DR LUIGI PALOMBI

THE AUSTRALIAN NATIONAL UNIVERSITY

SENATE INQUIRY INTO GENE PATENTS

MONDAY, SEPTEMBER 14, 2009

[Slide 1] – Name, Organisation

Senators,

Before I begin I would like to thank the Committee for extending me this indulgence. I know that you are all very busy with other duties and responsibilities. I appreciate very much the time which you have managed to find this morning so that I may give my evidence.

I also appreciate that we only have an hour so I will try to be succinct and leave some time for questions.

[Slide 2] – So What's This Inquiry About?

[Slide 3] – NBC TODAY SHOW – Lisbeth Ceriani

[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 from some of the

questions that have been taken on notice that there has been some preoccupation with 'human' genes; perhaps, even an over emphasis, if I may be so bold, and 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 August 20, 2009 para 15-18

In its opening statement of August 20, 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.

Now, in reply I want to make these 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.

Indeed, when I examined IP Australia's database in February this year I found that there were [Slide 10] 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 all to believe, evidence from other sources suggests that the number of gene patents is likely to grow in the future.

Over the weekend I searched the Patent Application database of the World Intellectual Property Organization (WIPO).

[Slide 11] Photo of WIPO, Geneva, Switzerland

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's 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.

To help me find out what’s happening with patents over ‘isolated’ things [Slide 15] I inserted that word in the field called ‘claims’. In other words, any patent application which defines the invention as something that is ‘isolated’ will be included.

[Slide 16]

As you’ll see, this shows that 14,710 patent applications contains 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 don’t think so.

Just to give you a flavour for what these ‘inventions’ are – and by using this word to describe them, I don’t mean to suggest that I agree that they are, in fact, ‘inventions’. I merely use the word to save time.

Let me give you two examples. This is all time permits.

[Slide 18] PCT/US2009/030998 – COMPOSITIONS AND METHODS RELATED TO A HUMAN CD19-SPECIFIC CHIMERIC ANTIGEN RECEPTOR (H-CAR) [Cover Page]

[Slide 19] Slide 18 (Magnified)

You see that the patent applicant is the University of Texas.

You will also see that the priority date of the patent application is [Slide 20] 14 January 2008, that is, about 8 years after the human genome was decoded.

You will also see that Australia is designated as a country under the PCT, so eventually this application may be examined by IP Australia.

[Slide 21] Claims

These are 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, the 'invention'.

[Slide 22] – Claims (Magnified, with arrow)

The primary claim (claim 1) defines the invention as follows:

"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 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'll see the letters 'IL' in the application number.

[Slide 27] The priority date is 27 December 2007, that is, about 7 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 simply 'Novel Protein'. Sounds interesting? Well, let's see what it really is!

[Slide 30] Specification Page 1

Note that the field of the invention also 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 cttctgtct atcctggtt tctggtctg tgcgttgtg ggtagcagc attggcgta ttacgccgg agggagcag gctgagcga ggctccaga aggtgcgca atagccgga gaggaaagg gcgatgctg tcacctagc cccctccct gagactcca ttcagccca gaaaaagga gctgctttc tcccccatc taccctagg agaaaa (SEQ. ID. NO: 1)

MPGHSRLLSILVSGLCVVGSSIGVLRRREQAERGSRRCAIAGEE RAMLSP SPLPETPFSPEKGAAFSPIYPRRK (SEQ. ID. N0:2)”

You will notice that the patent application uses [Slide 33] 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 to naturally occurring DNA.

The truth is that the protein is not ‘new’ at all. It already existed. All the inventors did was ‘discovered’ and ‘isolated’ 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 see here at page 13 of the Specification that the inventors admit this:

[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 the 21 claims.

[Slide 38] Slide 37 (Magnified)

You will see 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.

Later on [Slide 40] at claim 9 you will see that the invention also includes the DNA in an 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.

Now 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 this:

[Slide 41] IP Australia: March 19 (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 this:

[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.

First, 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 treatment or vaccine, might be, but the gene itself! As Lisbeth Ceriani, the breast cancer sufferer that we saw at the beginning said "it's mind boggling".

But beyond this brief survey of WIPO's patent database is the evidence of scientists such as Prof Ian Olver, the Chief Executive

Officer of the Cancer Council of Australia.

[Slide 45] Prof Ian Olver Quote

On August 5, Prof Olver said in evidence that:

“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.” (page 8)

“The way medicine is going, I think there will be a strong incentive to try and monopolise parts of the gene.” (page 10)

“… 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 … ” (page 28)

[Slide 46] Prof Amor

Then there is Prof Richard Amor from the Human Genetics Society. He told the Committee on August 3 that:

"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." (page 50).

[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 includes 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:

[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. … ‘[T]o 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] … 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] s.51 Australian Constitution Act

[Slide 53]

Section 51 sub-section 18 provides that the Commonwealth Parliament has power to make laws for ‘patents of invention’.

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’.

The limitation is also contained in two key international agreements:

[Slide 54] art 27.1 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

So TRIPS requires that patents only be granted for ‘inventions’.

This requirement is repeated in the US and Australian Free Trade Agreement:

[Slide 55] art 17.9.1 US-AU Free Trade Agreement

And while it is true that both TRIPS and the US-AU FTA requires 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] Prof Ian Frazer – The Australian, Aug 8, 2009 page 11

Prof Ian Frazer said:

"… [t]here 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, winner of the Nobel Prize in Physiology or Medicine in 2002 and who played a major role in decoding the human genome says this:

"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] Dr Graeme Suthers (interview on Sixty Minutes, 2002)

An then there is Prof Amor who 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." (page 51)

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 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.” (page 105)

[Slide 59] Cover of Danish Council or 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.”

