence and put it in a bottle. It has no function as such but the knowledge attached to it has a function. Am I talking about what you are asking about?

CHAIR: No, I am not talking about that.

Ms Halton: More information, please.

CHAIR: I am still coming from the basis that I think there is not a series of differences between them, the series of differences go to IP rights versus property rights. For example, maybe IP Australia can clarify for us whether someone actually owns the physical gene, whether they actually own the molecule, or whether they own the invention.

Ms Moore: They do not actually own anything. A patent holder does not own anything except for the right to stop somebody getting commercial advantage from that thing. They do not actually own the gene.

CHAIR: That is right. I am still putting to you that I do not believe there is a difference of opinion with the department of health. The way I see it, Ms Halton, is that the view of your department is that you should not be able to own the gene, you should not be able to own the molecule, but you should have a right to be able to use it.

Ms Halton: No, that is not correct. Our view is very clear. It is our view that you should not be able to have a right over the gene—if we are talking about gene for a second—you should have a right in relation to the steps, the technology—

CHAIR: You could have the intellectual right.

Ms Halton: No. We do not believe you should have the intellectual right over something called a gene in this particular example. We agree that you should have the intellectual right over the technology and in fact that might actually prevent anybody else even getting their hands on it because you do not disclose that technology but, if someone else were to develop the technology to get access to the thing we are talking about, the gene in this particular case, they should be able to use the gene.

CHAIR: All right. But do you believe someone should have the intellectual property rights for a molecule?

Ms Halton: If they invent it, yes.

CHAIR: The instances that Ms Beattie gave with the BRCA, for example, would satisfy that requirement.

Ms Halton: No, it would not from our perspective. That is precisely my point and one of the reasons that we have had this whole problem with that particular example. The general counsel has gone through why we were not able to invoke the Crown use issues at the time. That has been in terms of human health potentially enormously problematic. This is our point: we think that we have blurred this boundary between discovery and intervention.

CHAIR: But you do not believe this bill sorts that out either.

Ms Halton: No, not the raising the bar bill.

CHAIR: Okay.

Mrs Beattie: Did you mean the private member's bill or the IP rights bill.

CHAIR: I mean the private member's bill.

Ms Halton: The private member's bill, as we said in our introductory statement, actually casts a broader net. We think the intent of it is probably consistent with what we are saying but we think the way it is currently drafted does not tackle it because it goes more broadly. We have told the proponents of the bill quite directly that the language in the bill is too broad and too all-encompassing. As I understand the intent of the draft, it does go to the issue.

CHAIR: I want to ask another question of IP Australia and from my perspective I asked before whether or not the mechanism for the patent system as a whole should move with technology and with the advances for example. You make a distinction between the manner of manufacture and the test for novelty, usefulness and the inventive steps. Are you making this distinction because you have a particular preference for how the patent system should be reformed in order to move more effectively with the technology?

Mrs Beattie: One of the issues that was raised in the options paper by ACIP in their review of the manner of manufacture test was: do we do away with the manner of manufacture test and do not have an eligibility test at all; just go straight to novelty, inventive step, industrial applicability. You would then simply assess anything that comes through against inventive step, novelty and practical use. You would not have to worry about whether or not it was an invention or a discovery. You would simply judge it on those three criteria.

Senator HUMPHRIES: Is that what the ACIP recommendations affectively do?

Mrs Beattie: No, that is what they proposed in their options paper during the consultations, and that was not accepted by the stakeholders.

CHAIR: Can you then try to explain to me why you think it is necessary to make a distinction between what is eligible for a patent and what satisfies the inventive step?

Mrs Beattie: It is the way it has been. That is the way the patent system is at the moment. The manner of manufacture test is the eligibility element that has to be satisfied before you consider whether something is worthy of a patent grant.

CHAIR: So that should take the same approach in all technologies.

Mrs Beattie: It is the same approach in all technologies, yes.

CHAIR: And with all manner of products rather than just isolating the biological product.

Mrs Beattie: Yes.

CHAIR: Is that the problem with this bill: it isolates the biological product?

Mrs Beattie: We believe that it is much more technology specific.

Senator HUMPHRIES: There are two conclusions that I draw from the evidence we have heard in this inquiry. One is that there is considerable dissatisfaction with the way in which patentable material is defined, particularly in the area of genetic invention/discovery. That has been highlighted today. The second issue is that it is not evident that the bill is the vehicle to solve that problem but that something else needs to be considered, maybe in conjunction with the bill or maybe in some other process, to deal with this issue. Personally, I am not sure that it is an issue that actually ought to be in the political domain at all at this point in time.

