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Proof Committee Hansard

SENATE

LEGAL AND CONSTITUTIONAL AFFAIRS LEGISLATION COMMITTEE

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

(Public)

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SENATE

LEGAL AND CONSTITUTIONAL AFFAIRS LEGISLATION COMMITTEE

Thursday, 28 April 2011

Senators in attendance: Senators Barnett, Boyce, Crossin, Furner, Heffernan, Humphries, Pratt, Siewert and 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

Committee met at 09:08.

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

I want to remind all 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 the 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 a committee.

We prefer all evidence to be given in public under the Senate's resolutions but witnesses have the right to be heard in private session or in camera. If that is what you believe you need to do then you can make approaches to us and we will facilitate that. If a witness objects to answering a question, the witness should state the ground upon which the objection is taken and the committee will determine whether it will insist on an answer, having regard to the ground which is claimed. Having made that formal introduction, I now welcome representatives from the Peter MacCallum Cancer Centre and the Walter and Eliza Hall Institute of Medical Research.

CLARK, Dr Julian, Head of Business Development, Walter and Eliza Hall Institute of Medical Research

HILTON, Professor Douglas, Director, Walter and Eliza Hall Institute of Medical Research

LOFTHOUSE, Dr Shari Amanda, Manager of Intellectual Property and Development and Acting Director of Commercialisation, Peter MacCullum Cancer Centre

MITCHELL, Dr Gillian, Clinical Oncologist and Director, Familial Cancer Centre, Peter MacCallum Cancer Centre

CHAIR: We have a submission from the Peter MacCallum Cancer Centre, which we have numbered 24 for our purposes and which is on the website. We have also received a submission from the Walter and Eliza Hall Institute of Medical Research which we have numbered 59. Do you need to make any changes or amendments to those in the first instance? If not, I will invite you to make an opening statement before we go questions. I just want to highlight, though, that there are a lot of senators here and a lot of interest in the bill. We probably get more benefit out of a question-and-answer scenario, so if your opening statements could be fairly brief that would be appreciated. Then we can spend the best part of our hour talking to you about the issues. Who is going to go first?

Dr Mitchell: I would like to start by saying I would not normally read a prepared statement, but I think this is such important issue that we have prepared a brief statement and I will read from this. I will start by thanking you, Madam Chair, and the other senators for the opportunity to discuss this matter today. The issue of gene patents in particular is one that creates great uncertainty for us in our day-to-day clinical practice and research operations. We genuinely appreciate that Senator Heffernan has recognised the community's concerns and introduced this bill, which has highlighted the issue and invited a very broad discussion on the topic.

My interest and involvement in this goes back to 2008, when personally and as an institution Peter Mac experienced firsthand the negative consequences of gene patents and the associated patent and licensing arrangements. I think it is important to see this as a continuum and not just gene patents in isolation. Our experience is in both the clinical and research setting, and we gave examples of this when we made our statement to the first Senate inquiry.

Our experience started off in the research setting, and there was a clinical consequence where GTG tried to put a stop to the public testing of BRCA genes in the general community in Australia. Fortunately, that situation was resolved—partly as a consequence of the negative publicity in the Senate inquiry that arose at the time—and we can now continue to offer clinical testing through public clinical laboratories in Australia. But that resolution did not happen before the situation caused significant distress to patients, who were worried that genetic testing was not going to be available to them, distress in the community and uncertainty for us about whether we were able to carry on with the genetic testing in the way that we always had done.

As a clinician, the intricacies of the legal position at the time were not really very clear to me. It certainly seemed at that time that it all revolved around the patenting of the sequence of the gene, although after speaking to Shari and other colleagues who have a much greater handle on the fine detail it seems it is not just the gene patents that were the problem; it was the additional licensing and patents surrounding the application of that gene sequence. The gene sequence itself was a part, although not a major part, of the genetic testing action.

I cannot claim to understand the full detail of these arguments, but what is becoming more clear is that simply banning patents on gene sequences per se would not actually have solved the problems that we had in the research and the clinical settings in 2008. But Peter Mac does still take the position that a patent on a gene sequence per se should not fulfil the requirements for a gene patent. In other words, a patent on a discovery of nature does not really fulfil the requirements for the novelty, utility and the inventive steps. So we see that current patent law in itself is not problematic; it was more the application of that patent law to gene sequences in the past that was the problem. But, despite all those difficulties in 2008, we are actually glad that the current situation about gene patents and the wider discussion have come to the fore, because genetic technology and genetic information are the way of the future; they are what is going to give us the biggest strides and advances in developing new

treatments and improving outcomes for the general population. I think it is timely to be looking at how we harness that information, both using it and providing protection for the people who are involved in the research setting and in the commercialisation of what we find in research.

The Peter Mac, though, has some concerns that this particular bill may not actually be able to address the problems that we experienced in 2008, so we welcome the opportunity today to discuss some of those problems and how we might best address these in the future so that the community can benefit from these rapid discoveries in the normal and disease-associated biological processes. The patent issue does impact the Peter Mac, as an institution involved every day in the development of new diagnostics and treatments for cancer patients, in a number of ways. In a clinical setting, we want our patients to be able to access the new technologies as soon as they become available, and in our research laboratories it is essential that our scientists are able to use the new, cutting-edge information to try and move things along, particularly so that we can conduct internationally competitive research unfettered by legal sanctions and so that the intellectual property the research generates can be protected. Protecting IP is an essential prerequisite in attracting the commercial funding that is vital for research. Particularly in the current funding crisis in publicly funded research, the private and commercial funding is very important.

We did previously express an objection to the patenting of gene sequences, and we do still hold the view that genes per se should not be patentable. Having said that, in practice gene patents now are rarely granted on the sequence per se, and those that are granted are now restricted to those that generally meet the standards of patentability with novelty and utility. We do not have any arguments with those, but the situation around the gene patent issue has shifted as the technology has developed, and in future other technologies will arise again that have the capacity to create confusion about what is patentable and what is not. I think our concern is that, if we have something that is too tight and restrictive right now, it will only cause problems in a year or two years time as technology evolves as rapidly as it does.

So our preference is really now to ensure that the patent system is appropriately structured to provide safeguards for all the stakeholders regardless of what the subject matter is, whether it is a gene or a new protein that is discovered, and also—and particularly—to ensure the stringent examination standards of whatever is submitted for a patent to ensure that only genuine inventiveness is rewarded. Ideally we would like a general research exemption to be somehow built into any act that is granted to allow scientists to work without threat across all types of patented inventions. Finally, we need to ensure that patent holders have appropriate protection but also that they cannot unreasonably restrict access to the information itself.

So the Peter Mac's position is essentially to ask for a tightening of the existing Patents Act to ensure that it functions as intended, and we are very pleased that Senator Heffernan's bill has opened up the discussion for us to be able to move forward with this, but we do have some concerns that the bill as currently described will not adequately address the concerns or those of the community at large. But we are very encouraged by the wide-ranging aspects of this bill and also the upcoming patent amendment bill drafted by Senator Carr, which has been some years in gestation but has had a lot of careful thought put into it on the ramifications of the bill. We really look forward to having greater engagement with that bill to raise the standards of patentability and provide adequate safeguards to our researchers, our clinicians and, most of all, our patients so that we can actually help them. That is, after all, why we are here. Thank you very much.

CHAIR: Thanks, Dr Mitchell. That is great. Dr Lofthouse, did you want to—

Dr Lofthouse: No, that was our opening statement.

Professor Hilton: I will add to her statement.

CHAIR: No worries. Thank you.

Professor Hilton: Thank you again for the opportunity to present. We think there are many reasons, which were outlined in our submission, that argue quite compellingly against the amendment. I am not going to highlight all of those, just because of time, but I would like to just highlight three. The first comes down to my motivation as a medical researcher. I work in a laboratory. I am interested in two types of diseases, cancer and inflammatory diseases. My laboratory works at the basic end of the research spectrum, but we hold very seriously the need to work with our clinical colleagues and commercial groups to take those innovations that we make in the lab through to improvements in patient diagnosis and treatment. That is the reason we have got into the game as medical researchers.

For many therapeutics, that requires hundreds of millions of dollars, and the only avenue for obtaining that sort of funding is through the private sector interaction with Australia and the international buyer pharmaceutical companies. So my main concern with the amendment as described is that it will dry up our capacity to translate

our innovations in the lab into discoveries that make a difference in patients' lives. That is a very visceral reaction as a researcher but also, I think, a compelling argument from the viewpoint of the community.

One of the reasons put forward for the amendment is to enable better access to diagnostics and therapeutics, and we believe that, quite counter to that, the amendments will reduce the capacity of the community to access new therapeutics generated from our own discoveries; but—perhaps even more importantly, given Australia does three per cent of the medical research internationally—we also believe that it will reduce the capacity of the community to access innovations that have developed overseas. That is particularly important in 2010-2011 because the majority of new therapeutics that come onto the market would be covered under the term 'biological materials': antibodies, vaccines, small molecules that are based on natural products. So we believe that it is an exceptionally broad amendment in its scope and would really significantly reduce the capacity of the community to benefit from medical innovation.

We also would like to highlight the imprecise wording of the amendment as stated. The breadth of the amendment is large. It is not an amendment that seeks to exclude simply DNA; it excludes biological materials and derivatives. We believe that that uncertainty will also reduce the capacity to access funding for translating medical research breakthroughs and will also lead to a lot of determinations in court.

I think that sums up where we are and the key issues we would like to highlight in our presentation. As I said, there are a number of other issues that we can perhaps address at question time. I will stop there. The executive summary of our submission covers those pretty well, and I do not think there is much point rehashing them.

CHAIR: Thank you very much.

Senator HUMPHRIES: Thank you for a couple of extensive submissions here. I will take first the submission of the Walter and Eliza Hall Institute of Medical Research. It talks at length about the circumstances of research and the reliance of research on patents. It takes the particular example of the BRCA gene patent issue that Dr Mitchell referred to earlier on in her evidence. You say in the submission:

Myriad's BRCA1 patents are often cited as examples of IP protection that stifles research even though they were granted in Australia and the US more than 10 years ago. There is no significant evidence of these patents hindering research.

Isn't the argument about BRCA1 not so much the hindering of research as the question of the use of the patent to prevent the use of testing for cancer-prone cells within women? Isn't that the issue that is being raised by this legislation? How is your understanding of the work that you and other people who use that sort of testing affected by the passage of the bill?

Prof. Hilton: My understanding is there are two motivations for the amendment. The first is the one you have raised, which is to ensure that diagnostics are used within the community as freely as possible. The second issue that is raised is that these gene patents have proven to be barriers to research. It is difficult to look into the crystal ball to see which of those two in the particular issue of BRCA1 was foremost in the mind. My view is that there is absolutely no evidence that the patents have stifled research. In fact, in my experience of 25 years a researcher working in Melbourne and in Boston at MIT I do not think there has been one instance where either I or my colleagues have felt in any way stifled to do the research that we were passionate about by the presence of patents on biological materials. For us it has been an absolute non-issue. In practice, researchers take an exemption for granted anyhow. I am probably not the best person to comment in terms of testing; that is probably more of a Peter MacCallum issue.

Senator HUMPHRIES: Then I ask Peter MacCallum to comment on that.

Dr Mitchell: I will give an example of what happened to us in 2007-2008 which precipitated the gene patent issue here in Australia. Professor David Bartel and I were granted a large grant from the American Department of Defense as well as a grant from Cancer Australia here in Australia to undertake BRCA genetic testing in a large Australian cohort of women with ovarian cancer. The large proportion of that funding was to perform genetic testing. We looked around for a number of places that could do genetic testing as cheaply and quickly as possible because there were 1,000 cases and it could take years to do if one did it in a single laboratory with a single machine, as it were.

As a consequence of that we found our research delayed, because we went originally to Myriad, who were happy to do it as a commercial research collaboration. Myriad then had to withdraw because GTG, as it was then here in Australia, had a licensing arrangement. I do not understand the intricacies of the licensing arrangement, but the consequence was that Myriad was not permitted to do either research or clinical genetic testing for BRCA genes on Australian samples because of that arrangement. As a consequence we met with GTG as researchers to talk to them about what they could then offer. In fact, our first wish was that they would allow Myriad to do it. They would not allow Myriad to do it; they wanted to it. They were not offering either a quick enough turnaround

time or a competitive cost to do so. But even more than that was the insistence that if we went with GTG the Peter Mac would stop doing clinical genetic testing for the BRCA genes. The comment from the CEO at the time was that he could not understand how there was public laboratory BRCA testing in Australia when GTG had the licence to be doing the clinical testing in Australia.

That was a new CEO, I think, who was partly coming to see what was happening in the company and could not understand the situation, and the consequence of that was a legal letter that went out to all our clinical laboratories to cease and desist genetic testing which then precipitated all the problems that we had. Consequently our research was held up whilst the uncertainty about who could and could not do testing was resolved. In the end we did it in-house, and we have only just completed it just over two years later. So it has held up our research. Whether one says that is because of the patent holding up the research or the licensing arrangements and the confusing that occurred there that has held up the research is somewhat semantic. The consequence was that we were not able to do our testing as quickly as we had anticipated and our research is two years late in completion.

As far as I was concerned, the research and clinical issues all became embroiled in the same thing, and gene patents were part of but not the whole problem in terms of the experiences that we had at the time. So certainly what I do not want to have in the future is something similar to that again. The comment that I made in our opening statement was that I am not sure how much the bottom line came down to a gene patent that Myriad holds on the actual sequence itself and how much came down to the legalities of licensing and agreements. But we still had a lot of problems. The comment that we made in our statement was that how much this new amendment would clarify or prevent that problem that we had happening I am not sure about, and I think this is where you are going.

Dr Lofthouse: To add an answer your question about what would happen if this bill were passed in that situation: it would have been exactly the same situation. You would have removed the gene claims, but there were still claims there to the diagnostics and the methods.

Senator HUMPHRIES: Are you saying that the passage of the legislation would or would not have prevented the original patenting of the gene?

Dr Lofthouse: It would not have prevented the original problems. There were still patent issues surrounding the diagnostics and the method of BRCA testing once you remove the gene sequence information.

Dr Clark: We strongly support that view. Enacting this amendment would not solve the problem that Gillian Mitchell and Peter Mac had entered into. This is an anomaly caught up between GTD and their business relationship with Myriad, and superimposed upon that are the two issues of whether you are perceived as doing commercial damage, for a patent holder, and the research question is completely separate to that. In our submission, we believe that there are other mechanisms that are much more is precise to address specifically these issues, because this amendment as proposed will not solve the problem. Do not forget, there are roughly 68 BRCA1 patents in Australia, of which only a small number are Myriad.

Senator HUMPHRIES: Did Myriad hold a patent over a gene or a gene sequence, in your opinion?

Dr Lofthouse: They did, but the patent included a number of claims, of which I think the first 17 were to gene sequences. The remainder of claims were to diagnostic methods, which we still would have been prevented from using if they had proceeded.

Senator HUMPHRIES: But if they have not been able to claim, apparently successfully, the gene sequence—surely the claim over the diagnostic use of that sequence would have fallen?

Dr Lofthouse: No. They still want the method surrounding the diagnostic testing, which would stand, and it may even be a broader invention than they initially had.

Senator HUMPHRIES: Professor Hilton, you said that you did not believe that there was any likelihood of the system of patenting, which includes the patenting of processes relating to genes, affecting Australia's capacity to undertake research. I think you made a comment that reflected on something that Professor Drahos says in his submission. He posed the question:

3. Would enacting the Bill adversely affect investment in the Australian biotech sector?

He says:

No, it would not. Australia represents less than 2% of the global pharmaceutical market. Investment decisions by pharmaceutical multinationals are driven by three markets—the US, the EU and Japan ... Australia's patent law does affect the access rights of Australian consumers and researchers, but it does not affect global investment decisions because of the small size of the Australian pharmaceutical market.

Do you want to comment on that?

Prof. Hilton: I would disagree with that very strongly. There are a number of breakthroughs that have been made and patented within Australia. I can give you some examples, which are listed there. GNCSF is a good example here. We have a number of programs that we have commercial investment in within the Walter and Eliza Hall Institute to develop them from discoveries within the lab to therapeutics. Some of those are with Australian biotechnology companies like CSL, others are with multinational companies like Genotech and Avid Pharmaceuticals. So I think the evidence compellingly suggests that, if discoveries are important enough and they are made in Australia, international biopharmaceutical companies and other sources of capital will come here and invest.

Dr Clark: I would also add that that argument is fundamentally dangerous because it argues that Australia should accept being a fringe dweller, saying it is two per cent. The reality is that Australia has the 10th largest patent office in volume in the world and it is the seventh largest when it comes to non-residential applications. If you look at IPS Australia, I think at the last look 92 percent of patents granted in Australia are nonresidential. In other words, that says how attractive Australia is as an IP regime—robust. What this certain amendment will do is align us with Ecuador, Peru and Venezuela—a lack of robustness. They do not have access to therapies fast in the way that Australia does. That is the fear.

Senator XENOPHON: Professor Clark, you said that we would be up there with Peru and Venezuela; does that include Brazil?

Dr Clark: Yes.

Senator XENOPHON: So you are saying that in Brazil it is pretty open slather; they do not have the restrictions we have in our current legislation. You have got concerns that that would slow down research.

Dr Clark: Slow down the adoption of research and commercialisation of effective therapies.

Senator XENOPHON: And Brazil is in that category, is it?

Dr Clark: Absolutely. 20 years down the track only some of these drugs are coming into Brazil.

Senator XENOPHON: I am just looking at a media release that Amgen put out on 8 April. Amgen is the world's largest biotechnology company. In a quarter of a billion dollar deal they acquired Bergamo, a privately held Brazilian pharmaceutical company. Isn't the fact that you are getting the world's biggest biotechnology company willing to make that substantial investment in Brazil inconsistent with the view that Brazil is not a good place to invest in research and in biotechnology?

Dr Clark: There are two issues there. There is no evidence of consistent research there in the innovation space at all.

Senator XENOPHON: Why would Amgen spend a quarter of a billion dollars?

Dr Clark: The pharmaceutical industry globally is suffering from very low growth rate and so all of those companies are entering into countries like Brazil, Mexico, Turkey and Russia which traditionally have not been territories for patent protection. But you have highlighted exactly my point. Amgen's thrust was 20 years ago. Only now are they going to Brazil, just to get market growth. The Brazilians have been denied access because of the patent regime.

Senator XENOPHON: Some might see it as a vote of confidence in Brazil, though, mightn't they?

Dr Clark: No, it is just looking for growth many decades after when Amgen actually got its growth.

Senator XENOPHON: But do you agree that the bill does not prohibit the patenting of inventive products, processes and methods?

Dr Clark: Methods and processes are notoriously difficult to defend and work in the pharmaceutical and biotech industries since 1978 as it is quite clear that companies always would prefer composition of matter claims, in other words sequences of protein.

Senator XENOPHON: But isn't there a seminal issue in terms of the patenting of the biological material. In terms of methods and processes you need to get over that. That is a substantial hurdle and there is an argument that subsection 163(1) of the Patents Act, which relates to crown use, is something that could deal with methods and processes in terms of opening up the use of methods and processes. It is rarely invoked, but that is a separate issue. Would you agree that it is a seminal issue to deal with the patenting of genetic materials?

Prof. Hilton: Biological materials.

Senator XENOPHON: Biological materials. Isn't that the first hurdle that people have to get over?

Dr Clark: The patenting of biological materials has been well accepted for many decades and is the basis of many valuable therapeutics.

Senator XENOPHON: Sure, but this bill is quite restricted. It is not related to all biological materials, only those that are identical or substantially identical to those that exist in nature.

Prof. Hilton: There is the problem, isn't it?

Dr Clark: Therein lies the lack of precision.

Prof. Hilton: Cells, proteins, acids.

Senator XENOPHON: So where do you draw the line?

Dr Clark: You can change the current law. The Patent Act works very well. We are changing it because of something that happened a long time ago and now we are post hoc—

Senator XENOPHON: That is not the case. Dr Mitchell, in your evidence you said that current patent law is not problematic. I think all witnesses agree with that. It is the application. Is that really the case, though? Isn't it the case that the way the current patent law is structured at the moment is actually stymieing research? I am surprised to an extent by your evidence today, because back in the inquiry that was chaired by Senator Siewert in March 2009 for the community affairs committee your submission, which I have in front of me, did express concern about the problems you had with Myriad that really slowed things down. You are now saying that the issue of the patenting of biological material was not an issue or was only a partial issue. I am trying to understand the emphasis.

Dr Williams: Absolutely. I think at that time we were just coming out of that and the detail of exactly what was causing the problem was difficult to ascertain. I think what has become clear since then is that, yes, the problem existed and it was all to do with the fact that originally Myriad holds a patent to do with the BRCA1 gene, but it was not just the sequence that was a problem but the fact that the patent was larger than just the sequence. The consequence of that and the arrangements with GTG caused the final problem that we experienced. What is difficult to unpick from all of that is that the problem we experienced was not just because of the gene sequence in there. I still strongly believe that we should not be patenting a sequence that is there and is part of all of us. But it is everything else that comes around it that was causing the problem as well. So by just focusing on one little bit, on the one gene sequence, does not solve the problem that we experienced. What is difficult to unpick from all that is that the problem that we experienced was not just because of the gene sequence. I strongly believe that we should not be patenting a sequence that is there as part of all of us. But it was everything else that came around that caused the problem as well. So I do not think that just focusing on one little bit, one gene sequence, would not solve the problem that we experienced.

Senator XENOPHON: Would it be fair to say that the emphasis of the submission that was made to the community affairs committee inquiry back in March 2009 was that your concerns about the problems with Myriad were in relation to current patent laws, whereas now it would be fair to say that you have reconsidered that to the extent that you now consider that it was more to do with the application of patent law?

Prof. Mitchell: No. At the time, we said it was a problem with the application. If one took patent law to say that there had to be inventiveness and the other things to do with it, those features do not apply to discovering the gene sequence. What we said at the time was that you cannot patent those things because they do not fulfil the criteria under patent law.

Senator XENOPHON: At the time, you said that there are few concrete examples of the impact of patent monopolies on health care and the use of genetic testing has been relatively limited. You went on to say that you were concerned that these few examples herald the likely difficulties that you will experience once indications for genetic testing in terms of cancer prevention are clear. I would have thought that was an emphasis on current patent laws rather than on application.

Prof. Mitchell: The fact is that the patent law allowed that gene sequence to be patented. That is the point that I was trying to make. A patent was allowed to be granted on a sequence when a sequence cannot fulfil the requirements of the law.

Senator XENOPHON: Isn't that the problem that this bill is trying to address?

Dr Lofthouse: No. Our concern is that it is only discussing gene sequences. Gene sequences are not patentable per se. They need to reach the standards of patentability: novelty, utility and non-obviousness. Even though it is suitable material, most genes now will not be patented, because things have been published and methods are widespread out there. It is not really a problem for us anymore. We are concerned about the occasional—

Senator XENOPHON: There was a problem back in 2009, though, wasn't there?

Dr Lofthouse: Yes. What we are concerned about is that we are carving out a piece of patentable subject matter when we may experience the same problem with a company that has produced a chemotherapy. Our concern is that if we keep carving out pieces of patentable subject matter as they become a problem for us in one or two cases it is going to create confusion. We would prefer to have fallback mechanisms in place, such as better access to the crown use provisions or compulsory licensing. If the occasional company does come along and try and enforce a monopoly beyond the rights that it should have, then we can fall back on crown use and compulsory licensing. There would be no need to confuse things around what is patentable and what is not, as that would be a very hard line to decide on.

Senator XENOPHON: I am conscious of time. My colleagues have questions. So you are saying that you do not support this bill, because the system is not broken. If anything needs to be changed, you say that it needs to be the way that the crown use provisions operate—that is it.

Dr Lofthouse: Yes, or some sort of safeguard to enable us to affordably and without going through a major court case series—which we simply cannot afford—address some of the companies that may do this.

Senator XENOPHON: But doesn't this bill address that, though?

Dr Lofthouse: Only as far as singular genes. It does not address diagnostics; it does not address chemotherapy.

Senator XENOPHON: But it does address the issue of singular genes, doesn't it?

Dr Lofthouse: It would not have solved the problems that we had with the Myriad GTG case, because there are still diagnostic claims that would not have been included in the biological—

Senator XENOPHON: Sure. But this addresses some problems. It does not address all problems, but it does address some of the issues.

Dr Lofthouse: I cannot think of a problem that it addresses.

Prof. Hilton: It causes problems.

Dr Lofthouse: It would cause more problems, just because—

Prof. Hilton: Our example would be GM-CSF. Probably about five million patients have been treated with it. That was a biological linked to complementary DNA claims. That protection gave the composition of matter, which enabled Immunax to invest in that. They would not have invested if it had been a method or process claim.

Senator XENOPHON: You are not suggesting that this bill would prevent that investment, though, are you?

Prof. Hilton: Absolutely.

Dr Clark: Absolutely. That is the way that the industry works. That is the way they think. You need protection to invest. Composition of matter is by far the most valuable thing. If you have a choice of investing, capital will flee to where that certainty is on composition of matter—in other words, offshore.

Senator XENOPHON: Maybe you could take this on notice, but there was a patent granted on 8 January 2009 for the prostate stem cell antigen and back on 8 September 2008 there was a patent granted over the flea head. How is that something—

Senator HEFFERNAN: It is genetic material.

Senator XENOPHON: It is the genetic material of a flea head?

Senator HEFFERNAN: Of a flea head.

Senator XENOPHON: How will that not restrict others' research?

Prof. Hilton: I think there is an issue of what the patent office does and what the patent law does. There are a lot of decisions at the patent office that are overturned subsequently. Those are simply bureaucratic errors, in my mind. Given that I have not looked at the patent that you are talking about, I do not think it is really fair to be able to comment.

Senator XENOPHON: Perhaps you could take it on notice?

Dr Clark: Could I just comment on that? If tomorrow we decided to get into flea head research we would go and do that research. The fact that that patent had been granted would not stop us doing research. That is the way the system has worked for decades.

Senator XENOPHON: Perhaps you could take it on notice, in fairness?

Dr Clark: We would be happy to look at those.

Senator FURNER: Professor Hilton, in your opening comments you made suggestions of threats to funding. What was the figure you were quoting in that respect?

Prof. Hilton: The amount that it takes to translate an innovation that would be made in a lab like mine to the point where it is marketable in the clinic as a product that has gone through pre-clinical testing—phase 1, phase 2 and phase 3, and may involve many tens of thousands of patients—is hundreds of millions of dollars. The protection afforded by a patent system over composition of matter is a very important determinant of where those funds will come. There are often many choices of where funding can go and the security afforded by the patent system is important in making those choices. It is something that has been discussed as part of every research and development agreement that I have had with the corporate world—nationally and internationally.

Senator FURNER: Also, in your executive summary you mention that 40 per cent of future therapeutics will be under threat of no patent protection in Australia. What is the overall cost of that, if you have an idea?

Prof. Hilton: I could not tell you off the top of my head, but the big issue here is the breadth that would be covered with the wording; it is imprecise. You could argue that there are a number of small molecules that are based on natural products where medicinal chemists alter one or two atoms in those natural products to develop a compound that is specific and has few side effects. They would almost certainly be covered by this type of approach.

Dr Clark: I can expand on that 40 per cent. One of the issues here is that the reality of working in a transnational, pharmaceutical biotech company is that you focus on those jurisdictions where you have reduced the risk through patent security. What it would mean is that ultimately Australia would get those drugs but, just like the example of Brazil we discussed with Senator Xenophon, it will come many years later—five to 10 years later—because they will put priority on a protected jurisdiction first. Those are the psycho-economics of transnationals.

Senator FURNER: So if there is a loss of funding there is a loss of protections for therapeutic goods, and whatever the case may be in all the other identified matters associated with bill. What is the overall loss in jobs then? Can you put a figure on that?

Dr Clark: I think the biggest loss is in welfare care. Care of standard getting fast access to world-class, cutting edge health care—that is the real economic cost to this nation.

Senator FURNER: But surely there are people employed doing research in this respect as well. If this is going to—

Prof. Hilton: In our institution we have about 750 employees. Of those, around 550 are doing experiments—we call them wet lab people—working either in the laboratory or in the clinic. Off the top of my head, I would suggest that 15 per cent to 20 per cent would be employed in translational projects that have significant private sector input into co-development of those—so perhaps 50 or 60 people within our institute. One of our major collaborators are CSL. I do not want to speak for them but, again, just from the discussions that I have had with them, the investment that they make internally and externally—so in our lab and within their own laboratories—is predicated on having good patent protection for the new therapeutics they are trying to develop. For example, my own laboratory is collaborating with CSL, and perhaps another 10 or 12 people in CSL would be employed on that project, and that is predicated on patent protection.

