



COMMONWEALTH OF AUSTRALIA

# Official Committee Hansard

## SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

**Reference: Gene patents**

MONDAY, 14 SEPTEMBER 2009

CANBERRA

BY AUTHORITY OF THE SENATE



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## SENATE COMMUNITY AFFAIRS

### REFERENCES COMMITTEE

Monday, 14 September 2009

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

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

**Senators in attendance:** Senators Heffernan, Moore, Siewert and Williams

#### Terms of reference for the inquiry:

To inquire into and report on:

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

- (a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:
  - (i) the provision and costs of healthcare,
  - (ii) the provision of training and accreditation for healthcare professionals,
  - (iii) the progress in medical research, and
  - (iv) the health and wellbeing of the Australian people;
- (b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of the any matters identified by the inquiry; and
- (c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

**WITNESSES**

**PALOMBI, Dr Luigi, Private capacity ..... 1**



**Committee met at 9.03 am****PALOMBI, Dr Luigi, Private capacity**

**CHAIR (Senator Siewert)**—The committee is continuing its inquiry into gene patents, and I welcome back Dr Luigi Palombi. I know that you have already appeared before but I also understand that you have been given information on parliamentary privilege and the protection of witnesses. We have, of course, before us your submission and also your answers to some of the questions that have been raised. I would like to invite you to make a brief opening statement and then we will ask you some questions.

*The presentation given by Dr Palombi is available on the Senate Community Affairs References Committee website—*

*Slide 1—Name, organisation*

**Dr Palombi**—Before I begin I would like to thank the committee for extending me this indulgence. I know that all of you are very busy with other duties and responsibilities. I appreciate very much the time that you have managed to find this morning so that I might give my evidence. I also appreciate that we only have an hour, so I will try to be succinct and to leave some time for questions.

*Slide 2—So what's this inquiry about?*

*Slide 3—NBC 'Today' show*

Ms Lisbeth Ceriani: “That there's a patent on the gene itself. Not on the test. Not on the process, but on the actual gene. It's just mindboggling.”

*Slide 4—Terms of reference*

Firstly, I want to take you back to the terms of reference, to remind you that this inquiry is not just concerned with patents over human genes and proteins—that is, biological materials derived or sourced from human beings.

*Slide 5—Terms of reference, arrows*

I have noticed from the *Hansard* transcripts and some of the questions that have been taken on notice that there has been some preoccupation with ‘human’ genes, perhaps even an overemphasis, if I may be so bold. This preoccupation has led, in my opinion, to a misconception—namely, that the granting of gene patents is a diminishing problem in Australia.

*Slide 6—IP Australia, statement of 20 August 2009, paragraphs 15-18*

In its opening statement of 20 August, at paragraphs 15 to 18, IP Australia made the following assertions:

*Slide 7—*

That its data shows the number of patents claiming isolated human nucleic acid molecules steadily declining since the publication of the human genome project.

*Slide 8—*

That there are only 202 Australian patents claiming an isolated human nucleic acid molecule in force.

In reply I want to make some points.

*Slide 9—Gene inquiry terms of reference, with arrows*

First, as I have just said, this committee is not charged with looking only at human gene patents. It must look at ‘the impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form’. Even if it were correct that there are only 202 Australian patents claiming human DNA currently in force, as IP Australia claim, it is beside the point. How many Australian patents claim human proteins? How many claim DNA or proteins derived from DNA sourced from humans? IP Australia make no mention of these.

*Slide 10—*

Indeed, when I examined IP Australia’s database in February this year I found that there were over 15,000 patents and patent applications that concerned both human and microbial genes and non-coding sequences, proteins, and their derivatives. This is not an insignificant number.

Second, rather than being a diminishing problem, as IP Australia would like us to believe, evidence from other sources suggests that the number of gene patents is likely to grow in the future.

*Slide 11—Photo of WIPO, Geneva, Switzerland*

Over the weekend I searched the patent application database of the World Intellectual Property Organisation, WIPO. WIPO is an agency of the United Nations and it administers 24 intellectual property treaties, including the Patent Cooperation Treaty, which is otherwise known as the PCT. The PCT enables a patent application which commences life in one country to be simultaneously applied for in all 141 PCT countries. So WIPO collects data on patent applications that are international.

*Slide 12—WIPO search page*

Looking at these patent applications therefore gives us a pretty good idea of what is coming. So what did my brief search reveal?

*Slide 13—WIPO search page, highlighted*

You can see from this page that the total of all PCT patent applications is 1,627,114. This covers everything and anything that could conceivably be an ‘invention’.

*Slide 14—Back to slide 10*

You will notice that there are 12 search fields.

*Slide 15—*

To help me find out what is happening with patents over ‘isolated’ things, I inserted the word in the field called ‘claims’. In other words, any patent application which defines the invention as something that is ‘isolated’ will be included in the search.

*Slide 16—*

This showed that 14,710 patent applications contain such claims. Then I inserted the term ‘nucleic acid’, which means DNA, or ‘amino acid’, which means protein.

*Slide 17—*

This produced a result showing 13,818 patent applications. In other words, out of the 14,710 patent applications about something ‘isolated’, 13,818 of these were about ‘isolated’ DNA or proteins. Does this suggest to you that the problem is diminishing? I do not think so.

Just to give you a flavour for what these ‘inventions’ are—and by using this word to describe them, I do not mean to suggest that they are in fact inventions; I merely use the word to save time. Let me give you two examples. That is all time permits.

*Slide 18—PCT/US2009/030998—Compositions and methods related to a human CD 19-specific chimeric antigen receptor, h-char, cover page*

*Slide 19—Slide 18, magnified*

As you will see, the patent applicant is the University of Texas.

*Slide 20—*

You will also see that the priority date of the patent application is 14 January 2008, that is, about eight years after the human genome was decoded. You will see in that Australia is designed as a country under the PCT, so eventually this application may be examined by IP Australia.

*Slide 21—Claims*

This shows the first 13 of the 22 patent claims. It is in this part of the application that the patent applicant defines the scope of the patent monopoly, in other words, what the invention is.