Or Prof Amor:

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

[Slide 60] Sir John Sulston

Or Sir John Sulston:

“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.”

Or Dr Jillian Mitchell:

“Having looked at a number of submissions over the years dealing

with why DNA patents can exist and stating that somehow when the DNA is taken out of the human body and becomes a chemical in a test tube, it is no longer human and can now patented—it is now just a chemical that can be patented—I fail to see how once it is in a test tube it is different from the sequence it was when it was in the human body." (page 105)

[Slide 61]

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 THEY 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.

Prof Amor said: [Slide 64]

"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."

Prof Mann said [Slide 65]:

"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." (page 11)

And even if you don't 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 Free Trade Agreement, it is permissible for countries to legislate to:

[Slide 66 and 67] – Art 27.3(a) TRIPS and art 17.9.2(b)

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

And there are good reasons to consider doing this.

First, the evidence from the Peter McCallum (Dr Jillian Mitchell and Prof Bowtell pages 114-115) and the Murdoch (Dr Desiree Du Sart – in camera) confirms that genetic tests patents are seriously hampering medical and scientific research in Australia;

Second, as stated by Prof Ian Frazer: "[C]laiming 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."

Third, the evidence from Cancer Voices (Ms Sally Crossing) and 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".

Fourth, the 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. As she said:

"I suppose my belief is that if you have a patent you are creating a monopoly, and it may shut down those researchers' abilities to use the tissue we have already donated to Peter Mac. Where would it go? Who has got that now?"

[Slide 68] Would a ban on isolated genes and proteins interfere with scientific progress?

In a word: No. A ban on the patenting of isolated biological

materials (that are identical or substantially identical to those that exist in nature) will not prevent the grant of patents with respect to novel, inventive and workable inventions that make use of those materials.

Therefore a gene therapy to treat cancer or a vaccine that immunises against a form of cancer will not be excluded from patentability.

As Prof Ian Frazer has argued [Slide 69]:

"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?

The evidence suggests not. [Slide 71]

There have only been 3 compulsory license 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 licenses 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 multi-disciplinary review of the workings of the patent system.

[Slide 75] Third, that there be the Office of the Regulator of Intellectual Property be established to monitor, audit and ensure that IP Australia and patent attorneys and lawyers act lawfully.

[Slide 76] It is to be remembered that the Australian Law Reform Commission undertook a review of gene patents and patent law between 2002 and 2004. Unfortunately the ALRC did not recommend such a ban. The consequences was that in July 2008 a second attempt was made by Genetic Technologies Limited to enforce its patent rights over BRCA 1 and BRCA 2 genes and genetic testing.

Should this Committee take a similar approach as that taken by the ALRC, it will be only a matter of time before another attempt is made, perhaps not by Genetic Technologies but by another patentee, to enforce their patent rights over a gene or genes.

In closing, it is worth repeating the words of Prof Ian Frazer:

> “Five years ago the Australian Law Reform Commission completed a seemingly exhaustive review of gene patenting in Australia. Nowhere in its report did it make the simple point that gene patents should no longer be granted because sequencing genes amounts to tailoring pre-existing technology to discover something in our bodies.
>
> The report cites academics as arguing that "the cloning and sequencing of a gene is unlikely to amount to an inventive step". It then recommends that patent examiners receive additional training and examination guidelines be developed for biotechnological inventions.
>
> But how much education do you need to learn that patenting genes is fundamentally invalid? It would have been easier for the report to simply say genes are not inventions and they should not

be patented. Law reform, apparently, is not that simple.

Hopefully, the Senate inquiry into gene patents, which began this week, will be much more direct in its recommendations."

[Slide 76] Should there be patents on isolated biological materials?

[Slide 77] President Clinton & British PM Blair

[Slide 78] Graeme Suthers Sixty Minutes 2002

[Slide 78] Summary

Dr Luigi Palombi
Centre for the Governance of Knowledge & Development
The Regulatory Institutions Network
The Australian National University

So what's this Gene Patent Inquiry about?


BC
TODAY

SENATE COMMUNITY AFFAIRS COMMITTEE

INQUIRY INTO GENE PATENTS

Terms of Reference

The Senate has referred the following matter to the Community Affairs Committee for inquiry and report by the last sitting day of 2009:

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

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

  (i) the provision and costs of healthcare,

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

  (iii) the progress in medical research, and

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

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

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

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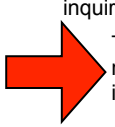

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Tip or end of the iceberg

15. We have also heard varying views about whether we are at the tip or end of the iceberg.

16. IP Australia's data shows the number of patents claiming isolated human nucleic acid molecules steadily declining since the publication of the human genome project. We expect only a small probability of additional such patents. These may arise where the published sequence has a fundamentally significant error or novel and inventive variants of a sequence of clinical or therapeutic significance.

17. At present there are 202[1] Australian patents claiming an isolated human nucleic acid molecule in force. Patents granted in other countries are not enforceable in Australia unless also patented in Australia.

18. Conversely we are seeing a rise in patents claiming downstream uses of isolated human nucleic acid molecules. This indicates to us that basic research and innovation are not being stifled by patents.