Senator HEFFERNAN: I would like to table a proposed amendment.

CHAIR: Actually, this is a very good time for you to do that. So you are tabling those?

Senator HEFFERNAN: Yes.

CHAIR: We will accept that as a tabled document.

Senator HEFFERNAN: Thank you. Is it correct that you got $55 million in 2009 from the Commonwealth government?

Prof. Hilton: It was probably a little less than that, I think.

Senator HEFFERNAN: About $55 million.

Prof. Hilton: I think that was not total Commonwealth funding.

Senator HEFFERNAN: Is it your position that the law defends having genes in patents?

Prof. Hilton: Are we talking about biological materials or genes?

Senator HEFFERNAN: The proposed amendment is that biological materials, whether isolated or not, however made which are identical as they exist in nature be not patentable. You do not agree with that?

Prof. Hilton: We do not agree with that.

Senator HEFFERNAN: Do you think that the discovery work of a gene is patentable?

Prof. Hilton: No; it requires utility, novelty and inventiveness.

Senator HEFFERNAN: But, let us—

CHAIR: Senator Heffernan, we have a very eminent medical researcher appearing before us. I am going to ask you if you would let Professor Hilton finish what he is saying before you ask your next question.

Prof. Hilton: Clearly, the sequence of a gene as is is not patentable. It requires inventiveness, utility and novelty. I think there would be relatively few sequences in the human genome that would fulfil that because the genome has been sequenced. Therefore, the novelty argument, at least for the sequence, would be aggregated. I think part of the problem with the amendment is exactly highlighted by your initial comments. You were talking about gene sequences as being the focus, but clearly the scope of the amendment is far, far broader and talks about biological materials 'substantially identical'—I think that is what the wording is—which seems to me to be an oxymoron at best.

Senator HEFFERNAN: So you do not agree that the interpretation of the 352 of the Patents Act 1990, which defines patentable subject matter by referencing the manner of new manufacture within section 6 of the Statute of Monopolies can be the inventive work but has to include, under your interpretation, genetic material as well as the inventive work?

Prof. Hilton: The matter of substance can be part of a bona fide patent if it is important within the utility and in the invention. So it clearly has been.

Senator HEFFERNAN: So if, for instance, in the BRCA1, you took out the claims to the biological material, as you have said, it would still be a patent on the process?

Dr Lofthouse: On the process and the diagnostic testing, yes.

Senator HEFFERNAN: It would not include the biological materials, which means that I or someone else could go to the biological material and perhaps come up with a better test or a smarter way of doing business.

Dr Lofthouse: You can already do that.

Prof. Hilton: You can do that now.

Senator HEFFERNAN: This takes us to the exemption, which is the government's solution to the problem. I take it that you aggressively agree that there be a defined research exemption?

Prof. Hilton: We would be delighted to have a defined research exemption, but we do not think it is a problem in practice now. The clarification would be welcomed, but there has not been one occasion that we have solved the issue—if the straw man builds it.

Senator HEFFERNAN: Say the government legislates to give an exemption for research to all those people on six-month contracts who are tucked away in the back of Westmead hospital. If you are the person who holds the patent that allows me the exemption and I have a smarter laboratory than yours with better technicians and I beat you to wherever it is that you wanted to take the rights to the patent to commercialise it, do I have to go back to you and say: 'Can I now have an exemption so that the gene is included in my commercialisation which could well be competing against yours?'

Prof. Hilton: You describe something that is a very common commercial issue but it is not common for gene patents. There are many, many instances with an initial patent where the public disclosure—and the public disclosure is the quid pro quo of the patent system—stimulates a whole raft of innovations. Normally, you would have a commercial negotiation with the person who holds the initial patent. That is bread and butter for them. That happens very regularly. One of the reasons for having a patent system is that it publicises innovations and allows the community, broadly, to improve on those innovations. It is why the government grants a 17-year monopoly.

Senator HEFFERNAN: If the government grants me the exemption to do the research and then I want to commercialise my research, which under the present interpretation of the law needs to include the gene, are you saying that I would be able to do that and include the gene in my patent which you hold without any money changing hands?

Prof. Hilton: We are talking about biological materials not genes.

Senator HEFFERNAN: Why would you hold the patent in the first place?

Prof. Hilton: Could you repeat the question? You keep interrupting me.

Senator HEFFERNAN: If you are going to grant the exemption and then the permission to commercialise the work that I have done on the gene, why hold the patent or the gene in the first place?

Prof. Hilton: The patent would not be granted simply on the biological material. The biological material would not be granted if it did not also have utility and novelty and inventiveness. There are a number of innovations that may include a matter of substance for biological material that would also include, for example, therapeutic use, a method of administration or a disease that can be treated that may not end up being the final product that goes to market. The beauty of the patent system as it currently stands is that companies in exchange for that monopoly publish and make publicly available the details of their original invention. Improvements are made all the time to initial patents and those improvements and innovations are developed as part of a commercial negotiation. It is not something that is even specific to biological material.

Senator HEFFERNAN: If I am a researcher tucked away somewhere and I have an exemption for research and I come up with a wonderful new application for a biological material which is going to make me a squillion—

Prof. Hilton: Or cure patients.

Senator HEFFERNAN: Yes, all of that—can I go and commercialise it without referring back to you?

Prof. Hilton: No, you would patent it because you built it.

Senator HEFFERNAN: I would have to get your agreement.

Prof. Hilton: No, you do not have to get my agreement. You would patent it and depending on your freedom to operate—that is, the extent of other patents; it may be methods of production—you would have a commercial negotiation. That happens all the time in almost every industrial sector.

Senator HEFFERNAN: Some cancer treatments cost from $60,000 to $80,000 per patient and under the PBS the patient pays a few hundred dollars. How long can the world afford for the taxpayers to pick up that bill before the system falls apart?

Professor Hilton: I think that is an excellent question. I think that the economic sustainability of a first-class healthcare system, whether it is around diagnostics, pharmaceuticals or preventatives—vaccines—is a huge issue for the government. I think that is one of the reasons we need a robust health economic research portfolio within the country.

Dr Clark: I would also add that this bill does nothing to address that.

Senator HEFFERNAN: No, I was just—

Dr Clark: What it means is that we would not have access to leading therapies. Then the discussion is: what is the price?

CHAIR: Senator Siewert, you were going to ask a question.

Senator SIEWERT: I think Senator Heffernan has covered the research question I was going to cover, so I want to go back to the Crown use. Dr Lofthouse, you commented on Crown use. When we held the previous inquiry—which you are aware of and which Senator Xenophon referred to earlier—the issue around Crown use came up, as did the fact that those provisions have not been used.

Dr Lofthouse: Yes.

Senator SIEWERT: I am wondering: do you see that there are additional amendments needed to deal with Crown use? The fact is that it has not been used properly. If we do amend it, how do you foresee us dealing with it?

Dr Lofthouse: I do not know if we need amendments to the Crown use or the compulsory licensing. In practice, as we said, we can always do research; we have never been threatened with an infringement for research. The occasional company such as GTG has bothered us with regard to clinical use, but over 20 years of genetic patenting that has happened to us once. So we are concerned that, if this bill goes into place, it is going to create a whole lot of confusion that just is not necessary. What we need is a fallback position, whether it be compulsory licensing or Crown use. I know that they are already in the act. I am a little unsure about how we would access those at an affordable cost. Peter Mac simply would not have the funds to go through a court case, and that is what concerns me. I know those provisions are there, but we just need to make sure it is accessible, and I am not really in a position to talk about the law about how you can do that.

Senator SIEWERT: Dr Mitchell, you look like you wanted to make a comment.

Dr Mitchell: No.

Senator SIEWERT: Okay. This is one of the problems, isn't it? It has not been used and it is expensive. We have seen the recent court case, but those sorts of court cases are few and far between.

Dr Clark: I could add that we very much support Dr Lofthouse's view there that there are other mechanisms but they are seldom used. Of course, if we take this specific case here, the patent amendment, Myriad will still be

running those tests, so it would not address that. In fact, other mechanisms ought to be in play, without tampering with the patent system itself.

Dr Lofthouse: Of course, even the people within this room disagree about what the term 'biological materials' would encompass, so it is going to create a whole lot of confusion and court cases—case law—to resolve those. We are very concerned that that is going to cause more problems than it would solve.

Professor Hilton: The other way of trying to address the issue is to create a system a little bit like the PBS for diagnostic tests. The PBS has delivered the sorts of therapeutics that Senator Heffernan described, probably more cheaply for Australians than for any other group internationally. I think it works quite well. I agree that that still leaves the macro health economic issue as a major challenge, but for individual members of the community that may be a mechanism.

Senator SIEWERT: I am conscious of time, so I have one more question, and that related to a comment made by someone—Dr Clark, I think it was you or Professor Hilton. I apologise: I cannot remember quite who said it. But, on the issue from when we were talking about the flea head and the comment I made about overturning IP Australia decisions, how often has that occurred? During our discussions on this whole issue, we have heard of numerous decisions made by IP Australia over patenting genes. We were told, 'No, you can't do that,' and then there was example upon example of where it had occurred and not been overturned. So I am just wondering how often it has happened, to your knowledge, and who has triggered it.

Dr Clark: If I could answer that, the real issue is: has it had an impact? Whenever a new technology comes in, yes, there will be decisions made: 'Yes, we'll grant a patent on that.' So the patents that were granted in the 1990s might not be granted today.

Senator SIEWERT: I apologise for interrupting; I am a little conscious of time. We have heard that before, and I understand the argument, but the fact is that these patents have been granted on the flea head—did you just say 2008? There have been numerous patents. That argument does not wash with me, because there have been numerous patents granted over genes in the 2000s, when we should know better if it were just that this is about new technology.

Dr Clark: Getting to the thrust of your question, we assume a research exemption. That has worked extraordinarily well in Australia. I do not find any significant case law about patent holders taking research institutes to court for infringement for research. The research exemption, although it is not crystal clear in law and maybe we should clarify it, in practice works extremely well.

Senator SIEWERT: Are we at the point, though, at the moment, where we have not gone far enough in developing some of the patents that we heard about before in our previous inquiries? We heard that other people are not looking at it enough and there has not been enough research done yet to start challenging that or for that to be implemented. Is it the case that when we get to implementation we find that we have not had enough case law or examples yet where they have been challenged?

Dr Clark: Not at all. Many of these patents are now coming up to expiry. A lot of time has elapsed since the patents were granted. We are looking back two decades.

Senator HEFFERNAN: So the old ones are running out and new ones are being granted on biological tourism and genes.

Senator SIEWERT: To go back to my original question: how many times are you aware of a grant by IP Australia being overturned?

Prof. Hilton: We can take that on notice.

Senator SIEWERT: Okay. Thank you.

Senator PRATT: I want to ask, briefly, about the way both organisations would ideally see patent law operating. I am just trying to distinguish the extent to which you differ in what you are saying. I am interested to know the extent in which you do not agree on patenting, whether it is to do with the material itself or the application of it. For example, I mean a biological material—not its own biological function but a different function. What do you think an ideal law would look like that could overcome some of the kinds of issues that have been discussed today?

Dr Clark: I will start off by saying that, generally, the current patent law works extremely well. Senator Carr, with IP Australia, has a review in place which will lead to some clarification and the lifting of Australia's patenting law standards to be in line with other leading jurisdictions. So we are definitely on the right track. Along with that is the implementation of the recommendations from the Australian Law Reform Commission

several years ago, which are still quite valid. I think we do have a robust patent system that is going to get stronger once the IP Australia reform goes through.

Senator PRATT: So you are arguing that it adequately carves out biological material already, in terms of distinguishing whether it has a novel use or whether you are just patenting the existence of such material.

Dr Clark: Absolutely. The threshold for inventiveness is increasing all the time as we work through technologies. With regard to the classic technology, for example, for GTG, the so-called junk DNA sequences that were granted in the nineties, with the benefit of hindsight you would probably say that they would never have been granted. But the reality is that they were granted at the time and they are enacting their rights. They have granted patents worldwide. As the technology matures it becomes more rigorous in setting a higher and higher threshold for inventiveness.

Senator PRATT: That answers my question. Thank you. And the other organisation?

Dr Lofthouse: We agree with the WEHI view.

Senator PRATT: Do you distinguish at all? What would be the differences in the two positions put by the Peter MacCallum Cancer Centre and the Walter and Eliza Hall Institute today?

Dr Lofthouse: I do not think we have any differences. I just think that when people talk about gene patents we talk about different things. Can you patent something that is of the human body or a human gene? No, you cannot. A gene sequence in itself may be patentable subject matter but it is clearly not inventive unless there is some human activity—

Senator PRATT: Novel use for it.

Dr Lofthouse: novelty or nonobviousness beneath it. So we are quite well protected. I honestly do not understand why you would want to carve out one particular type of subject matter when the issue is across the board of all inventions and the patent system does work quite well.

Senator PRATT: If you are not allowed to patent biological material at all, other than the biological, you would be prevented from creating commercial applications from biological materials for their nonbiological function and their original biological function as it might exist in nature.

Dr Lofthouse: If biologicals were excluded we would not have vaccines, we would not have antibody based therapeutics, which are becoming more and more important. I believe personalised medicine research, which is at the forefront of medical research at the moment, would be greatly affected.

Dr Clark: Forty per cent of current therapeutics in Australia would not be allowed. And that is increasing because the biologics component is increasing.

Senator PRATT: And that is because they have got a novel and inventive utility that has been distinguished from the original biological function?

Dr Clark: Yes, isolated from the body. Absolutely.

CHAIR: Thanks, Senator Pratt. We need to move on to our next witnesses. I think Senator Boyce is going to ask a question to take on notice.

Senator BOYCE: I was just wanting the opinion of both organisations on the provisions that are being suggested in the 'raising the bar' bill.

CHAIR: They have already answered that.

Dr Clark: We strongly support that. We have been engaged a lot in dialogue with IP Australia about that. It is absolutely essential to raise the bar. Globally the bar is being raised. If you look at our main competitors, like China, they are raising their own bars. We support it very strongly.

CHAIR: Can I place on record our thanks for your submission and for your personal appearance here today. We certainly appreciate the time you have taken to travel to Canberra to be with us, given your workloads. I want to place on record our deepest thanks.

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

CHAIR: The college has sent us a submission, which numbered 4, for our purposes. Before I invite you to make an opening statement, do you need to make any changes to the submission?

Dr Suthers: No, the statement stands.

CHAIR: If you would like to briefly talk to your submission, bearing in mind we have got a lot of people who want to ask a lot of questions, and then we will move to questions.

Dr Suthers: Thank you very much for the opportunity to meet with you today. The Royal College of Pathologists is the peak body in Australia representing the medical professionals who provide medical tests. At the outset, we do not profess to have expertise in matters of intellectual property and law. Nonetheless, we have taken a keen in this issue over recent years. We have made submissions to the ALRC, to inquiries by IP Australia, to the Australian Council on Intellectual Property and to the previous Senate inquiry. You might ask why we have taken such an interest in matters that lie beyond our professional remit. The reason is that we do have expertise in the provision of medical testing, and we are very concerned that the current operation of intellectual property legislation in Australia compromises the equitable delivery of health care. IP Australia itself has identified that a person with a patent over a gene sequence can restrain another person from using that sequence. This means that the patent holder can restrict a doctor's freedom to make a diagnosis. This restriction is not based on the machine or process by which the doctor might make the diagnosis but is focused solely on the biological basis of the disease itself. Our view is that such a restriction should have no place in a free society.

We have documented in our submission to the previous Senate inquiry that patents can and have compromised the equitable delivery of accurate genetic tests, and we will not repeat those examples today. But I would like to draw your attention to an instance cited in a recent report from the Us Secretary's Advisory Committee on Genetics, Health, and Society. This report noted that a company which holds the IP rights in the US for the major genes causing a serious familial heart disorder does not offer prenatal genetic diagnosis for that disorder. This makes the testing unavailable in the US. The company claims that there are technical difficulties in distinguishing maternal from foetal DNA, which is an interesting position. It is difficult to understand, because there are well-established techniques for managing genetic testing in this context that are used daily, both across Australia and internationally. So irrespective of one's views about prenatal diagnosis and termination of pregnancy, it is of extreme concern to the college that a patent holder can control this issue for both an individual and for a society. The Royal College of Pathologists does not seek to make genes a special case that require special consideration in patent legislation. Human genes are a natural phenomenon and, on that basis alone, should not be patentable.

We support the intent of the proposed legislation to prevent the restriction of genetic testing and making a diagnosis. We note that various inquiries by various bodies have yet to yield any change to the patent legislation under which these genes have been patented and medical diagnostics have already been compromised. So given this situation it is tempting to support these proposed amendments, because they directly, albeit imperfectly, address our fundamental concern. But, as outlined in our written submission to you, we do have reservations about the wording.

In addressing the specifics of these amendments it is essential that the committee remain focused on the overall goal of patent legislation, which is to ensure that legal constructs designed to promote innovation do not compromise fundamental societal goals, such as access to health care. So we submit that there are really two issues to be addressed, and they have already been touched on in discussions with the previous people who were here. The first is that many genes have already been patented under the current legislation and regulations, and any amendment to the Patents Act is not going to address these extant patents. In the US, the Secretary's Advisory Committee on Genetics, Health, and Society has proposed the creation of a statutory exemption from liability for medical tests that have been developed under a patent. They have also proposed exemption from liability for those who use patent protected genes in pursuit of research. The college would support such a move. We recognise that the creation of a specific exemption means that genes are being considered exceptional, rather than the matter being resolved on first principles. Nonetheless, we think this is an essential interim measure to address the issue of extant gene patents.

The second issue is the patentability of genes in the future. As we have noted, any naturally occurring substance should not be patentable. The distinctions between a discovery and an invention should be described in precise yet general terms in the legislation, and we submit that this would constitute a suitable and, importantly,

sustainable amendment to the Patents Act. With those opening comments, I would be pleased to answer any questions.

CHAIR: Thank you. Senator Xenophon?

Senator XENOPHON: I will be very brief, Chair. Dr Suthers, thank you for your submission. As I understand it, your association is saying that the system is flawed as it is and that these amendments will not necessarily fix it.

Dr Suthers: Correct.

Senator XENOPHON: And you have put forward some suggested drafting for other amendments to deal with it. As I understand it, the US government does not believe that isolated genomic DNA is a patentable subject matter, and this is your understanding as well.

Dr Suthers: Correct.

Senator XENOPHON: You may be aware that Senator Heffernan has tabled something in response to some of the submissions made–

Senator HEFFERNAN: A bit of tightening up.

Senator XENOPHON: Yes, a bit of tightening up, as Senator Heffernan puts it. Won't that really fix part of the problem—in a substantial way, at least?

Dr Suthers: You are right that it may fix part of the problem. The concern that we have—this is where I want to freely acknowledge that we are not experts in how to steer through this particular space in a legal sense. But the original provision in the Patent Act 1990 is that human beings and the methods of their procreation et cetera are not patentable. That was a societal consideration. We are now adding into this a more technical consideration about gene patents, and we were uncomfortable that that did not seem to be the right place to put it. I think the proposed amendments as they stand are better than what we have got, but are they really where we should be aiming? We have a major issue in diagnostics currently, and we think that that will only get worse. If these amendments go through, yes, that will address part of it, but we are concerned that there will be other issues that come up down the track which may not be so easily addressed.

Senator XENOPHON: So it would deal with some of the problems but not all.

Dr Suthers: Correct. We agree with the intent but we see that there are potential problems as exemplified by both public comments and comments this morning about the choice of wording.

Senator XENOPHON: Sure. You may not have had a chance to reflect on the proposed amendments to this bill that Senator Heffernan has tabled. Would you want to comment on that?

CHAIR: They are not public. They were just given to the committee this morning, so those amendments have not been tabled in the Senate, they are not on our website and none of the witnesses will have seen them today. It is not a public document as such. They were tabled this morning, but they will not be out there for witnesses today unless they are given a copy as they arrive at the hearings.

Senator HEFFERNAN: But he has a copy.

Senator XENOPHON: There is not an issue if I reflect on what has been tabled, and perhaps Dr Suthers can take it on notice if he does not feel comfortable.

CHAIR: That might be the way to go.

Senator XENOPHON: So do you want to comment on it now or later? I am in your hands.

Dr Suthers: I can comment on it now. I think the statement as it stands would address our concern about diagnostics; but, as has been flagged by the people from Peter Mac that we hired et cetera, it may also limit the access to therapeutics. Therapeutics lies outside the remit of the college of pathologists. That is why in our presentation we have focused on the issue of diagnostic testing. The words as they stand may compromise the therapeutic side of the equation, but I am not in a position to argue that.

Senator XENOPHON: Finally, there is one view that says, 'If we go down this path research is going to grind to a halt.' That is obviously not a view of your association.

Dr Suthers: We support ensuring that researchers have access to genes to do their research—we think that is essential—but we are primarily a professional organisation responsible for the delivery of tests, not research advocates. That is not our primary role.

Senator XENOPHON: Thank you.

Senator SIEWERT: I think you were here in the room earlier and heard the comments of Eliza Hall and Peter Mac. They do not seem as enthusiastic about the bill as, for example, you do. Do you have comments on the fact that you are taking a slightly different view?

Dr Suthers: It is a fair question, and this is where it does get very difficult to find the right line. Patents have been an integral part of the delivery of health care for hundreds of years. Our laboratories are full of patented machines and processes, and long may that continue, because it has been a superb driver. The concern, though, is that as we move from patenting a process to patenting a discovery of something that has been around for tens of thousand of years, if not longer, we begin to compromise the ability of other people to develop products, ideas and so on from that. I think that, from the researchers' perspective, they want to have reasonable access to patented materials so that they can develop better therapeutic products, and that is fine.

But the time line and the cost for developing a therapeutic product is very different from the time taken to develop a diagnostic product. If we take the BRCA gene, which is responsible for breast cancer, as an example, the research was based on finding an association between a particular bit of DNA and the risk of breast cancer in families. Once that association was made, the association could be used to predict the risk of breast cancer in certain families. From a diagnostic point of view, it went from discovery to application very quickly. But to take that information and turn it into a therapeutic based on that information is going to take lot longer and be a lot more expensive. We essentially need different game rules for those two scenarios.

Senator SIEWERT: The argument, if I understand it correctly, is: if we change the act for this particular instance, we then start changing it for others as well and this will make it more complicated.

Dr Suthers: It is our concern that there are lots the biologicals. One of the advantages of phrasing it in very general terms as biological materials is that there are lots of diagnostic chemicals that we want to analyse and that we need to analyse in the delivery of health care. They are not just genetic ones. So I think it is important that this not be couched in just gene terms. Coming back to first principle: we fail to see why something that has been discovered should be patentable. Matter is not patentable and nor is an electron. Why should human genes be any different?

Senator SIEWERT: Playing devil's advocate with this issue of discovery—what is a discovery and what is not a discovery—is an argument that we have heard several times, which is that a discovery is not patentable under the current laws.

Dr Suthers: I struggle with that. I have trained in medicine. I think I am a moderately intelligent person. I struggle with the language, the literature and the law in relation to this. It is not clear. I fail to see how someone identifying that this particular DNA is associated with a particular cancer risk can ever be constituted as an invention, because the association pre-existed the patentee's birth and the patentee has not actually created the association, the breast cancer or the gene. So I think at first pass it has to be deemed to be a discovery. To say that it is an invention is playing with words to step around the issue.

Senator SIEWERT: I understand your argument but the counter to it is: 'We've made mistakes in the past and now we realise that in fact it is a discovery and not an invention and that it is okay, guys, we'll get it right from now on."

Dr Suthers: 'Trust us; we're the experts.' I am sorry, when we look at the last 20 years of how the IP experts have handled the issue of gene patents, they have not done well. The evidence that we have submitted both to this inquiry and to the previous inquiry highlighted the fact that those processes did not work well. I do not think we should accept the status quo as being adequate for the future. The stakes are high. As was flagged earlier, we are seeing a tremendous shift in the type of therapeutics that have developed. They are now more and more biological rather than straight chemicals. We are going to see a similar shift in diagnostic testing as we do more and more genetic testing. So I think we have to get this right now, otherwise we are going to run into real problems down the track. The example I gave of prenatal diagnosis being dictated by a patent holder in the US is an example of the potential societal outcomes that we should not accept.

Senator SIEWERT: I have another question around the issue of crown use and the argument that provisions are already in the current act. It has always intrigued me that we have these protections but they are never used. Do you think it is reasonable for us to rely on just the protections that currently exist in the act in terms of compulsory licensing and crown use?

Dr Suthers: The current provisions in the act may be sufficient but, as you mentioned to the earlier speakers, they have not actually been invoked and utilised. We would need to have a mechanism that was quite prompt in picking up on issues and resolving them. To also put this in context, it would be important to know which element of the Crown, as it were, was going to be involved. The great majority of genetic types of tests performed in

Australia are only performed in one or two labs nationally, so there are a lot of samples flying across state borders. Which jurisdiction will be responsible for making use of the Crown provisions?

CHAIR: On the last page of your submission, you talked about two issues to be addressed. In your answers to questions from Senator Siewert you talked about the second issue, which is the distinction between discovery and invention. Going to the first issue, you have talked about genes that have already been patented under current legislation. What effect would this legislation have on that?

Dr Suthers: Given that these patents are already extent and have been provided, I am assuming that the legislation would not have retrospective effect.

CHAIR: It is not clear, is it?

Dr Suthers: My interpretation was that it does not have retrospective effect. If it is to have retrospective effect, then that would need to be made very clear in the legislation.

CHAIR: So what is the extent of not having retrospectivity?

Dr Suthers: It comes down to what gene patents have been granted, say, in the last 15 years and the specific limits placed on their use in a medical diagnostic setting. It is very difficult to get that sort of information. The diagnostic laboratories across the country do not have IP experts on hand as you might in a large research organisation, so most of them close their eyes and hope that nothing happens. Occasionally, things do happen as per our previous submission. I would like to be able to answer your question but I do not have access to those data and I do not know that anyone has a good handle on the current situation in Australia as to what genes are patented and what the restrictions might be for the diagnostic labs. At an informal level, speaking to one of the major providers in South Australia, they estimated that about half of the genes that they currently test are covered by Australian patents.

Senator FURNER: Concentrating on the bill, you picked up on a number of areas of concern. In your opinion are there any areas of further ambiguity in respect of that that might cause issues associated with local court challenges?

Dr Suthers: If the bill goes through as it stands, then again I do not know what role it would have in the current challenge between Cancer Voices and Myriad because that is an extent patent already established. Presumably, it would have to be resolved on the ground rules prior to this being passed. If there was a retrospective element added to this amendment, then I do not know; I do not have sufficient experience or expertise to give you an informed comment.

Senator FURNER: You made it clear in your opening comments how gene patents can and do compromise equitable delivery of health care. You also commented that you did not want to touch on those. Again, unfortunately, I was not involved in the last hearing and you cited an example from the US. Can you possibly touch on some of those issues at home.

Dr Suthers: Sure. I will refer to our written submission so I stick with what we submitted to the last committee. The examples that we have in Australia relate to tests important in the diagnosis of certain types of leukaemia where the patent holder essentially ended up inadvertently—or maybe advertently—shutting down the delivery of this test for many laboratories across the country. They insisted that laboratories either use the company's kit or obtain a sublicence. The cost of that was such that the laboratories that had been providing the cost of the test at about $200 or so dollars per test were unable to continue the provision of the test, so it lead to a skyrocketing of the price.

We had a second example with a UK based company holding a patent for the P450 gene. The Australian laboratories were providing testing of this gene for about $250. Again, when the patent was enforced, the laboratory stopped testing it because it just blew the prices sky high.

Bio-Rad Australia holds the patent for a gene causing haemochromatosis, a relatively common liver disorder, and in the US it has enforced its patent and it has led to a substantial decline in the delivery of the test for this very common genetic condition. In Australia, it has not sought to enforce the patent but it is also a provider of many other biological reagents which diagnostic laboratories use. I surmise that there may have been some concern that they could lose an important part of their supply there. We discussed the issue of GTG and the rollercoaster ride of BRCA1 genetic testing, which remains unresolved. That is not finished. We also discussed GTG with its patents on the non-coding DNA. Although that has not seriously compromised the delivery of genetic testing in Australia, it was a major issue in New Zealand when they sought to enforce those patents. That was a very drawn-out and expensive process. So we have seen concrete examples of the patenting impairing the delivery of genetic tests and of tests not being done.

Senator HEFFERNAN: Would it be fair to say that the introduction of this bill has lit up the landscape in discussion on problems with the interpretation of the law over some years?

