Senate inquiry into gene patents – supplementary statement

Cancer Council Australia, Clinical Oncological Society of Australia

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Cancer Council Australia is Australia's peak non-government national cancer control organisation. Its member bodies are the eight state and territory cancer councils, whose views and priorities it represents on a national level.

The Clinical Oncological Society of Australia is the peak multidisciplinary society for health professionals working in cancer research or the treatment, rehabilitation or palliation of cancer patients.

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Background

On Wednesday 5 August, Professor Ian Olver, chief executive officer of Cancer Council Australia, and Professor Bruce Mann, president of the Clinical Oncological Society of Australia (COSA), appeared before the Senate Community Affairs Committee in Sydney as part of the inquiry into gene patents.

Professor Olver and Professor Mann took three questions on notice, pending legal advice:

1) Could Cancer Council Australia/COSA recommend a formula for amending the Patents Act 1990 as recommended in general terms in the organisations' joint submission "to ensure genes that have already been patented are exempt from licensing fees or monopolisation"?

2) Could Cancer Council Australia/COSA recommend a revised threshold test for disqualifying gene sequences and gene products from the definition of patentable subject matter?

3) Could Cancer Council Australia/COSA recommend the criteria for a threshold test?

The committee also asked if Cancer Council Australia/COSA was engaged in a separate process, led by the Department of Innovation, Industry, Science and Research, exploring intellectual property law in relation to, inter alia, medical technology. Attached for the committee's information is Cancer Council Australia's September 2008 submission to the Australia Council on Intellectual Property's review of patentable subject matter, which expresses the same concerns and calls for the same response as our joint submission to this Senate inquiry.

Questions taken on notice

Following consultation with patent lawyer and academic Dr Luigi Palombi, who has provided pro bono advice on patent law to Cancer Council Australia/COSA throughout the Senate inquiry process, Cancer Council Australia/COSA respond to the questions on notice as follows.

1) Formula for amending the Patents Act 1990

Cancer Council Australia/COSA support the following proposed amendment to the Patents Act 1990.

18 Patentable inventions

Patentable inventions for the purposes of a standard patent

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

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

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

(2) The following are not patentable inventions:

(a) Human beings, and the biological processes for their generation.

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

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

(4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process.

7 Novelty and inventive step

Inventive step

(2) For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed anywhere in the world before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).

(2A) For the purposes of this Act, an invention that includes or makes use of a biological material as a component will be taken to involve an inventive step when compared with the prior art base unless the incorporation or use of that biological material, regardless or

whether it was known or unknown, in the manner claimed in the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed anywhere in the world before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).

(3) The information for the purposes of subsection (2) or (2A) is:

(a) any single piece of prior art information; or

(b) a combination of any 2 or more pieces of prior art information; being information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood, regarded as relevant and, in the case of information mentioned in paragraph (b), combined as mentioned in that paragraph.

2&3) Criteria/test for patentability threshold

The following draft explanatory memorandum for Cancer Council Australia's/COSA's proposed amendments to the Patents Act 1990 (above) provide primary and secondary thresholds, as stated under sections *18(1)* and *18(2)*.

The primary threshold related to 'manner of manufacture', that is, the patent should only be applied to something defined as an 'invention' (s.18(1)(a)). This should automatically exclude genetic sequences.

However, if secondary thresholds are required due to ambiguity in the definition of a genetic product, the invention must be 'novel' and its invention must clearly 'involve an inventive step'. The invention must also be 'industrially applicable'. This is explained in the context of the proposed amendment to the act as follows.

Explanatory Memorandum
Proposed amendments to the Patents Act, 1990
to exclude biological materials and their non-inventive application

Patentable Subject Matter

Section 18(1) sets the thresholds for patentability. Each must be satisfied to establish patentability. There are four thresholds:

- First there must be a 'manner of manufacture', that is, something capable of being an 'invention' (s.18(1)(a))

Unless that threshold is satisfied there is no need to consider the remaining thresholds. Assuming, however, that it is, then:

- Second, the invention must be 'novel'; (s.18(1)(b)(i))
- Next, the invention must 'involve an inventive step'; (s.18(1)(b)(ii)) and
- Finally, the invention must be 'industrially applicable' (s.18(1)(c)).