*Slide 22—Claims, magnified, with arrow*

The primary claim—claim 1—defines the invention as:

An isolated human CD19-specific chimeric antigen receptor polypeptide (hCD19CAR) comprising an intracellular activation domain, a transmembrane domain and a heterologous extracellular human CD 19 binding domain.

So we can deduce from this description that the invention is derived from the human body and that it has been isolated from it. We also know that it is a protein, that is, human material.

However the patent applicant also claims the nucleic acid or DNA of the isolated protein defined by a claim 1.

*Slide 23—Claims, magnified, with arrow*

Claim 8 also defines the invention as: ‘a nucleic acid encoding the polypeptide of claim 1’. Notice here that the word ‘isolated’ does not appear. This is therefore a claim to the human DNA as it exists in the human body. Not that this distinction means anything really. We already know that the DNA, whether isolated or not, is identical or substantially identical. Let me take you to the second example.

*Slide 24—PCT/IL2008/001674—Novel protein, cover page*

*Slide 25—Slide 24, magnified*

This patent application starts life in Israel.

*Slide 26—*

You will see there the letters ‘IL’ in the application number.

*Slide 27—*

The priority date is 27 December 2007, that is, about seven years after the human genome was decoded.

*Slide 28—*

Again, Australia is designated as a PCT country so this application may eventually be considered by IP Australia.

*Slide 29—*

The application is entitled ‘Novel protein’. Sounds interesting? Well, let’s see what it really is!

*Slide 30—Specification page 1*

Note also that the title also says that it includes ‘therapeutic uses’ of this ‘novel protein’.

*Slide 31—Slide 30, magnified*

So it starts off giving examples of human autoimmune diseases. Then it goes on for another four pages referring to just about any human disease imaginable—why is never explained.

*Slide 32—Specification, page 6*

Then at page 6 we get to the point. This section is called ‘Summary of the invention’, and it defines the invention thus:

A novel protein, named KTPAF50, has now been discovered, based on a novel cDNA. The peptide encoded by the cDNA is 74 amino acids long and includes a signal peptide of 24 amino acids on its N-terminal end.

The cDNA sequence (SEQ. ID. NO: 1) and amino acid sequence (SEQ. ID. NO: 2) of KTPAF50 are as follows:

atgccaggc cattctagg ctctgtct atcctggtt tctggtctg tgcgttggtg ggtagcagc attggcgta ttacgccgg agggagcag gctgagcga ggctccaga  
aggtgagca atageccga gaggaaagg gcatgctg tcacctagc ccctcct gagactcca ttcagccca gaaaagga gctgcttc tccccatc tacctagg  
agaaaa (SEQ. ID. NO: 1)

MPGHSRLLSILVSGLCVVGSSIGVLRREQAERGSRRCAIAGEERAMLSP      SPLPETPFSPEKGAASFPIYPRRK  
(SEQ. ID. NO:2)

*Slide 33—*

You will notice that the patent application uses the word ‘novel’ and the term ‘cDNA’. This may suggest to you, I imagine, that this is something that is not of human or natural origin. The word ‘novel’ suggests that it is something new.

*Slide 34—*

The term ‘cDNA’ which means ‘complementary DNA’ implies that we are dealing with something different from naturally occurring DNA.

The truth is that the protein is not new at all. It already existed. All the inventors did was to discover and isolate it from a human being. And so that you know, cDNA is ultimately, though not directly, a derivative of human DNA. The point is that the genetic sequence of the cDNA is something that neither the inventors conceived of nor created.

*Slide 35—Specification, page 13*

You will see here at page 13 of the specification that the inventors admit:

*Slide 36—Slide 35, magnified*

A novel cDNA has been isolated from human cDNA libraries.

So what do they define as the invention?

*Slide 37—Claims*

On this page we have 12 of 21 claims.

*Slide 38—Slide 37, magnified*

You will see here that the primary invention is defined thus:

*Slide 39—*

An isolated polypeptide comprising an amino acid sequence of SEQ. ID. NO: 2 or SEQ. ID. NO: 4.

This is therefore a protein that has been isolated from a human being.

*Slide 40—*

Later on at claim 9 you will see that the invention also includes the DNA in isolated form.

An isolated nucleic acid molecule comprising a sequence encoding for an isolated polypeptide according to Claim 1.

This therefore is the DNA of the human protein, both being biological materials which have been isolated from a human being.

Before I move on, I want you to take note of something that IP Australia have said to justify the grant of these patents. During the opening of this inquiry in March, Mrs Beattie, the Commissioner of Patents, said in her evidence:

*Slide 41—IP Australia: 19 March, page 4*

... if ingenuity has been applied to a discovery to produce a new and useful result, it is an invention and may be patentable. A practical application of information to a useful end translates a discovery into an invention because a step is taken from knowing to being able. For example, for a patent to be granted over a gene sequence, the applicant must disclose a new and practical use for the sequence. Typically, this will include evidence of the association of the sequence with a particular disease and its use as a diagnostic or therapeutic.

With respect, the commissioner's statement is misleading. As the commissioner very well knows, the scope of the patent monopoly is defined by the patent claims. In other words, the invention is that which is defined in the patent claims. In determining if there has been infringement of the patent monopoly the courts look to the words used in the claim. Now, when one looks at the claims in the examples that I have just given, you will note that there is no reference whatsoever to the use of those isolated biological materials.

*Slides 42 and 43—Patent claims*

The invention is to the biological materials in an isolated form per se. There are no qualifying words which link those materials to a new and practical use. Indeed, any use of those biological materials will constitute an infringement.

Mrs Beattie also said:

*Slide 44—*

Australia's current patents law does not give IP Australia any clear basis in law to refuse to patent gene sequences solely because the patent relates to these areas of technology. Gene related inventions are not made unlawful under any existing Australian regulations, and courts have been reluctant to refuse patentability on the ground of generally inconvenient, believing it is best left to parliament to decide whether matters of ethics or social policy are to have any impact on what is patentable.