Dr Suthers: I am delighted that we are now getting the opportunity to bring these issues to—

Senator HEFFERNAN: Would it be fair to say, 'We do not want to muck it up but we are certainly delighted that we have lit up the landscape'? In terms of solutions, even talking about retrospectivity—and if it is not retrospective it is not retrospective—the various patents for invented works that are around would still stand. It is just that biological material claims in 30 or 40 claims would come out. The actual commercialisation would still stand as a patent, wouldn't it?

Dr Suthers: You are now taking the questions out of my comfort zone and what I feel competent to respond to, I am afraid.

Senator HEFFERNAN: Would it be fair to say that the present arrangements are convenient and, while Statute of Monopolies 1623 says that we should not be doing what we have been doing, it is very comfortable for everybody up to the point of lighting of the landscape to stick with it? Would it be fair to say that in many ways it restricts research rather than encourages research?

Dr Suthers: Let me take it a step further: it restricts the delivery of tests. I would like to repeat something that I mentioned at the last hearing at which you were present but which Senator Furner and Senator Xenophon were not. We had an instance where a diagnostic laboratory wished to do a genetic test for a particular clinical need. That meant sending off to a supply company to ask for the short stretches of DNA which are necessary to do this test. The company came back to the diagnostic laboratory and said, 'This is a patented gene. Do you have permission from the patent holder to do this? Because, if you do not, we will not supply you with the reagents.'

Then we have the laboratory supply companies acting as agents of the patent holder to enforce the patent in this country. The laboratory took it up through their particular food chain—this was a public sector laboratory in another state—and it was deemed that they would not pursue that further and a test was not developed. They also said that they did not want the details of this case to be released, so I am being very careful not to tell you which state it was or which gene. So it seems that there is the potential for all sorts of almost cryptic and below-the-radar compromises—

Senator HEFFERNAN: Would it be fair to say that the present system is working, as it were, by a wink and a nod?

Dr Suthers: I think that is a fair assumption.

Senator HEFFERNAN: What about if we put in, as the government proposes, an exemption for research? Most researchers, if they find something decent, want to send it on to a commercialisation trial to become a better cure and create competition in the market and come up with a cheaper test. Telephones went from $3,500 to $300 because of competition. What if I am the person who has the exemption, I have the smartest laboratory and I beat the person who holds the gene which under the Statute of Monopolies they should not hold anyhow because it is not included? The district courts have certainly said genes and biological cures do not fall within the definition of a patent material. If I get to the prize first and want to commercialise it I then have to go back to the person I got the exemption from who holds the patent on the biological material and say, 'I have beaten you to the prize and now, because that is the interpretation at the present time, I want to include the biological material in my patent, for which you hold the patent.' If they say yes, I am going to do them out of what they saw as their potential profit. So why did they hold the patent in the first place if I can research it and then commercialise it. If they say no, it defines the case for anticompetitive behaviour.

Dr Suthers: You are touching on the issues of research leading to a therapeutic, and that is an expensive and challenging area, as per the previous discussions. But it does not strictly apply in the area of diagnostics, particularly in genetics. You walk into any diagnostic genetic laboratory in the country and they will have the resources to sequence DNA and to work out the exact ACTG sequence of a particular gene. Discovering in this arena, in the diagnostic sense, is recognising that this particular variant and a particular gene are associated with this particular clinical outcome. You do not need any special new tool to implement that; it is immediately applicable as a diagnostic test using the bench standard DNA sequencing material.

So in fact there is no commercial advantage in identifying a diagnostic test, a gene that predicts a particular outcome, unless you can control the price of that diagnostic test. And in controlling the price of that diagnostic test you are then limiting people's access to get the testing that they want.

Senator HEFFERNAN: It certainly applies to the BRCA—

Dr Suthers: It certainly applied to the BRCA and it was compounded there where Myriad Genetics not only controlled the price, which precluded testing for quite a period of time across Canada—and I do not have the details of the Europe situation—but they also failed to implement better methods for detecting variations of genes.

Senator HUMPHRIES: Could you explain how the exemption for medical testing would work in terms of the way the law would operate in this ideal that you have proposed?

Dr Suthers: I can give you what I will call my high-level view. But in terms of the implementation that would call on expertise of people other than me as to how to actually implement this. The proposal in the US, and it would have potential here, is to say that if a test is being performed on a patient for medical purposes the biological basis of that test—the fact that that particular biological variable is associated with an outcome—involves no infringement of a patent that captures that. It would have, in effect, a retrospective effect so that patents that are already held would not be breached if a person used that information to provide a medical test.

Senator HUMPHRIES: So if a company develops a test that is dependent on the use of a gene sequence, for argument's sake, and, like many listed patents, it involves a large amount of research and investment and a test that is relatively expensive, not because it is complicated to conduct but because it has taken a great deal of effort to get to the point where it needs to be applied, is it fair to deny that company? Would it not be the consequence of the model you have just spoken about that the company would be denied the revenue from conduct of that test?

Dr Suthers: It is a matter of developing therapeutics based on that or to license those to other people to develop them. I am wary of accepting the premise that the companies are the sole drivers here. A lot of the research in this area, both nationally and internationally, is coming from the public purse for the benefit of the public anyway.

Senator HUMPHRIES: But that is the way the patent system works all over isn't it? People take bits of information from different segments. The patent system still protects people's right to patent what is an invention. If they have invented a diagnostic test that is patentable under present rules, irrespective of where they have drawn that intellectual knowledge from, wouldn't you potentially have this phenomenon—and you heard the earlier evidence of the two other research institutes that talked about the potential flight of investment dollars from areas where patents could not be obtained—that people will be less inclined to invest in diagnostic testing because they could not reap the commercial benefits of any discoveries they made?

Dr Suthers: In looking at the medical evidence at the moment and the genetic scientific literature there is an enormous amount of stuff in the public domain from university environments where commercial impetus is not the primary impetus. In fact there have been surveys of genetic researchers across the US—and I am not aware of similar recent data in Australia—where patentability is not the prime motivation for most of these people.

Senator HUMPHRIES: I agree that that maybe the case, but—

Dr Suthers: Let us take it that it is the case. T have some concern then about the wording that the company has invented a diagnostic test. The company may discover an association between gene sequence and clinical outcome but that is an association that is longstanding. The company may well be able to capitalise on being the first to discover it so they are the first ones to appreciate the novelty, as it were, of this observation. But it is a pre-existing novelty that they have now come across and, if they can market that as a good test, well and good.

Senator HUMPHRIES: Admittedly, the law on invention has been much battered about in evidence to this and the other committee, but it is clear that if someone discovers something which is inventive they are entitled to a patent over it. But you are saying that in respect of testing they should not be entitled to the patent. Again, would that not potentially drive investment in such testing away?

Dr Suthers: I have struggled with the concept that a discovery can be an invention. I appreciate that that may be there in law—

Senator HUMPHRIES: So all diagnostic testing must by definition be discovering, not invention?

Dr Suthers: Yes, in principle I would agree with that, because a diagnostic test is identifying the biological basis of a person's disease. How you make that diagnosis, how are you analyse the biologic, is eminently patentable. Our laboratories are full of those machines and I have no problems with that at all. But the fact that this particular variation in gene sequence or level of a hormone or vitamin is associated with the disease is a discovery; it is not something that has been created or invented.

Senator Humphries: It is a matter of principle if a patent is granted, irrespective of whether it ought to have been granted in the first place or not, and that patent might be in existence for some years, and then retrospectively someone says that the patent should not have been granted, is it sound to withdraw that patent in

those circumstances and jeopardise what could be a substantial investment based on the patent? Is that reasonable in principle?

Dr Suthers: This is not he is not my comfort zone in terms of being familiar with this, but I guess I have a concern, and the college has a concern, that what the patent legislation says and how it has been used are two different things to our non-expert eyes. The way it has been used has led to a series of consequences that have driven us to the situation where we are today. If you accept that you can patent a gene, then you end up with a series of commercial decisions, and venture capitalists et cetera coming on board, to build on that opportunity, and you are now asking me a question about some steps up that spiral as to whether we go back to the beginning and remove the patentability of that particular item. If you do that, there will be some adverse consequences in the commercial sense.

Senator HUMPHRIES: If you apply it retrospectively.

Dr Suthers: That is why I think we do need to recognise that people have taken up patents on genes legitimately. I do not necessarily agree with the interpretation of the law, but there is no suggestion that companies like GTG or Bio-Rad et cetera have been illegal. But it is certainly not clear as to what the boundaries to legality are. So I think that we do need to change something prospectively, and the college is of the view that we should address that in issues of first principle and not to make genes a special case. We also have to address the fact that companies have already made investments—that, in fact, the commercial consequences of perceptions that were formed a decade ago have already been built into the system. We are not out to beat those companies up and penalise them. What we are concerned to ensure is that diagnostic testing is freely available and that we do something about the future.

Senator PRATT: You outlined a number of historical issues in relation to patents being put on biological material and some of the consequences of that but that gene mapping and the fact that most of the human genome has now been mapped seems to have changed our understanding of that and it is no longer seen as an incentive. So we seem, I suppose, to be better able to distinguish between discoveries versus something novel. Can I ask you to elaborate on that and why we seem to have evolved these kinds of contradictions in the law?

Dr Suthers: That is a big question and I am probably not the best person to answer it. There are at least two issues that have led to the current stalemate in relation to genes and their use in diagnostics. One is that our understanding of genes and genetics is changing rapidly. Thirty years ago we thought of one gene, one function; one gene, one disease. For the rare familial disorders which were the target of research in those days it was a reasonable premise that if you had a particular gene then mutations in that gene only caused one condition. We now realise that that is not true. In the last 15 years it has become abundantly clear that even common disorders that historically we have thought of as being due to a single gene are better regarded as polygenic disorders with multiple genes being involved and one gene can have many can have influences on many different disorders. So, if you have a gene patent that applies to the association between a particular gene and a particular clinical disorder, does that patent, in law or in practice, inhibit the work of researchers or diagnostic laboratories in testing that gene for a second disorder which has only been recognised to be associated with that gene some years down the track? I think our understanding of the relationship between a genetic test and a person's clinical situation is in a state of rapid flux at the moment.

A second issue really comes back to my opening admission, when I said that the issues of intellectual property and law are not my comfort zone. In the nicest possible way, senators, I do not want to be here today. I have another job. I have been trained for that other job. It involves a different language, a different mindset and different perspectives. I do not think that we have had particularly good communication between the IP community and the medical community over this issue.

Senator HEFFERNAN: Hear, hear!

Senator PRATT: Thank you.

Senator BOYCE: Dr Suthers, can I ask you, on notice, to give me the college's view of the draft raising the bar bill that is currently being considered? My question goes to certainty around IP for pathologists. Could you explain to us what the procedure is that you currently use so that practising pathologists are not spending half their day wondering about whether they are breaching someone else's IP?

Dr Suthers: I can answer that now. It is essentially Senator Heffernan's wink and a nod. It is not that there is a wink and a nod that pathologists knowingly flout patents, but they are operating in an area of uncertainty. There is no clear and really accessible repository of what genes are patented in Australia and what restrictions are entailed in those patents. That is a major issue. We do not have easy access to that. We also recognise that there are patents there that could potentially restrict diagnostic testing but which many patent holders have chosen not to

enforce—and I think that they too want to get clarity about this. Having seen the GTG saga over the last decade, I imagine that the industry would be really keen to get some clarity about this as well. So, when I say 'a wink and a nod', I do not want to suggest that people are being dishonest or doing things under the table, but they are in a vacuum in terms of knowledge about what the law says—

Senator BOYCE: So common practice is 'we do it like that because we've always done it that way', so to speak?

Dr Suthers: Yes.

Senator BOYCE: Perhaps you could tell us on notice where that repository should be.

Dr Suthers: Very happy to do that.

CHAIR: Okay. Dr Suthers, thanks very much.

Senator HEFFERNAN: By the way, we are very pleased you are here, even if you are not!

Dr Suthers: Thank you!

CHAIR: We do not have any other questions, but can I ask you to pass on to the college our thanks for their submission, and thank you personally for appearing before the committee. You can run away and do your other job now!

Dr Suthers: My other job! Thank you for your time.

CHAIR: The committee will take a short break for morning tea.

Proceedings suspended from 10:55 to 11:12

DRAHOS, Professor Peter, Director, Centre for Governance of Knowledge and Development, Australian National University

CHAIR: I now formally welcome you, Professor Drahos. I hope I am pronouncing your surname correctly!

Prof. Drahos: It is close enough!

CHAIR: All right. We have your submission, which we have numbered 25 for our purposes. Before I invite you to speak to that submission, do you have any changes you need to make to it?

Prof. Drahos: No, thanks.

CHAIR: All right. If you want to provide us with a brief opening statement and speak to your submission, we would welcome you doing that, and then we are going to go to some questions.

Prof. Drahos: Sure, thank you. My submission was very short—2½ or three pages—and, as you would see from the submission, it is broadly supportive of the bill. I am happy to answer any questions.

Senator HUMPHRIES: Thanks, Professor Drahos. One of the difficult elements of this inquiry, as was the case with the previous inquiry, is starkly conflicting evidence between different witnesses. I took the liberty earlier today of putting to the representatives of the Walter and Eliza Hall institute, for example, the comments you make in part 3 of your submission about the bill adversely affecting investment in the Australian biotech sector, and Professor Hilton from the institute quite dramatically disagreed with what you say there. I do not know if you were present when he made that comment; perhaps you were not.

Prof. Drahos: No, I was not.

Senator HUMPHRIES: It might be worth perusing the *Hansard* and maybe putting something to us in writing about that. Elsewhere in their evidence, the Walter and Eliza Hall Institute of Medical Research and the Peter MacCallum Cancer Centre made a comment to the effect—I think I have summarised them correctly by saying—that they thought an exclusion of biological materials from patentability would knock out something like 40 per cent of patents granted in, I think they said, the area of therapeutic practice in Australia. That would again be in stark contrast to what you seem to suggest in section 3 of your submission. Can you convince us that you are right and they are wrong about that?

Prof. Drahos: In order to do that I will have to spend a long time looking at some very dull econometric evidence and evidence about foreign direct investment, but I will do my best to summarise that. Countries that have moved down the path of regulating gene patents—for example, Brazil—have suffered no adverse impact on investment; to the contrary, investment continues to rise in those countries in the biotech sector. China has recently strengthened its compulsory licensing provisions in order to make it very clear that any anticompetitive use of patents including gene patents will result in the issue of a compulsory licence, and the biotech sector in China is growing dramatically.

There is no evidence that moving down the path of regulating gene patents, whether directly through excluding naturally occurring biological materials through patentability or alternatively through other indirect methods, adversely affects investment. The reason is that investment decisions in this area are affected by a large range of variables including the size of the domestic market, the availability of scientific expertise, tax concessions and many other variables. The idea that one variable alone will cause investment to dry up is simply wrong. One can look at the investment patterns for all these other countries—China, Brazil—and see that that is wrong.

Senator HUMPHRIES: In respect of Brazil, again, the Walter and Eliza Hall institute said that in fact there has not been investment in Brazil, that their change to the law with respect to patenting genetic material has in fact resulted in many medicines which are available elsewhere in the world coming late to Brazil. Again, we have starkly contrasting evidence. Are there any primary source documents that you could point to where we could satisfy ourselves as to what the state of investment in Brazil actually is as an indicator of what kind of fate would await Australia if it were to go down that path?

Prof. Drahos: It is an odd thing. The Brazilian government now has for a number of years made biotechnology a priority area. If you look at OECD patent data, this is an area in which Brazil is figuring. I am absolutely stunned that that should be said. That simply is not consistent with the evidence.

Senator HUMPHRIES: My question, though, was: can you point to some evidence that we can rely upon rather than—with respect—the comments of two experts in this field with diametrically opposed views?

Prof. Drahos: I would look at the OECD reports on the state of the biotechnology industry. I would also look at government reports by Brazil in the biotechnology sector. This has been an area of increasing activity by Brazil. They would be the two sources I would look to: government reports issued by Brazilian authorities about what is happening in the biotechnology sector, as well as the OECD reports on the state of the biotechnology industry and where activity is occurring.

Senator HUMPHRIES: You made reference to China. In your submission—it is a bit brief—you say:

China has recently strengthened its compulsory licensing law. It also has the political will to use this law.

How recent has the strengthening of its licencing law been?

Prof. Drahos: It is in the last 18 months.

Senator HUMPHRIES: Can we draw any firm conclusions about the effective investment in China into genetic related research for example, on the strength of a reform that only happened 18 months ago?

Prof. Drahos: I was in China last week at the invitation of the State Intellectual Property Office which is the office that administers the Chinese system and I asked them about this. Investment is booming. I spoke to Chinese biotech companies and I was told the same thing.

Senator HUMPHRIES: You have heard, or perhaps you have not, that a number of previous witnesses have cast some doubt about the wording of the bill. The previous witness was from the Royal College of Pathologists expressing, I think it is fair to say, some sympathy with what the bill was trying to achieve but serious reservations about how well the wording of the bill actually achieves that objective. Do you accept, for example, that the definition of 'biological materials' as presented in the bill—and as potentially amended by a further amendment which has been circulated today by Senator Heffernan which you might have—casts a very broad exemption over what can be patented and that by exempting biological materials from patentability, as the previous witnesses indicated, that some very large segment of present patents being granted in this country might be incapable of being granted because of the breadth of that exemption.

Prof. Drahos: I do not accept the latter proposition. All that the bill is seeking to do is to exclude biological materials that are naturally occurring. As long as patent owners or patent applicants do not strive to go down that path it may be that almost nothing is excluded in practice. The phrase 'biological materials' is perfectly standard in all of these areas. If you look at the convention on biological diversity, the UPOV convention or the national legislation of various countries, the phrase 'biological materials' is used for the purposes of exclusion because what you are trying to do is to ensure that the law excludes those things that are naturally occurring. To confine it to some subset sets up the dangerous inference that other naturally occurring biological materials are patentable. That would obviously defeat the whole point of this exercise. There is nothing unusual about the phrase biological materials. It would be unusual not to use it.

Senator HUMPHRIES: So you would categorically reject the contention of those bodies that a large proportion of patentable discoveries would be excluded from patentability in the future if this amendment were passed?

Prof. Drahos: Discoveries are excluded—

Senator HUMPHRIES: Inventions, I am sorry.

Prof. Drahos: If it is an invention, it will not be excluded; if it is a discovery, it will be. What I am saying is that there is nothing unusual about the phrase 'biological materials'. It would be unusual not to use it. Every other treaty or national law that has moved down the path of exclusion or sets standards in this area uses that phrase.

Senator HUMPHRIES: The Law Council on the question of this bill's compatibility with Australia's treaty obligations says:

The proposed exclusion covers a far greater field than merely human genes or gene sequences.

They are concerned about the width with which the bill has been cast. Again, do you reject their concern about that? Do you maintain this merely confirms the existing state of the law and does not in fact change it?

Prof. Drahos: All that is required is for somebody to simply look at the treaties and the national laws to see that the phrase 'biological materials' is used. That is just a fact. I do not know what the Law Council is saying exactly, but it is just a fact. I did not bring copies of the treaties along and I imagine we all have better things to do than to listen to me go through the treaties and the national laws step by step. I am just saying to you that treaties and national laws use that phrase; it is perfectly standard. There is no reason for the Law Council to be so concerned about the use of this phrase.

Senator HUMPHRIES: I am sure you can appreciate our dilemma, though. We have evidence that goes in starkly different directions and we need to reconcile them in some way. You cannot suggest a way of doing that? It says here in the Law Council's submission:

It follows that IPC would not support a ban on the patenting of the broader class of "biological materials".

They go into extensive argument about why it would be inappropriate to do that. Have you read their submission by any chance?

Prof. Drahos: No, I have not. I appreciate the fact that you have contradictory submissions; the question is whether you have contradictory evidence before you. As someone who has studied patent systems and international trade law for 20 years, I can only call it as I see it. I am saying to you that when I have looked at countries like China and Brazil, as well as many other jurisdictions, there are many variables that affect the behaviour of patent applicants.

Essentially, this bill is making a modest contribution to improving the situation for Australia. Australia will be faced with a situation in which there will literally be millions of patents in this area. In the next three years, according to its latest state plan, China is going to shift patenting from 1.7 patents per 10,000 people to 3.3. Biotechnology is one its key priority areas. The world is going to be flooded by biotechnology patents. Australia has to do everything it can to ensure that (1) these basic materials remain open for scientific research and (2) that Australian consumers do not suffer welfare losses unnecessarily. So anything we can do to improve the functioning of the system is appropriate.

Many vested interest groups depend on the patent system for their income. Patent offices make money from patent applications. Patent attorneys make money from drafting very broad patent claims; they do not make money from exemptions from patentability. It is therefore not surprising that you would receive evidence that the sky will fall in if you go ahead with this exemption.

I am here suggesting to you that, when one looks at the evidence, the sky will not fall in. Essentially, by supporting this bill you will do one of two things: you will bring some measure of certainty to scientists and you will ensure that Australian consumers gain some guarantees about access to important technologies. I think it is a question of looking to the future and understanding that this area will grow more and more complex, that we cannot put our faith in IP Australia because it will probably be unable to cope with the flood of patents and that we have to think of regulatory measures that will improve the situation for Australia in this brave new world of biotech patenting. That is my position.

Senator HUMPHRIES: You say that this will bring certainty to scientists, but the only scientists who have appeared before us today have said precisely the opposite: that this will create uncertainty. They believe that this will in fact generate more litigation and more uncertainty about the way in which they can exercise research in this area.

Prof. Drahos: I think that this is not the only step that should be taken. I have argued for the creation of transparency registers. It is a problem, when there are so many patents with so many complex claims, for scientists to understand exactly what the position is. I think that one amendment alone will not solve all of our problems. In other submissions that I have made I have argued for the existence of transparency registers. One should think of this as a series of filters that will improve the situation. So I have some measure of sympathy for that view. What I would say in reply would be that other things have to be done as well to improve the situation. It is a very complicated area. Scientists live in a lot of fear because they hear stories, a lot of rumours. That is why action needs to be taken in this area.

Senator XENOPHON: I have some questions to put on notice. Thank you very much, Professor Drahos, for your submission and for your evidence. I am concerned about time constraints. The Law Council of Australia and the submission from the Peter MacCallum Cancer Centre have said that this will affect research. They have made a number of assertions. I know it involves extra work, but I would be grateful if you could address in a supplementary submission or as a response to questions on notice some of the matters raised by the Law Council and the Institute of Patent and Trademark Attorneys.

Prof. Drahos: I will see what I can do.

Senator XENOPHON: That would be very useful. Thank you.

Senator SIEWERT: I am trying to phrase this question without maligning people. You talked about vested interests. You mentioned some of the vested interests. Do you include research organisations in vested interests?

Prof. Drahos: Research organisations that have incomes from patents and use patents as the basis for seeking research funding obviously will have a perspective on patents that will be affected by their business model. So the

extent to which a research organisation has a business model that is patent driven will obviously affect how they see the patent system.

Senator SIEWERT: Okay. Thank you. Senator Humphries has covered quite a lot of the questions that I had. I want to ask a question that I asked earlier. The comment was made by the Walter and Eliza Hall Institute about IP Australia overturning some of their decisions. I asked them this question and they have taken it on notice. It was in connection with a question that was asked about the patent on the flea head. I must admit that I do not really know anything about the patent on the flea head. It seems a strange patent, I have to admit! But the point was made that IP Australia overturned some of the decisions. Are you aware of how many of their decisions have been overturned and who initiated that?

Prof. Drahos: I am scratching for an answer, as it were, to that question.

Senator SIEWERT: Thanks for that!

Prof. Drahos: I cannot answer that question.

Senator SIEWERT: You are not aware of examples of where IP Australia have overturned decisions?

Prof. Drahos: No, not off the top of my head.

Senator SIEWERT: Could you take on notice—without putting you to a whole lot of work—to let us know if any do come to mind?

Prof. Drahos: I will see what I can do.

Senator SIEWERT: Thank you.

Senator BOYCE: You have made the point that you think there is a huge tsunami—for want of a better term—of patent applications coming in the biotech area. Have you looked at the draft raising the bar bill? What is your view about that the proposals in that bill?

Prof. Drahos: Because of various other commitments I have not had time to catch up with the raising the bar bill. What I am confident of is that it will do probably nothing to address the problem of patent quality.

Senator BOYCE: Are you talking across the board here?

Prof. Drahos: Across the board, including in the biotech patent area. The reason is that there are about six million unexamined patents in the world—there are various estimates, but it is somewhere around that ballpark figure. Patent officers cannot cope; patent pendency in all the major jurisdictions is running at about two years. So essentially what is happening—and I have done a study of this, so I am very confident about I am saying—is that the solution of patent officers is simply to examine patents essentially to rubber-stamp them as quickly as possible. So the legislatures can pass bills that will raise the bar, but the bottom line is that patent officers will examine patents, taking approximately 10 to 20 hours to examine—that is the range; that is how much time is devoted to the examination of patents. There will in practical terms be very little quality control, which is why you need a series of filters and why the Australian parliament should be looking to think about this as putting in place a series of filters. It is a mistake to put all your eggs in one basket. So one should have a patent office, and that patent office should strive for patent quality, but that will be difficult, for the reasons I have outlined. One can raise the bar, but the practical impact of that will be difficult, for the reasons I have outlined. One can create exemptions in certain areas. One can create transparency registers. One can create audit systems, which are very common in other areas of regulation. When you do all of those things, you will improve the situation.

Senator BOYCE: How many unexamined patents in Australia are you aware of?

Prof. Drahos: I do not know what the backlog in the Australian patent office is exactly, and a lot depends on various treaty processes—the Patent Cooperation Treaty being one of them—as to whether they are Australian and so on, but the ballpark figure for the number of unexamined patents in the world at the moment is around six million. It is very hard, because of the complexity of the system, to calculate that exactly, but that number will continue to rise because of what is happening in China as well as other countries.

Senator BOYCE: Obviously a lot of your work would be around the fact that the patent system itself needs an overhaul. I have some concerns about changes in one little spot of patent law. Could you comment on that.

Prof. Drahos: Sorry—what are your concerns about?

Senator BOYCE: Unintended consequences, and the question of why, if we are looking at an overhaul of an entire system as you propose we should, we would not be seeing this as something that we do as part of an overall review, not as a one-off.

Prof. Drahos: I think it is a question of how you sequence these things. We have a concrete draft before us. I think the evidence is reasonably clear, based on my work and the work of others, that we need to do something.

There are other things one should also be doing. It is not a question so much of overhauling an entire system as of making regulatory adjustments. So, in my view, what we should be doing is to see this as a series of steps in making regulatory adjustments to the system, coping with some of the problems that are coming down the pipeline, as it were.

In terms of unintended consequences, based on my work, as I have already explained, I do not see any problems with this amendment. If investment were to suddenly dry up, we could take steps to do that, but I am very confident that that would not be the case, because it has not dried up in other countries. As I say, many variables affect investment. Australia has very good scientific expertise. Australia has good regulatory structures. The Therapeutic Goods Administration is a high-standard organisation, so companies look to TGA approval because it helps them in other markets. That is another important variable. So, when one looks at all of these variables, the claim that this amendment alone will suddenly cause investment to dry up in Australia is frankly nonsensical.

Senator BOYCE: Senator Heffernan, are you intending to ask the witnesses about your amendments that you have circulated?

Senator HEFFERNAN: You can.

Senator BOYCE: Senator Heffernan has circulated some amendments to his proposed bill. Have you had an opportunity to look at those? Given that you have said that you like it exactly the way it is, what is your view of the amendments?

Prof. Drahos: I have not seen Senator Heffernan's amendments.

Senator FURNER: You have cited the Brazilian market as an example of the way things are working in that particular country. No doubt you would be familiar with the recent acquisition by Amgen, the largest independent biotech company, of a Brazilian pharmaceutical company over there. Is it not the case that the exclusion of the Brazilian patent laws is certainly narrower than what we have here? Is that an example why that acquisition was successful and was indeed able to be acquired and to be working quite appropriately?

Prof. Drahos: I do not read Portuguese so I am only relying on an official English translation of the Brazilian patent amendment. That amendment uses the phrase, biological materials, or the Portuguese equivalent, and I see it as being very widely drafted. I should also add that we find not only that exemption in Brazilian law but also that the final say over the grant of patents in Brazil in the pharmaceutical area is not up to the Brazilian patent office. It is actually up to ANVISA. ANVISA is the equivalent of the Therapeutic Goods Administration Act body. The Brazilians do not actually trust their own patent office, so pharmaceutical patent applications are sent to the equivalent of the Brazilian TGA for approval. So you actually have scientists working in the public sector assessing those applications. When this amendment was put into place in Brazilian law, most patent attorneys in Brazil said it would be the end of the world and that all investment in Brazil would vanish. Of course the Brazilian equivalent of the Therapeutic Goods Administration Act was looking after the interests of Brazilian citizens. It was essentially trying to stop what is called evergreening behaviour by patent companies. Despite all the protests from Brazilian patent attorneys and companies, investment in Brazil continued. Brazil continues to provide pharmaceuticals to the Brazilian population at a very cheap and reasonable price. Many poor people in Brazil would go untreated but for the steps that the Brazilian government has taken.