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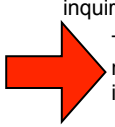
INQUIRY INTO GENE PATENTS

Terms of Reference

The Senate has referred the following matter to the Community Affairs Committee for inquiry and report by the last sitting day of 2009:



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

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	Application number	Title	Applicant(s)	Filing date	Application status	Earliest priority date	PCT number	First IPC mark
4801	2004237922	Secreted and transmembrane polypeptides and nucleic acids encoding the same	Genentech, Inc.	2004-12-14	SEALED	1998-12-16		C12N15/12
4802	2004237923	Secreted and transmembrane polypeptides and nucleic acids encoding the same	Genentech, Inc.	2004-12-14	SEALED	1998-12-16		C12N15/12
4803	2004299829	Corn plant MON88017 and compositions and methods for detection thereof	Monsanto Technology LLC	2004-12-14	SEALED	2003-12-15	PCT/US2004/041723	A01H5/10
4804	2004240157	Caspase-8 interacting proteins	Yeda Research & Development Co. Ltd	2004-12-15	SEALED	1998-12-24		C07K14/47
4805	2004240199	Conserved Neisserial antigens	Novartis Vaccines and Diagnostics S.r.l.	2004-12-17	SEALED	1999-04-30		C12N15/31

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AND	Int. Class	=	
AND	Inventor Name	=	
AND	National Phase Country	=	
AND	Description	=	
AND	Claims	=	

Search

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Results of searching in PCT for:
(CL/isolated): 14710 records
Showing records 1 to 25 of 14710 :

[Search Summary]

	Title	Pub. Date	Int. Class	App. Num	Applicant
1.	(WO 2009/111706) POLYPEPTIDES HAVING BETA-GLUCOSIDASE ACTIVITY AND POLYNUCLEOTIDES ENCODING SAME	11.09.2009	C12N 9/42	PCT/US2009/036341	NOVOZYMES A/S

The present invention relates to isolated polypeptides having beta-glucosidase activity and isolated polynucleotides encoding the polypeptides. The invention also relates to nucleic acid constructs, vectors, and host cells comprising the polynucleotides as well as methods of producing and using the polypeptides.

2.	(WO 2009/111692) POLYPEPTIDES HAVING ENDOGLUCANASE ACTIVITY AND POLYNUCLEOTIDES ENCODING SAME	11.09.2009	C12P 19/02	PCT/US2009/036316	NOVOZYMES A/S

The present invention relates to isolated polypeptides having endoglucanase activity and isolated polynucleotides encoding the polypeptides. The invention also relates to nucleic acid constructs, vectors, and host cells comprising the polynucleotides as well as methods of producing and using the polypeptides.

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Results of searching in PCT for:
(CL/isolated, AND CL/"nucleic acid", OR CL/"amino acid"): 13818 records
Showing records 1 *to* 25 *of* 13818 :

[Search Summary]

	Title	Pub. Date	Int. Class	App. Num	Applicant
1.	(WO 2009/111706) POLYPEPTIDES HAVING BETA-GLUCOSIDASE ACTIVITY AND POLYNUCLEOTIDES ENCODING SAME	11.09.2009	C12N 9/42	PCT/US2009/036341	NOVOZYMES A/S
	The present invention relates to isolated polypeptides having beta-glucosidase activity and isolated polynucleotides encoding the polypeptides. The invention also relates to nucleic acid constructs, vectors, and host cells comprising the polynucleotides as well as methods of producing and using the polypeptides.				
2.	(WO 2009/111692) POLYPEPTIDES HAVING ENDOGLUCANASE ACTIVITY AND POLYNUCLEOTIDES ENCODING SAME	11.09.2009	C12P 19/02	PCT/US2009/036316	NOVOZYMES A/S
	The present invention relates to isolated polypeptides having endoglucanase activity and isolated polynucleotides encoding the polypeptides. The invention also relates to nucleic acid constructs, vectors, and host cells comprising the polynucleotides as well as methods of producing and using the polypeptides.				
3.	(WO 2009/111599) PLASMODIUM MALARIAE AND PLASMODIUM OVALE GENES AND USES THEREOF	11.09.2009	C07H 21/00	PCT/US2009/036098	ABBOTT LABORATORIES
	The subject invention relates to nucleic acid sequences and amino acid sequences encoded thereby, derived from the Merozoite Surface Protein (MSPI) gene of the Plasmodium species P. malariae and P. ovale. Such genes and proteins have many beneficial diagnostic as well as therapeutic uses.				
4.	(WO 2009/111258) DETERGENT COMPOSITION COMPRISING LIPASE	11.09.2009	C12N 9/20	PCT/US2009/035231	THE PROCTER & GAMBLE COMPANY
	The invention provides detergent compositions comprising lipolytic enzyme variants having improved in-detergent stability. Lipolytic enzyme variants with improved in-detergent stability are obtained by substituting certain specified amino acid residues in a parent lipolytic enzyme.				

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(71) Applicant *(for all designated States except US)*: **THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM** [US/US]; 201 West 7th St., Austin, TX 78701 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **COOPER, Laurence, J.N.** [US/US]; 71 Patti Lynn Lane, Houston, TX 77024 (US). **MANURI, Pallavi** [IN/US]; 14502 Morningside View Dr., Houston, TX 77047 (US). **OLIVARES, Simon** [US/US]; 8450 Cambridge St., Apt. 1186, Houston, TX 77054 (US).