Again, she is misleading this committee. Firstly, Australian patent law does give IP Australia a clear basis to refuse to grant a patent on gene sequences because gene sequences, as we are about to learn from scientists, are not inventions but are discoveries. Patents are only about inventions. The problem is that IP Australia have for 20 years deliberately ignored the law so that now we are faced with an enormous problem and requiring the parliament to impose an express ban on this illicit practice.

Secondly, she talks about gene related inventions. Well what is she talking about? An isolated gene and the protein that it codes for is not a gene related invention. Perhaps the use of these materials in new, inventive and useful ways, such as a gene therapy or vaccine, might be, but the gene itself is not. As Lisbeth Ceriani, the breast cancer sufferer that we saw earlier said, 'It is mind boggling'.

But beyond this brief survey of WIPO's patent database is the evidence of scientists such as Professor Ian Olver, the Chief Executive Officer of the Cancer Council of Australia.

*Slide 45—Professor Ian Olver quote*

On 5 August, Professor Olver said in evidence:

In the next couple of decades the genetic sequence of, say, a cancer will be the most important aspect of it, now that we can measure multiple genes, so the pattern of your cancer's genes will tell you what type of cancer you have, what targeted treatments you should have and what the prognosis or the aggressiveness of the cancer is. The whole thing will be determined by your genetic sequence. Looking down a microscope will not be an issue anymore; it will be the genetic pattern of the changed genes.

If you are looking at economic efficiencies, the targeting of individual genetic patterns by the appropriate targeted therapies will mean that you are not wasting a treatment that cannot possibly work because it has not got the target, for example. This is where the efficiencies in cancer treatment lie. But it is not only economic efficiencies; it means the patients will not have the side effects of inappropriate treatment. Because the targets are usually a genetic change that is specific to the tumour, you are not touching the normal tissue so you will not have the same side effects as, say, chemotherapy, which kills everything that is dividing, hoping that the normal body will recover quicker than the tumour. This is what we are looking at. When I talk about 'before the floodgates open', that is the nature of the floodgate. We have the precedent of a couple of tests for breast cancer, but we are talking about the whole sequence in cancer, which is what I know about, but it is replicated in epilepsy and other diseases as well.

He also said:

The way medicine is going, I think there will be a strong incentive to try and monopolise parts of the gene.

And then he said:

We would challenge the idea that there have not been very many patents applied for on the basis of the fact that clinically we are aware that genes and gene products are going to be the basis of diagnosis and treatment of diseases like cancer increasingly over the next 10 to 20 years ...

*Slide 46—Hansard, Professor Amor, 3 August 2009, page 50*

Professor Amor from the Human Genetics Society told the committee on 3 August:

... I think you could easily end up with thousands and thousands of patents. As I said in my introduction, we can visualise it relatively easy at the moment when we just talk about the BRCA1 gene, for example. Everyone kind of knows what it is and it is just one. But that is not the future. The future is tests that will look at many different genetic factors in the one test.

*Slide 47—*

Is there a diminishing problem?

*Slide 48—Summary*

To summarise: firstly, a substantial number of patent applications are coming through the PCT still directed to 'isolated' biological materials that are identical or substantially identical to those that exist in nature. Despite the decoding and publication of the human genome in 2000, these include applications that include biological materials derived from humans. Secondly, rather than being a diminishing problem, the likelihood is that over the next 10 to 20 years they are going to be a growing problem.

*Slide 49—Invention or discovery*

My next point is that patent law is only about inventions, not discovery. All this talk about not depriving researchers of the incentive that a patent provides is mischievous and, with respect, misinformed. Since 1623 the Anglo-American patent systems, of which the Australian patent system is an example, have excluded from patentability anything other than an 'invention'. The term that was coined was 'a manner of new manufacture', a term which remains part of the Australian legal lexicon today. And even though no-one is suggesting that the word has the same meaning as it did in 1623, a central principle of patent law is that which:

*Slide 50—*

... excludes from patent protection ... laws of nature, natural phenomena and abstract ideas.

In 2006, Justices Breyer, Souter and Stevens of the US Supreme Court confirmed that:

*Slide 51—*

... this principle finds its roots in both English and American law.

Moreover, the rationale for this principle, they held:

... does not lie in any claim that “laws of nature” are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race.

But even so, they say:

... the reason for the exclusion is that sometimes too much patent protection can impede rather than “promote the Progress of Science and useful Arts,” ...

This distinction is not some academic exercise. It is of paramount importance to maintaining the right balance between the needs of society and monopolists. Indeed, it is a matter of Australian constitutional law.

*Slide 52—Australian Constitution Act s.51*

*Slide 53—*

Section 51(xviii) provides that the Commonwealth parliament has power to make laws only for ‘patents of inventions’. The word ‘invention’ is an express limitation. This parliament therefore cannot make laws about the grant of patents over things that are not inventions. And a gene and protein that is derived from nature, even if it is isolated, is not, according to the scientific evidence, something that is capable of being an invention. This limitation is also enshrined in two key international agreements.

*Slide 54—Agreement on Trade Related Aspects of Intellectual Property Rights, TRIPS, article 27.1*

So TRIPS requires that patents only be granted for ‘inventions’. This requirement is repeated in the Australia-United States Free Trade Agreement.

*Slide 55—Australia-United States Free Trade Agreement, article 17.9.1*

And while it is true that both TRIPS and the Australia-US FTA require that patents be technologically neutral, that neutrality extends only to things that are inventions. Scientist upon scientist has said, in unequivocal terms, that an isolated gene or protein that is derived from nature is not an invention.

*Slide 56—Professor Ian Frazer—The Australian, 8 August 2009, page 11*

Professor Ian Frazer in the *Australian* said:

... there is no more invention in isolating and characterising biological material that exists in our bodies, using existing research techniques, than in collecting and arranging a set of postage stamps.

*Slide 57—Sir John Sulston*

Sir John Sulston, the winner of the Nobel Prize in physiology and medicine in 2002 and who played a major role in the decoding of the human genome, said:

Genes are naturally occurring things, not inventions, and the heritage of humanity. Like a mountain or a river, the human genome is a natural phenomenon that existed, if not before us, then at least before we became aware of it.