Senator FURNER: Would you know what the size of their market is?

Prof. Drahos: In world terms I think it is bigger than Australia's but that is easy to say as we are a small market. I do not know exactly where it ranks in world terms, but they are, I think, the tenth biggest economy in the world so I imagine it is a significant market.

Senator HEFFERNAN: Following on from that, Amgen have just invested a quarter of a billion dollars and Amgen themselves are the world's biggest biotech company and they had the patent on EPO, for which I think they got something like $1.9 billion in licensing benefit. I come to IP Australia. In two inquiries we have been tangling with IP Australia. We started off this inquiry, going back to the previous committee, with people saying, 'No, we don't patent genes. Don't be silly!' That was until we turned up with a truckload of gene patents. They then said, 'Oh, well, isolated genes are materially different to the natural situation.' That is of course a furphy too. They then said, 'That's a matter of the past. We have learned from all of that and it is no longer an issue. Of course we have learned today, and we have known of other patents granted last year, in 2009-10, that still include huge slabs of biological material. Doesn't this indicate that if discovery is not patentable, that IP Australia, and we have heard from earlier evidence, 'Yes, but they were mistakes and we don't make those mistakes anymore,' and yet we are still doing it as much as last year. Doesn't that say that IP Australia is either inadequately resourced or just cannot process the mountain of work that is in front of them?

Prof. Drahos: We should not be critical of IP Australia alone. All patent offices are struggling because of the sheer volume of work. The bottom line is: if you are an examiner in a cubicle and you are faced with a patent application that stretches for hundreds of pages, and you are under a quota—and many patent offices have quotas—

Senator BOYCE: Does IP Australia have a quota?

Prof. Drahos: That is a question that is better directed to IP Australia. My understanding is that there are incentive schemes operating in IP Australia. Most patent offices in the world have incentive schemes, which obviously means there is a bias in terms of the grant of patents.

Senator HEFFERNAN: They of course are funded by the licence application fees.

Prof. Drahos: They are funded, indeed, by the licence application fees. IP Australia is in the same boat as other patent offices. They are struggling to cope. Unfortunately, as I have indicated earlier, the problem is only going to get worse, which is why we need to think of a set of steps—

Senator HEFFERNAN: Hear, hear!

Prof. Drahos: If we do not do something about this, the problem will really get much worse than it is now.

Senator HEFFERNAN: You are referring to the filter and might I just for the committee's benefit note that some recent patent applications run between 700 and 900 pages, so I would like to know how you get through that in a few hours.

Prof. Drahos: The examination time for most patents, based on my study of 45 countries, was between 10 and 20 hours. That includes administrative processing time.

Senator HEFFERNAN: They must be quick readers. The next step down—trying to get away from ignoring the elephant in the room—is crown use, which as I understand we have not used. When you sat back and thought about it, wouldn't it be a matter of the person who was prepared to pay the lobbyist with the most influence on the government—retired government members, mates, et cetera, the leeches of the industry—and a matter of the most powerful lobbying? Wouldn't that be a dangerous concept, as you point out in the United States, to rely on crown use?

Prof. Drahos: I agree with you that it is a matter of political will or courage to use these things. The problem is that the United States has been a great opponent of the use of compulsory licensing and crown use. It has essentially brought trade pressure to bear on countries like Thailand, that have gone down this path. It is much more sensible for Australia to adopt strategies that will not bring it into confrontation with the United States, which of course remains a very important strategic partner. The United States' position on this I think suggest that it would be much smarter for Australia to go down this path—the path of creating transparency registers. The US has a system like that, called the 'orange book' in the pharmaceuticals area. It is much smarter for Australia to create specific exemptions in its patent law rather than relying on the politically difficult decision to issue a compulsory licence.

Senator HEFFERNAN: If we had our time again and we learned from the mistakes of the past and we were honest enough to own up that you actually cannot include in a patent a discovery which clearly, the statute of monopolies says—even though we do in the case of the BRCA patents, you would still have the patent on the test but you would just rub out several of the claims—which amount to 24 claims—and the patent would still apply for the inventive step commercialisation that work. So I do not understand why people say that the world is going to fall apart. What troubles me most—after the global food task—is the cost of the human race living an extra 10 years every 30 years due to wonderful discoveries and materials. I do not see how we can afford to remain with the proposition that it is a comfortable cartel that endures. BRCA is a really good example. In the US it has just gone up to $4,000 a test, I think. The guy who was the whatever of Genetic Technologies Australia is now in jail. They discovered Myriad breaching one of their patents. All the tests for BRCA in Australia would have had to go to the US and be subject to their costs, due to the cartel. How in the hell in the future is the world is going to be able to afford it? Most taxpayers want to pay less tax. We have got a $79,500 subsidy by the taxpayers in Australia—generously—for an $80,000 test. I just do not see how this eventually will not fall off a cliff if we do not do something about it. I absolutely agree with you—

CHAIR: We are running out of time. Have you got a question?

Senator HEFFERNAN: —that we need filters in the system. Having the wherewithal to agree that biological materials are not patentable would be one of those filters.

Prof. Drahos: Yes. I think drawing attention to the oligopoly problem and the pricing problem is incredibly important. We want competitive open markets, so we want competition over diagnostic tests. That does benefit

consumers. Taking one step to improve the quality of patents would help to bring about that competitive market. So I agree with you that we must address the pricing issue and keep markets competitive and free in this area, and this would be one way to do it. The problem is that other countries may, for trade reasons, allow these oligopolies and may be perfectly happy for these oligopolies to operate globally and extract rents from consumers. We in Australia must make sure that Australian consumers do not suffer as a result.

Senator HEFFERNAN: Going back to Genetic Technologies Australia, my conversation with them when this first started, some years ago now, was 'Why are you enforcing the patent?'—which they had attempted to do. The answer was, 'Because we are in financial trouble.' I said, 'What happens if you fail and you go broke?' The answer was, 'We'll sell our goods and chattels.' That would include the patent rights that they hold the licences to. Who could buy them? Anyone. A money launderer could buy the licence and live off the income of the licence, which gets a long way from a person who is tucked away in a laboratory at Westmead. As I said earlier, I think this process has lit up the landscape. Isn't it time that we came to terms with the long-term impact of the acceptance of cartel behaviour in this industry?

We want to allow for reward for commercialisation, but this is locking up access. They say now we will give an exemption for research, but, if you are going to give an exemption for research which then leads to a commercialisation possibility for which you need a further exemption to the patent on the biological material to commercialise, which puts the person who holds the head licence out of business—

CHAIR: Senator Heffernan, we are going to have to finish here.

Senator HEFFERNAN: Isn't that an example of: why the hell have they got the patent on the biological material in the first place? It is restrictive, surely.

Prof. Drahos: Addressing concentrated market structures or cartel behaviour is challenging, and there is no doubt that patents play a role in that. As I say, I think it is a question of improving the system on a step-by-step basis. This is one very positive step that can be taken. There are of course other things that one should be looking at.

Senator HEFFERNAN: I would hope that this committee would extend for some time to make sure that we can cover off all the objections and unintended consequences and possibilities, to enable the thing to be viable.

CHAIR: Prof Drahos, thank you very much for your submission and your time and availability today. It is much appreciated.

Prof. Drahos: Thank you very much.

[11.56 am]

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

HAMER, Mr Richard, Deputy Chairman, Intellectual Property Committee, Business Law Section, Law Council of Australia

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

OBRANOVICH, Dr Tania, Fellow, Institute of Patent and Trade Mark Attorneys

CHAIR: The Law Council of Australia has provided us with a submission which we have numbered 48 and the Institute of Patent and Trade Mark Attorneys has lodged a submission with us which we have numbered 49. Before I ask you to speak to those submissions, do you need to make any changes or alterations to them?

Dr Davies: No.

Mr Hamer: No.

CHAIR: sometimes people do have fixes to errors or additions that they want to provide. If it is the case that there are no changes that you need to make, I invite each of the groups to make an opening statement and then we will go to questions.

Mr Hamer: I did not want to repeat comments which were made by a number of parties this morning when both just to note that the Law Council does consider the view that patent protection prevents the development of biological medical technologies is misguided, even if well intentioned. It is very clear to us from our experience dealing with people in this area that patent protection is commonly a prerequisite to taking a product from the bench to the market. Therefore, although it does impose a cost on subsequent uses of the technology, it is critical for that technology to use in the first place. I think that is a misconception that has plagued a number of submissions that have been made. But I will leave the detail of that to others.

What I did want to comment on more specifically was the view of the Law Council that the carving out of specific technology exceptions in patent litigation is an unsatisfactory approach. It leads to complexities and the use of loopholes. Ironically in this case it would be a trivial matter to find loopholes to protect the BRCA test cancer kit, which was the start of all of this debate. Whereas it would not be anywhere near so trivial to find an exception to a new antibiotic or other biological compound that might have been discovered and which I think most people would agree would be worthy of patent protection. So those sorts of exceptions and complexities are unsatisfactory.

We do consider that the legislation would not comply with TRIPS or the US FTA, at least to the extent that the amendments have the effect of excluding inventions as opposed to discoveries—and we think they do. Finally, we agree that there have been issues with patents in Australia being granted to readily. I think this is something that has affected all areas of technology and we think that the raising the bar patent bill which we generally support—we have some detailed comments on it—is the right way to approach this in a generic way rather than creating exceptions and the resulting complications. Lawyers would benefit from the complications but, nevertheless, we do not promote that as a legislative approach.

Dr Obranovich: Thank you for inviting the institute to appear before this committee. The issues which underpin the establishment of the original Senate Community Affairs inquiry stem from GTG's actions in relation to its breast cancer diagnostic. These actions, very understandably, caused a lot of concern in the community. In summary there was concern that the existence of gene patents posed a risk to public health and that they drove up costs and stifled research, and also that genes are a discovery not an innovation. IPTMA's position has always been that these are completely legitimate concerns which have to be appropriately addressed. To this end, we acknowledge and support the intent of the sponsors of the bill to deal with these concerns. In our opinion, this particular bill is too blunt an instrument which cannot achieve this outcome.

The bill proposes to exclude from patentability all biological materials which are identical or substantially identical to materials as they exist in nature. Since the ban extends to all organisms, the bill would adversely impact not only health care but also sectors as diverse as agriculture, animal husbandry and food technology. The

breadth of biological materials which the exclusion would encompass is enormous. Therefore, the potential impact of the functioning of all of these sectors would be significantly impacted.

Ironically, what would clearly remain patentable, if the bill was enacted, would be the very technology which ignited the issue—that is, diagnostic methods. In addition to the fact that the bill would do very little to alleviate the very real concerns of the community, we believe it would also unintentionally create a range of new problems. Firstly, if it was enacted it would introduce uncertainty into the law as to its language. This would require interpretation to clarify its full scope. The issue of interpretation can only be settled by the courts. I think everybody would agree that more litigation is not where we want to go.

Senator HEFFERNAN: The lawyers don't.

CHAIR: Please continue. We will not interrupt you as you continue your opening statement.

Dr Obranovich: That is fine. I disagree with the litigation interpretation. An even greater risk is that whatever judicial interpretation does occur that may result in the inadvertent exclusion of biological materials which were never intended to be excluded.

Secondly, the absence of patents to biological materials in Australia will not change the fact that all other developed countries will continue to offer such patents. This could further encourage, as Professor Hilton said, the shift of Australian research overseas. Thirdly, in the absence of patents to biologicals, we run the risk of missing out on accessing new patented medicines. I believe Medicines Australia will address this issue in more detail. Without patent protection, a company may be less likely to invest in seeking the regulatory approval and go through those hurdles in order to release its product into Australia which it would do in competition with third parties. We are a very small market when considered globally. Enacting legislation which would effectively make us less desirable as a potential market would seem unwise.

Fourthly, we believe enacting the bill would likely place Australia in breach of its international obligations. The relevant treaties to which we are signatories require us to make patents available in all fields of technology. Of note, for example, Europe expressly enshrines the patentability of biological materials—it uses that language. If we enact this bill, we immediately place ourselves directly at odds with Europe.

In terms of the question of discovery versus invention, the fact is that across the entire developed world isolated biological materials are regarded as patentable, on the basis that they represent an artificially created state of affairs. However, the fact that they may form patentable subject matter does not mean that they will be patented. In order to be patented they also have to be new, they have to not be obvious to have been developed and they have to be useful. This is where issues of all of those arguments about whether it would be easy to isolate a gene or another protein become relevant, and it is the reason that gene patents are virtually never granted now.

On any logical risk-benefit analysis, we believe that enacting the bill opens us to significant risks for the sake of very little actual benefit. We believe that community concerns are best addressed by providing a solution which is technology neutral and which regulates the exercise of patent rights. This is where we come to compulsory licences and the crown use provisions—which is what China are doing. They have not banned biological materials; they are strengthening the compulsory licence provisions. This would enable the public or the government to forcibly obtain a licence to a patented technology if it is being refused. The research exemption is in train. We believe that it would be in the public interest to focus our discussions on the smooth operation of those safeguards. The five inquires which have been held in the last nine years in relation to these issues have all consistently recommended against amending patentable subject matter, but they have said to focus on the existence of safeguards and to ensure that the patentability thresholds are high enough and that they are properly implemented.

We believe that the present bill is not the right way to move. We believe that it should be discontinued in favour of the raising the bar bill, which has been released by IP Australia. This bill seeks to introduce a research use exemption, tighten up patentability thresholds, which we agree with, and is consistent with all of the recommendations which have been made by the previous inquiries, and we think it would be a more effective means of bringing to the community the outcomes which they are looking for. Thank you.

CHAIR: We will go to questions.

Senator XENOPHON: You said that China has strengthening compulsory licensing provisions. Wouldn't that pose problems in Australia given that there is a constitutional right whereby, if property is compulsorily acquired, there must be just compensation?

Dr Obranovich: We already have compulsory licensing provisions in our act. We are just talking about actually using them.

Senator XENOPHON: Would that cause difficulties in terms of the compensation provisions in the Constitution?

Dr Obranovich: I do not believe so. I am not a constitutional lawyer. I presume that had there been issues of that type—

Senator XENOPHON: I did it 35 years ago at uni, so neither am I.

Dr Obranovich: I presume that had there been issues of that type they would have been raised at the time that this was being enacted and they would have been discussed, and if there were problems it would not have been introduced into the act. But the provision has been introduced into the act. It is actually there.

Senator XENOPHON: I think Mr Hamer referred to one of the misguided if not well-intentioned people that you refer to as one of the proponents of this belonging with Senators Siewert, Coonan and Heffernan. There is a problem though, which was raised in relation to the inquiry that Senator Siewert chaired a couple of years ago into the issue with Myriad. You acknowledge though that there was a problem there in terms of slowing down research. I think Dr Mitchell, in her previous submission, said that Peter Mac's research into the BRCA gene was delayed for two years and ended up costing three times as much because Myriad could not give permission. I think her evidence was that there were other factors as well, to be fair to her. But isn't this an impediment? This bill is trying to deal with that mischief.

Dr Obranovich: The issue of research is an important one and that concern applies across all technologies. That is where the research use exemption is going to solve that problem. It is going to solve it in a technology neutral way so that next time that a GTG, rather than trying to prevent research on BRCA, is trying to prevent research on a chemotherapy drug, which is not biological, a research use exemption is going to far more effectively ensure that there are no hold-ups of that type.

Senator XENOPHON: But the bill does not prohibit the patenting of inventive products, processes and methods that use biological materials for medical applications, does it?

Dr Obranovich: Not the application, no.

Senator XENOPHON: Have you had an opportunity to see the proposed amendments to the bill—and if you have not I understand—that Senator Heffernan tabled earlier today?. I do not know whether you had a chance to look at that.

Dr Obranovich: We were handed them a few minutes ago.

Senator XENOPHON: Again I will be guided by the chair. I am happy for you to comment on those now or would you like to do that on notice?

Dr Davies: I have had a brief look at the proposed amendments. In my view and I think the view of the institute it still does not overcome the serious deficiencies in these proposals. There are two issues: (1) we do not think any amendment is necessary—

Senator XENOPHON: So the status quo—keep things as they are?

Dr Davies: Yes, there should not be an amendment to the act to preclude the patentability of one technology or a series of technologies. With regard to these proposed amendments there are still issues regarding the scope of exclusion that this proposal has put in. Biological materials are made up of a whole lot of subunits and so what exists in nature may be a very small part of the overall biological material. So it is going to be very hard to interpret what would fall within this exclusion and what would fall outside the exclusion. The amendments still do not address the clarity issues, how a court would interpret whether a particular biological material will fall within the scope of this exemption or not, and the same even with IP Australia—what are you trying to preclude from patentability with this sort of amendment?

Senator XENOPHON: I will wrap up now—I am conscious of time—but there are two things. Aren't you conceding that there is a problem with the applicability of the Patents Act and the way it is interpreted, which raises the question that it needs to be amended?

Dr Davies: No.

Senator XENOPHON: You are not?

Dr Obranovich: I think there can be a problem with how people exercise their rights, and I think that that can be dealt with effectively. If I could just make one comment about the question you asked earlier with regard to Peter Mac's research—and I only heard what you heard here—what I understand from the Peter Mac representatives is that the research they wanted to perform was a large-scale diagnostic test of a population. What needs to be remembered is that, even if this proposed act had existed at that time, that would not have changed the

problems that they had for that particular research project, because that research project was not based on using the gene; that research project was based on using the diagnostic method, and that is separately patented and would not be excluded by this proposed act. So that is an example of where this proposed act actually would not have made a difference to Peter Mac's particular project that was delayed, and that is where I think a research use exemption that applies across all technologies is so incredibly important.

Senator XENOPHON: Finally, I know it was Senator Heffernan's interjection, but I was going to ask about the flea head patent granted on 8 September 2008. You may want to take it on notice, but the first line says, 'The present invention relates to the nucleic acid molecules isolated from the head and nerve cord of a flea.'

Dr Obranovich: In reading a patent, it is not a good idea to read the first line; you need to go to the claims, because that is what was actually granted.

Senator XENOPHON: Sure, but are you familiar with it?

Dr Obranovich: No, I am not familiar with it.

Senator BARNETT: We need to hear that answer.

Senator XENOPHON: Sorry—if I could let you—

Dr Obranovich: No, that is fine. I was just going to say that you should be very careful reading what is in those introductory statements, because they often are broad, but what the patent office actually gives the rights across could be something much narrower, and it appears in the claims. No, I have not seen the patent, so it is very difficult for me to comment on it.

Senator HEFFERNAN: It is in the claims.

Dr Davies: Could I make a comment. At the moment an isolated nucleic acid molecule that may form a gene or part of a gene is patentable if it meets the patentability criteria: it has to be novel, to not be obvious and to have a reasonable use, and there has to be sufficient disclosure in the patent application to support the grant of the claims.

Senator XENOPHON: Perhaps you could take on notice—so it is not taken out of context—whether there are concerns about it, because I think there are others, including myself, who have concerns about the fact that a patent could be granted in those circumstances. Thank you.

Senator PRATT: I wanted to ask about the perceptions about diagnostic tests, the patentability of that part of biological material and how you distinguish the test from the biological material itself.

Dr Obranovich: Sorry—I am not sure what the question is.

Senator PRATT: That is probably not a very clear—

Mr Hamer: I think I got the question. I am probably not the best person to answer it, but I will answer it in any event. That is because a test will require a series of reagents and other things that are not biological materials, and possibly equipment as well, so it would be a combination of all those things. There is nothing in this proposal that would exclude the possibility of combining biological materials with other reagents to perform a function such as testing for a particular gene. So the drafting does not work if that is the objective.

Senator PRATT: Okay. In terms of the origin of the legal position some years ago in terms of the fructose—the research that took place—I suppose the legal premise of that is that there was a novel or innovative way of having invented and therefore patented that process for finding that particular gene.

Dr Davies: The observation that there may be a change in a particular gene that is tied to a disease or some genetic condition?

Senator PRATT: Yes.

Dr Davies: Through extensive research, the finding that there is a change and that you are able to detect that change by using, quite often, small biological materials is considered as being patentable.

Dr Obranovich: What is patented is the method. It is the notion of taking a biological sample, looking for a particular mutation and, if that mutation exists, diagnosing the particular condition. So it is not a patent over a biological per se; it is over a method.

Senator PRATT: I am a little bit unclear given that description of the difference between the biological material and finding it versus the method of finding it.

Dr Obranovich: In many diagnostic methods you do not even really work with the gene; you are taking a biological sample and you are probing it for the existence or not of a particular mutation. It is an entirely different type of technology. One technology relates to an actual substance—a molecule with a particular structure—and

you can claim that and have rights with respect to that. The other technology relates to a method of diagnosing a disease, and it is that method which is protected irrespective of how you do it and often irrespective of what reagents you do. That is certainly the case with the BRAC1 test. Howsoever you chose to do it, it was a method of diagnosing breast cancer based on whether or not those mutations existed.

Senator HUMPHRIES: Dr Suthers, from the College of Pathologists, said that a diagnostic test, by its nature, was always based on a discovery rather than an invention in that you were using materials to test the presence of some material or some factor that would lead to a conclusion. Is that your understanding of how that would work—that is, that you really could not legitimately ever grant a patent over a biological test because you are always dealing with a discovery rather than an invention?

Dr Obranovich: I disagree on the point that that is a discovery and not an invention. I think that identifying a link between a particular mutation that you did not know existed and a particular disease is actually an incredible step forward and very impressive. So defining a diagnostic method around looking for a particular mutation in a person and therefore deeming that person predisposed to cancer is, I think, an invention—and there is certainly nothing in this bill that disagrees with that either—and that is patentable.

In terms of what materials you use to perform the method, most of those diagnostic methods are not limited by reference to particular material, because there are 100 different ways that you can perform a diagnostic depending on what you are looking for—whether you are looking for a mutation in a gene or the existence of a protein, like in prostate cancer or something along those lines.

As far as I am aware, beyond what was said this morning, there is no dispute with the proponents of the bill that these diagnostics remain patentable. That is why it is so important that we put in place the safeguards to ensure that nobody can abuse their rights on that diagnostic, because this bill does not do anything to change the rights that exist and how they are exercised around that diagnostic.

Senator FURNER: Dr Obranovich, you made the observation that there were concerns of potential detrimental outcomes for agriculture, food, technology and all husbandry and cut flower industries. Can you elaborate in terms of the effects on those industries, please?

Dr Obranovich: If you look at agriculture and foods which are trying to be generated—some of which are genetically modified and some of which have vitamins and the like built into them and plants that can be grown more easily—these are all technologies that are the subject of patents. Depending on what the specifics are of the technology and how the claim is hung together, they are often patents over biological materials. It is the same with animals in terms of the materials you give them—antibiotics and that sort of thing. It can affect those industries as well if those antibiotics are not brought to market or if they are available overseas but not here because we do not have patents over those molecules. It is in that respect that we made those comments in the submission.

Senator FURNER: So overall, if this bill succeeded, what would be the effect in terms of the economy and employment in those particular areas?

Dr Obranovich: I think it is potentially very significant, when you consider agriculture, for example, and the fact that we are a huge agricultural economy, that there would be any problem in obtaining patents in relation to biological materials surrounding plants and crops that would maybe prevent those crops from being planted or being grown on a large scale. I believe it is fairly self-evident where that would lead, not just to potentially less food being produced but in terms of farming and—

Senator Heffernan interjecting—

Senator FURNER: Please just go on.

CHAIR: Dr Obranovich, please continue.

Dr Obranovich: I believe that there will be representatives of the agricultural sector speaking tomorrow. It would probably be better to ask them those questions.

Senator HEFFERNAN: Yes, I would say so.

Dr Obranovich: Many of these comments are comments we hear from our clients. They are concerned, whether it is in regard to livestock or ornamental flowers or the like, that this bill would have impacts on their sectors and that it would have unwanted consequences. I think that the gentleman who is speaking tomorrow would be best placed to answer those questions in detail.

Senator FURNER: Okay, thanks for that.

Senator BOYCE: Mr Hamer, you commented on patents being granted too readily. Were you speaking in a historical context or are you saying that that is continuing to happen now?

Mr Hamer: Let me be clear that there is a difference between whether a patent is granted—that is, the patents office issues it—and whether the patent is in fact valid. The fact is that—

Senator BOYCE: I understood you to have said that it was a fact that patents had been granted too readily.

Mr Hamer: Yes.

Senator BOYCE: Yes. Go on.

Mr Hamer: Certainly there is no doubt historically, and I think even today there are patents being granted that will ultimately be found by a court to be invalid, and there are probably too many of those being granted in the sense that the patent office has not been applying a sufficiently—

Senator BOYCE: And this is across the board?

Mr Hamer: This is across the board.

Senator BOYCE: Including the area of genes and biotechnology?

Mr Hamer: Including this area. This is a symptom of a more general problem, as we see it, as opposed to being a specific—

Senator BOYCE: Sorry, you had something to say, Mr Jarvis?

Mr Jarvis: I was just going to add that it does not necessarily mean that the entire patent is invalid; it may just be a claim or a couple of claims in the patent that are invalid.

Senator BOYCE: I think you heard Professor Drahos's evidence earlier, where he claimed that there was going to be such a huge flood of patent applications, particularly in the biotech area, that it would be simply impossible for the global patent system, let alone the Australian patent system, such as IP Australia, to keep up with this and that we need to introduce filters now to preserve the integrity of the system. Given what you have said about patents being too readily available, what is your view on that comment?

Mr Hamer: I assume you are hearing from IP Australia at some point on this—

Senator BOYCE: Yes.

Mr Hamer: but my understanding of the approach that underlies this new bill is that it is in part to raise this bar.

Senator BOYCE: You are talking about the raising-the-bar bill. That was going to be my next question.

Mr Hamer: The raising-the-bar bill is partly to raise the bar, but it is also—and primarily, perhaps, from their perspective—designed to bring our law into line with the law in other countries. The intention of that is, as I understand it from IP Australia, that they will then be able to not have to examine so many patent applications because, if a patent application has been examined in Europe and we have substantially the same test, they do not have to examine it so rigorously, as opposed to the present position where a patent can be refused in Europe but they have to allow it in Australia because our law has been set at a lower level—and also they have to go through the process of examining it in detail in Australia as opposed to simply saying, 'It hasn't been allowed in Europe; we're not going to allow it here.' So I think that the raising-the-bar bill has two important effects, one raising the bar and the other bringing us into line, and that seems to be much more important than this.

Dr Obranovich: I can also add a comment to that. The issue of the patents and the backlogs is a big issue and everyone is talking about that. There are all sorts of mechanisms being discussed as to how that might be remedied worldwide—not just in Australia—by carving out a little bit of subject matter. Some of the mechanisms, for example, being discussed are mechanisms such as if a patent was granted in Europe would we therefore have a relationship with Europe where the equivalent patent could be granted here without undergoing full examination. So there are other ways of dealing with it. The issue of backlogs does not just apply in biotechnology; it applies in IT and everywhere—

Senator BOYCE: I appreciate that.

Dr Obranovich: So the solutions that are being proposed—

Senator BOYCE: But the evidence was that there will be a vast increase in the number of patents in the biotechnology area in the next few years.

Mr Hamer: The absolutely key problem is that by putting special legislation into Australia that is not in other countries we are wrecking that process because instead of being able to make the process easier we are making it more difficult because things have to be looked at specially in Australia.

Senator BOYCE: So it is a one-off rather than part of a comprehensive review—that is part of your concerns?

Mr Hamer: Yes, it is actually counterproductive.

Senator BOYCE: I mentioned to Professor Drahos my concerns about the unintended consequences if this bill was to be passed. While he did not agree with me that there would be, he said, 'If there were and if the investment dried up, you could look at changing the bill again.' From a patent attorney's perspective, once investment dries up do you see any difficulties in reigniting investment by changing the law?

Dr Davies: If the investment dries up you would probably lose the pool of expertise, such as the researchers, the private companies and the underlying skills and technology that drive this industry. If that goes, just reversing a poorly drafted exemption in a patent act would not change the situation straightaway.

Senator BOYCE: Switch it back on, so to speak?

Dr Obranovich: I think what we need to bear in mind is that when you talk about investment drying up it is not that it dries up—the investment will still be there; it is just going to go elsewhere. That is the problem. It will still be there. If it goes into the US or Europe our scientists will follow it and set themselves up in laboratories over there. It is hard enough as it is to get our post-docs to come back to Australia to do research here. The last thing we need to do is to make it even more difficult for them to come back. Once they set themselves up over there, and if that is where the investment exists, you do run the risk that if you reverse the legislation they may not come home and you will lose a generation of scientists. Yes, you will get that back in time, but how long does it take? Another generation?

