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By Email
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Committee Secretary
Senate Legal and Constitutional Affairs Committee
PO Box 6100 Parliament House
Canberra ACT 2600

Re: Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010

Dear Sir/Madam,

I refer to your letter of 9 December 2010 inviting a submission in relation to the above inquiry by 25 February 2011 and now forward a submission on behalf of Davies Collison Cave.

Although the members of the firm of Davies Collison Cave are members of the Institute of Patent and Trade Mark Attorneys of Australia, we are providing a separate submission in relation to the matters which have been referred to the Senate Legal and Constitutional Affairs Legislation Committee for inquiry.

If the Committee wishes to explore the matters raised in our submission further, I would welcome an opportunity to discuss these further at a public hearing as suggested in your letter.

Yours faithfully
DAVIES COLLISON CAVE

John Slattery

Melbourne
Sydney
Brisbane
Canberra
Newcastle

In association with:
Davies Collison Cave Law
Intellectual Property

SENATE LEGAL AND CONSTITUTIONAL AFFAIRS COMMITTEE

PATENT AMENDMENT (HUMAN GENES & BIOLOGICAL MATERIALS) BILL 2010

Submission by

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February 2011

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INTRODUCTION

This submission is made in response to the invitation to contribute to the Inquiry into the Patent Amendment (Human Genes And Biological Materials) Bill 2010 which has been referred to the Senate Legal and Constitutional Affairs Committee, and which, according to its long title, is a Bill "to amend the Patents Act 1990 to prevent the patenting of human genes and biological materials existing in nature, and for related purposes".

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 "biological materials" and technologies, including 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 in this field which have been developed overseas, for example in USA, Europe and Japan.

PURPOSE OF THE BILL

According to the Explanatory Memorandum, the Bill "(a) reinforces the applicability of the proviso in section 6 of the Statute of Monopolies within the meaning of section 18(1)(a) and section 18(1A)(a), (b) reinforces the applicability of the distinction between discovery and invention and (c) applies that distinction by expressly excluding from patentability, biological materials which are identical or substantially identical to such materials as they exist in nature, however made".

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 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 present inquiry.

The ALR Report specifically addressed 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 the context of the present inquiry, it is noted that ALRC 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.*

5. "Review of Patentable Subject Matter" – Advisory Council on Intellectual Property (ACIP) (December 2010)

Following a recommendation in the ALRC Report that the "manner of manufacture" test be reviewed, ACIP was requested to conduct a review of patentable subject matter, including the appropriateness and adequacy of the "manner of manufacture" test as the threshold requirement for patentable subject matter under Australian law. ACIP released an Issues Paper in July 2008, and following the release of this Paper written submissions were received and public consultations were held with interested parties. In September 2009, ACIP released an Options Paper and a number of written submissions were received in response. The final report by ACIP to the Government has just been made public. While this report does include a recommendation that patentable subject matter be defined in the Patents Act 1990 "using clear and contemporary language that embodies the principles of inherent patentability as developed by the High Court in the NRDC case and subsequent Australian court decisions" (Recommendation 3), for the purposes of the present inquiry it is important to note that the report does <u>not</u> recommend the introduction of a specific exclusion to prevent the patenting of human genes and genetic products, and recommends the retention of the specific exclusions currently set out in sub-section 18(2) of the Patents Act (Recommendation 6).

6. "Gene Patents" – Report of the Senate Community Affairs References Committee (2010)

In general terms, this Committee considered the impact of "Gene Patents" on healthcare, medical research and the health and wellbeing of Australians. After extensive investigation and inquiry, the Committee indicated that a number of considerations persuaded the Committee that it

would not, at that point in time, recommend that the Patents Act 1990 be amended to expressly prohibit the patenting of genes. The Committee did, however, include a recommendation that the Government provide a combined response addressing the Committee's enquiry into gene patents, the 2004 report on gene patents by the Australian Law Reform Commission, the review of patentable subject matter by ACIP and the review of Australia's patent system by IP Australia (Recommendation 4).

