



25 February 2011

Committee Secretary

Senate Legal and Constitutional Affairs Committee

PO Box 6100

Parliament House

Canberra ACT 2600

**By email: [legcon.sec@aph.gov.au](mailto:legcon.sec@aph.gov.au)**

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

Dear Sir/Madam,

We refer to the opportunity provided by the Committee for public comment on the amendments proposed in the above mentioned Bill to s18 of the Patents Act 1990.

The members of LESANZ are members of other organizations including the various state based legal societies, Ausbiotech Ltd, the Institute of Patent & Trade Marks Attorneys and Knowledge Commercialisation Australia which have provided, or will provide submissions on behalf of their members to this Committee on this issue. LESANZ submits these comments as proponents of technology and knowledge transfer and commercialisation throughout Australia and internationally.

If the Committee wishes to further discuss an aspect of these comments, we welcome the opportunity to do so in any appropriate forum that the Committee chooses.

Yours Faithfully

**Licensing Executives Society of Australia and New Zealand, Inc**

Karen Sinclair

President

SENATE LEGAL AND CONSTITUTIONAL AFFAIRS COMMITTEE

PATENT AMENDMENT (HUMAN GENES & BIOLOGICAL MATERIALS)  
BILL 2010

Submission by

The Licensing Executives Society of Australia and New Zealand

25 February 2011

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## **EXECUTIVE SUMMARY**

LESANZ represents a broad range of personal opinions and as such does not, in this submission, comment on the detail of the amendments proposed in the Bill to s18 of the Patents Act 1990. This input is more appropriately provided by others. LESANZ has had the advantage of reading briefing notes in this respect prepared by several organisations including for example, Ausbiotech Ltd. In general terms, LESANZ agrees that the amendment proposed in the Bill goes far beyond any measure necessary to address the concerns that have been publicly raised concerning access to patenting genetic technologies.

LESANZ wishes to stress that it views the amendments proposed to be made to s18 as unnecessary in view of alternate provisions in the Patents Act 1990 which allow Government to enforce, or itself have, access to technologies which are considered in the national importance or to which access is inappropriately prevented by the patentee.

These alternate options include:

- Crown use provisions (s163 Patents Act)
- Compulsory License provisions (s133 Patents Act)
- Compulsory Acquisition by Government provisions (s171 Patents Act)
- Competition law (Competition and Consumer Act 2010)

While rarely used in the manner proposed in this submission, these provisions all exist to address precisely the access issues at the heart of the gene patent debate and must be fully explored as viable alternatives by the Committee before it recommends that the current Bill be passed by Parliament.

## **BACKGROUND**

LESANZ is an organization of over 500 members involved in commercialisation of intellectual property. Membership is split approximately evenly between service providers (patent attorneys and lawyers) and others (research organisations, industry, academia). This response represents the view of the organisation collectively but may not reflect the views of individual members on all issues.

LESANZ recognises the importance of global harmonisation of IP laws and actively works to achieve this end through the parent body, Licensing Executives Society International (LESI). LESI has significant chapters throughout the world including USA, Europe, Japan, Germany, the UK and Korea.

Members of LESANZ are individuals many of whom are employed by organizations operating in the field of biotechnology and specifically in fields including research, development, marketing and sales of technology relating to “biological materials” and more specifically genetic materials.

## INTRODUCTION

After several deferments the Senate Community Affairs References Committee published a report on its Inquiry into the impact of patents directed to genetic material on 26th November 2010, making 16 recommendations. The executive summary stated that: “A number of considerations persuaded the committee that it would not, at this point in time, recommend that the [Patents] Act be amended to expressly prohibit the patenting of genes.”

The Inquiry directed at ascertaining the impact of so-called gene patents on healthcare, medical research and the health and well being of Australians took extensive evidence and concluded after a lengthy review that there were only isolated incidents of the impact of gene patents on the provision of healthcare and medical research, and that there is evidence that this impact has been positive. A highlighted deficiency was the inadequacy of health policymakers in Australia to monitor for, and collect, hard data of occurrences of gene patents negatively impacting on the health sector.

The Committee’s report suggested that reforms proposed by IP Australia, after extensive public discussion, to the inventive step test, the usefulness requirement and the full description and fair basis requirements for patentability under the Patents Act may go a long way to “limit the reach of claims so that the protection given to an inventor is not disproportionate with what has been described”.