(74) Agent: **LANDRUM, Charles, P.**; Fulbright & Jaworski L.L.P., 600 Congress Ave., Suite 2400, Austin, TX 78701 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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— *with sequence listing part of description published separately in electronic form and available upon request from the International Bureau*

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(54) **Title:** COMPOSITIONS AND METHODS RELATED TO A HUMAN CD19-SPECIFIC CHIMERIC ANTIGEN RECEPTOR (H-CAR)

(57) **Abstract:** Embodiments of the invention include compositions and methods related to a human CD19-specific chimeric T cell receptor polypeptide comprising an intracellular signaling domain, a transmembrane domain and an extracellular domain, the extracellular domain comprising a human CD 19 binding region.

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CLAIMS

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

2. The polypeptide of claim 1, wherein the CD19 binding domain is an $F(ab')_2$, Fab', Fab, Fv, or scFv.

3. The polypeptide of claim 2, wherein the CD19 binding domain comprises an amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:2.

4. The polypeptide of claim 1, wherein the intracellular activation domain is a T-lymphocyte activation domain.

5. The polypeptide of claim 4, wherein the T-lymphocyte activation domain comprises an intracellular signaling domain of human CD3ζ.

6. The polypeptide of claim 1, wherein the T-lymphocyte activation domain further comprises a human CD28 intracellular segment.

7. The polypeptide of claim 1, wherein the transmembrane domain is a CD28 transmembrane domain.

8. A nucleic acid encoding the polypeptide of claim 1.

9. The nucleic acid of claim 8, wherein the nucleic acid sequence is optimized for human codon usage.

10. The nucleic acid of claim 9, wherein the nucleic sequence is a nucleic acid of SEQ ID NO:3.

11. A cell expressing the polypeptide of claim 1.

12. A cell comprising an expression cassette encoding the polypeptide of claim 1.

13. The cell of claim 12, wherein the expression cassette is comprised in a non-viral vector.

CLAIMS

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

2. The polypeptide of claim 1, wherein the CD19 binding domain is an $F(ab')_2$, Fab', Fab, Fv, or scFv.

3. The polypeptide of claim 2, wherein the CD19 binding domain comprises an amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:2.

4. The polypeptide of claim 1, wherein the intracellular activation domain is a T-lymphocyte activation domain.

5. The polypeptide of claim 4, wherein the T-lymphocyte activation domain comprises an intracellular signaling domain of human CD3ζ.

6. The polypeptide of claim 1, wherein the T-lymphocyte activation domain further comprises a human CD28 intracellular segment.

7. The polypeptide of claim 1, wherein the transmembrane domain is a CD28 transmembrane domain.

8. A nucleic acid encoding the polypeptide of claim 1.

CLAIMS

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

2. The polypeptide of claim 1, wherein the CD19 binding domain is an $F(ab')_2$, Fab', Fab, Fv, or scFv.

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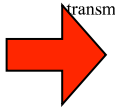
5. The polypeptide of claim 4, wherein the T-lymphocyte activation domain comprises an intracellular signaling domain of human CD3ζ.

6. The polypeptide of claim 1, wherein the T-lymphocyte activation domain further comprises a human CD28 intracellular segment.

7. The polypeptide of claim 1, wherein the transmembrane domain is a CD28 transmembrane domain.



8. A nucleic acid encoding the polypeptide of claim 1.

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(71) Applicant (*for all designated States except US*): **TWO TO BIOTECH LTD.** [IL/IL]; 9/7 Rosenblat street, Ramot Gimmel, 97460 Jerusalem (IL).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **SANDLER, Tamar** [IL/IL]; 318/7 Rozenblat Street, Ramot Gimmel, 97460 Jerusalem (IL). **DEVARY, Orly** [IL/IL]; 318/7 Rozenblat Street, Ramot Gimmel, 97460 Jerusalem (IL).

(74) Agent: **REINHOLD COHN AND PARTNERS**; P.O.Box 13239, 61131 Tel Aviv (IL).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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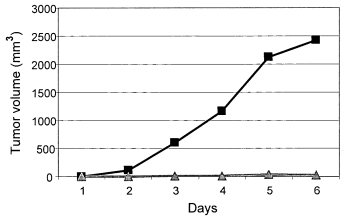

FIG. 6

(57) Abstract: A novel, isolated polypeptide comprising an amino acid sequence of SEQ. ID. NO: 2 or SEQ. ID. NO: 4, and the nucleic acid molecule which encodes it. The 5 polypeptide may be used in a method for treating various diseases including cancer, immune associated, viral and inflammatory diseases.

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NOVEL PROTEIN

FIELD OF THE INVENTION

This invention relates to a novel protein and therapeutic uses thereof.

BACKGROUND OF THE INVENTION

Diseases which affect human beings may be categorized according to the mechanism of their cause. For example, diseases that have an immunological component or etiology include infectious diseases, acute and chronic inflammatory diseases, cancer, transplantation and autoimmune diseases.

Examples of autoimmune diseases include multiple sclerosis (MS), autoimmune uveitis, autoimmune uveoretinitis, autoimmune thyroiditis, Hashimoto's disease, insulitis, Sjogren's syndrome, spontaneous abortions, experimental autoimmune myocarditis, rheumatoid arthritis (RA), inflammatory bowel disease (IBD), Crohn's disease, lupus (SLE), psoriasis and diabetes, particularly type I.