Dr Davies: I will make one other comment. At the moment the government has a requirement for research organisations that obtain NHMRC and ARC funding for their research that if there is any potential commercial avenues from that research they should be filing patent applications. The biotech industry and the medical research industry are quite large in Australia and at the moment there is a requirement that research organisations that are recipients of those funds should be looking at opportunities for protecting that research in order to hopefully get a return from that research by going down the commercial route. If you remove patentability of quite a large area of research it really goes against the desire to get some returns from that government funded research.

CHAIR: I thank the four of you for your attendance today and also for your submissions.

Proceedings suspended from 12:28 pm to 13:32 pm

MONK, Ms Deborah, Director, Innovation and Industry Policy, Medicines Australia

SHAW, Dr Brendan, Chief Executive, Medicines Australia

MURPHY, Mr Tim, Co-Chair, Innovation Strategic Committee, Medicines Australia; Head, Government Affairs and Policy, GlaxoSmithKline Australia

CHAIR: I now resume the Senate Legal and Constitutional Affairs Committee's enquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2] and welcome representatives from Medicines Australia. Medicines Australia has sent a submission to us which we have numbered No. 89. Before I ask you to speak to that submission, do you have any changes or alterations you need to make to it?

Dr Shaw: No.

Ms Monk: No, thank you.

CHAIR: I now invite you to make an opening statement.

Dr Shaw: Good afternoon and thank you for inviting Medicines Australia to appear before this committee. We represent the innovative prescription medicines industry in Australia. Our 50 member companies develop and market new medicines, vaccines and health services that benefit millions of patients in Australia. Mr Murphy is here today representing one of our members—GlaxoSmithKline Australia. The pharmaceuticals industry as a whole employs over 40,000 Australians, about one-third of whom are involved in research and development. In fact, our industry is Australia's third-largest investor in research and development. In 2009 alone we invested more than $1 billion in research and development. We are also Australia's largest exporter of high-tech manufactured goods. In 2010 we exported goods worth $4 billion, which is more than the Australian car and wine industries. Industry success in Australia is closely and unquestionably linked to the strength of this country's intellectual property laws. To undermine these laws is to undermine the future of one of Australia's most successful and innovative industries.

Last year, in November, the bill we are here to discuss was introduced into parliament. The bill seeks to ban patents on biological materials. This is in spite of the fact that three separate government and parliamentary inquiries, including one by the Australian Senate, have found no grounds for taking such action. In fact, they found no evidence to suggest that patents on human genes and biological materials pose a threat to public health or to scientific advancement.

As you are aware, senators, the bill is very brief, but its implications will have a significant impact. Without doubt, banning patents on biological materials will have devastating consequences for the pharmaceuticals industry in Australia. Our companies rely on the promise of future returns to attract investment in research and development. Simply put, no patents equal little or no incentive for investment. Certainly, our member companies will continue their business of researching new medicines and bring them to market elsewhere, but the incentive to do clinical trials and bring their products to market in Australia would be severely constrained.

This is important to consider in the context of this inquiry, additionally so because it has a direct impact on Australian patients. Right now, there are over 400 biological medicines in development globally, targeting diseases such as diabetes, cancer, AIDS, arthritis and Alzheimer's. It is uncertain whether these medicines would be eligible for patents in Australia if this bill becomes law. If even part of this global development cycle were threatened as a result of our decisions here, it would be Australian patients who, along with Australian industry, would pay the price. That is, if companies are forced to cease research and development into new products, or even if some of them choose not to bring patented products to Australia for fear of exposing their intellectual property to free riders, Australian patients would have to settle for older, less effective medicines—to say nothing of the likely contravention of Australia's international obligations. Australia is a party to international treaties that require us to make patents available for inventions in all fields of technology.

Following our testimony today, the committee will hear from representatives of the Generic Medicines Industry Association. You may hear from them that they will be able to fill the void if innovator companies choose not to bring certain products to the Australian market; however, we have a different perspective. Generic medicine companies rely almost entirely on data produced by innovator pharmaceutical companies to bring their products to the Australian market. If the innovator does not submit clinical data in relation to their products to the

Therapeutic Goods Administration, then there simply will not be any data for a generic company to rely on to bring their products to the Australian market. More importantly, the TGA requires that an innovative medicine be marketed in Australia before it allows a generic version of that medicine to be marketed here as well. More generally, the denial of patent protection to innovator companies will ultimately lead to fewer medicines for generic companies to bring to market at a later date.

Let me assure this committee that Medicines Australia and our members fully support the objectives of the sponsors of this bill. Like you, we want to find ways to improve Australian patients' access to new health technologies and we want to ensure that patents do not hamper research. But the way to achieve these objectives is not by undermining the patents system; instead, the way to achieve these goals is by taking a broader and technology-neutral approach to patent reform.

That is why we strongly support the implementation of the government's Intellectual Property Laws Amendment (Raising the Bar) Bill 2011, which is currently being drafted and which has been in development for over two years. Among other things, that bill contains a provision that will make it clear that scientists are free to conduct research on patented inventions so long as it is not their intention to infringe valid patents by selling or otherwise inappropriately using patented inventions. In addition, the raising the bar bill will raise the threshold in terms of what is and what is not patentable. That will directly address concerns among stakeholders that, in the past, patents have been granted too easily. Medicines Australia support these measures.

In conclusion, I would like to emphasise to the committee that banning patents on biological materials is bad policy. It will have far greater consequences than any of its supporters have anticipated. This is reflected in the overwhelming majority of submissions to this committee that describe their concerns with the bill. Notably, many of those submissions have come from researchers, research institutions, investors, patent attorneys, universities and companies outside the medicines industry. Therefore, I encourage this committee to recommend that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2] be rejected. My colleagues and I are happy to take any questions.

CHAIR: Thanks, Dr Shaw. Ms Monk or Mr Murphy, did you want to say anything?

Ms Monk: No, thank you.

CHAIR: I will start with some questions. I want to take you to the heading 'Impact on patients' on page 5 of your submission. Can you just take us through that list—the relationship between this list you have produced and the impact on patients and how that links to the bill.

Dr Shaw: I will start, then I am happy for my colleagues to comment. This is a list of medicines that are currently on the Pharmaceutical Benefits Scheme, and they are basically biological materials of varying types. In all cases, these would, to our minds, meet the definition as currently put forward in the bill, which would ban the patenting of these medicines. So the idea we are conveying is that there are medicines available now that might not have come to the market had they not been able to be patented. Typically, it takes a medicines company 15 years and $1½ billion, on average, to develop a new medicine and bring it to market. It is unlikely a company is going to do that if they are not able to get a commercial return from that through a patent protection. If a company is unable or is even unsure that it will be able to maintain a patent on that medicine and get the appropriate commercial return from that medicine, it is unlikely the company is going to invest in developing that medicine—or, at least, potentially not release it in those markets where patent protection is uncertain. So what we have tried to do, at least, is illustrate to the committee that there are medicines that Australian patients enjoy the benefits of today that might have been adversely affected had the provisions of the bill that is before the committee been in place earlier.

Ms Monk: And, as Dr Shaw said in his opening statement, there are many hundreds of medicines being developed globally that are biologically based, and their ability to obtain a patent in Australia would be threatened if this amendment to the patent law went through as proposed. That is our concern.

CHAIR: If this bill went through, how would those companies operate in this country?

Ms Monk: They would have to make an evaluation as to whether they would, firstly, bring those medicines to clinical trial, make them accessible and do clinical research on those medicines in Australia; and, secondly, they would have to evaluate whether they would actually seek to bring those products to market in Australia. So intellectual property protection is a very important consideration when a company is looking at investing and bring their products to market in any particular country. I am not saying it is the only consideration, but it is a very important consideration.

Mr Murphy: I might add to that. As GSK we consider Australia to be like the European Union in that we bring products to both Europe and Australia at the same time—they are first-world, developed, early-access

markets. If this bill were passed, it would be highly likely that we would bring products to this market later, once we recouped our investment in other markets where our patents are secured.

Senator FURNER: So would the R&D be done offshore then?

Mr Murphy: It would be done offshore. It would be more likely that we would look at this in a less favourable manner because the protections are not there, and another company could seek our IP in this market and take it offshore.

Dr Shaw: Also, arguably, it would send a signal to the international industry, because Australia would be pretty much a loner out in the international property space—there are not many other countries that we are aware of that would have these sorts of provisions in place. I think, if this legislation were introduced, it would send a signal to the rest of the companies operating around the world about Australia's attitude to intellectual property. There is also, as has been said before, the uncertainty that is created by the legal environment.

CHAIR: At the bottom of that same page, under the list, you say:

Had a ban on patents on biological materials been in place ten years ago, Australian patients today would likely not have access to many of the medicines …

How does the patent system deal with technology over time, then? As technology progresses, does it actually right itself or does it become increasingly difficult to prove you have a patent? What happens, from your experience?

Ms Monk: We are not patent attorneys, so we need to premise our comments on that basis, but the idea is that the patent law should be, as we say, technology-neutral so it is able to deal with changes in technology as they come about through increasing knowledge. By taking a technology-neutral approach we are saying that something that is an invention of man should be able to get a patent if it meets other tests, and then the tests are if it is sufficiently inventive, if it is novel and if you can demonstrate a use for the manufacture. Then you should be able to get a patent. By taking a technology-neutral approach, as technology changes over time the patent law is still applicable.

But certainly knowledge does change over time. Twenty years ago the sort of technology that was available was vastly different from what we have today, and we see the patentability of different technologies change as that prior art—that knowledge of what is available—changes over time.

Dr Shaw: The same pattern you can see in other industries as well. The Dyson vacuum cleaner, when it came out, was very expensive. That was a patented vacuum cleaner. It was really much better than all the old vacuum cleaners. But if I tried to get a patent now on what is the Dyson vacuum cleaner I could not, because the patent has expired, the price has dropped and there is a lot more supply there. It is the same with plasma screens, VHS video recorders and all those sorts of things: as technology changes, patents expire and new technology becomes old technology, new competitors can come in and competition can drive the price down, and then the technology wave moves on. The same thing happens, more or less, in medicines.

CHAIR: That is the threshold issue, isn't it—the difference between discovery and invention is what is really being explored in our debate today. Do you have any comments about gene patents on biological products when they start and stop being a discovery or invention?

Ms Monk: It is a very complex argument. We have read all the submissions to this committee, and many of them seek to talk about this concept of discovery and when something is an invention and when it is merely a discovery. That becomes very complex. But if you start to carve out types of technology because you are saying, 'That's a discovery and that's an invention,' we feel that you are undermining the overall principles behind the patent legislation. It should be an appropriate test of inventive step, novelty and usefulness that determines whether you should be able to get this monopoly right and the reward or incentive for investment.

CHAIR: I see. So you think that the fundamental structure of the IP regulatory system in this country has pretty much got it right?

Ms Monk: It has served us well over the years, but we do recognise that it could be improved, and that is what the focus of the raising the bar bill is: maybe the bar—the test of inventiveness or usefulness or how well an invention is described in a patent application—could be improved. That is what the raising the bar bill is trying to achieve, and we support those amendments. We support making sure that our law is equivalent to international law in this field.

Senator FURNER: In your experience, what is happening globally in biotechnology in your particular industry? Are you familiar with any other markets? We have heard some evidence today about Brazil, China,

India and those sorts of places. Are you able to give us some sort of summary of what is happening in other countries?

Mr Murphy: I am happy to give an overview. The countries that you mentioned, if anything, are moving towards a WTO framework for intellectual property. Historically, India is an example which, I think it is fair to say, in the past has not had developed-country-standard intellectual property laws. In fact, India is an interesting country because, historically, the international pharmaceutical industry has not gone into it precisely because the intellectual property system that operated in India for a long time had so many uncertainties that a lot of companies felt they could not do business in India. The sense is that countries like India and China are now more moving toward the WTO framework of intellectual property protection.

Senator FURNER: What about the likes of Brazil?

Dr Shaw: I do not claim to be an expert in Brazilian intellectual property law, but from my understanding Brazil pretty much allows patenting for most biological materials. Most of the biological materials you can patent.

Senator FURNER: We heard from one witness this morning that they do not lay a lot of trust in the organisation that patents the biological materials.

Dr Shaw: In Brazil?

Senator FURNER: Yes.

Dr Shaw: As I said, I am not an expert on Brazilian intellectual property law, but my understanding is that, particularly since 1997, Brazil has reformed its intellectual property laws and allows the patenting of most biological materials.

Senator HEFFERNAN: That is wrong.

Ms Monk: I would add to that that, as we said in our earlier comments, intellectual property law is an important consideration but is not the only consideration a company will take into account where they are deciding to invest. I understand Brazil is the fifth-largest pharmaceutical market in the world. It is a relatively undeveloped market. So the potential and scope for a company seeking to invest in Brazil is quite significant, and a company would be taking that into account when they weigh up whether they are going to make their investment into Brazil or not.

Dr Shaw: One of the international issues for our industry is that countries like India, China and Brazil are growing quite fast. As you have seen, in a lot of industries there are a lot of economic issues. Similarly, in the medicines industry they are growing very fast, and companies are looking at those markets as potential opportunities to do research, to do clinical trials and to do manufacturing. So, as Deborah said, Brazil is a large country—it is five per cent of the market and is growing quite rapidly: in the order of 15 per cent per year.

Australia is one per cent of the world market and is not seeing the growth in the market you see in these other, emerging and developing countries. In fact, if anything, in the last few years we have seen the number of clinical trials in Australia falling, not increasing. So one of the issues that Australia has to consider is how we remain competitive vis-a-vis these emerging markets. What you are seeing is the global companies and even Australian companies looking at these markets as potential investment opportunities in the future, and for Australia to remain competitive in that context intellectual property law is one of those factors that companies take into account.

Mr Murphy: We will use a different portfolio approach to each country. Australia, as I said earlier, as a developed market will have a similar portfolio of products to other developed markets that are compliant with WTO provisions, whereas for a developing market our portfolio of products will be very different.

Senator FURNER: Would you be familiar with the circumstances surrounding the acquisition of a Brazilian company by Amgen? Do you know how they entered into the market over there?

Dr Shaw: Not the particular details per se, but my understanding is that in Brazil the intellectual property framework they have that ere allows much more patenting of biological material than would be the case if this bill before the committee went ahead. It allows the patenting of a wide range of biological materials, much narrower than is specified in the bill.

Senator FURNER: You mentioned in your introduction 40,000 employees, one-third of those in R&D, as a result of the implementation of this bill. What is the likelihood of those jobs being lost? Is that a reality?

Dr Shaw: I think it is a clear and present danger, frankly. As we have explained, companies are always looking around the world for where the best places to locate research are, and in Australia over two-thirds of clinical trials are funded by the private sector. Clinical trials are conducted in hospitals, through universities and research institutes. They are often done in partnership with pharmaceutical companies. Companies are always looking around the world for where the best place to do research is, and one of the factors they take into account

is the extent to which their inventions are protected by intellectual property law. With a range of other factors to take into consideration, my fear is that if this bill were to go ahead it would put in real question a company's ability to protect its intellectual property while it was doing clinical trials and while it was doing research here. I think that would potentially have an adverse impact on the research effort that the companies would invest in Australia.

Senator FURNER: Thank you.

Senator HEFFERNAN: If that is the case, why is excluding the biological material going to exclude the patenting of the inventive work on the biological material?

Ms Monk: If you do not believe that you have a prospect of bringing a product to the market in the end, it would not be an ethical decision to make that product available and do clinical trials in that market.

Senator HEFFERNAN: You say, I presume, that biological materials ought to be included in patents.

Ms Monk: If they meet the tests of the patent law.

Senator HEFFERNAN: The defined patent subject matter has to pass the manner of new manufacture within section 6 of the statute of monopoly. If you do inventive work and take the step down which is unique and of some use, you certainly can patent that work. You agree with that?

Ms Monk: Under the current law, yes.

Senator HEFFERNAN: So why do you need to patent a gene?

Ms Monk: I think, historically, 20 years ago when the isolation of a human gene was something new, it took a lot of effort and was recognised as being inventive. It met those tests of the legislation.

Senator HEFFERNAN: The isolation process, that is—not the gene.

Ms Monk: What you are patenting is a thing—a physical manifestation. You are not patenting something that is written on a piece of paper that is a gene sequence. So if you are able to create this thing and it meets those tests of the law then you should be able to get a patent.

Senator HEFFERNAN: But you are not creating it. You are isolating it. It is no material difference to in situ, but the process of isolating it certainly was considered to be inventive when they did the first one. As you know, any PhD student can do it now. To go back to my original question: why is it necessary to lock up access except by an exemption for research? Then the question of exemption for commercialisation comes into play. Why do you need to lock up access to the gene when you can fully commercialise the inventive work on the gene to lead to a cure, vaccine or whatever? Why do we have to have this monopoly situation where no-one else without a licence or some sort of process can access the gene to get a better process or a cheaper test? Sure—it is a handy cartel, a tidy monopoly and you were paid by the industry to say what you say. But Amgen's EPO patent cost us about $1.9 billion in licence fees. You do not actually need the gene to have the patent. In the BRCA there are nine out of 20-odd claims which refer to biological materials. If they were wiped out, you would still have a patent on the inventive step.

Dr Shaw: What we are saying is that we agree that for a patent to be awarded it needs to past a certain number of tests that would be implemented by IP Australia. So it needs to have human intervention, it needs to be novel, it needs to be useful and it needs to have an inventive step. The concern we have—and this is the WTO approach—is that, rather than prescribing where that line falls, the best way to approach it is to have a technology-neutral approach which sets up a framework and the appropriate tests for awarding a patent, then letting the patent office make those assessments on a case-by-case basis.

Senator HEFFERNAN: But the patent office does not have the resources to even begin to look carefully at that. Should we be tracking the resources of the patent office? Everyone is admitting that there have been mistakes. 'Oops, sorry, we're not going to do that again.' But as recently as last year, they are still doing the same thing with our now famous 'flea head' biological materials. It is an interesting patent but it is too big to download., In the interests of the human race, it beggars belief why we allow companies—and plants were mentioned earlier in relation to seed supply—to be able to patent when the law clearly says, 'Defined patent subject matter is by reference to the manner of new manufacture within section 6 of the Statute of Monopolies 1623'. We have turned a blind eye to the fact that biological materials are not in that category. Should we change the law?

Dr Shaw: I guess there have been various inquiries since 1999 looking at this issue—

Senator HEFFERNAN: Until all this erupted, no-one did anything other than file it in a cabinet somewhere where it gathered dust.

Dr Shaw: We are involved in those—

Senator HEFFERNAN: ACIP, as you know, made some recommendations but, like a lot of people, they are as independent as the people they work for and they are all involved in the industry. So no-one wants change. As you know, the court system is not about the truth; it is about the law and law is often the interpretation of precedent. Why do you need the biological material when the patent is about the inventive step and work on the biological material in an area that can produce something that you can commercialise? If you go with the exemption, please explain this: if you are holding the patent to the gene and I get an exemption to do research which I then want to commercialise, do I have to go back to you and say, 'Do you mind if I commercialise this, and do I have your permission to include your gene in my patent?' If you say yes, why do you have the patent in the first place?

Dr Shaw: There are two things. If it is an issue of commercial exploitation then, yes, that is what the patent system is about—

Senator HEFFERNAN: If my exploitation is smarter, better and cheaper or whatever than yours and I have accessed the gene through the exemption which was blocked to me before, even though in a lot of cases a blind eye has been turned to that, why can't I legitimately say, 'I was smarter than you; therefore I can commercialise it?' Shouldn't everyone have access to the biological material?

Ms Monk: My understanding is that the second person would be able to gain a patent about their new invention which is an improvement on what went before, as long as it passed those tests of novelty, usefulness and inventiveness.

Senator HEFFERNAN: But, say, it is the BRCA1 test and I come up with a cheaper version, doesn't it include the gene? The person I got the exemption from has the gene from his commercialise work. Therefore, he needs to include the gene to protect the patent and I need to include the gene for which he has the licence. I would have to come to some sort of a commercialised arrangement with the original patent holder and that could become a lawyer's feast, a banker's delight and a researcher's nightmare.

Dr Shaw: I think we agree that there needs to clarity on how patents are awarded. Our view would be that the government's alternative bill, the raising the bar bill, helps achieve that clarity without trying to prescribe what technologies should and should not be patented. There is a whole range of legal, economic, scientific and policy reasons that that technology neutral approach is advocated by intellectual property experts, economists and the World Trade Organisation. I think that is because technology is always changing and what is a gene is always being debated, researched and looked at. Rather than trying to prescribe it in legislation—and my understanding is that that is quite hard to do—the government's bill is the appropriate way forward because it is setting the framework and the appropriate tests and thresholds, and allowing that to operate.

Senator HEFFERNAN: But you are saying that we should accept that—and this includes anything that is WTO authorised, like OIE Brazilian beef—it is fair play for them to continue to patent biological naturally occurring material.

Dr Shaw: The assessment should be made by the experts in the IP Australia patent office.

Senator HEFFERNAN: But clearly the interpretation by IP Australia includes naturally occurring biological materials in patents. By the way, the complexity and cost of new medicine means that it is hard to see how the taxpayer is not going to pay 120 per cent tax. It is beyond me how health care is going to be affordable. Everyone says that under their breath, but we do not want to go near that. I do not understand why what you argue needs to be argued to include biological material. Clearly, to answer Senator Furner's question, in Brazil the Brazilian patent and trademark office takes a position that claims to isolated DNA, proteins and antibodies are routinely rejected. Yet the sky has not fallen in on them.

Ms Monk: I would point out to you the table in the submission to this committee from IP Australia and the department of innovation. They provided in figure 1 a table of the number of patents filed for genes encoding for human and animal proteins. There has been a significant decline over the last decade in the number of patent applications.

Senator HEFFERNAN: I accept that. That means that the industry still thinks that it is fair, even though it is not defined, to apply for and be granted as late as last year a patent for biological materials when there is no question about there being any invention involved; this is discovery work. You think that to keep the peace we have to continue that process.

Ms Monk: If it meet the test of the law of being an act of man to create this thing and that it meets the tests of usefulness, novelty and inventiveness—

Senator HEFFERNAN: But once you give the biological material a tweak of some kind and it is not in the same situation in which it naturally occurs or if you give it a tweak that gives it another property then that

completely alters things. You are able to patent that, in my view. But not the original material. If Senator Xenophon or anyone else wants to access that material and commercialise without having an army of lawyers to bargain with Amgen, Monsanto or god knows who, he should be able to do that. I still do not see why it is necessary to have biological material in the patent.

Dr Shaw: I am not a scientist or an intellectual property lawyer, but the question is: what is a tweak? You are relying on—

Senator HEFFERNAN: I have to say—

Dr Shaw: I am not in a position to make a guess about what a tweak is.

Senator HEFFERNAN: That is a tiny little admission. It is as clear as crystal that discovery work is not patentable. It is as clear as crystal that what is in your body is not an invention. So why the hell are we allowing them to patent it?

Ms Monk: I would say that we are not currently, because that is what the data from IP Australia is showing.

Senator HEFFERNAN: What was a patent for biological materials granted last year for stuff in the head of a flea?

Dr Shaw: I am not aware of the particular example.

Ms Monk: Nor am I.

Dr Shaw: We are happy to have a look at it. What we are saying is that our understanding is that the best way to approach this is to have a good framework that provides better clarity for industry, for governments and for evaluators to assess what is inventive—what is an invention and what is a discovery.

Senator HEFFERNAN: No-one wants to make a decision. Do you think that there is any merit in the argument that we should filter before we get to IP Australia? Obviously, they are overloaded. They say that they are overloaded and that say, 'I cannot remember, your honour,' which is always a good defence. 'Sorry about that mistake—we're overloaded.' Isn't there a need for a huge improvement, given that in the future we will have triple and quadruple the number of applications for and solutions using genes? It will not just be work on one; there will be multiple applications.

Dr Shaw: I guess the issue of resourcing for IP Australia is something that you would have to take up with the government. Our approach is that it should be technology neutral, because you do not know where technology is going. It is a changing art and a changing science base. Trying to prescribe it in legislation runs the risk down the track of having unintended consequences when new technologies come through.

Senator HEFFERNAN: But you do not want to define that that biological material is not an invention.

Dr Shaw: I guess it comes back to what we were saying before which is that we think the best way to do it is having a good set of criteria and improving the IP legislation. If it is about resourcing IP Australia, as I say, that is—

Senator HEFFERNAN: But is biological material a discovery or not?

Dr Shaw: If it is a discovery, there is no inventive step.

Ms Monk: There could be a biological material that is an invention of man that imitates the naturally occurring biological material.

Senator HEFFERNAN: You are trying to go down the isolated path.

Ms Monk: No, I was not. I was actually thinking about this—

Senator HEFFERNAN: If it is different—

Ms Monk: If it is an invention.

Senator HEFFERNAN: If it has an inventor step and is different to what occurs in nature—

Ms Monk: Then it could still be a biological material.

Senator HEFFERNAN: But that would be okay under this.

Ms Monk: That is not how we have interpreted it.

Senator HEFFERNAN: But this is a useful exercise that we are having this discussion because obviously there is a wink and nod portion in the interpretation of laws at the present time. Do you think that the argument that your side of the industry puts that somehow by keeping where we are now we are going to increase competitive tension in the market is valid? For a lot of researchers especially if we go to multiple gene work, they are tucked away, they do not have lawyers and they are only on a six-month contract, do you really think it is fair

that they have to face up to the nightmare which is the lawyers' feast of negotiating an arrangement with three or four biotech companies with access to the gene which then they want to commercialise. That then becomes a multiple nightmare of giving commercial consideration to 'What am I going to charge you when I am the monopoly holder of the gene which the law says you cannot patent but I have a patent for.'

Dr Shaw: If the law says that you cannot patent it, there are also mechanisms both with IP Australia and through the court system to challenge patents. As I have said, we support the government's raising the bar bill which I think has a quite clear research use exemption which everyone thought existed until 2004 anyway. Everyone thought researchers could already get exemption from patent protection; it was only when the Australian Law Reform Commission put their hand up in 2004 and said, 'Hang on there is a bit of a vagary here.' The raising the bar bill makes clear that, if you are doing research, there is an exemption. If you are commercialising it, if you are a company that wants to commercialise it, then that is what the patent system is built on. It is a different issue if it is commercial exploitation.

Senator HEFFERNAN: But raising the bar does not address the question of discovery and invention and no-one seems to want to address that. I will leave it there. Thank you.

CHAIR: Before we go to Senator Xenophon, I have a question I want to ask you. Have any members of Medicines Australia had problems with cross-licensing provisions in developing treatment?

Mr Murphy: It is a very complex area of commercial activity but it depends on what you mean by problem. As a company we licence from a whole range of different suppliers through the development path to then take the product to the market. We have a sophisticated way of managing that.

CHAIR: My understanding is that you can apply for a cross-licensing order from the courts. I am wondering whether any of your members have used that provision under the act.

Mr Murphy: Not that we are aware of but equally we are not aware of any problems. We have not had companies beating down our door to say that the current system does not work.

CHAIR: Okay.

Senator XENOPHON: Some of the members of Medicines Australia would include Pfizer, Abbott, Roche, Novartis, Merck, GSK and Wyeth as well as Amgen—which is the world's biggest biotech company. I am not saying this in a pejorative sense but effectively you represent the big pharmaceutical companies that have their head offices in the UK or the US, largely. Is that a fair statement?

Dr Shaw: Yes, we represent them. To add a bit more detail, we also represent Australian companies that do similar research. CSL is a member and there are other Australian companies that do research that we represent as well.

Senator XENOPHON: But predominantly your membership is—

Dr Shaw: They are part of our membership.

Senator XENOPHON: One thing I do not understand is that I read your submission and then I read the submission of the Generic Medicines Industry Association, who are going to give evidence after you, and it is as though you are talking about two separate bills. That concerns me. For instance, the GMiA says:

Global common law trends are away from the patentability of certain biological materials (eg EU and US), but no region has felt it necessary to legislate to facilitate that change—

But they discussed the Monsanto decision in June 2010, the court of justice of the EU, that you are familiar with. There is also the US case in the district court of the southern district of New York, about isolated DNA—the Association of Molecular Pathology v US Patent and Trademark Office. Would you agree that the way that the common law has been shifting is basically in the direction of, or this bill is consistent with the direction of, those common law decisions in Europe and the US?

Dr Shaw: No, I would not, and that is not because I am trying to be pejorative. My understanding is the reporting of some of those overseas developments has been not entirely correct in the US situation. Certainly the provisions in the bill that are before the committee today are much wider than anything that is in the European Union or the US.

