SENATE COMMUNITY AFFAIRS COMMITTEE

INQUIRY INTO GENE PATENTS

Submission by Davies Collison Cave

Davies Collison Cave
1 Nicholson Street
Melbourne
Victoria 3000
Australia

INTRODUCTION

This submission is made in response to the invitation to comment on the "inquiry into gene patents" which has been referred to this Senate Community Affairs Committee, and which relates to the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in isolated form.

Davies Collison Cave is a leading Australian firm of Patent Attorneys, having a substantial patent practice in the field of biotechnology, and in particular in patents relating to genetic materials and technologies. In this field, the firm acts on behalf of a wide range of clients within Australia (including substantial and "start-up" biotechnology companies, universities and other academic organisations, and medical and other research institutes) in obtaining patent protection both in Australia and overseas for inventions arising out of their research and development activities in Australia. In addition, the firm also acts on behalf of a large number of overseas clients (covering a similar wide range as set out above) in obtaining patent protection in Australia for inventions which have been developed overseas, for example, in USA, Europe and Japan.

TERMS OF REFERENCE

The Community Affairs Committee has been requested to inquire and report on the following:

> *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 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.*

BACKGROUND

By way of background, it must be noted that there have been a number of prior reviews and reports which have addressed issues relating to the Terms of Reference of the present inquiry, either generally or specifically, in the context of the present Australian Patents Act 1990, and in addition one such review is on-going.

These are:

1. "Patents, Innovation and Competition in Australia" – Report of the Industrial Property Advisory Committee (IPAC) (1984).

This report led to the introduction of the Patents Act 1990, and on the issue of "patentable subject matter", the Committee recommended that the present threshold test for patentability by reference to s.6 of the Statute of Monopolies and to the expression of "manner of new manufacture" be retained, without specific legislative inclusion or exclusions. This recommendation was accepted and is embodied in the Patents Act 1990, with the exception of a specific exclusion contained in s.18(2) of the Patents Act 1990 which provides that "human beings, and the biological processes for their generation, are not patentable inventions".

2. "Genetic manipulation: The threat or the glory?" – Report by the House of Representatives Standing Committee on Industry, Science and Technology (February 1992).

This report addressed legal issues arising from the patenting of living organisms, particularly genetically modified organisms, and after considering arguments against patenting such organisms, the Committee indicated that it considered that there was no justification for denying the biotechnology industry the opportunity to use the Patents Act to seek a reward for effort. The Committee also noted that "(T)he Patents Act is not the appropriate vehicle for hindering, or preventing, the development of technologies to which society may have an objection. If that is the aim, more direct means such as legislation should be used".

3. "Review of Intellectual Property Legislation under the Competition Principles Agreement" – Report of the Intellectual Property and Competition Review Committee (IPCRC) (2000).

This Committee considered the issue of patentable subject matter in Australia having regard to the use of codified lists of patentable subject matter in jurisdictions such as the European Patent Office, but concluded with a recommendation similar to that of IPAC indicating that the Committee believed that Australia has on a whole benefited from the adaptiveness and flexibility that is characterised the "manner of manufacture" test, and accordingly recommended that this test be retained.

4. "Genes and Ingenuity – Gene Patenting and Human Health" – Report of the Australian Law Reform Commission (ALRC) (2004).

As part of its broad-ranging review of gene patenting and human health in Australia, after an extensive consultation process involving both an initial Issues Paper and a subsequent Discussion Paper, the ALRC made recommendations in particular in relation to Patentability of Genetic Materials and Technologies (Chapter 6), Exclusions from Patentability (Chapter 7), Publicly Funded Research and Intellectual Property (Chapter 11), Patents and Human Genetic Research (Chapter 12), An Experimental Use Exemption (Chapter 13), Research Culture, Patents and Commercialisation (Chapter 14), Patents and the Biotechnology Industry (Chapter 18), Gene Patents and the Healthcare System (Chapter 19) and Gene Patents and Healthcare Provision (Chapter 20). All of these areas of the ALRC Report are directly applicable to the Terms of Reference set out above.