From the point of view of scientific research, human genetic sequences are as basic as you can get in terms of biological information. There is still much to learn about the products of our genes – what they look like, when or where they are produced, and how they interact with one another. In order to translate this information into medical advances, the basic data must be freely available to everyone to interpret, change and share. The situation is too complex for a piecemeal approach, in which a single entity holds the keys to any given gene.

*Slide 58—Channel 9, ‘60 Minutes’*

Dr Graeme Suthers: “The BRCA gene is something that’s present in all of us.”

Ms Liz Hayes: “It’s a discovery. It’s not an invention.”

Dr Graeme Suthers: “It’s a discovery. Correct. You can’t patent Mt Everest; why can you patent a gene?”

And then Professor Amor, from the Human Genetic Society, said:

We are talking about the human body. It is the equivalent of saying that you can patent every single part of the human body and then what is a doctor to do when they examine a patient and they are examining all the different parts that have been patented—the heart, the lungs and the brain? It is a nonsense.

And what about Dr Jenny Leary, who said:

DNA exists in nature; it is not an invention. Its information is not lost and it is not changed by its isolation from the body.

Not to mention Dr Jillian Mitchell, from the Peter MacCallum Cancer Centre, who said:

The DNA is part of what we are. The basis of our submission is that we cannot understand how we can patent something that is part of us. Just discovering the genetic sequence is not innovative.

*Slide 59—Cover of Danish Council of Bioethics Report, ‘Patenting Human Genes and Stem Cells’*

On the point of isolation in 2004 in its report, the Danish Council of Bioethics rejected, for being unreasonable, the argument that:

... a sequence or partial sequence of a gene ceases to be part of the human body merely because an identical copy of the sequence is isolated from or produced outside of the human body.

Again, Professor Amor said:

No, to me that distinction [of isolation of a gene] is a semantic distinction.

*Slide 60—Sir John Sulston*

Sir John Sulston further said;

Promoters of gene patents argue that genes are patentable when they are “isolated and purified,” or removed from the body and placed in a form so that they can be replicated outside the human body. This argument seems absurd to me. The essence of a gene is the information it provides—the sequence. Copying it into another format makes no difference. It is like taking a hardback book written by someone else, publishing it in paperback and then claiming authorship because the binding is different.

Dr Jillian Mitchell noted:

Having looked at a number of submissions over the years dealing with why DNA patents can exist and stating that somehow when the DNA is taken out of the human body and becomes a chemical in a test tube, it is no longer human and can now be patented—it is now just a chemical that can be patented—I fail to see how once it is in a test tube it is different from the sequence it was when it was in the human body.

**CHAIR**—Dr Palombi, I am a bit conscious of time. We have been going half an hour and we would like to ask some questions.

*Slide 61—*

**Dr Palombi**—I am almost finished. In summary, the scientific evidence is overwhelming. An isolated biological material that is identical or substantially identical to one that exists in nature is not an invention.

*Slide 62—Gene tests*

*Slide 63—They might be things that qualify as possible inventions but are then inventive?*

Again, the scientific evidence is that the application of genetic materials or sequences to produce a gene test is not inventive activity but is routine and standard science.

*Slide 64—*

Professor Amor said:

The test is not rocket science. You name a gene and the gene sequence is on the internet. You can look it up. Any student could design a test. There is no terribly great skill required to do that.

*Slide 65—*

Professor Mann said:

The issue there is that, with modern genetic technology, once you know what the sequence is, an honours student would be able to design a test to look for a mutation.

And even if you do not accept this, even if you believe that there is invention in the development of a genetic test, the fact is, under both TRIPS and the US FTA, it is permissible for countries to legislate to:

*Slides 66 and 67—TRIPS, articles 27.3(a) and 17.9.1(b)*

... exclude from patentability: (a) diagnostic ... methods for the treatment of humans or animals.

And there are good reasons to consider doing this. Firstly, the evidence from Peter MacCallum—Dr Jillian Mitchell and Professor Bowtell, pages 114-115—and the Murdoch—Dr Desiree Du Sart, in camera—confirms that that genetic tests patents are seriously hampering medical and scientific research in Australia. Secondly, as stated by Professor Frazer, ‘Claiming a monopoly on the use of a particular gene sequence in an already existing diagnostic test method can lead to restricted public access to vital diagnostic services.’ Thirdly, the evidence from Cancer Voices, Ms Sally Crossing, and from the Breast Cancer Action Group, Ms Janet Green, of the need to maximise public access to genetic testing in concert with, ‘highly qualified clinical geneticists and genetic counsellors’. Fourthly, there was evidence from Ms Heather Drum of the need to ensure that data voluntarily provided to research institutions by patients remains available for use in further research into cancer.

*Slide 68—Would a ban on isolated genes and proteins interfere with scientific progress?*

*Slide 69—*

As Professor Ian Frazer has argued:

The patent system should protect inventive medicines developed from research using data on gene sequences. But a gene sequence used to develop the invention should not qualify the gene’s sequencer to receive benefits.

*Slide 70—Is compulsory licensing or Crown use an effective remedy?*

*Slide 71—*

The evidence suggests not. There have only been three compulsory licence applications in the 106 year history of the Australian patent system. According to IP Australia, letter of 4 June 2009, there have been no compulsory licences issued. There is no evidence of the exercise of Crown use.

*Slide 72—What should the committee do?*

*Slide 73—*

First, that the Patents Act 1990 be amended to (a) ban the patenting of biological materials that are identical or substantially identical to those that exist in nature, and (b) increase the inventive step threshold so that uses of such materials in applications that are routine and standard, such as in diagnostics, will no longer be patentable.

*Slide 74—*

Second, that there be a comprehensive multidisciplinary review of the workings of the patent system.

*Slide 75—*

Third, that there be the Office of the Regulator of Intellectual Property established to monitor, audit and ensure that IP Australia and patent attorneys and lawyers act lawfully.

*Slide 76—Should there be patents on isolated biological materials?*

*Slide 77—US President Clinton and British Prime Minister Blair*

*Slide 78—Channel 9, '60 Minutes'*

Ms Liz Hayes: "And it's the privatisation of public health that alarms scientists like Graeme Suthers. This corporate gold rush that's taking control of us and our bodies."