I take it from what you said, Mrs Beattie, that you are agnostic about whether or not the ACIP recommendations as they were finally produced are suitable as a means of reforming this law, since you are particularly critical of the law as it stands at the moment, I take it.

Mrs Beattie: The ACIP review does not actually recommend a change to the manner of manufacture test per se. It says that it should be restated in more modern language based on the legal precedence to date.

Senator HUMPHRIES: Can I ask, Ms Halton, if what ACIP has recommended addresses the concerns that you have raised today?

Mr Reid: I think we generally support what ACIP says. It is moving things in the right direction but it does not fundamentally address the problem which the bill before the committee seeks to address, which is the problem of gene patenting and the BRCA1/BRCA2 situation.

Senator HUMPHRIES: Do you have a recommendation as a department as to how we might resolve those issues which are reflected in a number of submissions that have been made?

Ms McDonald: The area in the ACIP report that does cause us a bit of grief—and I think it is the nub of the issue here at the moment—is the question of discovery versus inventiveness. There is a technical issue about being able to isolate a gene which is the same gene as in the body but, because it is isolated, it gives you a technical reason under the current interpretations used by IP Australia as to why, if you find a use for that, you can then patent it. If you clarified the discovery versus invention definition and went in the opposite direction to what is said in the ACIP report, instead of locking in the current arrangement, which is an artificial state of affairs in a field of economic endeavour, that might achieve it. But that is probably the key thing, and the question is then: where is the boundary. It really is that issue of discovery versus invention that is the difference between our interpretations.

Senator HUMPHRIES: My question was more about process and how we address that issue. I suppose that is a problem for us rather than you.

Ms McDonald: It comes down to section 18 of the Patents Act.

Ms Halton: And let us be clear: it is not our role or responsibility to comment on patents law more broadly, and I am not going to go there. It is not my remit. My remit is the health system and access to technology in the health system and that is my concern. That is why if we take the bill that is currently being discussed, not the raise the bar bill—that bill does not deal with that issue because it is too broadly conceived. If it were narrowed, that bill would deal with my portfolios and department's particular concern. It is not my role to comment more broadly.

Senator HUMPHRIES: Indeed. We have heard too much concern about those issues for us not to deal with them in some way, or for someone to deal with them. I take your point.

I wanted to ask about a couple of other things that we have heard. If you want to take these on notice that is fine. We heard from Professor Drahos before that there was an incentive scheme. We thought there might have been an incentive scheme operating at IP Australia, which I think he was implying might have been driving unnecessary patenting of things that otherwise ought not to be patented. I would appreciate you taking on notice that question.

Mrs Beattie: I can answer that now. There is not an incentive scheme in IP Australia for driving increased patenting. There is a performance management scheme, as there is in every other public agency, in relation to performance of staff. So, yes, we do have a performance management scheme in place.

Senator HUMPHRIES: But that does not drive the patenting of more things, in your opinion.

Mrs Beattie: It actually drives delivering a quality product.

Senator HUMPHRIES: There was a question about how, retrospectively or otherwise, preventing people from using patents that they have already been granted, it was alleged inappropriately over genetic materials and the problems this gave rise to with respect to the constitutional barrier on the Commonwealth acquiring things otherwise than on just terms. I think you have answered that question already, Ms Moore, by saying that people do not acquire the unfettered right to exercise some right under a patent. They only have the right to exclude other people from using the intellectual property. I assume that that excludes the crown. The crown does not give away its rights to use that right over the property that it is granting to a patent holder.

Mrs Beattie: Crown use provisions allow the crown to use the invention without seeking permission from the patent owner. However, there is an obligation to remunerate appropriately the patent owner and to advise the patent owner that they are using that invention. Similarly, compulsory licensing requires there to be appropriate remuneration.

Senator HUMPHRIES: I will put any other questions I have on notice.

CHAIR: I thank all of you for your time today—especially you, Ms Halton and Mrs Beattie—and for your submissions. If we have got other questions, which some of the senators may well have, we look forward to the answers to those questions. A couple of weeks will be fine for the answer. We do not report until the middle of June.

Committee adjourned at 13:04