A number of other committees and commissions have conducted inquiries over the last 25 years into what is appropriately patentable subject matter and into gene patenting in particular. The outcomes of these reviews are currently reflected in the current wording of s18 of the Patents Act. The detail of the outputs of these various reviews insofar as they result to the patentability of genetic material must be taken into consideration by the current Committee. The issue of the patentability of genetic materials has been one of the most controversial, constant and most studied aspects of the patent regime since the seminal US case in *Chakrabarty*<sup>1</sup>. That it is an

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<sup>1</sup> *Diamond v. Chakrabarty*, 447 [U.S. 303](#) (1980),

emotive issue is without question. That there should be unprecedented amendment to a fundamental principle of patent law upon which Australian jurisprudence<sup>2</sup> is considered seminal is reactive, unnecessary and fails to take into consideration legislative alternatives in the Australian Patents Act 1990 and in consumer protection legislation which exist to address precisely the issue at the heart of the debate: access at a reasonable price, and in volume to patented technologies, no matter their type.

Alternatives to banning DNA and related technology from patentability can be found in the Patents Act. These are all government-implemented measures to address the inappropriate exploitation of a patent in a way that greatly impacts on others in society. These are discussed in further detail below and the relevant provisions may be found in the Appendix to this submission.

### **CROWN USE PROVISIONS**

Under Section 163 of the Patents Act, the government or an authorised representative may exploit a patent without infringement liability if exploitation of the invention is necessary for the proper provision of government services within Australia. Australia has a strong public hospital network and a universal, government-funded healthcare system, both of which might be able to exploit these provisions.

The Government must inform the patentee and reach an agreement with it in relation to the terms of exploitation and remuneration.

The exploitation of a patent for crown use has occurred on only two occasions, both of which were contested by the patentee. The cases are *Stack v Brisbane City Council* ((1994) 31 ALR 333) and *General Steel Industries Inc v Commissioner for Railways (NSW)* ((1964) 112 CLR 125) – the former related to water meters and the latter to railway carriage construction.

According to the Australian Law Reform Commission, Crown use provisions involve significant interference with the rights of the patentee to exploit the invention according to their terms. There is an argument that exercise of Crown use provisions should be employed only in situations such as public health emergencies or for the protection of citizens. Nevertheless, *Stack* and *General Steel* provide precedents for the government to take action in a public policy matter without the need to enact revisions to the law.

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<sup>2</sup> NRDC v Commissioner (1959) 102 CLR 232

If there is no empirical evidence to suggest that gene patents generally hinder research or the ability of diagnostic labs to perform testing, then the accessional miscreant may be dealt with by the threat of crown use of the invention by a public organisation, such as a hospital that provides genetic testing.

One advantage of invoking Crown use provisions is that the healthcare authority would not need to instigate court proceedings or undertake protracted negotiations.

### **COMPULSORY LICENCE PROVISIONS**

A person may apply under s133 of the Patents Act 1990 to a prescribed court for a compulsory licence to exploit a patent after a period of three years from the date of patent grant.

The court may award a compulsory licence if:

- The reasonable requirements of the public with respect to the patented invention have not been satisfied.
- The patentee has not given a satisfactory reason for failing to exploit the invention.
- The applicant has tried for a reasonable period to obtain a licence on reasonable terms.

The reasonable requirements of the public may be considered not to have been met if an industry or trade in Australia is unfairly prejudiced, or the demand for the patented product or process is not reasonably met because of the patentee's failure to:

- Manufacture the product or part of the product to an adequate extent, and supply it on reasonable terms.
- Perform the patented process to a reasonable extent.
- Grant a licence on reasonable terms.

The Intellectual Property Laws Amendments Act 2006 enables a court to grant a compulsory licence if the patentee is acting anti-competitively in contravention of Part IV of the Trade Practices Act 1974 or an application law as defined in Section 150A of that act.

It appears that no compulsory licences have been granted in Australia since Federation, nor have many been granted in other countries with similar provisions. However, they have been granted to

remedy anti-competitive conduct (in the United States, generally in response to large mergers), to facilitate access to patented medicines (in Zambia, Zimbabwe and Thailand) and in the public interest (Cipro in the United States' readiness to treat Anthrax in 2001).