"INVENTION" - PATENTS ACT 1990

Schedule I of the Patents Act 1990 contains a definition of "invention" as:

> "any manner of new manufacture the subject of Letters Patent and grant of privilege within Section 6 of the Statute of Monopolies, and includes an alleged invention".

The Statute of Monopolies, enacted in England in 1623, declared all monopolies "for the sole buying, selling, making, working and using of any thing within this realm" to be contrary to law and utterly void, with certain exceptions, including the exception provided in Section 6 of the Statute as follows:

> "Provided also, and be it declared and enacted, that any declaration before mentioned shall not extend to any letters patent and grants of privilege for the term of 14 years or under, hereafter to be made, of the sole working or making of any *manner of new manufactures* within this realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters or grant shall not use, so as also they not be contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient (emphasis added).

In the decision of the High Court of Australia in National Research and Development Corporation *v.* The Commissioner of Patents (NRDC) (1959) 102 CLR 252, which considered this definition of "invention" in the previous Patents Act, the approach to be adopted in determining whether the invention claimed in a particular patent application constitutes proper subject matter for the grant of a patent under Australian law was stated to be:

> The right question is: "Is this a proper subject of the letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies?"*

For an invention to be a "manner of manufacture" as interpreted by the High Court in NRDC, it must be an "artificially created state of affairs" which belongs to the useful arts rather than the fine arts, it must provide a material advantage, and its value to the country must be in the field of economic endeavour.

Judicial interpretation of the "manner of manufacture" test has also recognised a number of categories of subject matter that will fail to satisfy the test. These include mere discoveries, ideas, scientific theories and laws of nature.

"PATENTABLE INVENTION" – PATENTS ACT 1990

Schedule I of the Patents Act 1990 defines that "patentable invention":

> "means an invention of the kind mentioned in Section 18".

Section 18 (1) provides that, so far as claimed in any claim, an invention is patentable if it meets all of the following criteria:

> (a) is a manner of manufacture within the meaning of Section 6 of the Statute of Monopolies;
>
> (b) is novel and involves an inventive step;
>
> (c) is useful, and
>
> (d) has not been used secretly within Australia prior to the filing of the patent application.

Section 18 (A) sets out similar criteria with regard to Innovation Patents, with the exception of the requirement of "an innovative step" rather than "an inventive step". The comments in this submission with regard to Section 18 (1) are equally applicable in relation to Section 18 (A)(1).

PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

It is significant to note that the Bill does not propose any amendment to Schedule I of the Patents Act 1990. Accordingly, no change is proposed to the current interpretation of "invention" under the Patents Act 1990, nor to the approach to interpreting the concept of "invention" based on the decision of the High Court in NRDC.

The Bill does, however, propose an amendment to Section 18 (1)(a) to read:

> (a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies

It is not apparent what, if any, difference there is between the current term "within the meaning" and the proposed term "within the full meaning". Accordingly, it is submitted that unless there is some readily apparent difference in meaning arising from this change in terminology, the effect of the change will be to simply introduce an unnecessary ambiguity into the legislation.

Similarly, although Section 6 of the Statute of Monopolies is itself expressed as a proviso as set out above, it is not apparent what is meant by the proposed term "including the proviso", as there is no proviso within Section 6 itself. Section 6 does include the qualification relating to the letters patent and grants of privilege permitted under that section that "they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient", however it is not clear whether the proposed term "including the proviso" relates to this qualification in Section 6, or not. Accordingly, it is submitted that the proposed inclusion of the term "including the proviso" would also introduce unnecessary ambiguity.

In summary, it is submitted that the amendments proposed to paragraph (a) of Section 18(1) by the Bill would lead to ambiguity and undesirable uncertainty in the interpretation of this subsection.

The major amendment to Section 18 proposed by the Bill is the amendment to Section 18 (2) which currently provides that "human beings and the biological processes for their generation, are not patentable inventions". The Bill proposes that this subsection be amended to:

(2) The following are not patentable inventions:

(a) human beings, and the biological process for their generation; and

(b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

In addition, the Bill proposes insertion of a new subsection 18(5) as follows:

(5) In this section:

biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids.