Dr Graeme Suthers: "If we fail to address it soon, then we will face the situation where there will be controlled access to your genes for diagnosis and health care and indeed for the rest of Australia."

Ms Liz Hayes: "In every part of my body?"

Dr Graeme Suthers: "In every part of your body. So that will mean that other companies control your access to your genes."

*Slide 79—Closing summary*

**Senator HEFFERNAN**—This is a question of when does a discovery cease to be a discovery and become an invention? Do you think that, given the overwhelming evidence from the clinically driven, vocationally guided and humanely inspired side of this debate, which is lining up against, from what I can see, a bunch of lawyers, bankers and people who are financially driven, it is time for the Commonwealth to step up to the plate and fund a test case and we can just sort this out in the courts?

**Dr Palombi**—We definitely need to have this issue resolved. There is no question about that. If a test case were to be brought I think that it would be completely appropriate for the Commonwealth to fund the litigation to resolve what is going to happen to the patents that have already been granted. Whatever this committee recommends and whatever the parliament decides from here on in will be fine for the future, but we still have to resolve what happens in respect of patents that have already been granted. No Australian patent is guaranteed validity. Section 20 of the Patents Act expressly states that. We are probably going to need a court decision to make it clear as to whether or not these patents are valid or whether the claims over isolated biological materials are valid.

**Senator HEFFERNAN**—Bear in mind the danger of the courts as opposed to the parliament is that the driver in the courts, as people will discover if they go to court often enough, is actually the law and not necessarily the truth. So that is the risk there. It seems to me that a lot of this relates to a very old law that really has not kept pace with technology and the plotting of the human genome and it has allowed patents that are so broad that they absolutely lock out other people's access. Part of the defence—usually a lazy and blind defence—is that somehow the person putting up the opposition is biased. From your interpretation of what has happened, is it

fair to say that people like Ian Frazer, who made those comments about how important this committee hearing is and how important this is to the future wellbeing of mankind, is biased? This is against the background of IP Australia's saying that this is a diminishing issue and we are not doing this anymore. I believe you gave evidence this morning of a 2009 patent—so it is up to date and they are still on the pace and here there are pages and pages and it is so broad that you could drive a truck over it—so would you say that Ian Frazer is biased in saying what he did?

**Dr Palombi**—No, Senator, I would not say that Ian Frazer is biased. I would say what you—

**Senator HEFFERNAN**—Would you say that he is concerned about the wellbeing of mankind?

**Dr Palombi**—Absolutely I would.

**Senator HEFFERNAN**—This may be putting—as I often do—words into people's mouths—

**CHAIR**—I was just thinking that.

**Senator HEFFERNAN**—Isn't one of the difficulties now that, because this is turning into an apparent river of gold, once you make these patents tradable they will be acquired for greed? You have given some good examples. For instance, there is the company in Melbourne that has the licence in Australia despite all the hard work others had done. As your paper points out today, a lot of research went into the breast cancer genes and it just happened that the person who jumped the highest over the pack at the last minute got the patent despite tens of years of man hours of research by many others. Is it possible, under what we are now presented with, that these sorts of patents could become just like a share ticket and to be seen just as a financial deal where you could live off the dividend? You could acquire gene technology as Australia goes broke and anyone from a money-launderer to a financial trader or whoever could actually buy the patent with no regard to the clinical wellbeing and guidance for people, especially people in the familial cancer area? Isn't it possible that these just become another financial instrument traded for greed rather than wellbeing?

**Dr Palombi**—The answer is yes, and they have already been that for the last 20 years. I have not gone into the details of hepatitis C but that was an appalling patent granted by IP Australia back in 1992. I noticed that on 20 August they tried to be very clever with you and suggest that some of the claims that you are referring to—the claims, for example, over vaccines—were no longer applicable.

That is true. Chiron was very clever to amend its patent claims in 1997. But it only did that because my client, Murex, had sued to invalidate those claims. IP Australia granted claims that no other patent office in the world had granted—namely, patents over things such as purified hepatitis C virus. Those claims that were amended in 1997, by the way, were exactly the same as the patent claims that were granted by the European Patent Office. What is generally not known is that those claims were then subject to challenge in Europe. I was part of the team that led that challenge. The European Patent Office eventually reviewed those claims in 2000 and decided that the claims were in fact invalid. They virtually invalidated that patent. It took seven years to do it in Europe, but they did it. IP Australia failed to react. IP Australia did nothing. IP Australia

did not even seek to re-examine the Australian hepatitis C patent once the European Patent Office invalidated the very claims that IP Australia had approved.

**CHAIR**—So what you are saying is that the patent that was amended in 1997 still exists despite the fact that it has been amended in Europe?

**Dr Palombi**—It has now expired.

**CHAIR**—Sorry. But up until it expired—

**Dr Palombi**—It expired last year. But in Europe, the very same patent claims were found to be invalid. In 2000, those claims were invalidated. They could have been invalidated here, but IP Australia did not act.

**CHAIR**—What has been the consequence of somebody holding the patent over hepatitis C?

**Dr Palombi**—It was enormous. It cost this country billions.

**CHAIR**—What I am trying to do is get on the record what you think the impact that it had in terms of research and any consequences in terms of health outcomes.

**Dr Palombi**—The first thing is that it cost enormous amounts of money, because the price that Chiron and its licensees placed on hepatitis C testing was way above the norm. When their tests first hit the market, it was \$14 a test. The normal cost was \$1.50. That was the first thing. The second thing is that they refused point blank to make tests that were relevant to Australia. The NHMRC hepatitis C taskforce reported to the government back in November 1993 that there was a desperate need for a secondary test that was different to the Chiron tests because of the degree of false positives that were coming through. This was critical in relation to a population that was low risk in terms of contracting hepatitis C, such as the blood donor pool. The result was that there was a terrible concern that blood donors were going to be incorrectly diagnosed as being positive with hepatitis C and thereby excluded from the blood donor pool system. There was a critical need for a secondary line test. That is what the NHMCR told the government. The health departments did not act. It took my client, which sued Chiron in the Federal Court. That is the only reason why ultimately a secondary test became available in Australia and remained legally available in Australia.