Additional examples of autoimmune diseases include Acute necrotizing hemorrhagic leukoencephalitis, Addison's disease, Agammaglobulinemia, Allergic asthma, Allergic rhinitis, Alopecia areata, Amyloidosis, Ankylosing spondylitis, Anti-GBM/Anti-TBM nephritis, Antiphospholipid syndrome (APS), Autoimmune aplastic anemia, Autoimmune dysautonomia, Autoimmune hepatitis, Autoimmune hyperlipidemia, Autoimmune immunodeficiency, Autoimmune inner ear disease (AIED), Autoimmune myocarditis, Autoimmune thrombocytopenic purpura (ATP), Axonal & neuronal neuropathies, Bal's disease, Behnet's disease, Bullous pemphigoid, Cardiomyopathy, Castleman disease, Celiac sprue (nontropical), Chagas' disease, Chronic fatigue syndrome, Chronic inflammatory demyelinating polyneuropathy (CIDP), Churg-Strauss syndrome, Cicatricial pemphigoid/benign mucosal pemphigoid, Cogan's syndrome, Cold agglutinin disease, Congenital heart block, Coxsackie myocarditis, CREST disease, Essential mixed cryoglobulinemia, Demyelinating

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SUMMARY OF THE INVENTION

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 cttctgtct atcctggtt tctggtctg tgcgttgtg ggtagcagc attggcgta ttacgccgg agggagcag gctgagcga ggctccaga aggtgcgca atagccgga gaggaaagg gcgatgctg tcacctagc cccctccct gagactcca ttcagccca gaaaaagga gctgctttc tcccccatc taccctagg agaaaa (SEQ. ID. NO:1)

MPGHSRLLSILVSGLCVVGSSIGVLRRREQAERGSRRCAIAGEERAMLSP SPLPETPFSPEKGAAFSPIYPRRK (SEQ. ID. NO:2)

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DETAILED DESCRIPTION OF EMBODIMENTS

Example I

A novel cDNA has been isolated from human cDNA libraries.

The following primers were used for RT-PCR analysis:

5' - GCT TCT GTC TAT CCT GGT TTC TGG - 3' (SEQ. ID. NO: 5)

5' - TTT CTC CTA GGG TAG ATG GG – 3' (SEQ. ID. NO: 6)

The following PCR conditions were used:

95°C for 2 min

40 cycles of :

95°C for 45 sec

59°C for 45 sec

72°C for 5 min

End cycles:

72°C for 5min

The product of the PCR was sequenced.

Following the PCR analysis on Agarose gels and staining with Cybar Green (Invitrogene), the intensity of the PCR product was evaluated using BioRad ChemiDoc analyzer. The results are as follows:

cDNA library	Signal	G3PDH	(Signal/G3pdh)	minimal ratio
Heart	3675	5434	0.676297	1.209034
Brain	3340	5971	0.55937	1.000001
Placenta*	6029	4668	1.29156	**2.308954**
Lung	2929	4116	0.711613	1.272169
Liver	4809	6002	0.801233	1.432385
Skeletal muscle	5849	6273	0.932409	1.666891
Kidney*	8272	4069	2.032932	**3.634324**
Pancreas*	8384	3898	2.150847	**3.845123**

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cDNA library	Signal	G3PDH	(Signal/G3pdh)	minimal ratio
Heart	3675	5434	0.676297	1.209034

CLAIMS:

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

2. An isolated polypeptide comprising an amino acid sequence of SEQ. ID. NO: 2 or SEQ. ID. NO: 4, in which one or more amino acid residues is added, deleted or replaced, without significantly affecting the biological characteristics of the modified molecule as compared to the unmodified molecule.

3. An isolated polypeptide comprising a partial contiguous sequence from SEQ. ID. NO: 2 that includes at least 8 amino acid residues, which contiguous sequence is included as a contiguous sequence in said SEQ. ID. NO: 2.

4. An isolated polypeptide according to claim 3 comprising SEQ. ID. NO: 7 or SEQ. ID. NO:8.

5. An isolated protein or polypeptide comprising an amino acid sequence of the polypeptide according to any one of Claims 1-4.

6. An isolated polypeptide according to claim 2 comprising a modified sequence of SEQ. ID NO: 2 or SEQ. ID. NO: 4, in which up to three residues are each substituted by another amino acid residue by conservative substitution.

7. A polypeptide sequence according to any one of Claims 1-6, wherein one or more amino acids are replaced by the corresponding D-amino acid.

8. A polypeptide sequence according to any one of Claims 1-7, in which the amino acids are in the reverse order.

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

10. An isolated nucleic acid molecule comprising a sequence of SEQ. ID. NO: 1 or SEQ. ID. NO: 3 in which one or more nucleic acid residues has been replaced by another nucleic acid residue, as permitted by the redundant nature of the genetic code.

11. An isolated nucleic acid molecule comprising a nucleotide sequence of SEQ. ID. NO: 1 or SEQ. ID. NO: 3, in which one or more nucleotides has been added, deleted or replaced, without significantly affecting the biological characteristics of the modified molecule as compared to the unmodified molecule.

12. An isolated nucleic acid molecule consisting of a sequence selected from SEQ. ID. NO: 5 and SEQ. ID. NO: 6.

CLAIMS:

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

2. An isolated polypeptide comprising an amino acid sequence of SEQ. ID. NO: 2 or SEQ. ID. NO: 4, in which one or more amino acid residues is added, deleted or replaced, without significantly affecting the biological characteristics of the modified molecule as compared to the unmodified molecule.

3. An isolated polypeptide comprising a partial contiguous sequence from SEQ. ID. NO: 2 that includes at least 8 amino acid residues, which contiguous sequence is included as a contiguous sequence in said SEQ. ID. NO: 2.

4. An isolated polypeptide according to claim 3 comprising SEQ. ID. NO: 7 or SEQ. ID. NO:8.

5. An isolated protein or polypeptide comprising an amino acid sequence of the polypeptide according to any one of Claims 1-4.