It is submitted that these proposals would introduce substantial and wide-ranging uncertainty into the Patents Act 1990, arising principally from the scope and potential impact of these proposed amendments, particularly in relation to the ambiguity, or lack of clarity which exists in relation to most of the terminology proposed to be introduced.

Firstly, the term "biological materials" is extremely broad and on its plain meaning, would extend to any material found in a living organism, whether it be animal (including human), plant, insect, microorganism (including bacteria, parasites, viruses and the like), yeast, mould or fungus, and the like. That the proposed understanding of the term "biological materials" is extremely broad in scope is also indicated by the definition of the term "biological materials" in proposed subsection 18(5) as including, (that is, not limited to) DNA, RNA, proteins, cells and fluids".

This definition makes it quite clear that it is proposed that the term "biological materials" extend not only to chemical molecules such as DNA, RNA and proteins, but also to more complex structures such as cells, and to fluids which may in fact contain both chemical compounds and more complex structures such as cells, for example, blood or fractions thereof. As one simple illustration of the extremely broad scope of the term "biological materials", it would encompass all chemical compounds and other substances having valuable therapeutic or other properties extracted or otherwise derived from plants, insects, microorganisms, yeasts, moulds or fungi.

As well as excluding all "biological materials", subsection 18(2) as proposed to be amended would also expressly exclude "their components and derivatives". It is submitted that this terminology would also introduce undesirable ambiguity as the scope of the terms "component" and "derivatives" is not only extremely broad but extremely unclear. By way of example, is a compound having valuable analgesic properties which has been identified as a component of a snake venom (a biological material) to be excluded? Furthermore, if the chemical structure of that compound is altered to make it a more effective analgesic, is this also to be excluded as a derivative of the compound? Given the very broad nature of the term "biological materials", it is almost impossible to ascertain what is the scope of the terms "components" and "derivatives" in relation to the entire range of "biological materials".

According to the proposed amendments, "biological materials" which are to be excluded from patentability are those "which are identical or substantially identical to such materials as they exist in nature". However, the terms "identical" and "substantially identical" are also unclear and again introduce unnecessary ambiguities since the proposed amendment does not indicate the parameters under which the identity or substantial identity are to be determined. By way of example only, is a piece of bone (a biological material) which has been chemically treated so that it can be used as an implant "identical or substantially identical" to the bone as it exists in nature because it has the same appearance as the original bone, or is it not "identical or substantially identical" because it has been chemically treated? As another example, is a protein molecule based on a molecule found in the human body but which has been chemically modified to improve its oral bioavailability without altering its therapeutic properties "identical or substantially identical" to the original protein molecule on the basis that it has the same therapeutic effect as the molecule existing in nature?

Finally, it is to be noted that the amendment proposed to subsection 18(2) would exclude biological materials "whether isolated or purified or not and however made". In this regard, it is important to note that in view of the "manner of manufacture" requirement of the Patents Act 1990, both in the definition of "invention" in Schedule I and in paragraph (a) of subsection 18 (1), it is <u>not</u> possible to secure patent protection in Australia in respect of biological materials (including genetic materials) in the form in which they exist in nature. As noted above, following the decision of the High Court in NRDC, the "manner of manufacture" requirement has been interpreted such that in order to secure patent protection in Australia in respect of such biological materials, in addition to meeting the novelty, inventive step and utility (usefulness) requirements, there must be an artificially

created state of affairs established through human intervention, with the result that such biological materials can only be protected in an isolated, purified, or synthetically produced form. Australia's present patent legislation would not allow a patentee to obtain the grant of a patent in respect of biological materials, including genetic materials, as they exist in nature, for example in the human or animal body or in a plant, insect, microorganism, yeast, mould, fungus or the like. As an example, under the present patent legislation, a compound having useful analgesic properties identified as a component of a snake venom can be protected provided it is claimed in an isolated or purified form, that is, in a form that reflects the artificially created state of affairs established through human intervention in isolation or purification of the compound. Clearly, the isolated or purified compound does not exist in nature in this form, although the compound as such is identical to the compound as it exists as a component of the snake venom.