**CHAIR**—So in other words we had a financial and a negative health outcome through somebody owning that gene patent.

**Dr Palombi**—Absolutely.

**Senator WILLIAMS**—Dr Palombi, in simple terms, have the current patent laws in Australia restricted research into health and held back solutions to sicknesses and diseases? Have our current patent laws restricted our research, in your opinion?

**Dr Palombi**—As a lawyer who has been involved in this area now for more than 15 years and who has spoken to countless scientists around the world, I can tell you categorically that these sorts of patents are interfering with the ability of scientists to undertake research. The claims are

directed to the actual biological materials. We are not talking about claims to inventions; we are not talking about the use of these materials in new, inventive ways. If we were, perhaps we would not be having this discussion. These patents are over the materials—the genes; the information that those genes contain. Those patents impose restrictions. To a degree, we have been given a free kick, because most scientists have sort of ignored them. But, as we saw with the BRCA1 situation, the moment someone does decide to enforce those patents, all hell breaks loose.

**Senator WILLIAMS**—The point I make is: as legislators, and as members of this committee, surely we must look at what is in the best interests of human health and of the people. Are you saying that, under our current laws of patents, cures for diseases et cetera are being held back because of our current patent laws?

**Dr Palombi**—I am saying that—the way the laws have been interpreted, certainly, and the way they have been practised by IP Australia and by certain people—that is most definitely the case.

**Senator WILLIAMS**—Thanks, Dr Palombi.

**Senator HEFFERNAN**—So, isn't the flaw in the precedents? Law is about precedent. Haven't the precedents that have been set in gene law been flawed, and everything else has flowed from those precedents? You will not be surprised to know that the people from IP Australia have been gasping, as you have been giving your evidence, and waving their arms about and looking around the room in horror. We will come to that in due course. But it has been almost as if somehow you are heretical in what you have been saying. But it seems to me, Madam Chair, that it is patently obvious that this is a piece of interpretation of law that has slipped under the radar, and it really does come down to the interpretation of what is an invention and what is a discovery.

No sensible person wants to block the patenting of an invention coming out of a discovery. But I have not met anyone yet, other than the bankers and lawyers, who thinks that maybe there is a case for locking up our access to the genes so that no-one else can get the patent. They will say, 'Well, it is not clear.' And, as you say, people are turning a blind eye to that—except when they get into financial stress like gene technologies Australia did, and suddenly go from 'This is a gift to the people of Australia', or to Westmead, to Peter MacCallum and other places—Peter MacCallum gave us evidence in Melbourne where it held up research for two years—to, suddenly, 'Pay up or get out—surrender all your testing to us.' And, obviously, in places like Canada, as you have pointed out, the cost of this to public health will be a river of gold, where they put up the price 250 per cent just like that.

**Dr Palombi**—If I can just answer your—

**CHAIR**—There was a question there!

**Senator HEFFERNAN**—There was a question.

**Dr Palombi**—Can I answer it this way: the law has been very clear for 400 years. You only get patents for inventions. The problem is the way the law has been interpreted and the way it has been enacted.

We have, supposedly, a check and balance within the patent system in the form of people being able to challenge patents and go before the courts. The problem is that in this instance that check has failed. It has failed miserably. Not only that, IP Australia did not take up the position of actually testing the law in the courts. When we brought the hepatitis C action, IP Australia was, in fact, served with the proceedings. It has an obligation—or a right, I should say—to participate in the action. It did not take up that opportunity. It actually did not participate in those proceedings, even though, clearly, it was in the public interest that it do so. It could have refused the patent and forced the patentee to take it up to the courts to get a decision and clarification on the law. It did not do any of those things. It simply took the line of least resistance, which was to interpret the law in such a way that, I say, it was a perversion of the law.

The result is: we have had an explosion of patents in this country. And the patent offices are now paying the price because there are only so many patent examiners; there is only so much time that a patent examiner can sit and read a complex patent. There is one patent that I have seen—and I have given it to Senator Heffernan—which is over 500 pages long. Most of it is genetic sequence; I will give them that. But these are enormous documents. So, in a sense, they have created their own problems.

But the real problem is that we have no efficient way of testing the validity of these patents. It costs millions of dollars, it costs a lot of time, and you need to be a very sophisticated litigant to actually test the validity of these patents. You need the cooperation of scientists. How is that going to happen? It is also very difficult for non-profit, charitable organisations, such as the Cancer Council, to run the risk of litigation. Under the rules in Australia, if you sue and you lose you have to pay the costs, even if lawyers were to do that case for free. I offered to do that, to test the validity of BRCA1 and BRCA2, but they refused to accept that because of the possibility that, if they lost, they would have to bear the costs of the legal proceedings. So the whole system is stacked against anyone other than the patentee.

**CHAIR**—You touched briefly on what happens if we ban the gene patenting in Australia, if we came out and said, ‘Okay, no more gene patenting,’ and we actually put that in the law. You were there for a lot of the evidence and IP Australia argued that we do not patent genes in Australia, but we have had a lot of evidence to suggest that we are. So if we came out and banned it in Australia, a couple of our witnesses have said, ‘If we ban it in Australia, that would mean that companies would not bring their medicines that result from gene patents to Australia because they would not be able to enforce their IP.’ Can you take us through what in your opinion would happen if we banned it in Australia? What happens to the existing patents and what happens into the future if, as other witnesses have suggested, we do not get access to that international IP?

**Dr Palombi**—That is very good question. As you will have noticed, these patents have many different types of claims. They are complex documents. One of those categories of claims would be the claims over the isolated biological materials. Then there will be all sorts of other claims—claims to the use of those materials and diagnostics, then claims to the use of those materials in various other medical technologies. If you were to impose a ban on the isolated biological

materials, it would not invalidate the entire patent; it would simply invalidate the claims to those types of materials. So you still leave it completely open for people to come along and develop new and inventive ways of using those materials. The question that we have raised in the course of this inquiry is whether or not that is actually inventive anymore in terms of diagnostic tests. The evidence indicates, at least from the scientists, that it is not, that merely applying a gene in a diagnostic test today is a fairly routine scientific step. But clearly if you can use that material to develop a gene therapy or a vaccine then I do not see that we have a problem. I do not see that that is an issue, and that has never been the issue for this inquiry.