Section 18(2) applies regardless of the thresholds in s.18(1) and provides for per se exclusions to patentable subject matter. The exclusion is applied to *entire* classes of invention or potential inventions.

At present there is only one class expressly excluded: 'Human beings, and the biological processes for their generation.'

Inventive Step

Section 7 is the key provision setting the tests for the secondary thresholds of novelty and inventive step. For present purposes novelty is not germane.

In terms of inventive step, the central criterion is the state of the art in Australia for it is this upon which the invention is assessed for compliance with this threshold. Currently, the state of the art is defined as 'the common general knowledge' as it existed *in Australia* before the priority date (the earliest filing date of the patent application).

The law requires that 'a person skilled in the relevant art' applies the test.

Therefore, if a person of ordinary skill in the art accessing the common general knowledge as it existed in Australia before the priority date comes to the view that the 'invention', as a whole, was obvious, then it lacks an inventive step and fails the test.

Patentable Subject Matter and Gene Patents

There are two separate and distinct issues that arise with respect to gene patents.

First is patentable subject matter as it applies to biological materials that are identical or substantially identical to those that exist in nature.

An example of the sort of claim in question is found in Australian Patent 686,004. Claim 1 states:

An isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.

Such claims are typical in gene patents. There are many such examples and although they all vary slightly in language they all generally use the isolation of the relevant biological material as the point of distinction between it and the same material as it exists in nature. Another point of distinction sometimes used is purification; so that highly purified or concentrated biological materials are deemed to be different from their corresponding natural equivalents. Either way, whether isolated or purified, these biological materials are functionally and structurally identical to their natural counterparts. Their point of distinction is directed to their physical state not what they are nor what they do.

The claim in the above example is directed to gene mutations (genetic abnormalities) found in the human gene BRCA1 and which predispose women who carry these genetic mutations in the DNA in their bodies to be predisposed to breast and ovarian cancers.

It should be noted that the claim is not directed to any specific process of isolation. This means that no matter how it was isolated, so long as it comes within the genetic sequence parameters, it comes within the scope of the patent monopoly. Accordingly, the claim is directed to the human gene mutations on the BRCA1 gene in an isolated form, regardless of the method used to perform the step of isolation. Accordingly, the route taken to achieve the 'invention' as defined in the claim is irrelevant.

Thus, the patent monopoly applies to the actual human BRCA1 gene mutations in an isolated form per se (that is, regardless of how it was isolated or how it was produced).

Apart from the fact that no one conceived or invented the BRCA1 gene mutations, so it cannot be said that there is an 'inventor' as such, the biological material which the claim defines, the BRCA1 gene mutations, are nucleic acids which in themselves have no utility other than to enable the machinery of human reproduction or cell division to express a protein (which consists of amino acids).

Proteins are also biological material and they are the end result of the genetic information. So if the genetic information contained in a gene (made of nucleic acids) is the blueprint, the protein (made of amino acids) is the gene's physical embodiment.

Much like a the plans for a house which tells the builder what the constructed house should look like, genes tell the cellular machinery of humans how to make the proteins which collectively build and enable a human being to live.

Again using Australian Patent 686,004 as an example, patent claims to proteins that correspond to the claims to the isolated BRCA1 gene mutations are also found. Claim 10 states:

A preparation of a polypeptide substantially free of other proteins, said protein being a mutant or polymorphic BRCA1 polypeptide compared to the BRCA1 polypeptide having the amino acid sequence set forth in SEQ.ID No:2 which is obtainable by expression of a nucleotide coding sequence derived from the nucleotide sequence set forth in SEQ.ID No 1 by incorporation of one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.