6. An isolated polypeptide according to claim 2 comprising a modified sequence of SEQ. ID NO: 2 or SEQ. ID. NO: 4, in which up to three residues are each substituted by another amino acid residue by conservative substitution.

7. A polypeptide sequence according to any one of Claims 1-6, wherein one or more amino acids are replaced by the corresponding D-amino acid.

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

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invention may be regulated by other laws, international standards and guidelines. For example, for a new drug, its availability and cost may depend on whether it is determined to be safe by the Therapeutic Goods Administration and whether it demonstrates cost effectiveness to allow its listing on the Pharmaceutical Benefits Scheme.

In accordance with international obligations, Australia's patent system is technology neutral. Applications for gene patents are assessed by applying the same patentability criteria applicable to all other technologies. IP Australia is also bound by parliament enacted law and court decisions interpreting this law. What can be the subject matter of a patent has been interpreted broadly by the courts. This has enabled the law to keep pace with scientific and technological developments. As such, Australia has granted patents over substances and materials isolated from nature since at least 1924, where they have met other requirements for patentability.

The courts have also recognised that the distinction between discoveries, which are not patentable, and inventions can be extremely fine. However, 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.

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. Jurisdictions like the European Union have other exclusionary provisions based on protecting public order and morality, but these have not been used to exclude gene sequences from patentability.

As stated in our submission, we address a few apparent misunderstandings about patents and gene patents. For example, patents may be awarded to ground-breaking inventions as well as incremental advancements where they meet the requisite level of ingenuity required to be granted a patent—that is, the inventive step. The grant of a patent is awarded irrespective of the level of intellectual endeavour or effort exerted to achieve the invention. The validity of a patent cannot be judged on what is well-known or routine today but at the date the patent was filed—which could be many years in the past.

A patent over a gene sequence does not equate to ownership of that sequence. A patent to an isolated gene sequence does not impinge on the freedom of the individual to use their DNA.

IP Australia's data indicates that the number of granted patents that assert rights over an isolated human gene is less than 400 in total to date. The data also indicates that patent applications for methods or processes of using gene sequences are increasing relative to patent applications for isolated gene sequences themselves. This indicates that innovation efforts have shifted to downstream applications of gene sequences.

CLAIMS

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

2. The polypeptide of claim 1, wherein the CD19 binding domain is an $F(ab')_2$, Fab', Fab, Fv, or scFv.

3. The polypeptide of claim 2, wherein the CD19 binding domain comprises an amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:2.

4. The polypeptide of claim 1, wherein the intracellular activation domain is a T-lymphocyte activation domain.

5. The polypeptide of claim 4, wherein the T-lymphocyte activation domain comprises an intracellular signaling domain of human CD3ζ.

6. The polypeptide of claim 1, wherein the T-lymphocyte activation domain further comprises a human CD28 intracellular segment.

7. The polypeptide of claim 1, wherein the transmembrane domain is a CD28 transmembrane domain.

8. A nucleic acid encoding the polypeptide of claim 1.

CLAIMS:

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

2. An isolated polypeptide comprising an amino acid sequence of SEQ. ID. NO: 2 or SEQ. ID. NO: 4, in which one or more amino acid residues is added, deleted or replaced, without significantly affecting the biological characteristics of the modified molecule as compared to the unmodified molecule.

3. An isolated polypeptide comprising a partial contiguous sequence from SEQ. ID. NO: 2 that includes at least 8 amino acid residues, which contiguous sequence is included as a contiguous sequence in said SEQ. ID. NO: 2.

4. An isolated polypeptide according to claim 3 comprising SEQ. ID. NO: 7 or SEQ. ID. NO:8.

5. An isolated protein or polypeptide comprising an amino acid sequence of the polypeptide according to any one of Claims 1-4.

6. An isolated polypeptide according to claim 2 comprising a modified sequence of SEQ. ID NO: 2 or SEQ. ID. NO: 4, in which up to three residues are each substituted by another amino acid residue by conservative substitution.

7. A polypeptide sequence according to any one of Claims 1-6, wherein one or more amino acids are replaced by the corresponding D-amino acid.

8. A polypeptide sequence according to any one of Claims 1-7, in which the amino acids are in the reverse order.

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

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CHAIR—I think Professor Olver wanted to respond.

Prof. Olver—Can I just make one future contextual statement about this, to carry on from where Bruce and Sally left off. 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.

Senator MOORE—Bill, what are you reading from?

Senator HEFFERNAN—I am happy to table it for the committee. It cost $58 for excess luggage in the plane.

Senator MOORE—That it is the fourth specific patent that he has referred to. I am really impressed.

Prof. Amor—I agree. We get a bit sucked in by the fact that it is molecular medicine and it is very high-tech, but the reality is that it is part of nature. It is no different to saying someone can patent an opposable thumb or something like that.

Senator HEFFERNAN—I would not be game to read you the dialogue here, because I cannot get my head around the words. Thank you very much.

Senator WILLIAMS—This could be ongoing. If someone could identify the gene that causes macular degeneration of eyesight and patent it then research could be brought to a stop on that sort of thing. The limits of the current form of the IP regulations have been bought out in this committee. Obviously what could be patented is never ending if this is allowed to continue. Would you agree with that?

Prof. Amor—Yes, 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. How is anyone going to get their head around the IP issues of that when presumably you are going to be talking about a whole lot of different patent owners? And then there are the administration costs of negotiating that. I suspect at the end of the day these patents will not be enforced because it will be too hard for the owners as well. At the end of the day it seems like a whole lot of money is going to go to lawyers and administrators.