The reason why the opponents have raised it in this way is in a sense to muddy the waters. They want you to be concerned that somehow the sky is going to fall in on the biotechnology industry or on medical and scientific progress if you make this incremental step. I say that actually it will do the exact opposite. By banning these sorts of patents on those very limited types of claims, these claims of these materials, you are actually opening up the door to further innovation because you are maximising the ability of scientists to freely use these materials—which are part of nature anyway—so that they can make an invention. That is what we want. We want them to make these sorts of massive leaps in technology, not grant patents over elementary processes and non-inventive applications such as diagnostics.

**CHAIR**—That brings me to the next question. We have had a number of people raise with us that we should clarify this issue around research exemptions. People are arguing that if we clarified that, because from the evidence it is quite clear that there is mass confusion over research exemptions, would that deal with some of the issues you have just raised? In other words, you could then use the information that is patented for research. Judging by your facial expression, you obviously do not think that is going to solve the issue. Could you explain why?

**Dr Palombi**—I have done a submission to the inquiry on experimental use, and my comments are that the test that is proposed by IP Australia is completely unworkable. They use a sole purpose test. If the sole purpose of the experimentation is experimentation, non-commercial, then it is exempted. How many universities, how many people, these days actually do experimentation solely for the sake of experimenting? They don't. Everything is applied, everything is got a commercial link. It is so easy to get around that exemption that it is hardly worth the trouble of even making it legislation.

There are enormous problems with this whole question of where you draw the line between research and commercialisation. A patent that is granted on an invention gives the patentee the exclusive right to do whatever they like with that invention. If we allow patents to be granted on things that are not inventions, that is when we hit trouble, because then we start interfering with experimental work. That is what has been happening. As the so-called 'patentability subject matter pie' has expanded we have started to hit these sorts of problems.

We never had these problems 30 years ago. We knew where the dividing line was. In terms of research, I suppose it was a bit easier 30 years ago because universities truly were non-profit, non-commercial entities. But today they are not. That is the reality. So when you talk about a research exemption you are creating enormous problems.

I think that the easiest thing to do, frankly, is to make sure that we have a very strict dividing line between what is an invention and what is not and make sure that we keep to that. And in

terms of whether or not we grant a specific exemption for research, it is going to be problematic but I think that the sole-purpose test, as suggested by IP Australia, is unworkable.

**Senator MOORE**—You have answered many of the questions I was going to ask, but we heard evidence in Melbourne about ongoing reviews that are happening within the IP Australia at the moment. In terms of process, Professor Christie, has got one going, which is public and looking at the whole thing that we are looking at. The recommendation in his submission was that we have a review operational so why not let that one do its course and then come in on top of that rather than coming up with recommendations that would cut across what they are doing. What is your response to that, particularly in view that those reviews are highly advertised but, as he was saying, not many people come and give evidence? When you gave evidence this morning you said that there is not a multidisciplinary approach. There is nothing in that review that I can see in the terms of a reference that precludes a multidisciplinary approach. It just may be that multidisciplinary people do not take part in it. Can you have a go at that?

**Dr Palombi**—Sure, Senator. I think that you have to look at the way policy has been developed in terms of intellectual property in this country for the last 30 or 40 years. We have had many reviews into the patent system but essentially they had been dominated by patent lawyers.

**Senator MOORE**—Yes.

**Dr Palombi**—Consequently they tend to view things from a single perspective. Professor Christie is a notable patent academic and I have the highest regard for him, but he has a particular view of patentable subject matter that I happen to disagree with. He published a paper in 2002 where he said that even the formula  $E=mc^2$  could be patentable subject matter. I draw the line and say no: that is a mental abstraction; it is not an invention. So when you have people of that view chairing inquiries into what is going to be patentable subject matter, it gives you an indication, if I might say so, Senator, of what you can expect. I actually have no faith that the Advisory Council of Intellectual Property, which is completely stacked with IP lawyers and the patent bureaucracy, is capable of undertaking a fair review of what the law should be. And when I say 'multidisciplinary', we need engineers, scientists and doctors and researchers. Now perhaps the reason we have not had their involvement is because they have, in a sense, been excluded by the way those policy bodies have been put together.

**Senator MOORE**—So it is systemic exclusion rather than something that is written down?

**Dr Palombi**—Absolutely. I think that is correct.

**Senator MOORE**—The other point that has come out consistently—and I think that you have touched on it in previous answers—is that we have heard evidence that one of the strengths of the patent system is that there are not individual preclusions, that it is a general patent law that people then have to interpret and look at in that way. I hope I am not verballing the evidence, but it is to the extent that, if we start precluding individual things, we then actually end up with a way more complex system. If we have a clear patent law so that everything is looked at in the same way, which it should be—whether it is a novel invention or not—that would cover everything and you would not have start precluding things. I think that is a fair enough summary. On that basis, what is your response?

**Dr Palombi**—If is about something that meets the invention threshold—that is, it is patentable subject matter—then today, under TRIPS and under the US free trade agreement, we are not allowed to discriminate. So we cannot exclude, for instance, medicines from patentability. In the past, we used to do that. In Europe until 1978 you could not get not get a patent on a medicine. You could get a patent on the process but not on the medicine itself. So the rules that exist today mean we cannot discriminate on technological grounds between things that care inventions. But the thing we are discussing here is the threshold of a discovery invention. When you talk about excluding, you are not really excluding anything; you are actually clarifying the law in this instance. What we are seeking here is for the committee and for the parliament to simply say that, under Australian law, the isolated gene and the protein that is identical or substantially identical to that which exists in nature in accordance with all the scientific evidence is not an invention; it is part of the discovery process. So you are not really interfering with that non-discriminatory clause that exist in both TRIPS and the US free trade agreement.