5. "Patentable Subject Matter" - Issues Paper from the Advisory Council on Intellectual Property (ACIP) (July 2008).

This Issues Paper relates to a review being conducted by ACIP into what types of subject matter should be able to be patented in Australia, and whether the law is meeting the country's needs. Following the release of this Issues Paper, written submissions have been received by ACIP and public consultations with interested parties have been held recently. ACIP is to provide a report following this review.

INTERNATIONAL AGREEMENTS

It is important to note that Australia is a signatory to the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and therefore bound to comply with the provisions of this Agreement. The Agreement provides minimum standards of IP protection which must be provided by members. The most relevant articles of TRIPS to the present inquiry are Articles 7, 8, 27 and 30, and these Articles are provided in Appendix I.

In addition, the Australia-United States Free Trade Agreement (AUSFTA) contains provisions relating to patents which reflect the TRIPS provisions with only minor differences. Article 17.9 of the AUSFTA is relevant to this inquiry, and is provided in Appendix II.

A key feature of Article 27 (1) of the TRIPS Agreement (and Article 17.9 of the AUSFTA) is that Australia is obliged to provide a system whereby patents are 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", subject only to provisions of paragraphs 2 and 3 of Article 27 whereby certain specified subject matter may be excluded from patentability. Article 27(1) also mandates that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether patents are imported or locally produced".

Accordingly, amendment of the Patents Act 1990 so as to expressly exclude patent protection in respect of genetic materials such as "human and microbial genes and non-coding sequences, proteins and their derivatives, including those materials in an isolated form" would conflict with the requirement of Article 27 of TRIPS that patent protection should be available for inventions "without discrimination as to .... the field of technology", as these genetic materials do not fall within the specified subject matter that may be excluded from patentability.

In a similar manner, the AUSFTA stipulates in Article 17.9 that the parties shall make patents available for "any invention" whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application". This Article also stipulates that the parties may only exclude from patentability certain inventions where prevention of commercial exploitation of the invention "is necessary to protect *ordre public* or morality", for example 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 law.

Accordingly, amendment of the Patents Act 1990 so as to expressly exclude genetic materials such as "human and microbial genes and non-coding sequences, proteins and their derivatives, including those materials in an isolated form" would conflict with the obligation of Australia under the AUSFTA to make patents available for "any invention ..... in all fields of technology", as these genetic materials do not fall within the category of inventions which may be excluded from patentability under the AUSFTA.

TERMS OF REFERENCE

The Terms of Reference require the Committee to inquire and report on the impact of the granting of patents in Australia over "human and microbial genes and non-coding sequences, proteins and their derivatives, including those materials in an isolated form". Such materials will be referred to hereinafter as "genetic materials".

(a) The Committee is firstly required to have particular reference to the impact which the granting of patent monopolies over such materials has had, is having, and may have had on four specified areas, which are addressed separately below.

(i). The provision and costs of healthcare

As already noted, the ALRC Report specifically addresses issues arising from the impact of patents in the biotechnology industry (see Chapter 18), and more particularly the impact of current patent laws and practices related to genetic materials and technologies in the healthcare system (Chapter 19) and their impact on healthcare provision (Chapter 20). A specific recommendation of the ALRC Report which is pertinent to the present term of reference is Recommendation 19.3, as follows:

> *"Where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should consider whether to exercise any existing legal options to facilitate access to the inventions. These options should be exercised only with appropriate legal or patent attorney advice, and include:*
>
> *(a) challenging a patent application or granted patent by initiating proceedings to oppose a patent application; requesting re-examination of a patent; or applying for revocation of a patent under the* ***Patents Act 1990*** *(Cth) (****Patents Act****) (see Chapter 9);*
>
> *(b) making a complaint to the Australian Competition and Consumer Commissioner where evidence arises of a potential breach of Part IV of the* ***Trade Practices Act*** *1974 (Cth) (see Chapter 24);*
>
> *(c) exploiting or acquiring a patent under the Crown use and acquisition provisions of the* ***Patents Act*** *(see Chapter 26); or*
>
> *(d) applying for the grant of a compulsory licence under the* ***Patents Act*** *(see Chapter 27)."*

This recommendation emphasises that current patent laws provide appropriate options for action where particular patent applications or patents relating to genetic materials are regarded as having an adverse impact on medical research or the cost-effective provision of healthcare.