Although the words 'isolation' and 'purified' are not used, the phrase, 'substantially free', is instead. In the context of the claim, this phrase is just another way of saying 'purified'. Once again, this claim defines the invention to be the *purified* proteins that are identical or substantially identical to those found in the body of women that are predisposed to familial breast and ovarian cancers. Like in the case of the claim to the BRCA1 gene mutations, the *sole* point of distinction is the state of the protein, not what it is or how it functions. Thus structurally the protein (i.e., its amino acid sequence) is identical to its natural equivalent in the human body.

In both case the patent monopoly covers any use of either of these biological materials as if they were products per se. That use can include experimental use or commercial use. It does not matter how the materials are made. Any process or method that produces or uses them will come within the scope of the patent monopoly. The invention, if there is one, is therefore, to the actual products – the gene and the protein that the gene codes for. Of course, no one actually invented either of them.

Just like no one invented uranium in the earth. Certainly it is possible to search for uranium. That search may be expensive and take many people much time. By itself it is a mineral. A product of nature. No one can patent uranium even in an isolated form, removed from the earth. However, if someone can find a use for it and develop a process that, for example, can generate electricity, and if that process is new, inventive and useful then a patent can be granted over the use of uranium in that specific process, but not over the uranium itself.

Because no one actually invented these biological materials it is arguable, as the law presently stands, that the claims discussed fail to describe 'a manner of manufacture' as required by s.18(1)(a) and are not inventions and therefore are not valid patent monopolies under Australian patent law.

Unfortunately, because the law has not been scrutinised by the Australian courts over the past 20 or so years, so many of these kinds of patent claims have been granted by IP Australia and are continuing to be applied for in Australia (mainly from overseas) that that it can be fairly argued that Australian patent law has been, and will in the future be, ignored unless an express exclusion to patentability of these materials is inserted in the current patents legislation.

That this amendment to the Patents Act, 1990 continues to be necessary can be seen from the numbers of patent applications that are being made internationally and which nominate Australia as one of the countries to which that application is directed. According to the World Intellectual Property Organization (WIPO), the UN agency which administers the Patent

Cooperation Treaty (PCT) and through which international patent applications are facilitated, there are currently some 11,000 international patent applications that relate to isolated genes and proteins. An example of one such application is the following.

The Board of Regents of the University of Texas System filed an international patent application (PCT/US2009/030998) on January 14, 2009 nominating Australia as one of the designated countries in the application.[1] The patent application is entitled "Compositions And Methods Related To A Human Cd19-Specific Chimeric Antigen Receptor (H-Car)". Claim 1 states:

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.

In short this is nothing more than a claim to a patent monopoly over a human protein in an isolated form. As the patent specification explains, this specific protein is associated with a receptor on a T cell (also a natural human product).

What this and the other 11,000 international patent applications show is that rather than this type of claim being a diminishing problem, it is a growing problem. It must be understood that there are some 23,000 human genes, but there are many more thousands of specific proteins, just like the human CD19-specific chimeric antigen receptor in the above example. The potential number of these kinds of patents is, frankly, enormous.

An amendment to s.18(2) is proposed.

Currently s.18(2) states:

Human beings, and the biological processes for their generation, are not patentable subject matter

The proposed amended s.18(2) states:

(2) The following are not patentable inventions:

…

(b) Biological materials, including recombinant materials (including but not limited to their components, parts or derivatives, whether isolated or purified or not and regardless of their state and processes used in their production) which are identical or substantially identical, individually or collectively, to those that exist in nature.

…

This amendment merely excludes, as a class, a patent monopoly over naturally occurring biological materials regardless of their actual physical state or their method of production. So long as the biological materials are identical or substantially identical to the naturally occurring biological materials they cannot be the subject of a patent monopoly, even if they are recombined. Accordingly, if the individual parts of a recombined and isolated gene are nothing more than a fusion of genetic parts, each of which are identical to their corresponding natural equivalents, then the recombined product is also excluded.