Is there a diminishing problem?

1. There are about 14,000 international patent applications over isolated biological materials in the pipeline.

2. Cancer scientists are telling us that over the next 10 to 20 years gene patents are going to be a growing problem.

Invention or Discovery

Anglo-American Patent Law
"excludes from patent protection ... laws of nature, natural phenomena and abstract ideas"

“This principle finds its roots in both English and America law”

Part V—Powers of the Parliament

51 Legislative powers of the Parliament [*see* Notes 10 and 11]

The Parliament shall, subject to this Constitution, have power to make laws for the peace, order, and good government of the Commonwealth with respect to:

(i) trade and commerce with other countries, and among the States;

(ii) taxation; but so as not to discriminate between States or parts of States;

(iii) bounties on the production or export of goods, but so that such bounties shall be uniform throughout the Commonwealth;

(iv) borrowing money on the public credit of the Commonwealth;

(v) postal, telegraphic, telephonic, and other like services;

(vi) the naval and military defence of the Commonwealth and of the several States, and the control of the forces to execute and maintain the laws of the Commonwealth;

(vii) lighthouses, lightships, beacons and buoys;

(viii) astronomical and meteorological observations;

(ix) quarantine;

(x) fisheries in Australian waters beyond territorial limits;

(xi) census and statistics;

(xii) currency, coinage, and legal tender;

(xiii) banking, other than State banking; also State banking extending beyond the limits of the State concerned, the incorporation of banks, and the issue of paper money;

(xiv) insurance, other than State insurance; also State insurance extending beyond the limits of the State concerned;

(xv) weights and measures;

(xvi) bills of exchange and promissory notes;

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SECTION 5: PATENTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[5] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

   (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

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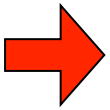
Article 17.9 : Patents



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(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.

Sharing genes is patently obvious

IAN FRAZER

AS a scientist and patent holder I can understand why clinical researchers seek to have their inventions patented. Individuals or corporations whose talent and hard work result in a useful invention ought to benefit from a system that protects their investment of time and effort — and their willingness to make the invention public — by ensuring their labour and creativity are rewarded.

Patent law was developed in the 17th century as an incentive to ingenuity, to help make the benefits of invention widely available and to further develop novel uses for the invention. However, patenting of a naturally occurring gene sequence and claiming the right to benefit from the use of that gene sequence by others fails on both counts.

First, 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. Second, 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.

Gene patent owners have told a Senate committee that awarding gene patents is necessary to encourage investment in biotechnology research. The reality, however, is that a gene patent can also be a licence to monopolise its use, eliminating the competitiveness and information sharing essential to the development of genetic therapies whose invention should be rewarded by a patent.

Restricting the research use of a gene sequence could delay the development and testing of truly inventive and practical uses of the gene and its protein product for diagnosis and therapy. This would be to the detriment not only of the wider community, but also of the biotechnology industry itself.

Gene patent attorneys and their clients contend there is sufficient inventiveness in isolating a gene sequence to claim a patent over the process and over the gene sequence itself. But the evidence suggests otherwise.

Five years ago the Australian Law Reform Commission completed a seemingly exhaustive review of gene patenting in Australia. Nowhere in its report did it make the simple point that gene patents should no longer be granted because sequencing genes amounts to tailoring pre-existing technology to discover something in our bodies.

The report cites academics as arguing that "the cloning and sequencing of a gene is unlikely to amount to an inventive step". It then recommends that patent examiners receive additional training and examination guidelines be developed for biotechnological inventions.

But how much education do you need to learn that patenting genes is fundamentally invalid? It would have been easier for the report to simply say genes are not inventions and they should not be patented. Law reform, apparently, is not that simple.

Hopefully, the Senate inquiry into gene patents, which began this week, will be much more direct in its recommendations.

Science sits on the cusp of a surge in the use of genes in the diagnosis and treatment for major illnesses. The collegiate tradition of sharing raw data among researchers must be allowed to continue unfettered so new technologies can be developed to benefit all.

Major medical science breakthroughs such as Pasteur's immunology discoveries or Florey's penicillin antibiotic were gifted to humankind for global benefit. They have contributed enormously to the increases in life expectancy we enjoy today.

Clearly, medical science has evolved phenomenally. Patent law remains rooted in its own dark age.

If we allow patenting of genes we're allowing patenting of ourselves. 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.

It is now more than nine years since then US president Bill Clinton and British prime minister Tony Blair made a joint announcement that gene patents should be banned. Unfortunately, we are no closer to a resolution.

Since then the US and Europe have been caught up in legal battles around the issue, including an American case at present before the Supreme Court.

For Australia, however, there is limited value in looking to international precedent for guidance. We do not have a huge domestic biotechnology sector and we are not uniquely placed to trade with the US.

But our unique circumstances could be an advantage. Australia's government can set a precedent for putting the public interest at the forefront of genetic science. It could do so by declining to grant future patent applications seeking to protect genetic sequence information if there is no subsequent inventive step leading to a defined practical application.