### **ACQUISITION BY THE COMMONWEALTH**

The provisions of Section 171 of the Patents Act allow the government to acquire a patent or patent application with compensation to the patent holder.

There are no guidelines under this section as to the circumstances that must occur before the government may acquire the invention. Circumstances may arise in respect of national security or simply to affect social policy. However, although there are no reported instances of patent acquisition by an Australian Federal Government, and although any such acquisition powers are appropriately exercised in a manner, reasons other than the obvious national security purposes would seem appropriately considered under this heading.

### **COMPETITION LAW**

One final option exists in the consumer protection laws which could be amended to discourage more definitively anti-competitive behaviour by patent holders in relation to public health issues.

### **CONCLUSION**

It is submitted that the proposal to amend s18 is likely to lead to unexpected consequences that go far beyond the intention of those that propose it. These include a diminution of Australia's ability to compete internationally, and a likely decrease in the engagement of researchers from both Australia and off shore in commercial activities necessary to generate wealth and well being for Australia.

It is submitted that alternate provisions of the Patents Act provide existing solutions to the problem of access to patented genetic technologies and that these present a viable solution if properly utilized by Government in the manner in which they were intended.

## APPENDIX – extracts of the Patents Act 1990

### COMPULSORY LICENCE PROVISIONS

#### 133 Compulsory licences

(1) Subject to subsection (1A), a person may apply to the Federal Court, after the end of the prescribed period, for an order requiring the patentee to grant the applicant a licence to work the patented invention.

(1A) A person cannot apply for an order in respect of an innovation patent unless the patent has been certified.

(2) After hearing the application, the court may, subject to this section, make the order if satisfied that:

(a) all the following conditions exist:

(i) the applicant has tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions;

(ii) the reasonable requirements of the public with respect to the patented invention have not been satisfied;

(iii) the patentee has given no satisfactory reason for failing to exploit the patent; or

(b) the patentee has contravened, or is contravening, Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.

(3) An order must direct that the licence:

(a) is not to give the licensee, or a person authorised by the licensee, the exclusive right to work the patented invention; and

(b) is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used;

and may direct that the licence is to be granted on any other terms specified in the order.

(3B) If the patented invention cannot be worked by the applicant without his or her infringing another patent:

(a) the court is to make the order only if the court is further satisfied that the patented invention involves an important technical advance of considerable economic significance on the invention (other invention) to which the other patent relates; and

(b) the court must further order that the patentee of the other invention:

(i) must grant to the applicant a licence to work the other invention insofar as is necessary to work the patented invention; and

(ii) is to be granted, if he or she so requires, a cross-licence on reasonable terms to work the patented invention; and

(c) the court must direct that the licence granted by the patentee of the other invention may be assigned by the applicant:



- (i) only if he or she assigns the licence granted in respect of the patented invention; and
- (ii) only to the assignee of that licence.

(4) An order operates, without prejudice to any other method of enforcement, as if it were embodied in a deed granting a licence and executed by the patentee and all other necessary parties.

(5) The patentee is to be paid in respect of a licence granted to the applicant under an order:

(a) such amount as is agreed between the patentee and the applicant; or

(b) if paragraph (a) does not apply—such amount as is determined by the Federal Court to be just and reasonable having regard to the economic value of the licence and the desirability of discouraging contraventions of Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act).

(6) The patentee or the Federal Court may revoke the licence if:

(a) the patentee and the licensee are agreed, or the court on application made by either party finds, that the circumstances that justified the grant of the licence have ceased to exist and are unlikely to recur; and

(b) the legitimate interests of the licensee are not likely to be adversely affected by the revocation.

#### 134 Revocation of patent after grant of compulsory licence

(1) Where a compulsory licence relating to a patent is granted, an interested person may apply to the Federal Court, after the end of the prescribed period, for an order revoking the patent.

(2) After hearing the application, the court may make the order if satisfied that:

(a) both:

(i) the reasonable requirements of the public with respect to the patented invention have not been satisfied; and

(ii) the patentee has given no satisfactory reason for failing to exploit the patent; or

(b) the patentee is contravening Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.

#### 135 Reasonable requirements of the public

(1) For the purposes of sections 133 and 134, the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied if:

(a) an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure:

(i) to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or

(ii) to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or

(iii) to carry on the patented process to a reasonable extent; or

(iv) to grant licences on reasonable terms; or

(b) a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or

(c) if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.