Senator XENOPHON: Dr Shaw, would you agree then that the trend in those decisions is in the direction of this bill rather than in the position that you are seeking to take?

Dr Shaw: The issue is obviously being debated, and I think we understand that technology is changing and that there has been a debate here and internationally for a number of years as technology has developed. It is often the patent system and the intellectual property system where the changes in technology come to grief or where the issues start appearing, because that is where technologies start becoming public. That debate has been happening

for a number of years. Certainly other countries and regions are looking at this issue, but I would disagree with you that the bill that is before the parliament today is similar to what you see in the US or in Europe. I think that the bill that is before the parliament today is much broader than anything you are seeing in those regions.

Senator XENOPHON: If I could put to you what Judge Dyk said in his decision in Intervet v Merial Limited in August 2010. He said:

… it appears that in order for a product of nature to satisfy section 101, it must be qualitatively different from the product occurring in nature, with "markedly different characteristics from any found in nature," … It is far from clear that an 'isolated' DNA sequence is qualitatively different from the product occurring in nature.

Do you agree with the general principles that Judge Dyke set out?

Dr Shaw: I think what we are saying is that test, inventiveness versus discovery, needs to be clarified. That is an issue that is going to be debated for some time. I guess what we are saying is that as the association representing a range of medicines companies that operate here in Australia, all of our members are telling us that the bill before the committee at the moment gives them real concern about their ability to do research here, about their ability to bring medicines to Australia and to have the confidence and the certainty that if they bring their medicines here or develop them indigenously here in Australia, they will be able to get sufficient patent protection to allow them to do that.

Senator XENOPHON: They are concerned about the commercial implications of this bill.

Dr Shaw: They are concerned about the impact it will have on commercial operations, which then will have an effect on the research that is done in Australia and the availability of medicines for Australian patients.

Senator XENOPHON: Again, GMiA, by way of contrast—the two submissions are like chalk and cheese, and they are coming from a different perspective. They say in their submission:

the Australian pharmaceutical and biopharmaceutical industries, innovation, research, and market competition have been unnecessarily stymied because of the increasing reach of patent rights.

You do not see the potential for that increasing reach of patent rights to stymie innovation?

Dr Shaw: No, in fact I think the trend is actually the other way. What you are seeing is that the generics sector of the market is growing rapidly here and internationally as a range of patents expire, and I think there are opportunities available for the generics sector if those new medicines are developed. I come back to some of the statements I made in my opening remarks, which is that an issue for the generics industry would be if the development of new medicines in the pipeline stopped as a result of intellectual property law. Generics companies rely on the originator companies to develop the new medicines in the pipeline and bring them to market, because ultimately it is the generics companies that then can benefit from that with the patents expiring. There are more medicines around for the generics to participate in.

Senator XENOPHON: Then consumers benefit from that as well.

Dr Shaw: Absolutely, yes. As I said before, that is part of technological development, not just in medicines but in other industries, whether it is plasma screens or vacuum cleaners or whatever. When a patent expires other competitors come in, they make a product cheaper and that drives competition.

Senator XENOPHON: Finally—because I am concerned about time constraints—this bill is not directed to all biological materials, only those that are identical or substantially identical to those that exist in nature. What is wrong with giving some clarity through this bill in terms of that? Isn't that something that stymies research? If people whack on a patent, that itself is a disincentive to research.

Dr Shaw: As I say, we are always happy to look at wording and those sorts of things. But as we understand it all the advice we have heard, not just from our members but also from a range of lawyers and advisers and researchers—both connected with the industry and I have to say separate—has been that they are very concerned about the bill that is before the parliament because of the impact it is going to have on their research. Sorry, I have forgotten the second part of your question.

Senator XENOPHON: If it is only directed at being done as research.

Dr Shaw: As we have said a couple of times, the research use exemption we absolutely agree needs to be clarified so that researchers can do unfettered research on patented material.

Senator XENOPHON: So you do see scope for improvements in the Patents Act; you just do not like these particular amendments.

Dr Shaw: As we said, the government's forthcoming bill, the raising the bar bill, has an explicit research use exemption which clarifies the fact that scientists and researchers can do research on material that is patented. As I say, up until 2004 the understanding was that that already existed. But unfortunately it has taken this long for

those findings in 2004 to be acted on with a bill now here in 2011. It is evidence based policy but it has taken a long time for the evidence to be transformed into policy.

Senator XENOPHON: I guess we may see you again in relation to how effective the government's bill would be to deal with those issues.

Dr Shaw: But there is that exemption there and I think it is available for public comment. I guess we are saying that that is important clarification that needs to be made and we would support that.

Ms Monk: If I may add, a number of submissions to this committee have come from researchers and research institutes that have said that this bill would be damaging to their own research in the future as well. It is not just commercial enterprises such as we represent that have concerns with the bill. Research institutions have said that they would also have concerns about their ability to do research and ultimately commercialise the fruits of their research if this bill came into law.

Senator HUMPHRIES: I just want to follow up on what Senator Xenophon said about biological materials which are identical to such materials as they exist in nature. That is a slightly narrower exclusion than simply banning biological materials. In relation to the list of medicines that you provide on page 5 of your submission you say that people would not have had access to many of those medicines and vaccines if the legislation had been in place. So are you telling us that some of these medicines are medicines which are essentially made from biological materials which are identical to those or nearly identical to those which appear in nature? If so, can you say which ones have that characteristic?

Dr Shaw: We would have to take that on notice. I guess the argument being that that the scope of the bill that is before the parliament is so broad that it covers biological materials isolated or not—

Ms Monk: Components and derivatives.

Dr Shaw: Components and derivatives. And arguably most, if not all, of these medicines would meet that definition, because you are talking about biological materials that are derivatives or developed. I guess what we are trying to illustrate is that, while there have been some concerns raised about that process, the fact is that there are 28 medicines on the Pharmaceutical Benefits Scheme today that Australian patients are benefiting from because those companies have been able to develop those biological materials and bring them to market. There are treatments there for arthritis, multiple sclerosis, blood clots, fertility, osteoporosis, prostate cancer, Chrohn's disease, colorectal cancer, macular degeneration, HIV—and the list goes on.

Senator HUMPHRIES: Yes, but I wonder how many manufacturers of those would concede that their inventions are actually just reproductions of naturally occurring biological materials. I expect they would not make that concession.

Ms Monk: They would look at the description in the legislation and at the words such as identical or substantially identical. Many of these biological materials are mimicking a protein that is naturally produced in the body to have their therapeutic effect. So if you are using words such as components and derivatives purified or not and identical or substantially identical, you find they have a very broad scope for biological materials. The way that biological medicines work is in many cases to mimic naturally occurring biological processes.

Dr Shaw: The issue there as well is the uncertainty. When you read the amendments proposed in the bill, you see there is—as I think other submissions have identified—a range of uncertainties in interpretation as to what is in the bill. I guess this comes back to this technology-neutral approach. By trying to specify a thing you run the risk of having unintended consequences affecting the development of medicines. Certainly our members, as the companies research and develop and bring new medicines to market, are telling us that the bill before the committee has so much uncertainty around it that, when they are looking at where to do clinical research and do clinical trials and do R&D and at where to commercialise their medicines when they are looking around the world for such places, if Australia were to have this legislation in place Australia would stand out in the international sphere as particularly having laws that would stand out as being separate from those of the rest of the world, so out of step with the rest of the world.

Senator HEFFERNAN: Why would it be affected?

Dr Shaw: As I said before, companies spend 15 years and take on the commercial risk of developing new medicines and invest, on average, $1.5 billion to develop a medicine—and that is for the ones that make it to market, so it is depending on which set of figures you use but one in every 5,000 molecules gets to market and the other 4,999 do not. So if you are a company that is investing 15 years of time and effort and money into developing a medicine you want to be able to be sure that you can have patent protection for that medicine when it finally gets to market. If Australia is a pariah in the international field of intellectual property law, companies have got a lot of other places they can go to to do that research and to take the medicines to other markets.

Senator HUMPHRIES: I want to move to another issue. We have had diametrically opposed evidence on a number of points in the course of this inquiry.

Dr Shaw: I do not envy you your task, to be honest.

Senator HUMPHRIES: You say in your submission with respect to the US-Australia free trade agreement:

As under the TRIPS Agreement, excluding biological materials from patentable subject matter would be in clear violation of Australia's obligations under its Free Trade Agreement with the United States.

And Professor Peter Drahos, from the Regulatory Institutions Network at the ANU, says:

The international framework allows states to exclude subject matter from the meaning of invention.

He refers particularly to the US-Australia free trade agreement. Is he right? Can you exclude subject matter from the meaning of invention, so you redefine what invention is as part of your legislation on a state-by-state basis? If so, would that overcome the difficulties imposed by the US-Australia free trade agreement?

Dr Shaw: I have to confess that I am not an expert in intellectual property law. But my understanding is that not just the Australia-US free trade agreement but also the TRIPS provisions of the WTO require patents to be awarded on a technology neutral basis. I know that we keep coming back to that phrase. But we need to allow the possibility for all technologies to be patentable. I guess it comes back to the fact that it is provided that they meet the criteria for the awarding of a patent. That is what the TRIPS agreement and the Australia-US free trade agreement talk about. The advice that we have and our interpretation is that prohibiting the patenting of biological materials would in effect be at odds with—I was going to say 'trip up', but that would be a bit of a joke—the TRIPS agreement and with the Australia-US free trade agreement. If you did that, you would not have a technology neutral approach. You would be saying that there are some sorts of technology that you are not going to let patents apply to.

Senator HUMPHRIES: Professor Drahos addresses the question of investment in the Australian biotech sector. He poses this question: 'Would enacting the bill adversely affect investment in the biotech sector in Australia?' He responds:

No, it would not. Australia represents less than 2% of the global pharmaceutical market. Investment decisions by pharmaceutical multinationals are driven by three markets—the US, the EU and Japan. China and India have an increasing influence on those decisions. Australia's patent law does affect the access rights of Australian consumers and researchers, but it does not affect global investment decisions because of the small size of the Australian pharmaceutical market.

Do you think that that is a fair reflection of how little impact this legislative change would have on investment in Australian pharmaceutical?

Dr Shaw: He is right when he says that it would not affect global investment patterns. As we have already said, companies are looking around the world to see where to invest. You are right that there are various markets in which companies can invest in research and development. In fact, one of the issues that we are dealing with on a number of fronts and policy areas is competition from other countries. Some of the countries that we talked about before—the BRIC countries: China, India and Brazil—are becoming more competitive in research. Without having seen his testimony or his submission, I think that he is probably right in that it would not have an effect on global investment. That would continue. The issue is what would happen in Australia. I have a real fear that if this bill went forward what would happen is that those companies would, when looking at different countries in trying to assess where to invest their research dollars, look at this. As we talked about already, they look at a whole range of factors. But one of the things that they look at is where they can have confidence that the law is going to protect their intellectual property when they bring it to market and start doing clinical trials. If Australia is out there on its own on a limb with an intellectual property system that has so much uncertainty around it and an enormous amount of risk for companies, why would they bring it here? Why wouldn't they go elsewhere? They can go to Singapore or other countries and do the research there and have intellectual property protection that is probably better.

Senator HEFFERNAN: If there is an exemption for research—

Senator SIEWERT: Senator Humphries touched on the area that I want to go to, which is the list of medicines that have biological materials in them. I want to understand the element of the biological materials that would have been covered by patent. Wouldn't the patent be on the medicine? I am struggling to understand why there is a concern there in terms of biological materials. Are they actually in the medicine?

Ms Monk: The active ingredient in these medicines that we have given as examples are what we would interpret as being covered under the definition of 'biological material' in the bill.

Senator SIEWERT: That is your interpretation.

Ms Monk: Shared by many other submitters to this committee—the principles behind what we have argued are shared by many.

Senator SIEWERT: Okay. That then ties back to this issue about discovery and invention, doesn't it? I must admit that I was little bit disconcerted to hear the comments by you and a previous witness about what is discovery and what is an invention. That was one of the things that came out of the previous Senate committee report: what people rely on as the interpretation of the definitions of 'discovery' and 'invention'. It is fair to say that IP Australia have moved further. They acknowledge that some of the previous patents that they have granted were based more on discovery than invention. From what I understood, Ms Monk, and I am sorry if I misunderstand what you said, you rely on the other things in patentability, which include novelty et cetera, rather than invention and discovery. I understood that that difference between invention and discovery was particularly important in the act. So I am very nervous now when I hear you and the Law Council say that it is not so important and that discovering the makeup of a gene is an invention not a discovery. That makes me even more nervous, I have to say.

Ms Monk: Perhaps I have not explained it very well. My understanding is that the way our current law works is: the first step is to decide, 'Is this something that may be the subject of a patent?' Something that may be the subject of a patent—patentable subject matter—is something where there has been the intervention of man to create something, to invent something.

Senator SIEWERT: It is whether it is an invention or a discovery.

Ms Monk: Over time, our interpretation of the level of inventiveness or intervention of man has shifted, and I think that was really drawn out in the IP Australia submission – that we cannot judge decisions that were made 20 years ago on what we know today about the inventiveness or the ease of doing something, or on what the prior art was, historically. We cannot judge decisions that were made 20 years ago, granting a patent, on what we know today. So the first step is saying, 'Is this something that may be the subject of having a patent – something where there has been the hand of man to create this thing?' And then, if you say yes, you look at the steps: 'Is it novel?' 'Is it, compared to what we already know – the prior art – sufficiently inventive?' 'Is it new?' 'Is it useful?' And then you apply those tests.

Senator SIEWERT: You could then describe anything as an invention that relates to biological materials, because you could say, 'Yes, the hand of man' – or, as I would say, humans – 'has had some level of intervention; we have discovered the microscope.' So just actually finding it does not make it an invention, if you follow your line of thinking.

Dr Shaw: The tests that are in the Patents Act are designed to test whether something is an invention or a discovery, and Deborah has run through a couple of the criteria. Under the act, whether something is a product of human intervention, is novel, is useful and involves an inventive step – those are the criteria and the tests that the patent examiners should be using to assess the patent. IP Australia, I understand, are appearing before the committee tomorrow. That set of criteria is designed to be able to tease out whether something is a discovery or an invention. Say I discover the theory of relativity; it is a great discovery and I get lots of articles, but it is not an invention. If I invent a time machine based on the theory of relativity, that is an invention. I guess it is having the criteria to be able to assess the difference between the theory of relativity and the time machine. What we are saying is: there are provisions in the act now that should be able to provide clarity to the patent assessors as to whether something is a discovery or an invention. We think they work well. We think there are improvements that could be made but they work well.

Senator SIEWERT: I am not saying that the medicines you have here have not involved a level of inventiveness, but I am still not entirely convinced that, if this bill went ahead, you could not make those medicines.

Mr Murphy: Would those medicines still have been made? Absolutely. Would they be brought to this country and have patent protection? That is less likely.

Senator SIEWERT: I beg your pardon for my phrasing. So you would not have been able to patent them?

Mr Murphy: We would not have been able to patent them in this country under this bill.

Senator HEFFERNAN: Under raising the bar, the exemption deals with the exemption for research, but it does not deal with an exemption for commercialisation. Wouldn't that be the same for anyone thinking about investing here?

Mr Murphy: That is an entirely separate bill.

Senator HEFFERNAN: You did raise the raising the bar bill.

Mr Murphy: Indeed. The issue of commercialisation is entirely separate from the issue ahead of us in this bill.

Senator HEFFERNAN: You argued that we are going to lose work because people are not going to be able to see security in commercialisation. You then argued that the raising the bar bill is a wonderful thing because it addresses the exemption for research. But it does not deal with the commercialisation.

Dr Shaw: We do not think the commercialisation is an issue.

Senator HEFFERNAN: It is good to get that on the record.

Dr Shaw: I think it is important to say that the research use exemption is very important because we need to be clear that researchers can do research on patentable material so that they can continue the development of knowledge and find the cures.

Senator HEFFERNAN: But then they have to hold it.

Dr Shaw: If they then want to set up a company and commercialise an invention that someone else has already made and make money out of it, that is a different issue. That is a fundamental principle of the Patents Act—and not just patents; but intellectual property generally that is traded.

Senator HEFFERNAN: It would be what you call market power by the big players.

Dr Shaw: I think it is recognised in intellectual property that already exists. Making sure that the person who invented the invention actually gets the reward due.

Senator HEFFERNAN: The exemption is for access to the biological material for research purposes under the raising the bar bill—agreed?

Dr Shaw: It is my understanding that it is any research.

Ms Monk: Yes.

Senator HEFFERNAN: So, if the person who gets that exemption then does something pretty smart with it—whatever it is—they have to go back and be beholden to the market to negotiate a commercial arrangement with the person who holds the original exemption for which they have got the research. That in itself is a use of market power which could put the little researcher out of business. Anyhow, I will leave it there.

CHAIR: Dr Shaw, Ms Monk and Mr Murphy, thanks for your submission and thanks for your time today. Your personal appearance here is much appreciated.

[2.42 pm]

CROSS, Dr Martin George, Chairman, Generic Medicines Industry Association

HANNAH, Mr Colin, Vice President, Australia and New Zealand, Hospira Pty Ltd; Board Member, Generic Medicines Industry Association

CHAIR: Welcome. We have received a submission from the association which we have numbered 71 for our purposes. I assume that you have no changes or amendments to make to that. I invite you to make a short opening statement and address your submission and then we will go to questions.

Dr Cross: Patents are given for inventions. Plants, animals and humans are not inventions, no matter how you try to argue the situation. What I would like to do is cover three very brief points that I think bring home this situation. The first one is around this whole area of patents and intellectual property. Firstly, patents are an amazing gift that society gives through a social contract to smart people and inventors. What a patent does is give a unique monopoly for 20 years on somebody who is smart and has invented something that is of use to society. On that basis, the person received a monopolistic situation.

The GMIA are absolutely in support of appropriate intellectual property in patents, because when this is done property it really does ensure that research moves forward and it encourages appropriate research and gives appropriate reward. The challenge is when intellectual property is inappropriately given out. In that case you inappropriately give a monopoly to people which they will then try to commercialise. So, from our perspective at this point in time, we absolutely are in support of intellectual property but not in the case of inappropriate intellectual property.

As I have already mentioned in my first statement, the issue we have here is that when we then look at the areas of biological material, this is clearly not an invention; this has existed in nature and is a natural product. So when we see patents that have been granted over the years around these areas. the challenge that we have here is that this is not rewarding an invention; it is rewarding a discovery. There are a lot of consequences that go down the line as a consequence of giving this inappropriate intellectual property. These in effect become like 20-year time bombs ticking away from a societal perspective, because it means that certain things are not possible and it creates blockages in terms of moving forward.

If I look at the situation, especially the copy I have received today of the amended Patents Act bill, I believe this bill is absolutely appropriate for Australia in terms of clarifying the current situation, because it is very clear at this point in time that intellectual property is being granted that should not be granted, because it fails the test of inventiveness, and this is around biological material. If I look at the impact of the bill, firstly, we are hearing apocryphal tales of woe and disaster and what will happen to research in Australia and to commercialisation of new products in Australia if this bill goes ahead. I do not believe that is the case, especially with the words I have seen now, which make this much, much clearer. Many of the products that we see—these biological medicines—do not appear in nature as it currently stands. Many of them are combinations between human and mouse or hamster DNA and the subsequent proteins that come off them, so they are not found in nature as it currently stands. So I believe there is more than sufficient inventiveness possible to allow that not to be the case.

Secondly, in the area of intellectual property, not only can you get a patent for substances; you can also get patents for use and you can get patents for production and the way the products are produced. In the Generic Medicines Industry Association, we are often at the other end, when products are going off patent. We often come across molecules that have 100 patents around them that have been put around these products over the course of their lives. Some of them are to do with the substance, but many of them are to do with production and many of them are to do with use. All of these have to be cleared before we are able to commercialise and bring affordable generics to the market.

Thirdly, there is an argument at the moment that, if we have this bill move forward, this will discourage innovation. I believe that this is actually different and this bill will encourage innovation, because at the moment what we are seeing is that the building blocks of life—which are discoveries, not inventions—are being blocked from researchers and other people being able to work off them. I will just give you an example which I think would sum up why this could be the case. If we take something like insulin—this was discovered back in the 1920s, but let us assume it has just been discovered—and I decide to take out a patent on insulin because I found

this material, what would happen then is that I could potentially stop other people developing analogues and other inventions off insulin, because I own the basic molecule. What has happened with insulin over the years is that smart people have manipulated insulin. What they have done is change the amino acid sequences, and as a consequence they have created short-acting insulins so that, instead of a patient having to wait half an hour, they only have to wait five to 10 minutes before they can eat after they have taken their insulin. That is smart, that is inventive and that should be rewarded. Similarly, other smart people have changed the amino acid sequences and also added in fatty acids and turned insulin into long-acting insulin so that, instead of a patient having to have multiple injections, they only need one. Again, to me, that is smart and inventive and it is not found in nature.

In summary, patents are given for inventions. Plants, animals and humans are not inventions and, no matter how you argue the situation, never will be. So the consequence of that is that we are in support of the bill, especially, I believe, after seeing the amended bill here, because I believe there was some ambiguity and this really takes out a lot of the ambiguities as well.

CHAIR: Thanks, Dr Cross. Mr Hannah, do you have anything you wanted to add there?

Mr Hannah: No.

CHAIR: Dr Cross, can you give me an idea about the Generic Medicines Industry Association. You represent companies, as does Medicines Australia—

Dr Cross: Yes.

CHAIR: but companies that actually produce generic medicines?

Dr Cross: Yes.

CHAIR: Can you give me an idea of some of those names. I am pretty familiar with Medicines Australia's members, but maybe not yours.

Dr Cross: We have six members, so we are a small and select group. We bring these affordable medicines after the patents go off. The companies are Alphapharm, Apotex, Hospira, Ascent, Spirit. I have forgotten one. Sorry, it is because the name has just changed with the change of ownership.

CHAIR: Ariad Pharms? You quote Ariad Pharms in one of your footnotes.

Dr Cross: No, it is Aspen.

Senator BOYCE: Mr Hannah, are you involved with one of those manufacturers?

Mr Hannah: Yes, I am Vice-President in Australia and New Zealand for Hospira. We are a speciality injectable manufacturer.

CHAIR: Can I start by clarifying dot point No. 9 on the last page of your submission. It says that you support the bill but you want a further dialogue on the definition of biological materials and other initiatives. Are you saying that in principle you support the bill but there is more work to be done on it?

Dr Cross: As I mentioned earlier, we had some concerns that the bill was too broad, in terms of not being specific and not allowing some inventions that we believe are truly inventions to progress. But seeing the reworded amendments here I believe that would adequately cover our concerns.

CHAIR: Senator Heffernan?

Senator HEFFERNAN: I agree with them.

CHAIR: Do you have any questions, then?

Senator HEFFERNAN: We have been through this journey of gradually breaking down the denial, which has been caused, I suppose, by legal precedent over many years. That has ignored the basic concept of invention and discovery, and by legal precedent and interpretation into law of that legal precedent we have endless patents that lock up access to the gene. Now the solution of the government, without upsetting the industry and the world and losing the next election and all the rest of what comes into political consideration, is that raising the bar is going to solve all the problems. It will give a research exemption. The argument from a lot of the people who have appeared today is that research will not come here; they will go somewhere else because they can get a better return. We are going to raise the bar and allow an exemption for research. Surely that will not solve the problem, if raising the bar does not also address the commercialisation of the research, because most researchers like to have a reward. So isn't it sort of phoney just to have a research exemption and think that that is going to fix it? Given that there will be multiple gene solutions in the future, isn't that a phoney sort of proposition?

Dr Cross: I believe it will not. It is like trying to put Elastoplast over a wound: it does not solve the fundamental problem, which is that these patents are being inappropriately granted at the moment for areas they

should not cover. My understanding is that of the four areas of patents, the raising the bar bill covers only the inventive step side. It does not cover the subject matter, which is what the gene patent bill is covering.

Senator HEFFERNAN: It absolutely does not deal with the discovery side of the argument.

Dr Cross: To your point, you can see myriad issues, if you will excuse the pun, which will come out if somebody comes up with something novel from working off a gene that somebody else has patented and therefore owns the intellectual property for. You can see a huge issue running forward on that basis.

Senator HEFFERNAN: I am sure the lawyers are all rubbing their hands together. It will be a lawyers' feast. Say I got an exemption from you because you hold the biological material patent and I have a brilliant laboratory and I go, 'Wow, I want to commercialise this.' Do I have to go back to you and say, 'Do you mind if I commercialise and include in my commercialisation the patent for which I have an exemption to research but not to commercialise?' If you say yes, doesn't that deliriously make the point: why did you have the patent in the first place if anyone else can access it and commercialise it? What is the point of having it, besides the fact that interpretation of the monopolies law says that you cannot have the patent in the first place?

Dr Cross: My view would be, firstly, it would be very unlikely that the patent holder would say yes. If they did say yes, that really says, 'Why have you gone to the effort of patenting and getting a commercial ownership of this in the first place?

Mr Hannah: It is very true; it is exactly the case. The chance of it being sold, yes, it would probably go to the highest bidder.

Senator HEFFERNAN: If the answer is no then that would profoundly make the point that one of the coming issues for the wellbeing of the human race over the next 50 years will be monopolisation and cartel behaviour. If the answer is, 'Yes, but we need to negotiate a price,' and if you have major companies—and everyone is saying that little fellas cannot get a go—isn't market power going to crush the deal?

Dr Cross: Market power is difficult when you have inappropriate intellectual property. If I can give an example. We often end up in the generic sector having to challenge what we consider and often prove to be inappropriate patents that have been granted. Often we will get injunctions against us so that we cannot launch the products. When we go to challenge a patent, we normally expect—especially when we go through the appeals—that we are going to be delayed anywhere between 2 ½ to three years to get through all the appeals and the legal system, and it will normally cost somewhere in the region of $2 million to $3 million. That is what you are up against when you have to challenge a patent even if the patent is non-valid. Remember this: all the patent office says is, 'We have granted a patent'; they do not declare that the patent is valid. The only way that you can ultimately prove the validity of the patent is to go to court.

Senator HEFFERNAN: Court is driven by the law rather than the truth, and the law is often the interpretation by precedent of what has happened in the past. The reality is that there are two great defences: 'I can't remember, your Honour—the Alan Bond defence; and, 'Let's just run them out of money.' If you are the little bloke locked away in Westmead hospital, you have no chance.

Senator HUMPHRIES: There has been a lot of talk about motivations and vested interest in the court of today's hearing. Dr Cross, you say that GMiA is not antipatent. But it is true, is it not, that patents are in a sense the enemy of your particular section of the industry. Your members' commercial propositions do not start until patents expire for other companies that own them, and that is when the business case for your members presents itself. You are asking us to accept that a regime that diminishes the number of occasions when patents could be granted—which I think is the accepted outcome of this draft bill—is somehow in the public interest. In reality, it would be very much in the interests of your members if there were fewer such patents granted because there would be more opportunities for you to step into that marketplace—would there not?

Dr Cross: First of all, I do not agree with your first point that we are antipatents and anti-intellectual property. Most of the early part of my career I was with originator companies, so I absolutely understand and value patents. If we do not have new medicines being invented and coming to the market on a regular basis, and the only way we are going to have that is if there is appropriate intellectual property protection, then we will never have a generic marketplace. Unless today's new medicines become the future generics of tomorrow and the more successful the medicine is during its life and the more patient benefits because it is a great new invention, the more sales it gets and therefore when it does come off patent and we have the opportunity to compete in the market with it then at that point we get a chance of benefiting more. Because we do not put in the original research and development somebody needs to do that. Unless nations of the world are going to put forward the considerable sums of money and time that are required then the patent system is probably the most successful

incentive system that there is. Back to my first point, the patents have to be appropriately granted for appropriate inventions to do that.

As to the point I raised before, the Generic Medicines Industry Association is not anti intellectual property or anti-patent but it is against inappropriate granting of patents and intellectual property because that then does prevent often the genericisation of products moving forward. So it is a social contract. Smart people and smart companies get rewarded with a monopoly to make a lot of money from their smartness and their invention and at the end of that period society expects that the invention becomes commoditised and more affordable. That is what the Generic Medicines Industry Association does. I think we have a balanced view rather than a non-balanced view. If there was no intellectual property there would be no new medicines and there would not be a generics medicines industry beyond the older medicines that are still there. We need the newer medicines coming off patent to give us in effect more opportunity for more sales. We absolutely understand this balance.

Mr Hannah: I am a board member of the GMIA and in my organisations I have two of the components to my business, both of which are reliant on patents, and we defend them very vigorously. So we are totally in sync with the need for intellectual property and patents. In this example the invention creates the IP, the invention creates the market, the commercialisation. Discovery does not need to be part of that.