**Senator MOORE**—So it is a clarification rather than an exclusion?

**Dr Palombi**—It is exactly a clarification.

**Senator HEFFERNAN**—I think it would be fair to say that the evidence we received, especially in Melbourne, was that the only way they get around this dilemma is by ignoring the law.

**Dr Palombi**—That is right.

**Senator HEFFERNAN**—I recently spent three hours out at Westmead—from the laboratory to the ward—and I saw a great new leap in technology with melanoma. They did say that the melanoma gene had not been patented, so other people, like North Sydney, have access to that gene—which makes the point. And I saw patients being treated with their last chance. So why is it that lawyers et cetera come here and say they are not patenting the gene when claim 1 is that BRCA2 is an isolated nucleic acid coding for polypeptide.

**Dr Palombi**—It is because they invented this thing called ‘isolation’ as a point of distinction. It is a legal furphy.

**Senator HEFFERNAN**—But we have received evidence even from the prosecutors to say that it might have been an invention the first time they did it. Then they said they were not doing that any more, but you have come up with one from 2009 where they are still calling the isolated gene a patent.

**Dr Palombi**—The process of isolating a gene was hardly even invented when it was developed. Back in 1973, Stanley Cohen and Herbert Boyer really did the big work. They figured out that you can cut and splice a bit of gene from a foreign material and put into a bacteria or yeast cell and it would actually replicate the protein that the gene codes for. That was the big breakthrough. After that it was all fairly rudimentary.

**Senator HEFFERNAN**—As we have heard from everyone. Westmead Hospital has a great set-up. They need money, by the way. All their researchers are on time contracts because they do

not have a budget to pay for all this research. My God, talk about a great institution that is being ignored! The title of the haemophilia patent is 'Methods and compositions for use in gene therapy for treatment of haemophilia'. You could interpret that as saying this is a patent in anticipation.

**Dr Palombi**—Absolutely. There is no therapy for haemophilia. The patent was granted. It is all about the treatment for haemophilia—even human haemophilia. It was simply based on some experiments that were conducted with some animals. At the time that that patent was granted, I think scientific progress had shown that their theories about its application from animals to humans had failed and were not working. So we granted a patent that is completely useless.

**Senator HEFFERNAN**—Shouldn't a patent like that be chucked out?

**Dr Palombi**—It really is irrelevant.

**Senator HEFFERNAN**—Isn't this proof of what we are talking about? Sure, you can ignore the law, but if you were where Gene Technologies Australia were, these people could enforce this and tell you to go to hell.

**Dr Palombi**—The problem is this: it is not so much a question of whether they are going to enforce it or not—it remains on the register and, therefore, it is like a property right. We do not know whether, in the 20-year period while it remains on the register, it will be activated. The point is that if researchers take the view that they cannot ignore these things, they are going to have to sit there diligently and waste a lot of time and money searching all of these patent and finding out whether they can navigate their way through this mess of patents. That is the big problem. Whether these patents are worth anything is anyone's guess. The likelihood is that they will not be worth very much until somebody actually achieves something useful with them—and then of course they will come out and say what it is worth.

**Senator HEFFERNAN**—In the case of the ageing gene, once again it is an isolated nucleic acid. I think that mob in Melbourne has got it—I do not have time to look it up. Obviously there is an anti-ageing gene. Isn't this locking up access to work on that?

**Dr Palombi**—A patent that claims a gene of that kind is going to interfere with the freedom of researchers to simply do the work that they have got to do. If that act legally, if they act within the law, they would have to seek the permission of the patent owner to make those materials.

**Senator HEFFERNAN**—I rang Gene Technologies Australia before the government, in its great wisdom, decided to have this inquiry. They said, 'We're not worried about you.' But they did say that Australia got a good deal out of their deal with Myriad in America because they had discovered Myriad breaching one of their patents and they came to a legal settlement—and bear in mind that we are talking about human health here—so that the testing could be done in Australia and not be returned to America, as Japan has to do. In other words, it becomes a gold bullion bar for them if they execute that—which they tried to do last July. Doesn't that say it all—that this is just about money? No, that might be a bit unfair. For these people it is their vocation and they are dedicated to it. They are not in it for the money. They are at Westmead or Peter MacCallum or wherever—there are nine or 10 of these laboratories—every day. During every waking hour they are trying earnestly to better human health—with very little regard for

how much they get paid and all the rest of it. You only have to walk through Westmead Hospital to know what wonderful work they do. Isn't it a contest between people who are driven between vocation and clinical outcomes and those who see it as just cold hard financial exploitation of knowledge?

**Dr Palombi**—A patent gives people the exclusive right to do what they like with the patient. If we grant patents over biological materials, we are giving people the power to behave in whichever way they wish. If they wish to act in a way which is against the best interests of this country, they can and there is very little that can be done about it. There is no evidence that compulsory licensing or Crown use provisions—which would be useful in ameliorating some of the worst excesses of the patent system in this instance—have never been effectively used. So we are unfortunately in a situation where, as with the BRCA1, we have an Australian company that, had it acted within its rights, could have actually sought injunctions to close down all of the public testing in this country for breast and ovarian cancer.

**Senator HEFFERNAN**—That is exactly right. The US Supreme Court has repeatedly held that natural phenomena like genes and proteins are free to all men and reserved exclusively for none. Why are we ignoring that?

**Dr Palombi**—There are two issues. There is the gene itself and there is the use of the gene in a non-inventive way. Basically the use of the gene in a diagnostic test is no longer inventive. That is one issue. Separately to that is what the US Supreme Court said—and you have just quoted it: we cannot grant patents over things that are natural phenomena. But we have been doing that, and that has limited the ability of Australian researchers to do research on the protein material.

**Senator HEFFERNAN**—Sadly, we have got to finish now.

**CHAIR**—Thank you very much, Dr Palombi. That was extremely useful evidence. We now adjourn this inquiry and we will be reporting on 26 November. Thank you to the secretariat and thank you to Hansard.

**Committee adjourned at 10.10 am**