(ii). The provision of training or accreditation for healthcare professionals

It is not considered that the granting of patent protection in respect of genetic materials could have any direct adverse impact on the provision of training and accreditation for healthcare professionals.

(iii). The progress in medical research

The ALRC Report specifically addresses the issue of patents and genetic research, both publicly funded research (Chapter 11) and more specifically, human genetic research (Chapter 12). The report also addresses the question of an experimental use exemption (Chapter 13) and more generally, research culture and commercialisation (Chapter 14).

It is submitted that the supposed adverse impact of patent protection on genetic materials arises to a large extent from a lack of understanding by researchers of the patenting process as well as a lack of experience and expertise to commercially exploit research. One area where the lack of understanding of the patenting process is clearly evident relates to the so-called "experimental use" defence to patent infringement in Australia. In its Report, the ALRC notes there are significant legal uncertainties about the existence and scope of any implied "experimental use" defence under current patent law in Australia, however it concluded that experimental use of patented inventions is consistent with the important goal of patent law to promote the attainment of new knowledge and the development of new and improved inventions. Accordingly, the ALRC recommended in Recommendation 13.1:

> *The Commonwealth should amend the **Patents Act 1990** (Cth) (Patents Act) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that:*
>
> *(a) the exemption is available only if study or experimentation is the sole or dominant purpose of the act;*
>
> *(b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and*
>
> *(c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the **Patents Act**.*

The question of an experimental use exemption was also addressed by ACIP in its 2005 Report "Patents and Experimental Use". This Report followed a specific reference to ACIP requesting it to examine and report whether Australian researchers and businesses would benefit from introducing an experimental use exemption provision into the Australian patent legislation, in particular whether such an experimental use exemption would help researchers more effectively use the patent system to commercialise their research and development. In this Report,

ACIP recommended (in Recommendation 1) that the Patents Act be amended to establish the following provision:

> *The rights of the patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent. Acts done for experimental purposes relating to the subject matter of the invention include:*
>
> - *determining how the invention works;*
> - *determining the scope of the invention;*
> - *determining the validity of the claims;*
> - *seeking an improvement to the invention.*

In its response (August 2007), the Government referred to both the ALRC recommendation as well as the ACIP recommendation and accepted these recommendations indicating that the Patents Act 1990 would be amended to introduce an experimental use exemption. To date, no such amendment has been made.

The ALRC also addressed the matters of lack of understanding and lack of experience and expertise in commercial exploitation in recommendations that researchers should be made more aware of intellectual property issues, specifically in Recommendations 14-1 and 14-2 as follows:

> *Research organisations should continue to take steps to raise the awareness of researchers in health sciences and biotechnology about intellectual property issues and the commercialisation of research, and should provide relevant advice to researchers as required.*
>
> *Universities should ensure that students undertaking degrees in health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research.*

It is submitted that a key benefit which could be achieved by raising awareness of researchers about intellectual property issues and commercialisation of research would be in the area of "freedom to operate", that is, an awareness of intellectual property rights of other parties which might impact on the commercialisation of research being conducted by the researcher. Good commercial practice dictates that such "freedom to operate" issues should be addressed at an early stage in the commercialisation of research so that the researcher is aware of the patent rights of other parties which could impact on this research. Of course, this practice is well established in commercialisation of research in other areas of technology, particularly pharmaceuticals, and the same principles which apply in those other fields of technology apply equally in the field of research relating to genetic materials and technologies.