Senator HUMPHRIES: I accept that statement of where you are coming from, but the fact remains that the evidence you put in your submission is starkly at odds with a number of other key stakeholders' evidence before this committee. For example, you say that this bill would address what you call Australia's drift away from global trends, where similar standards of patentability had been implemented differently in Australia as compared with the rest of the world. I think it is fair to say that the evidence from most of the other witnesses we have had today has been that to enact this legislation would take Australia away from the mainstream of patent regulation occurring in the rest of the world. It is argued that it would put us at odds with international agreements like the TRIPS agreement and would create a situation where we were not part of those conventions that applied elsewhere such that there might be a flight of investment from Australian research. These are submissions being made by people like the Peter MacCallum Cancer Centre and the Walter and Eliza Hall Institute. Why should we accept your evidence over theirs?

Dr Cross: We come back to the initial and fundamental point, which is that unfortunately biological materials are not inventions and therefore should not be patented in the first place.

Senator HUMPHRIES: But those organisations argue that that is absolutely right but that the things that they conduct research into, which are based on biological materials in many cases, are nonetheless patentable because they are in fact inventions, not discoveries, and that the present distinction in the law between those two things, although it has obviously been subject to some criticism for bad decisions in some cases, is argued to be still a robust distinction which these organisations I have just referred to say needs to be preserved to protect the investment in Australian research. Why is that view not adequate?

Dr Cross: Firstly, regarding the convergence of intellectual property and opinion around the world, it is very obvious from the recent cases in America and in Europe that the view is forming very strongly that allowing the patentability of isolated biological materials was probably a mistake. Most of the rest of the world is converging and moving away from that area. My understanding is that Brazil has openly said that they are not going to move down this area of recognising patents in this area at this point in time.

Senator HUMPHRIES: But Brazil is a relatively isolated case. The rest of the world has not gone down the Brazil path, has it? The rest of the world has still adopted the law that applies to the United States and the European Union, which very much permits the patenting of biological materials.

Dr Cross: My understanding at the moment is that the US, recognising what is going on at the moment, the government has filed what I think is called an amicus brief—a friend of the court—in the Myriad case, saying that the longstanding practice of the United States Patent and Trademark Office relating to patents for isolated genomic DNA has found the practice to be contrary to the settled principle under the US Supreme Court precedent. I believe the direction that this bill is taking Australia is absolutely in line with the direction we see going and the results we are seeing in the court cases.

As I mentioned previously, the problem with granted patents is that there is no guarantee that the patent is valid until it is challenged. What we are seeing around the world is consistent challenge of the patenting of biological material, and so far it seems that the courts are starting to uphold the principle that isolated biological material is a discovery, not an invention.

Senator HUMPHRIES: We all agree with that. That is not under dispute. Are you saying to us that the fact that the US government has filed itself as an amicus curiae in a particular court case constitutes a foreshadowing of a change of the law of the United States?

Dr Cross: I do not think it will foreshadow a change in the law necessarily, but it will foreshadow a change of precedent.

Senator HUMPHRIES: Precedent by the court? The case has not been decided, with respect. It is far too early to come to that conclusion.

Dr Cross: I am saying that, to date so far through the long legal process, the courts seem to be finding in favour of the fact that isolated biological material is not patentable.

Senator HUMPHRIES: I put it to you that there is some evidence of a difference of trend on the part of some US court decisions. That is a far cry from proclaiming that the content of this legislation is the way that other major patent communities—the US and Europe in particular—are heading. There is a vast difference. With respect, this is pre-empting that in what you might say is a dangerous way without knowing where those changes in the US—if indeed there are changes—are going.

Dr Cross: I am taking us back to first principles. Patents are given for inventions.

Senator HUMPHRIES: We all agree with that.

Dr Cross: If somebody can explain to me what is inventive about isolated biological material then I think we would change our view.

Senator HUMPHRIES: That is what the law in Australia already says: it is not inventive to isolate biological material per se. But this legislation goes further than that, doesn't it? This legislation seeks to prohibit the patenting of biological materials that reflect something which occurs in nature. That is going rather further than what you have just suggested is the test.

Dr Cross: What we are currently seeing, I believe from what I am observing at the moment, is that our IP office is granting patents on products that should not be granted patents, because they are isolated biological material that fail on the inventiveness step. There is no invention there.

Senator HUMPHRIES: Does this bill fix that problem?

Dr Cross: I believe this bill clarifies the situation such that this will not happen running forward—

Senator HUMPHRIES: You did not believe it in the submission that you lodged. The submission was very cautiously drafted. You seem to have taken a different position now.

Dr Cross: I am basing this on the new amendment that I have seen today. Our concern was based around the belief that it was too broad.

Senator HUMPHRIES: So you believe it has been fixed with that amendment.

Dr Cross: I believe this amendment fixes it because it allows people to manipulate the material, be inventive—as in the case I described with the insulin—and, therefore, be appropriately rewarded for doing smart, inventive things with biological material.

Senator XENOPHON: To follow up on that: to be fair to Medicines Australia, your constituents are largely American or English based multinationals. Is that right?

Dr Cross: We have Canadian, US based—the way both the generics and large pharma are going is towards globalisation because of the economies of scale.

Senator XENOPHON: So there are no big Australian based generic medicine manufacturers.

Dr Cross: Base manufacturers, yes, but not wholly owned Australian ones. There are some small Australian wholly owned generic companies, but most of the generic companies are becoming global.

Senator XENOPHON: What challenges does your association see from the perspective of the trend towards the patenting of genetic and biological material that we have seen in recent years. I think the example that has been given is of a patent taken out for the flea head back in September 2008. Even in 2004 the schizophrenia gene was patented. What challenges are there with this? You mentioned also that litigation costs $2 million or $3 million. Could you reflect on that as well?

Dr Cross: This is a case of a social contract. The concept of the whole patent law is that a smart invention gets 20 years to recover the costs and get reward for it. What we are consistently finding as the Generic Medicines Industry Association is that we end up with what I describe as 'patent thickets' put around products as time goes on. So, if somebody comes up with a pharmaceutical invention, over the course of a product's life more and more

patents get added to the invention with the concept of what is called 'evergreening'. The concept here is I extend my monopoly way beyond what societally I should have.

Senator XENOPHON: With the tweaking?

Dr Cross: With the tweaking. I can give you some examples. We can end up with a product which has over 120 or 130 patents around it. You have one molecule with myriad patents that are laid round it. The concept is that, if you can find one of them that bites and works, you can then extend your patent life onto the date when that product goes off.

Senator XENOPHON: That was not a pun mentioning Myriad, was it?

Dr Cross: No, it was not. You can then extend your monopoly until the end of that next patent. So if you are very smart and you can really work well you can take what should have had a 20-year monopoly and extend it to 25, 30 or 35 years.

Senator XENOPHON: So you play the system.

Dr Cross: You play the system.

Senator XENOPHON: And you see this bill as an opportunity to reduce the ability to play the system.

Dr Cross: Any inappropriately granted intellectual property is bad news because it stifles invention and it stifles the opportunity. Society should, as part of the social contract, after rewarding the inventor for the invention, expect the invention to come at a more affordable price.

Senator XENOPHON: I am conscious of time, so you might take this on notice. This is incidentally related to the bill. Do you have any views about improving the process through which to resolve patent disputes? It seems that, if it costs $2 million or $3 million, you have to be a big multinational to take that on. What views do you have on improving the process to resolve such disputes?

Dr Cross: I also say that the challenge you have, even for large multinationals, is that you are not going to be able to take on 10 or 15 patent cases in a year, because you do not have the attorneys or the money to do it. The time delay does not only impact the company. I can give you one quick example. A recent product in Australia was delayed 29 months for the arrival of the generic medicines. That product was $180 million in sales being paid for by the Commonwealth. It should have had a 12½ per cent cut when the generic arrived. Because there was an injunction and 29 months of delay, the Commonwealth forwent 12½ per cent of $180 per year times 29 months. You can imagine that was a little bit of money that it cost the Commonwealth as well.

Senator XENOPHON: Roughly $50 million.

Senator SIEWERT: I want to go back to this list of medicines from Medicines Australia's submission that you heard me talking about. I am not a medical specialist, I think that is blatantly obvious, I do understand the argument but I do not know whether I believe that these medicines would not have been available in Australia if this legislation were in place.

Mr Hannah: If there was a biological material that was the discovery and if that biological material was then manipulated to become an invention then those products would have been available. One works by taking raw material and doing things to it to create invention, applications, process, method of use and so on. Once you have the fundamentals, what you do with it determines where you go.

Senator SIEWERT: That is what I understood. For these medicines is the argument being put that these are just straight biological materials and therefore they would be covered under this legislation? Is it in fact true that these are straight biological materials that are used in these medicines?

Dr Cross: It depends on the medicines. If I can maybe get specific I think that some of the concerns that we and other people had in the first rendition of the bill was because it covered things like components and derivatives. If you take a product like Herceptin, it is a recombinant DNA that is humanised monoclonal antibody but that also contains a murine mass DNA as well. This is not found in nature. This is a combination of an antibody—

Senator SIEWERT: It would clearly be inventive.

Dr Cross: Absolutely because it is taking components from the human genome, components from the murine mass genome and putting them together to create an antibody that has never been seen before in nature. This does not exist biologically. Therefore, especially under the terms of the amended bill it would not be covered and you could patent this material, in my view, because it clearly is not covered.

Mr Hannah: It is a classic example of somebody being very technically and scientifically clever, highly inventive, and producing something of great benefit to mankind.

Senator SIEWERT: Okay, thank you. In your opinion they would clearly meet the inventive and discovery step.

Dr Cross: It is an invention because it is not found in nature. The components of it are, but you have put it together in such a way that changes its mode of action. In a lot of cases the reason that you are combining together a mouse material and proteins and human proteins is to make them have less of an allergic response potential from the human than if it were just mouse oriented. There is a lot of cleverness that is going on in this area that enables these products to come forward. To my interpretation, especially with the amendment, I believe these products are absolutely excluded. Therefore, there is no reason whatsoever why you could not apply for a patent and because of the inventive nature of them there is no reason why the patent would not be granted.

Senator SIEWERT: Thank you.

CHAIR: Before you go, Dr Cross, could I ask you to clarify a point for me? Listening to your evidence today I get the distinct impression that you prefer raising the standard of one particular technology, for example under this bill, rather than the technology neutral approach, such as under the raising the bar bill?

Dr Cross: The issue we have got here is that we are trying to shut the gate after the horse has bolted. The IP Australia submission says that we have somewhere in the region of 400 patents now sitting as valid patents in Australia for biological material. I think this bill clarifies the situation and really says that in Australia you should not be allowed to gain a patent for isolated biological material because it is not inventive. I think this clarifies the situation, and that is the advantage of it. It also stops needless applications for patents and, most importantly, needless situations where researchers cannot research and needless situations where companies have to go through tortuous commercial negotiations in order to try and get freedom to operate and freedom to use. These materials, as I described before, are like life's building blocks, and everybody should be able to play with life's building blocks. They should not be commercially restricted.

CHAIR: So when you talk about a technology-neutral approach, are you talking about the test of novelty, usefulness and the inventive step?

Dr Cross: Fundamentally there should be no difference in the way pharmaceuticals and biologicals are treated and the way any other patentable product or invention is treated. The whole basis of the patent law is not limited to medicines and pharmaceuticals, although that is where it is very important because it often takes a long time to bring the products to market, so you do need the protection of intellectual property. In other markets, the speed of development runs so quickly that it is of less importance. Intellectual property is very, very important in this sector to drive innovation and appropriate reward. My view is, though, that we clearly have a situation here where inappropriate patents have been granted and continue to be granted over areas that are discoveries and not inventions. That is why I think it is useful if parliament passes this bill, because it absolutely clarifies the situation and, as I say, it really stops the inappropriate granting of intellectual property.

CHAIR: Under points 2, 3 and 4 in your submission, you talk about the need for standards for patentability to be raised. You talk about the standards being too low. Then you come to the conclusion that there should be a carve-out of particular technologies. Why have you come to the conclusion that, to solve the issues that you have identified in your points 2, 3 and 4, there should be a carve-out of particular technologies, when, under point 1, you support a technology-neutral approach? I am a bit confused here.

Dr Cross: The point we are raising in 2 is largely reflected in the raising the bar bill. One of the challenges we have in Australia is that there are other areas where inappropriate intellectual property is being granted, and, as already outlined, it is hard to revert the intellectual property and overturn it when it has actually come into place. We mention in 3 that the GMIA is concerned that often patents are easier to obtain in Australia. I can give you an example of one patent that we have faced recently, where somebody got a patent for the sequence they put the tablets in a pack, which was an interesting patent from our side. We strongly support the changes which realign the patent law with the global trends for patentability. So I am not quite sure where you are seeing this trend. We understand intellectual property law should be the basis of rewarding all inventions, and we do not see a fundamental difference between the area of medicine and other areas. We believe the intellectual property laws stand Australia well, but there are signs at the moment that certain intellectual property is being given too easily, and it has a lot of consequences, as we have said, when that occurs.

CHAIR: Going back to my very first questions, about trying to understand who you represent in your industry: do you or your members put money into research and development?

Dr Cross: Different companies do different amounts of research, so we all have research and development, but a lot of our research and development is often into how to find a different way of manufacturing the product, to overcome some of the patents that are already in place, because, as I have already mentioned, there are lots of

process patents. So our research and development finds different ways of synthesising the products, because we are looking to bring the affordable generics in as quickly as we can.

CHAIR: Would any of your members have patents? Or do you operate once the patent has expired?

Dr Cross: We do take out intellectual property and patents around our inventions as well, because as we work we make inventions.

CHAIR: That is your inventions; but do any of your people actually have patents on the material that you are dealing with in a primary sense? Or does your industry click in once those patents have expired and then you can use that material?

Dr Cross: One of the problems that is occurring in the industry at the moment is that there is a hybrid going on, so many of the originator companies are becoming generic. Novartis, which is one of the companies, is the second biggest generic company in the world as well as, I think, the fifth biggest originator company. Pfizer now has a generic division and AstraZeneca has a generic division. So there is a hybrid going on. Similarly, with many of the generic companies, some of them have what I would describe as small, innovative products with some intellectual property based around them as well. Hospira is probably in that situation.

Mr Hannah: Yes, we have patents around medical technology and around branded pharmaceuticals and we also have a biologics research and development centre in Adelaide.

CHAIR: But predominantly those patents would be around the work that you are doing to reproduce the medicines you have. Do you essentially commercialise the intellectual property that is currently under patent protection so that when that patent protection expires you then can use it commercially?

Dr Cross: We do not, because this is the social contract. We are not allowed under patent law to commercialise or do any commercialisation of the products ahead of the patent expiry.

CHAIR: But once it expires though—

Dr Cross: Yes, exactly.

CHAIR: You commercialise that intellectual property once it expires?

Dr Cross: There is no intellectual property; it has gone because it has expired. That is the whole point.

CHAIR: I see. And that is your basis for the operation—

Dr Cross: Yes. A lot of the research and development we do is to find our way around all these patent thickets. There will be a process patent that means you have to make the product in a certain way, and our R&D will find a different way of making it, producing the same result, so we are able to bring these affordable medicines sooner to the market.

CHAIR: So this bill will make it easier for your industry to operate?

Dr Cross: I do not think it will make it easier for us to operate per se; what it does which is really important is stop the granting of inappropriate intellectual property. As I described earlier, any intellectual property is like a time bomb ticking away if it is inappropriate.

CHAIR: But that is your definition of inappropriate as you have expressed to us in evidence today.

Dr Cross: My, and I think our, definition of inappropriate as it relates to this bill is as we described before: if it is not an invention, granting a patent for it is inappropriate. Our view is that biological material which is the same as is found in the body is not an invention; it is a discovery.

CHAIR: I thank you both for your evidence and your submission. We appreciate you making yourselves available to our inquiry.

Dr Cross: Thank you very much.

Proceedings suspended from 3.28 pm to 3.40 pm

LIDDICOAT, Mr Johnathon Edward, Private capacity

NICOL, Professor Dianne, Private capacity

Evidence was taken via teleconference—

CHAIR: I now welcome Professor Nicol and Mr Liddicoat, from the Centre for Law and Genetics at the University of Tasmania. You have lodged a submission with us which we have numbered 39 for our purposes. I am going to assume that you do not have any amendments or alterations to that.

Prof. Nicol: That is correct.

CHAIR: I invite you now to talk to that submission, and then when you are finished we have questions to ask you.

Prof. Nicol: Thank you very much for the opportunity to talk to the committee. I am really sorry that we cannot be there in person—coming all the way from Tasmania, of course. We did just want to mention a few things—first of all, a bit of background. Our group has been involved in research in this area for some time, and we have been funded by the Australian Research Council to conduct that research. We have been actively involved in the law reform process. As you are all no doubt aware, there have been extensive law reform inquiries that have been undertaken in Australia, including a major review of gene patents and human health by the ALRC. I was on the advisory board and acted as a consultant on that inquiry, as well as contributing two submissions. In some respects, we regret that these inquiries have not led to concrete law reform proposals, and we are pleased to see that this committee has finally been given the opportunity to review what we see as a really important issue. But we do think it is unfortunate that, in our view, the proposed bill is not the appropriate response to concerns that the current patent system has the propensity to impact negatively on research, innovation and access to health care in Australia.

Obviously we set out our concerns with the proposed bill in some detail in our submission, and we certainly apologise for the length of it, but to us this illustrates the complexity of the issue and our concern that this bill is unlikely to recalibrate the patent system in the way that is anticipated in the second reading speech. We just want to highlight a couple of points from our submission here. Obviously we do not want to go through and canvas everything again, but the first point I want to raise is our concern about lack of clarity and—if enacted—the potential of the bill to create uncertainty across the industry as a whole, whether in the research sector, in the commercial sector or in the clinic. In particular, we have concern about words such as 'components', 'derivatives' and the like. We also have concern right the way through to the title—the fact that the title talks about 'human genes' and other 'biological materials'.

One of the aspects of our research has been conducting interviews with participants in the biotech industry in Australia. At least one of them since the bill was tabled has said to us that they did not see the need to be concerned about it, because it relates to human genes, whereas they operate in the plant biotechnology area. To us this illustrates the point that people are confused by the 'human genes' in the title.

I just want to hand over to John now to raise a couple of other issues that are relevant and that we see as the most important aspects of our submission.

Mr Liddicoat: Again, thanks for taking time to hear our evidence on this issue. In our submission, we have written that many of the claims under the Gardasil patent would not be valid, and Ian Frazer, the co-inventor, has agreed in his submission to this inquiry. In our research, we are consistently told by directors and management of Australian medical biotechnology firms which actually engage in human clinical trials that one of the main uses of patents is to raise cash on the back of them. They say they need long, strong, unfettered, clear patent protection to raise tens of millions of dollars from investors to take products through rigorous clinical trials—a process, commonly, of 10 to 15 years. We see that there is a good chance that this bill, if passed, may have a dramatic chilling effect on investments, which may similarly knock out many Australian biotech firms. Ian Frazer is certainly an eminent scientist with deep and successful involvement in the commercialisation of discoveries—interestingly, one of the few success stories in Australian biotech.

We agree that there are problems with biotechnology in regards to fetters produced by patents. A few instances have arisen and been talked about in public; however, we do not believe that these will be solved by this human genes bill. In particular, we would like to highlight that the bill will not affect the breast cancer or rithroprodent patents, two of the primary reasons for this bill. The reason for this is that the bill is not retroactive. Similarly, we do not see that any great effect on similar simple human genomic genes in the future will occur, because the

human genome has been sequenced so many times now and these sequences are available on public databases. This makes gene claims per se much more difficult because a database is a form of prior arts and novelty and inventive step.

Moreover, even if this bill is passed, it does not take into account the claims for genes in methods of use, expression systems or claims for research tools such as recombinant nucleic acids, including vectors. We doubt that each of these claims will be substantially identical to those likely to be valid even under this bill. Such claims are also currently sealed in almost all so-called gene patents. Consequently, the current bill is not likely to have the handcuff-free intention it aims for.

From a solution point of view, some of the patent fetters that have been observed and discussed we believe can be dealt with by more traditional, nuanced and tailored ways that build on traditional patent law principles. The amendments form part of a raft of changes drafted by IP Australia. These changes are contained in the raising the bar bill, and I would like to highlight a few. The research exemption, although it is no panacea, will fix many issues of property theft affecting research, as will enhanced fair basing, sufficiency and utility combined with enhanced standard of proof for patent examiners. These are all designed to have the effect—amongst others—of stopping broad patent claims, as we have seen, giving inventors monopolies based squarely on their invention and assisting the creation of a fairer market.

Prof. Nicol: That was all that we wanted to say as our introductory statement. We hope that encapsulates some of the key issues that we wanted to raise.

CHAIR: Thanks, Professor Nicol and Mr Liddicoat.

Senator HEFFERNAN: Thank you for your evidence. You will not have seen an amendment to the bill which has been tabled today. It cuts out a lot of the vagueness, which you mentioned, including 'their components and derivatives'. It says:

... biological materials including their components and derivatives, whether isolated ... or not and however made ...

It cuts out the vagueness of terms such as 'components' and 'derivatives'. The raising the bar legislation does not address biological materials. Do you accept that?

Prof. Nicol: Of course we accept that. Senator Heffernan, can I say that we have just received an email with the tabled amendments. We can actually see them on our screen here.

Senator HEFFERNAN: Is it your view that the patent world will fall apart if we do not allow the continuation of granting patents that include biological materials?

Prof. Nicol: I do not think so. A lot of people in the biotechnology industry in Australia tell us that it does not really matter at all what happens in Australia because they will simply take out their patents in other jurisdictions. They are looking to US and European markets. Some actually say that they take out Australian patents just for heritage value almost. In that respect, I certainly do not think the world is going to crash. The only risk from our perspective is the uncertainty which the bill could create could actually drive these Australian biotech companies offshore in that there is not a great deal of incentive for them to stay in Australia.

Senator HEFFERNAN: You realise that the monopolies legislation does say that you should not be able to patent naturally occurring discovery type material. You accept that, do you?

Prof. Nicol: Certainly the way in which the manner of manufacture requirement has been interpreted in the breakthrough case of the National Research and Development Corporation says that there is a plea of distinction between inventions and discoveries.

Senator HEFFERNAN: But there is no distinction at the present time in the granting of patents. There are hundreds of patents which include biological materials. We have taken evidence today of a patent granted last year which includes the biological materials in a flea's head. Do you accept that that interpretation set by a precedent, I might say, is outside the confines of what it should be? In other words, it does in fact patent naturally occurring biological materials whether isolated or not. Do you think that is okay, or do you think that should cease? If the practice of the inventive step on those biological materials and the combination of biological materials which are patentable were to cease, do you think that would somehow cause the industry to fall apart?

Mr Liddicoat: It is quite difficult to comment on it without having actually seen the patent. Assuming that the patent is an artificial state of affairs as has been interpreted through NRDC, we do not think there is a problem with that.

Senator HEFFERNAN: Everyone says publicly that they accept you cannot actually patent naturally occurring biological materials. Do you accept that?

Prof. Nicol: Yes.

Senator HEFFERNAN: But under their breath they say: 'But we want them included as precedent, as was done in the interpretation of patent applications by IP Australia and others. We want them included in the patent.' And they are. What do you say to that?

Mr Liddicoat: They are not actually claimed as they are in the body. You do not have a claim over how that gene operates in any human body.

Senator HEFFERNAN: Are you saying that the genes are not claimed in the patents?

Mr Liddicoat: Genes in circumstances are claimed, yes.

Senator HEFFERNAN: With naturally occurring biological materials, you can go to any number of patents—for instance, you can start with BRACA1 and then go to BRACA2 or to a whole range of them. Out of 27 or 28 claims, the first nine claims in the BRACA1 claims are biological materials. Do you accept that that is the way it ought to be?

Mr Liddicoat: Genes, in certain circumstances, are claimed, yes, but—

Senator HEFFERNAN: No, no, the naturally occurring biological materials. If you went to any number of patents—you can start with BRCA1 and go to BRCA2; you can go to a whole range of them. The first nine out of 27 or 28 claims in the BRCA1 claim are biological materials. Do you accept that that is the way it ought to be? Inventive work and methods are further down the claimable list, which include commercialisation of an 'inventive step' and a useful purpose et cetera, which qualifies for the invention; but, by precedent, we have been allowing biological materials to be locked up. What is proposed in the raising the bar bill is that they will still be locked up but you will get an exemption to research them, and then the negotiations to commercialise the work you do with the exemption are going to be a lawyers feast. Do you not accept that, at present, the patent law includes biological materials which are most clearly and evidently 'discovery'?

Prof. Nicol: The way I see it interpreted is that what is being claimed is a biological material that has been isolated and is capable of synthetic production in the laboratory, which takes its outside the realm of being a naturally occurring biological material.

Senator HEFFERNAN: So your argument is that, if a gene which is naturally occurring is then isolated—which, the first time that happened, would be an inventive step; that is, the method of isolating the gene—the isolated gene is patentable because it is materially different to the naturally occurring gene?

Mr Liddicoat: That is not actually the test. The test is that it is an artificial—

Senator HEFFERNAN: No, but that is what is happening. We have been through this argument with so many witnesses over the last couple of years. Are you saying that the process that enables a gene to be isolated is patentable—and I agree that the method could be patentable—but that the gene itself, when it is isolated, which is not materially different to in situ, ought to be patented too?

Mr Liddicoat: Whether it is different to in situ is a legal question, and it is something that our courts have not considered and indeed is indeed the federal district—

Senator HEFFERNAN: I am asking for your position on this. This is the crux of the matter. We are quite happy to see inventive work patented and commercially rewarded, but I and others on the committee think that access to the gene to enable competition and other inventive work ought to be also be patentable. If you have competition, you have a lowering of prices instead of an increase in prices, but at the same time you have a commercialisation reward without having to negotiate with someone who has the monopoly power over the patent on the gene. But you think what we are doing at present is okay?

Mr Liddicoat: I think the material is fine. If I identified a natural occurring gene now and isolated it, I would not say that had an inventive step—but certainly the material, yes.

Senator HEFFERNAN: I will leave it there. I can see we are going to start going around in bureaucratic circles. Thank you very much.

CHAIR: Senator Humphries, do you have some questions?

Senator HUMPHRIES: Yes, thank you. I wanted to follow up on Senator Heffernan's last few questions. One of the issues we have dealt with in this inquiry and indeed its predecessor inquiry on a number of occasions is: in just what kind of shape is the patent system with respect to genetic material? There have been two extremes of views put to us. Some consider—which I think it is fair to say Senator Heffernan has said today—that there have been a plethora of patents granted in circumstances where, with the benefit of hindsight, we would call them discoveries, not inventions, and where indeed patents have been granted directly over genes or gene sequences, rather than over isolation and application of those sequences artificially. This is a common problem. The Patent Register is littered with such examples of inappropriately granted patents. At the other extreme is the view put by

IP Australia, which is that there have been some horses that have bolted and patents probably granted in inappropriate circumstances, but they have tended to be at the dawn of new technologies and those examples are largely historical. As people who have some practice in the law in this area can you give us some idea of which of those two views better represents what is happening with gene patenting in Australia today?

Prof. Nicol: Certainly today, regarding the sorts of claims that were put forward in the BRCA patents, for example, if they were taken to the patents office today I have serious doubts whether they would be considered to be valid. There would certainly be issues to do with inventive step and novelty. In that respect, I think the fact that the technology has now developed to a point where there has been so much prior disclosure means that the patent law is capable of dealing with those problems. I think that there should be some tinkering around with the inventive step test, for example, to make sure that it reflects the view that we should be looking at whether the techniques that get you to the invention are obvious.

So modern patent law, I think, is dealing with the problem. Certainly it was the case in the past that patents were granted with claims that were just simply too broad. So effectively I concede the point that the monopoly was too great given the scope of the invention. I suppose I support the IP Australia view that that often happens in newer areas of technology.

Senator HUMPHRIES: Is it possible to hazard a guess as to how many such patents might be on foot at the moment where we would say, had they been applied for today, they would not have been granted in Australia?

Prof. Nicol: I would have no idea. In any case—and there might be several thousands of them—it would not matter so much that the patents would not be granted, but that the claims would be narrowed to such an extent that it would only be that the more specific claims would be granted and that the claims from the broad monopoly would not be granted. I would say, potentially, there would be thousands.

Senator HUMPHRIES: The thrust of your submission today though, as I read it, is that it is a mistake to respond to that problem, if it is a problem, by attempting to narrow the basis for the granting of a patent so as to exclude biological materials as defined in the bill, and you give three interesting examples on page 10 of your submission about the enzyme that helps treat leukaemia. Is the kind of example you give there, which you say is a hypothetical example, a real and active example of what does happen in Australian patent law when one is granted patents over Australian patent law? What kind of risk would we place research at in Australia if examples like that of a replication of a genetic sequence in nature in a laboratory and then in a chemotherapy treatment were not available?