The purpose of the amendment is to stop the patenting of genetic and protein materials that are rudimentary, in the sense that they are identical or substantially identical to their natural counterparts.

In doing so, it will encourage further downstream innovation which utilizes these biological materials in new, inventive and practically useful ways.

[1] Patent provided as attachment to this supplementary submission

Inventive Step and Gene Patents

This leads to the second issue of how to measure the level of inventiveness in the downstream application of biological materials so that the secondary patentability threshold of inventive step is met to a satisfactory standard.

Currently, the test provided by s.7(2) states:

(2) For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).

This test is currently under review by IP Australia. This review has been necessitated by criticism directed to its interpretation by the High Court of Australia, the result of which, it has been argued, has effectively reduced the standard of inventiveness in Australia to a level below that of its major trading partners, such as the United States. We understand that this review is ongoing and that no final report has issued to date.

Of particular concern, however, are the words “in the patent area”. The concern is that they limit the scope of the “common general knowledge”, upon which an assessment of inventiveness is made, too narrowly. Effectively, the test distinguishes this common general knowledge between that in Australia to that in other parts of the world. Clearly, modern telecommunications and the internet mean that scientific and medical knowledge is rapidly, almost instantaneously, communicated so that developments in medical and scientific fields become part of the common general knowledge of the relevant scientists throughout the world much more rapidly than in the past.

Moreover, many of the patents granted by IP Australia originate overseas. Indeed, some 92% of all patents granted by IP Australia are granted to foreign patentees. Given that this is so, it would seem that a test of inventiveness that is limited to assessing the level of inventiveness of an invention at the date that it was first filed in an overseas country (which will be 12 months earlier than when it is filed in Australia) but that excludes from consideration the common general knowledge that applied *in that country* at that point in time is unrealistic. Apart from the point made in the preceding paragraph, namely that knowledge is rapidly communicated around the world, it seems absurd that a foreign inventor should be able to take advantage of a disparity, no matter how theoretical, between the common general knowledge (which might be higher in the country of application than it is in Australia) in the country of application and Australia and thereby secure a patent monopoly here that they may not have been able to secure in their own country.

Accordingly, it is recommended that s.7(2) be amended as follows:

(2) For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed anywhere in the world before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).

This amendment does not, however, deal with the appropriate level of inventiveness to be applied in the case of gene patents. This will require a further amendment.

The main reason for this is caused by the practice of IP Australia in accepting that the discovery of a naturally occurring biological material and the attribution to it of a particular function, such as in the case of BRCA 1 gene mutations to a predisposition to familial breast and ovarian cancer, is a sufficient inventive step in itself to warrant the grant of a patent over

the use of the relevant biological material and its attribution in medical technologies that are well known and routine.

As a result, the only distinguishing feature of such inventions, such as in the example of the diagnostic test for BRCA1 gene mutations, are the gene mutations themselves. Everything else about the BRCA1 gene test is standard and routine and was so at the time that the gene was discovered in 1993.

Accordingly, unless the inventiveness standard specifically as it is applied to gene patents is raised then the banning of genetic and protein materials per se will be easily overcome. In effect, the purpose of this amendment is not only to reinforce the ban on the patenting of genetic and protein materials that are identical or substantially identical to those that exist in nature, but to encourage the development of technologies that utilize these materials above and beyond the existing technology. The inventive focus must not be on the genetic and protein materials, nor on the use of these materials in conventional, routine and standard methods and technologies, but on the development of technologies that make use of them to deliver new and efficacious diagnostics, treatments and, hopefully, curers. For example, the development of gene therapies that can treat specific cancers or more rapid diagnostic platforms that enable more efficient, accurate and cheaper diagnoses.

The proposed further amendment is as follows:

(2A) For the purposes of this Act, an invention that includes or makes use of a biological material as a component will be taken to involve an inventive step when compared with the prior art base unless the incorporation or use of that biological material, regardless or whether it was known or unknown, in the manner claimed in the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed anywhere in the world before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).