Cancer Council Australia calls for a comprehensive government review of the problems of gene patenting and recommends that the law

BRCA - Statement of Support: Sir John Sulston (5/12/2009)

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Sir John Sulston is Chair of the Institute for Science, Ethics and Innovation (iSEI) at the University of Manchester and the former Director of the Wellcome Trust Sanger Institute in Cambridgeshire, England. He played a central role in both the Caenorhabditis elegans *worm and human genome sequencing projects. In 2002, he shared the Nobel Prize in Physiology or Medicine with Sydney Brenner and H. Robert Horvitz for their discoveries about how genes regulate tissue and organ development.*

I applaud the efforts of the ACLU and the Public Patent Foundation in challenging the patenting of human genes, and in particular the patents on BRCA1 and BRCA2. A patent on a gene specifically bestows the right to prevent others from using that gene. Rather than fostering innovation – one of the primary goals of the patent system – gene patents can have a chilling impact on research, obstruct the development of new genetic tests, and interfere with medical care.

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.

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.

Myriad's patents on the BRCA genes have had impacts well beyond the United States. In November 1995, a team of researchers at the United Kingdom-based Institute of Cancer Research (ICR) led by Michael Stratton found a mutation in some of their breast cancer patients, which appeared to lie in BRCA2. Shortly thereafter BRCA2 was sequenced by the Sanger Institute. Over the next two weeks, the ICR team confirmed their results and identified five additional mutations. But the day before their findings were published, Myriad Genetics' chief scientific officer, Mark Skolnick, filed a patent application for BRCA2. Myriad used its patent applications to claim rights over the entire BRCA2 gene, including the mutations identified by ICR.

Myriad has since claimed proprietary rights for the diagnostic tests for the BRCA genes. One of their tests focuses on a mutation discovered by the ICR team that is commonly found among Ashkenazi Jews from central and eastern Europe. Myriad has benefited directly from the work of the international scientific community, while their practices have driven up health care costs and impeded further research on these genes that might lead to future therapies.


PATENTING
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The scientific evidence is overwhelming
Isolated genes and proteins that are identical or substantially identical to those that exist in nature are not inventions.

What about gene tests?

Is the Use of these materials in a gene test INVENTIVE?

Prof Amor: No. it is not rocket science

Prof Mann: No. a honours student can make one

SECTION 5: PATENTS

Article 27

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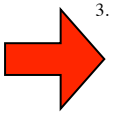

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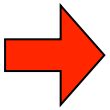

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Would a ban on isolated genes and proteins interfere with scientific progress?

Sharing genes is patently obvious

IAN FRAZER

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Major medical science breakthroughs such as Pasteur's immunology discoveries or Florey's penicillin antibiotic were gifted to humankind for global benefit. They have contributed enormously to the increases in life expectancy we enjoy today.

Clearly, medical science has evolved phenomenally. Patent law remains rooted in its own dark age.

If we allow patenting of genes we're allowing patenting of ourselves. 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.

It is now more than nine years since then US president Bill Clinton and British prime minister Tony Blair made a joint announcement that gene patents should be banned. Unfortunately, we are no closer to a resolution.

Since then the US and Europe have been caught up in legal battles around the issue, including an American case at present before the Supreme Court.

For Australia, however, there is limited value in looking to international precedent for guidance. We do not have a huge domestic biotechnology sector and we are not uniquely placed to trade with the US.

But our unique circumstances could be an advantage. Australia's government can set a precedent for putting the public interest at the forefront of genetic science. It could do so by declining to grant future patent applications seeking to protect genetic sequence information if there is no subsequent inventive step leading to a defined practical application.

Cancer Council Australia calls for a comprehensive government review of the problems of gene patenting and recommends that the law

Is Compulsory Licensing or Crown Use Effective Remedies?

Senate Standing Committee on Community Affairs
ANSWERS TO QUESTIONS ON NOTICE
Public Hearing of 19 March 2009
Senate Inquiry into gene patents
IP Australia

Question 4

Agency: IP Australia

Topic: Senate Inquiry into gene patents

Reference: Hansard Page: CA25 on 19 March 2009

Senator Boyce asked:

Who (if anyone) has used the compulsory licensing provisions available in the Act, and for what purposes? Have they been used by private companies or by institutions and organisations?

Answer:
IP Australia has only been able to identify three applications for compulsory licences in Australia since 1903; none under the *Patents Act 1903*, two under th *Patents Act 1952* and one under the *Patents Act 1990*.[1] The three cases are:

- *Patents Act 1952*:
  - Fastening Supplies Pty Ltd seeking a compulsory licence from Olin Mathieson Chemical Corporation; and
  - Mr Kenneth Mervyn Lown seeking a compulsory licence from Wissen Pty Ltd.; and

- *Patents Act 1990*:
  - Amrad Operations Pty. Ltd. seeking a compulsory licence from Genelabs Technologies Inc.

In each case a compulsory licence was sought to enable use of a patentee's invention in order to satisfy perceived unmet "*reasonable requirements of the public*" for the patented invention. No compulsory licenses were granted.

What should this Committee do?

First, it should recommend: (a) ban patents for isolated biological materials that are identical or substantially identical to those that exist in nature; and
(b) substantial increase in the inventive step so that their mere use in diagnostics is not patentable

Next, it should recommend a comprehensive multidisciplinary review of the patent system.

Finally, it should recommend the establishment of the Office of the Regulator of Intellectual Property

Should there be patents on isolated biological materials?

“raw fundamental data must be made freely available to scientists everywhere”.

US President Clinton & British PM Blair, March 2000

Summing Up

- Patents are about ‘inventions’.
- Genes and proteins are not ‘inventions’.

- Isolation of genes does not change what they are.
- Isolation of genes merely changes where they are.

- Purification of genes does not change what they are.
- Purification of genes merely concentrates them.

- Patenting genes is like patenting the moon.

- The US Supreme Court has repeatedly held that ‘natural phenomena’ (like genes and proteins) are ‘free to all men and reserved exclusively for none’.