Prof. Nicol: Certainly that example is really quite close to some of the examples of work that are being done in the Australian biotechnology industry. It is hypothetical but I think that it is quite a realistic example. I am not saying that particular companies doing that research would necessarily be prevented from doing their research and developing the products of their research, because they would be able to get patents elsewhere and they would be able to get patents on more downstream steps. That definitely is the case. The concern that we hear is that patents are often used as a tool to get venture capital and to negotiate with downstream pharmaceutical companies and partners, and they are all looking for robust intellectual property protection. So if there is any uncertainty about the scope of protection then it could well deter investment, deter downstream partnering opportunities. That is the primary concern that we have: it could create uncertainty but at the same time we are not convinced it will actually achieve the goals that it seeks to achieve.

Senator HUMPHRIES: You said you have seen the amendment to the amending bill, which Senator Heffernan has tabled today. Have you had time to form a view about whether it remedies the sorts of problems you have identified with the bill itself?

Prof. Nicol: Obviously we have not had time to give a detailed evaluation to it. Certainly some of the features like the components question is simply moved down to subsection 5, as far as I can see. I guess that what constitutes a component is perhaps going to be an issue. It is structurally and functionally identical.

Mr Liddicoat: Without any detailed analysis you could actually make a patent claim, say, if we had not seen the breast cancer gene, and you could actually claim the gene specifically as it exists. But then it does not have a function in nature, which indicates susceptibility to cancer. So if you specifically have a claim to its structure but a new function, then it is not identical. It seems to sort of work against the purposes of this bill.

Senator HUMPHRIES: You might care to consider whether there is a view you want to put to the committee about that amendment and give us something in writing. I think we would welcome that.

Prof. Nicol: Yes, we would be happy to do that. Thank you for that opportunity.

Senator HUMPHRIES: I am offering it on behalf of the chair, so I hope that—

CHAIR: That is fine.

Senator HUMPHRIES: One more question: you have a section in your submission on patents for method of use. You talk about it being possible for a patent to validly apply to diagnostic processes. It was put to us earlier today by the college of pathologists that, in essence, all diagnostic processes are really the application of discoveries rather than inventions. I am possibly oversimplifying the evidence they gave, but that would not seen to sit consistently with what you say in your submission. Rather than asking you to respond to it, you might like to have a look at the evidence of the college of pathologists today and, when you respond to the other issue, if you would not mind considering whether you agree with their submission about the patentability of diagnostic processes at the same time.

Prof. Nicol: The only thing that I would say is that work that is being done by our European colleagues, clearly those sorts of patents over methods of diagnosis are being granted in that jurisdiction and in the US and other jurisdictions. They perceive them as having potentially more of a blocking effect in terms of access to diagnostic tests.

Mr Liddicoat: It may well feed back into the inventive step comment that we made before, but we will consider that in our future submission.

Senator HUMPHRIES: Thank you very much.

CHAIR: Professor Nicol, I wanted to ask you some questions. You have actually got 10 dot points in your executive summary as to why you believe this bill should not be supported. If you look at the amendments proposed by Senator Heffernan in relation to the bill being unclear, you suggest that the definition of 'biological materials' is problematic, so you might want to look at the amendments and see if you still have that view. I want to clarify some of the other dot points you made, such as the bill being too blunt an instrument. You say that there are more ways for dealing with perceived problems caused by patenting biological materials. Can you expand on that for us.

Prof. Nicol: The difficulty we have in including biological materials is that it includes a whole array of things through to proteins, cells and fluids and so on that are currently patented and are the subject of new health care developments in the Australian biotechnology industry. So it does not have a nuanced approach in that it excludes all of them and potentially excludes things that would be really important developments in terms of treatments for cancer and the like. So rather than the broad-brush, exclusion-of-biological-materials approach, we believe that refinement to some of the disclosure and the scope of requirements such as the utility requirement and so on needs a more refined approach. So, give the opportunity for some monopoly rights, but not excluding whole fields or potential health care developments.

CHAIR: You have expressed a similar view with the inclusion of section 6, which you say is unwarranted; it is already incorporated in the Patents Act in its entirety. Are you saying that there is duplication and it is not needed?

Prof. Nicol: We are saying that it is not actually necessary to explicitly state that section 6 be included in its entirety, because there is an extensive body of case law that interpreted existing provisions to include section 6 in its entirety already. On the other side of the coin we are concerned about what value there is in including section 6 in its entirety. The key term is I guess 'general inconvenience'. Although that was introduced into legislation in 1623, there is a great deal of uncertainty about what it actually means. So our submission is that if we want to have some sort of public policy or morality provision then it would be better to state that explicitly rather than reaffirming an old provision from way back in 1623, which has that level of lack of clarity about it.

CHAIR: You have come to the conclusion, also, that the bill is too late and redundant. Is that because of the new 'raising the bar' legislation or because many of the controversial patents already have been granted or because technology is moving quite quickly? What makes you come to the conclusion about it being too late and redundant?

Prof. Nicol: I guess it is all of those points. Probably the public perception is that this will fix problems with the breast cancer patent and other objectionable patents. But it is not actually going to do anything in terms of the validity of those patents. It is only going to have effect on new applications. So I think there is probably a lot of confusion about that and the consequences of the bill in that respect. On the technology aspect, the technology has certainly moved on. There is so much prior art out there now that it is going to be much more difficult for applicants to obtain patents in this area. The other bill, if it goes through, will deal with a number of the issues that are relevant to this bill.

CHAIR: Professor Nicol and Mr Liddicoat, thank you very much for your submission and your time this afternoon. It is appreciated.

Prof. Nicol: Can I clarify what the time frame is for our responses to the amendment and the evidence of the College of Pathologists?

CHAIR: The end of next week or the week after would be useful. We do not report until 16 June, so we would be looking at starting to frame this committee's report after the next two weeks. Some time in the next two weeks would be useful.

Prof. Nicol: Okay. We will do our best. And the evidence from the College of Pathologists will be available on *Hansard* fairly soon, I would imagine.

CHAIR: Yes. Some time next week. Thank you both very much for your time this afternoon.

OLVER, Professor Ian Norman, Chief Executive Officer, Cancer Council Australia

CHAIR: I welcome Professor Olver, who is from Cancer Council Australia. Welcome to our inquiry. I am sorry that it is so late in the afternoon for you. Cancer Council Australia, in conjunction with the Clinical Oncology Society of Australia, has lodged a submission with us, which we have numbered No. 72. I take it that there are no changes to be made to that submission.

Prof. Olver: There are no changes to be made to the submission. I would like to comment on the new amendment as the only addition.

CHAIR: I invite you to make an opening statement. You can combine your comments on that amendment with that. When you have finished, we will go to questions.

Prof. Olver: Thanks very much. We reiterate that patents were introduced to protect intellectual property rights over inventions, rewarding inventors. They were never designed to reward just discoveries. Our interest in this was triggered in 2008 by the issue with Genetic Technologies and the BRCA1 and BRCA2 patents, in which they tried to enforce a monopoly over the testing for these breast cancer genes. What became clear then was that the current patent law and its interpretation did not prevent that from happening. The satisfactory outcome of that issue was due to other things—essentially, public pressure. We felt that an amendment to the patent law was required to prevent that happening again.

The reason we are very keen to prevent it happening again is because in our field, cancer, as we enter the ere of targeted therapies, we are going to see a very large number of therapies based on genes, targets and proteins that are the result of genetic mutations. These therapies will be very specific and they will knock out the mechanisms by which cancer grows. If there is a problem with patent law and its interpretation that allows monopolies over discoveries that prevents the competition of research then we need to sort it out now and not wait until further down the track. We are not anti research. Indeed the cancer councils around Australia put $50 million a year into cancer research. Nor are we against patents. We want inventive patents to reward invention. But we are against monopolies based on being able to be granted to just the discoveries of biological materials that exist in nature.

The other point we would like to make is that we have seen a lot of theoretical examples of what may happen if the patent law is changed. We started off with a practical example of what did happen when it exists as it is. Many of the examples we have seen, where people have claimed that inventions such as Herceptin and Gardasil would not be granted patents under the patent law, are just false, because both of those clearly involve inventive steps. We are suggesting that one of the remedies to the situations that occur is a change to patent law.

I would like to look at the amendments. We agree with them. I have been trying to understand as a nonlawyer, if you like, why these were written in the way they were in the first place and why the amendments have been useful. It turned out that phrases such as 'substantially identical' or phrases that included things like 'including components and derivatives' were actually put in as legal instruments based on wider patent law. Yet when they were put into this context they were misinterpreted as possibly that a small change in a gene or biological material may not be granted a patent because it was substantially still identical to the product. That was not the intent at all. The intent was to say that identical means identical in structure and function. But it does not mean that you can make a cosmetic change—stick an amino acid on the end of something which has no functional significance at all and claim that that is different. That is in line, as I understand it, with other patent law, where you cannot do something trivial and be able to claim a patent over something that you did not invent.

So we are quite happy with the concept that the actual wording needs to be refined so that people are comfortable that it does not knock out the ability to patent an inventive step, and we do not believe in any of the examples of patents granted to date that treatments like Gardasil and Herceptin would have been knocked out. On the other hand, there are patents still being granted over simple native biological material that I think later on could have a problem. You talk about prostate stem cell antigen being granted a patent, and that was granted in 2009; and type II cytokine receptor, which could be a target for some sort of treatment—and that has just been given a patent so that no-one except the patent holder will be able to develop a treatment if indeed one is going to exist over that native biological material.

I also make one other distinction that the broadening into biological materials was designed to knock out a whole lot of patents; it was there for consistency. If you are going to say the example case was the gene then it would be totally inconsistent to say, 'We will fix that but we will not fix it if it does not happen to be a gene—if it happens to be an amino acid or a protein or something like that.' The fact is that if it simply exists and you do nothing to it, it should not be able to be patented. That is what we believe patent law over the last 400 years has meant. So the remedy that we support is a change in the patent law to help remedy the situation. There are

arguments that it will not fix everything and we concede that of course it will not. There may have to be many remedies, but the fact is that it did not fix the one example in 2008 that threatened the well-being of patients with breast cancer in this country.

CHAIR: Okay, that is your opening statement? Thank you.

Senator SIEWERT: Medicines Australia have given us a list of medicines that they say would not have been available if this legislation was in place.

Prof. Olver: We have read a number of the claims—and I give Gardasil and Herceptin as examples—about things that would have been knocked out. In getting expert advice on these things, we have found that they all contain inventive steps. I think the issue here that has been misinterpreted is that a native biological material that is part of a construct of a medicine—you add a bit of mouse antibodies to it or whatever—becomes an invention. It is allowed to have some native material in it; it is just not allowed to be solely native material without change. We have maintained that the business of isolating it does not constitute an inventive step.

You could apply it to anything if you want to try to suggest that we are saying that it is native material with all sorts of other things around it; it is the 'all sorts of other things around it' in medicines that are the inventions that make it patentable. That is the clever stuff that we want to see rewarded by patent and that is the stuff that competition finds more quickly than if you just have a monopoly working away on their bit of gene or biological material.

Senator SIEWERT: Have you had a look at the raising the bar legislation?

Prof. Olver: I have not examined it in enough detail and I would like to put in a supplementary submission on that. I would like to say that I do recognise that there are a number of other remedies that could be put in place in concert with this to try to fix various problems of interpretation. The interpretation of what is an inventive step is clearly important, but whether you raise the bar or not on the criteria of an inventive step a discovery is not an inventive step. The law as it stands has been able to be interpreted in this country and others as allowing discoveries to be patented and for companies to be granted monopolies over natural or native materials—genes or other biological materials.

The reason I gave a couple of examples of things like prostate stem cell antigen is that they are not as interesting as flea heads, but to me they are things that could be targets for future treatment. They are things where I would like to see all interested researchers compete to find out the value of targeting those pieces of biological material.

Senator SIEWERT: You have touched on it, but we have also heard a lot of evidence today that this is doom and gloom and that this will stop research in Australia. It will mean that clinical trials are not held in Australia anymore and that there will be more research done overseas.

Prof. Olver: I simply do not accept that. For a start, we have talked about Brazil earlier today as being such a country—although it is perhaps an isolated country—but Glaxo has just opened up a large research facility there, so it is not putting them off. There are many reasons clinical trials are dropping in Australia—price competitiveness with Asia and eastern Europe—but it is not due to threats of the patent act. If you look at new drug research, for example, companies accept that they will go down a whole lot of blind alleys before they find the one drug that is a commercial success, and that is factored in. What will happen here is that companies will accept that they will discover a number of things before they eventually find something or an inventive step has made it into a commercial reality. That is the way it has always been in this type of research. You cannot hit a winning run from day one; you never have been able to. I do not think it will discourage research at all. We want to encourage research. What is actually happening now is the granting of monopolies over biological material is discouraging competitive research. We have already heard that if a research exemption was granted, you still have to go back if you invented something and negotiate to have a financial reward for that invention. So that does not seem a very helpful remedy; that seems to be complicating the uncertainty.

Senator SIEWERT: In your experience, how many research organisations or facilities make money from the patents that they have established?

Prof. Olver: Some of the bigger research facilities like the Walter and Eliza Hall Institute of Medical Research clearly hold patents on things they have discovered because they have been allowed to do that. I do not have the info on how many around Australia, and of course the bigger financial reward comes from an inventive step where a product can be commercialised. That is what everyone tries to do and that is why larger companies are being formed to exploit that.

Senator SIEWERT: The argument is that research will not occur in Australia if companies or research organisations cannot get access to patent their inventions using biological materials and that they will go overseas.

Even if research facilities are not put off, will they stop getting funding grants to do research if patents are not available?

Prof. Olver: I do not believe so. Companies go to research facilities because of the expertise in innovation that the group of scientists in the research facility hold. That is the value. The company often already either holds a patent or wants to explore a line of inquiry with a biological material and they hire, go to and fund a research facility to give them the expertise to do that. What is behind the question—and this is what I cannot understand—is this: if you want to stimulate discoveries, why would you use a misapplication of patent law to do that? Why don't you just give them tax breaks or do something that says, 'We're not going to give you a patent over a discovery but we will do something to reward it.' The misapplication of a 400-year-old law does not seem to me to be a way of rewarding discovery if you want to do it because it has the unintended consequence of actually monopolising that biological material, and in fact reducing the research that can be done by multiple companies competing to find that inventive step that will give them a commercial product.

Senator SIEWERT: Can we go the issue of invention and discovery. Today it was put to us that the step of finding the switch from nucleic acid that causes a particular disease is an invention not a discovery.

Prof. Olver: I will defer to the lawyers and their four criteria for inventive steps to see which one that fits into. But if you find something and you uniquely apply it to do something, I think that falls into one of the inventive steps. This is where you have to be very clear about specific cases. Finding something and not knowing what it does, for example, is not a discovery. Finding something and applying what it does to a treatment of a disease may well be an inventive step under the criteria for inventive steps that the law allows.

I think the devil here is in the detail, and I am not qualified to argue the legal issues of the distinction between discovery and inventive step. I allow for the fact that part of putting this bill forward is to stimulate a debate where experts will get that language right so that it is cannot be misinterpreted. What is clear is that at the moment there have been discoveries without any subtleties at all of whether they switch something on or not that have been given patent monopolies. That is what we have to remedy.

Senator PRATT: I would like to ask a question with respect to how the law has been misapplied in relation to novelty and inventiveness. There are clear premises within our current law, and it is does seem to have tightened up significantly, notwithstanding the fact that clearly biological materials have been patented. I am interested in the distinction that you might draw between the bill that is before us and the draft government bill in terms of the way it seeks to resolve those issues.

Prof. Olver: I would like to put in a supplementary submission on the draft government bill because we need more time to actually look specifically at that.

Senator PRATT: I do appreciate that it is not—

Prof. Olver: I will make the point that, given that we have discoveries where patents have been granted under the current law and given that I have quoted a couple of examples from 2009—so it is relatively recent history; so it is still happening over native biological materials—I do not take any comfort from people who are telling me that we will apply the law differently next time. I would suggest that the law needs to be changed so that it cannot have a misapplication next time as far as possible within legal interpretation. I am a realist: you can never plug all the holes.

Senator PRATT: Have you looked at the extent to which it is a question of resourcing of patents as opposed to the resources that may be chewed up in the courts on these questions that could otherwise be redirected to health, medical research et cetera?

Prof. Olver: That is why we are asking for greater clarity in the law. The hope is that the greater clarity in the law plus other remedies that may need to be put in place will actually help in the process of not requiring litigation, because people will be clearer in distinctions such as what they have to do to be granted a patent—and that is that they have to invent something.

Senator PRATT: Is it perhaps an issue that it is not necessarily the fact that the law has been unclear; it is just that we have required the law to prove that patents have been granted when they should not have been?

Prof. Olver: Well, the thing is that the law has not prevented those things from happening, and this is the difficulty that we see. With all the theoretical examples, some of which I think are incorrect, we have an actual example where the law not only allowed a patent—a monopoly—over BRCA1 and BRCA2 but could not or did not do anything or was not able to be used to remedy that. That is why I think people are asking questions about whether this law was misapplied. The New York District Court—I know it will go to appeal; it will be long—are asking the basic question: should we ever have granted a patent over this discovery? I think we are seeing in America, Brazil and Australia a very basic level of saying: 'There's something wrong here. We know that there's

something wrong because there've been examples like the BRCA1 and BRCA2 example. We've got to look at remedies and we'll start right back at first principles in the law.'

As I said, the reason this Patents Act amendment, the new bill, seeks to also include biological materials is simply a matter of consistency. If you cannot patent a native bit of DNA without doing anything inventive, why should you be able to patent a native protein or a native amino acid without doing anything? It is the same sort of thing. It creates a monopoly over something that exists and shuts everyone out of being able to compete to find the inventive step.

Senator PRATT: Thank you.

Senator HUMPHRIES: I am glad you said before, Professor Olver, that you defer to the lawyers, because I think, with respect, you have misinterpreted the bill that you are supporting here today. You point out that to be patentable an invention has to have an inventive step and proposed new sections 18(1) and 18(1A) reinforce that sense of there having to be an inventive step. It would seem to me that proposed section 18(2) provides a new test which is quite independent of whether there is an inventive step involved. It is a blanket prohibition on the granting of a patent in two circumstances, one where the 'invention' is human beings or 'the biological processes for their generation' and the second which is biological materials which are 'identical to such materials as they exist in nature'. So, if a particular patent in fact is a biological material identical to such materials as they exist in nature, the fact that it has involved an inventive step does not save it. As I read this amendment, it still means that the invention may not be patented.

This is the point that a number of witnesses have made already today: the blanket ban on the patenting of biological materials. If they replicate what exists in nature—that is, they are structurally or functionally identical—they are not patentable. Medicines Australia, for example, were listing a number of medicines that they said may fall into that category not because they do not involve an inventive step but because you could say, they suggest, that at least some of those medicines mimic the effect of certain biological materials in nature and therefore might be knocked out under this amending legislation.

Prof. Olver: I am surprised to hear that an inventive step gets trumped. My interpretation of this from a non-legal point of view, trying to make it as simple as possible, is that this is defining, if you like, what native material is, where by definition there is not an inventive step because it already exists. It is biological material unchanged in structure or function. It is worded to cover whether it is in the body or not, effectively, but my understanding is that once you do something else to that, once you do something inventive to that biological material, you either package it up with something so that it becomes a medicine or—

Senator HUMPHRIES: That is the usual test, I agree. That is what the test is.

Prof. Olver: But this does not prevent that.

Senator HUMPHRIES: Well, it does.

Prof. Olver: This just makes it clearer that a biological material on its own—a native biological material to which you have done nothing, excluding the fact that we are suggesting that isolating it now is not really doing anything to its structural function—cannot be patented in its own right; it needs something else; it needs an inventive step. So I cannot see at all that this knocks out a whole lot of medicines where there has clearly been an inventive step to that biological material. All this does is make it clear, because it was not clear before, that genes, or biological material, if you like—we started with genes, but to be consistent—if it exists in nature and you have just stumbled across it, is not patentable. If you do something clever with it, it is.

Senator HUMPHRIES: I put it to you that that is not the test. Have you read the submission of the previous witnesses, Professor Nicol and her team from the University of Tasmania?

Prof. Olver: Not in detail.

Senator HUMPHRIES: They give an interesting example in their submission, and I recommend you have a look at it because it actually relates to cancer. It is on page 10 of their submission. I will just read you the case that they pose:

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.

They point out in the submission that, at the present time, such a discovery, or such an invention, I should say—whatever you want to call it—would be patentable, because there is, as you put it, an inventive step involved.

They also argue, as lawyers, that under this legislation it would not be patentable because, irrespective of having an inventive test, it replicates a process involved in nature; it mimics that process using naturally occurring enzymes and therefore would not be patentable. If they are correct, you would agree, wouldn't you, that not being able to patent an enzyme of that kind, which has enormous potential, hypothetically, to help fix leukaemia, would be an unfortunate development?

Prof. Olver: I think that is an important example. I would need to see legal advice on that, because, from what you have described—and I will have to look into it in more detail—taking something from a plant and applying it to a human disease possibly does fit into a legal definition of invention, and that is what—

Senator HUMPHRIES: That is their point. They say it does involve an invention but it is not patentable because it mimics a process in nature, and this bill knocks out processes in nature being, in effect, patentable.

Prof. Olver: Well, it knocks out being able to put a patent on the basic material before you have done anything inventive with it. If there were two companies competing to find what this particular chemical in this plant actually did, then I would say you would want them to compete until they discovered that it worked for leukaemia, say. To me, that is the inventive step that deserves the patent. But I will have to take legal advice on those two points. The first is that I think the example you have given has an inventive step. The second is, if there is something in the wording of subsection 18(2) that can be interpreted as 'It doesn't matter what you do with it; just the fact that it is an unaltered biological material makes it unpatentable,' I think we need to look at that wording, because my understanding is that it very much does matter what you do with it. If you do nothing with it, it is not patentable; if you do something inventive with it, it is. To me, that is a legal interpretation or argument, and I am outside my field of expertise. But I think it is an important one to tease out, and I will also include that in a supplementary submission. But I believe you have described an inventive step which would make this—

Senator HUMPHRIES: Yes I am absolutely.

Prof. Olver: I cannot see how the clauses that seek to define native biological substances knock that out. If there is a form of words that needs to be changed then I agree.

Senator SIEWERT: Could I ask a supplementary question?

Senator HUMPHRIES: Yes, sure.

Senator SIEWERT: Your last comment was that you amend the words you do not get rid of the intent of the bills—is that what you mean?

Prof. Olver: As a non-lawyer the principles were particularly important. The principle of trying to have greater certainty around what is a discovery and what is an invention and the fact that you cannot patent native natural product that you just stumble across without doing something inventive is the remedy that we are seeking. I do not have the expertise to put that in the form of words that would satisfy legal scrutiny. I think it is important that we go through that exercise to demonstrate that this bill will not knock out invention because it was never intended to. We certainly do not want to knock out anti-cancer inventions. I do not believe it does that from the advice I have been given to date but I am happy to work through that example.

Senator HUMPHRIES: Can I put it to you that you, like a number of other witnesses who support this bill, have fallen into an intellectual trap of saying that the law in Australia with respect to patents is somewhat unsatisfactory or at least the practice of patenting is unsatisfactory and needs to be reformed, and this legislation comes forward with the intention of effecting such reform; therefore the Senate should pass this legislation. The first two are undoubtedly true but the third may not follow from those earlier comments. I take as an illustration of that problem a body like the Peter MacCallum Institute which, you will recall from the earlier inquiry of the community affairs committee, strongly argued for reform to the law and was one of the proponents arguing that there should be some reform to the law but has said about this legislation that it does not do the job. It is not the right legislation to effect that change. With respect, I think the sorts of issues that I have raised about whether that blanket exclusion of biological materials which as has been mentioned by so many witnesses opposed to the bill needs to be fixed is an issue that must be addressed before this legislation can be passed by the Senate.

Prof. Olver: I will address that in two ways. First of all I do not believe we did come at this as an intellectual exercise. This came about as a practical example where the law failed to protect breast cancer patients from a potential monopoly. We actually came at it from a very practical point of view that there was something wrong, not postulating that there was. Something actually happened that showed us that that was wrong. You are right, we are seeking a remedy to that. As I said, the framing of it to include biological materials is not to be seen as trying to wipe out all sorts of medicines at all. I will be very specific on that and my own quest to understand this. I would ask the question early on: what about if we just sought a remedy to the particular problem that we had with the BRCA 1 and 2 genes? We said, 'You cannot patent a gene as it is.' I got three legal opinions on that and

they all agreed with each other, so I was convinced. The problem with that is that I had initially thought that that may set a precedent for any like situation but apparently it is quite the opposite.

The judge would say, 'You have only legislated for genes, that means you are only meant to include genes and so you could in fact patent biological material as it exists in nature.' To me that is totally inconsistent. I guess what we are trying to do here is say, 'Let's have a go at this.' It will not fix everything, but it will try to fix, for the future—somebody said earlier it may not fix the BRCA1 or BRCA2 problem. That is fine, but what we are worried about is this raft of biologicals and targeted genes that are coming down the track, particularly as anti-cancer opens. We want to get clarity on this, but I will take the point that I am not arguing for a very specific form of words. The amendments here have sought to clarify some of the discomfort of what was, to me, a legal instrument but got misinterpreted as meaning wiping out a whole lot of medicines. I would welcome further argument on the precise wording to make sure that there cannot be misinterpretation as far as that can be achieved.

Senator HUMPHRIES: You mentioned your motivation was originally to deal with this issue, with the BRCA use of a patent against those diagnostic tests for breast cancer. I am not sure if you have read the submission from the Law Council, but they make the point:

… it is of particular note that the Bill would not affect the patentability of the diagnostic method which originally sparked the current debate: the Myriad BRAC1 and BRAC2 tests.

There was other evidence given today that suggest that the BRCA patents have a number of claims on them, as they usually do, and that the claims over the genes or gene sequences were independent of the claims over the diagnostic tests. And even if the former were invalid or fell, the latter patents would stand and that, therefore, their patent would still be enforceable against the people who try to use the tests that were in dispute at that time.

Prof. Olver: But as I mentioned, although an actual example rather than a theoretical one has triggered our interest in this, our remedy was not to revisit history so much as to insert some clarity because we realised that in therapeutics the type of patents we are talking about, the targeted therapies based on targets that are natural targets and so on, are going to be the backbone of cancer therapies. We want to remedy the situation at least from now on. It may not be possible to have a remedy that will clean up what has gone before. I know the American district court invalidated the patents, and I guess that does something subject to appeal and so on.

It is not primarily to fix the narrow problem and it is not going to fix everything; it is to draw attention to the need for clarity going forward because we are going to have a lot of these. When I saw 18 months ago sew on stem cell antigens being patented and type II cytokine receptors and so on, this is the problem we are trying to get some clarity around. They are discoveries, they are not inventions, and being tied up they may prevent an invention by tying up the tag that might be a target for future therapies. I do not necessarily have the answers. I am prepared to debate the wording to get that clarity. A lot of our opponents--Medicines Australia have put in their submission things like, 'This is a well-intentioned bill'. Well, yes, it is, so if it is well-intentioned then let us get the detail right so that the intention is what the Senate is looking at.

CHAIR: Professor, do you think the existing safeguards in the Patents Act, such as compulsory licensing and the Crown use, are sufficient to protect the public interest where patent owners use their exclusive rights over inventions unreasonably?

Prof. Olver: It does not appear that they have been. I think the Crown provisions have not been enacted—or they have once I think, way back in history somewhere—so our observation is they have not been sufficient because of the example of where we started all this, and that is why we seek more pointed remedies.

CHAIR: Do you think there are any overriding ethical or social considerations that should really inform the policy approach to patenting human gene sequences?

Prof. Olver: I want to tease out that question. We have always been advocates for this debate not just being a legal or biotechnology debate, but including the general public and ethicists and so on so that it becomes a community debate. We believe some of the community's values will be reflected if it is opened up for that sort of comment, and that is why we welcome inquiries like that which garner a whole range of opinions because we feel that that will work towards a workable piece of legislation.

CHAIR: As there are no other questions, Professor, I thank you for your submission and your attendance here today. We look forward to the further documents that you are going to provide to this committee for our inquiry. It has been a long day, but I thank everybody who has been in attendance and listened all day with keen interest. I declare this meeting of the legal and constitutional committee adjourned until 8.45 tomorrow morning when we will reconvene for further evidence in relation to this bill.

Committee adjourned at 5:01 pm