(iv). The health and wellbeing of the Australian people

It is difficult to see how the granting of patent protection in respect of genetic materials has any direct impact on the health and wellbeing of the Australian people.

(b) The Committee has also been requested to identify measures that would ameliorate any adverse impacts arising from the granting of patents over genetic materials, including whether the Patents Act 1990 should be amended, in the light of any matters identified by the inquiry.

In this regard, it is submitted that the recommendations of both ALRC and ACIP discussed above are clearly directed towards ameliorating any adverse impacts without the need for additional amendment of the Patents Act 1990.

(c) Finally, the Committee has been requested to consider whether the Patents Act 1990 should be amended so as to expressly prohibit the grant of patent protection over genetic materials.

It is important to note that the grant of an Australian patent does not give the patentee a positive right or authorisation to make or use the invention. Rather, the effect of the grant of a patent is to provide the patentee with a negative right, that is, the patentee can prevent third parties from making or using the invention without the patentee's permission. For example, the fact that a patentee has been granted an Australian patent in respect of a pharmaceutical for human use does not mean that the patentee is free to market that pharmaceutical in Australia; before doing so the patentee must secure marketing approval from the Therapeutics Goods Administration. Thus, the grant of a patent does not constitute endorsement by the Australian Government of the legality, safety or morality of a patented product or its use.

It is also important to note that in view of the "manner of manufacture" requirement of the Patents Act 1990, it is not possible to secure patent protection in Australia in respect of genetic materials such as genes, proteins or non-coding sequences, in the form in which they exist in nature. In order to secure patent protection in respect of such genetic materials, there must be an artificially created state of affairs established through human intervention, with the result that such genetic materials can only be protected in an isolated or synthetically produced form. Thus, Australia's present patent legislation does not allow a patentee to obtain the grant of a patent in respect of genetic materials such as a gene, protein or non-coding sequence as it exists in nature, for example in the human or animal body.

As already noted, the broad question of whether the current test of whether an invention is patentable on whether it is a "manner of manufacture", is the subject of the on-going ACIP inquiry, which focuses on three main issues; firstly the breadth of the test and whether patents are being allowed in subject matters where they hinder innovation, investment and public access to new technologies; secondly, whether it is too flexible and unpredictable; and thirdly, whether its structure and wording is confusing. The Issues Paper issued by ACIP clearly indicates that the report arising from this inquiry will address the issue of the patentability of genetic materials.

Similarly, the ALRC Report has already specifically considered and addressed the issue of the patentability of genetic materials and technologies (Chapter 6) and in

this regard, has made the following recommendations (in Recommendations 6.1 and 6.2):

> *Patent applications relating to genetic materials and technologies should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.*
>
> *The responsible Minister should initiate an independent review of the appropriateness and adequacy of the "manner of manufacture" test as the threshold requirement for patentable subject matter under Australian law, with a particular focus on the requirement that an invention must not be "generally inconvenient".*

(The on-going inquiry by ACIP addresses the current requirement that an invention must not be "generally inconvenient").

The ALRC Report also specifically addresses in Chapter 7 the existing exclusions from patentability under the Patents Act 1990 (in particular, in Section 18(2) of the Patents Act 1990), and the possibility of a new exclusion from patentability relevant to genetic materials and technologies. In this regard, ACIP recommended in Recommendation 7.1:

> *The **Patents Act 1990** (Cth) should **not** be amended:*
>
> *(a) to exclude genetic materials and technologies from patentable subject matter;*
>
> *(b) to exclude methods of diagnostic, therapeutic or surgical treatment from patent subject matter; or*
>
> *(c) to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.*

INTERNATIONAL HARMONISATION

In addressing the question of whether the Patents Act should be amended to expressly prohibit the grant of patent protection over genetic materials, consideration must also be given to International arrangements which Australia has with other countries, and in particular the move internationally towards harmonisation of intellectual property laws.