It is submitted that the amendments to Subsection 18 (2) and the new subsection (5) as proposed in the Bill would introduce unacceptable ambiguity arising from the broad and uncertain scope and meaning of the various terms in the proposed amendments.

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 bond to comply with the provisions of this Agreement. The Agreement provides minimum stands 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 biological materials as proposed by the Bill in amended subsections 18(2) and would conflict with the requirement of Article 27 of TRIPS that patent protection should be available or inventions "without discrimination as to ... the field of technology", as these biological materials do not fall within the

specified subject matter that may be excluded from patentability under Article 27, paragraph 3.

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 biological materials as proposed by the Bill in amended Subsection 18(2) and new Subsection 18(5) would conflict with the obligation of Australia under the AUSFTA to make patents available for "any invention ... in all fields of technology", as these biological materials do not fall within the category of inventions which may be excluded from patentability under the AUSFTA.

INTERNATIONAL HARMONISATION

In addressing the amendments proposed in the Bill to amend the Patents Act 1990 to expressly prohibit the grant of patent protection over biological materials as set out in amended Subsection 18(2) and new Subsection 18(5) 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 does <u>not</u> exclude biological materials in general, or more specifically genetic materials such as isolated DNA or RNA molecules, 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 (it is noted that this definition is much more specific and therefore much narrower in scope than the definition of "biological material" in proposed new Subsection 18(5)). Article 3 of this Directive 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, it is clear any amendment of the Patents Act 1990 so as to expressly prohibit the grant of patent protection over biological materials as set out in amended Subsection 18(2) and new Subsection 18(5) would be a move directed away from harmonisation with the intellectual property laws of the US (contrary to the AUSFTA) and Europe.

COMMUNITY CONCERNS AND ALLEVIATING THESE CONCERNS

The submission by The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) to the present inquiry contains a comprehensive outline and discussion of community concerns which led to the inquiry into "gene patents" by the Senate Community Affairs Committee, and to the introduction of the present Bill (see the Second Reading Speech of Senator Hefferman on 24 November 2010).

The IPTA submission also addresses the impact of the present Bill and its unintended consequences, highlighting the shortcomings of the Bill in alleviating these community concerns. This submission fully supports and endorses the IPTA comments and submissions in these areas.

ALTERNATIVE OPTIONS FOR DEALING WITH COMMUNITY CONCERNS

This submission also fully supports and endorses the IPTA submission that the present Bill is an ineffective mechanism for dealing with the community concerns which led, *inter alia*, to the introduction of the Bill, as well as the discussion in that submission of the alternative options which exist for dealing with these community concerns including both safeguards which already exist in the present Patents Act (compulsory licenses and Crown use) and those which have been proposed (research use exemption). In addition it is noted that the proposed "raising the bar" amendments to the present Patents Act are focussed on strengthening the present Patents Act by ensuring that the other patentability requirements in Section 18 (novelty, inventive step and utility) are appropriately and properly applied by IP Australia during the patent examination process.

CONCLUSION

It is submitted that the amendments to Section 18 (and Section 18A) of the Patents Act 1990 as proposed by the Bill would lead to ambiguity in the section which would result in a large degree of uncertainty in understanding the scope and impact of the legislation. Furthermore, it is submitted that these amendments would be in conflict with Australia's obligation under International Agreements (TRIPS: USFTA) and would constitute a substantial move away from harmonisation of Australia's patent laws with major jurisdictions, particularly the United States and Europe.

Finally, it is submitted that the amendments proposed by the Bill would be ineffective in addressing and dealing with community concerns which led, *inter alia*, to the introduction of the Bill, and that these concerns are better dealt with by alternative options both in the present Patents Act, and proposed in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011.

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 system, including 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 DIRECTIVE 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.