In this regard, paragraph 14 of Article 17.9 of the AUSFTA requires each party to endeavour to reduce differences in law and practice between their respective systems, and to endeavour to participate in International patent harmonisation efforts. Thus, it is relevant to note that current US patent law and practice does not exclude genetic materials and technologies from the scope of patentable subject matter.

Attention is also directed to Articles 2 to 6 of the European Directive on the Legal Protection of Biotechnological Inventions, attached as Appendix III. This directive requires that member states shall protect biotechnological inventions under national patent law, and requires them, if necessary, to adjust their national patent law to take account of the provisions of this directive. Article 2 of the directive defines "biological material" as meaning any material containing genetic information and capable of reproducing itself or being reproduced in a biological system, whilst Article 3 indicates that inventions which meet the requirements of being new, involving an inventive step and being susceptible of industrial application are to be patentable "even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used". This Article also stipulates that biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention, even if it previously occurred in nature. Article 4 sets out subject matter which may be excluded from patentability, and in this regard is similar to TRIPS Article 27.3. It is important to note that while Article 5.1 of this European Directive confirms that the human body and the simple discovery of an element thereof such as the sequence or partial sequence of a gene cannot constitute a patentable invention, Article 5.2 also confirms that "an element isolated from the human body or otherwise produced by a technical process", including the sequence or partial sequence of a gene, may constitute a patentable invention "even if the structure of that element is identical to that of a natural element". Clearly, this Article provides that genes and proteins isolated from the human body or otherwise produced by a technical process may be patentable in Europe.

Therefore, any amendment of the Patents Act 1990 so as to expressly prohibit the grant of patent protection over genetic materials would be a move directed away from harmonisation with the intellectual property laws of the US (contrary to the AUSFTA) and Europe.

CONCLUSION

It is submitted that the matters set out in the Terms of Reference of the present inquiry are matters which have been previously dealt with at length and in detail in the ALRC Report (and the 2005 ACIP Report, patents and Experimental Use"), and that implementation of the recommendations of these Reports is appropriate. Furthermore, the issues raised by the Terms of Reference of the present inquiry are already encompassed by the on-going inquiry by ACIP into patentable subject matter, and it is submitted that it will be appropriate to await the ACIP Report, and any recommendations made in that Report, before any action is taken in relation to the grant of patent protection in respect of genetic materials. More generally, however, it is submitted that any amendment to the Patents Act to prohibit the grant of patent protection over genetic materials would be in conflict with Australia's obligations under International Agreements, and would constitute a move away from harmonisation of its patent laws with major jurisdictions, particularly the US and Europe.

APPENDIX I – *TRIPS*

Article 7: *Objectives*

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8: *Principles*

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 27: *Patent 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. 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 and 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.

Article 30 ***Exceptions to rights conferred***

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

APPENDIX II – *AUSFTA*

Article 17.9: *Patents*

1. Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. The Parties confirm that patents shall be available for any new uses or methods of using a known product. For the purposes of this Article, a Party may treat the terms "inventive step" and "capable of industrial application" as synonymous with the terms "non-obvious" and "useful", respectively.

2. Each Party may only exclude from patentability:

(a) 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 law; and

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

14. Each party shall endeavour to reduce differences in law and practice between their respective systems, including in respect of differences in determining the rights to an invention, the prior art effect of applications for patents, and the division of an application containing multiple inventions. In addition, each party shall endeavour to participate in international patent harmonisation efforts, including the WIPO for addressing reform and development of the international patent system.

APPENDIX III - *EUROPEAN DIRECTION ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS*

Article 2

1. For the purposes of this Directive:

   (a) "biological material" means any material containing genetic material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

   (b) "microbiological process" means any process involving or performed upon or resulting in microbiological material.

2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 4

1. The following shall not be patentable:

   (a) plant and animal varieties;

   (b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.