(2) If, where paragraph (1)(c) applies, the court is satisfied that the time that has elapsed since the patent was sealed has, because of the nature of the invention or some other cause, been insufficient to enable the invention to be worked in Australia on a commercial scale, the court may adjourn the hearing of the application for the period that the court thinks sufficient for that purpose.

### 136 Orders to be consistent with international agreements

An order must not be made under section 133 or 134 that is inconsistent with a treaty between the Commonwealth and a foreign country.

### 136A Dealing with allegation of contravention of application law

Proceedings under section 133 or 134 involving an allegation of contravention of an application law that is a law of a State must be dealt with as if the law were a law of the Commonwealth.

Note: Those proceedings are in the Federal Court, which can only exercise the judicial power of the Commonwealth. This section lets the court deal comprehensively with the proceedings without the need for a court of the State to determine whether the application law has been contravened.

### 137 Revocation on surrender of patent

(1) A patentee may, at any time, by written notice to the Commissioner, offer to surrender the patent.

(2) The Commissioner must give notice of an offer in accordance with the regulations.

(3) After hearing all interested persons who notify the Commissioner in accordance with the regulations of their wish to be heard, the Commissioner may accept the offer and revoke the patent.

(4) Where relevant proceedings in relation to a patent are pending, the Commissioner must not accept an offer to surrender the patent without either the leave of the court or the consent of the parties to the proceedings.

(5) Where a compulsory licence is in force in relation to a patent, the Commissioner must not accept an offer to surrender the patent.

### 138 Revocation of patents in other circumstances

(1) Subject to subsection (1A), the Minister or any other person may apply to a prescribed court for an order revoking a patent.

(1A) A person cannot apply for an order in respect of an innovation patent unless the patent has been certified.

(2) At the hearing of the application, the respondent is entitled to begin and give evidence in support of the patent and, if the applicant gives evidence disputing the validity of the patent, the respondent is entitled to reply.

(3) After hearing the application, the court may, by order, revoke the patent, either wholly or so far as it relates to a claim, on one or more of the following grounds, but on no other ground:

(a) that the patentee is not entitled to the patent;

(b) that the invention is not a patentable invention;

(d) that the patent was obtained by fraud, false suggestion or misrepresentation;

(e) that an amendment of the patent request or the complete specification was made or obtained by fraud, false suggestion or misrepresentation;

(f) that the specification does not comply with subsection 40(2) or (3).

#### 139 Parties to proceedings

(1) The patentee, and any person claiming an interest in the patent as exclusive licensee or otherwise, are parties to any proceedings under section 133, 134 or 138.

(2) In any proceedings under section 133, 134 or 138:

(a) the applicant must serve a copy of the application on the Commissioner; and

(b) the Commissioner may appear and be heard in the proceedings.

#### 140 Commissioner to be given copies of orders

An office copy of an order made under this Chapter must be served on the Commissioner by the Registrar or other appropriate officer of the court that made the order.

### **CROWN USE PROVISIONS**

#### Chapter 17—The Crown

##### Part 1—Introductory

#### 161 Nominated persons and patentees

A reference in this Chapter to a nominated person or to a patentee includes a reference to the successor in title of the nominated person or patentee or an exclusive licensee of the nominated person or patentee.

#### 162 Commonwealth and State authorities

A reference in this Chapter to the Commonwealth includes a reference to an authority of the Commonwealth and a reference to a State includes a reference to an authority of a State.

##### Part 2—Exploitation by the Crown

#### 163 Exploitation of inventions by Crown

(1) Where, at any time after a patent application has been made, the invention concerned is exploited by the Commonwealth or a State (or by a person authorised in writing by the Commonwealth or a State) for the services of the Commonwealth or the State, the exploitation is not an infringement:

(a) if the application is pending—of the nominated person's rights in the invention; or

(b) if a patent has been granted for the invention—of the patent.

(2) A person may be authorised for the purposes of subsection (1):

(a) before or after any act for which the authorisation is given has been done; and

(b) before or after a patent has been granted for the invention; and

(c) even if the person is directly or indirectly authorised by the nominated person or patentee to exploit the invention.

(3) Subject to section 168, an invention is taken for the purposes of this Part to be exploited for services of the Commonwealth or of a State if the exploitation of the invention is necessary for the proper provision of those services within Australia.

#### 164 Nominated person or patentee to be informed of exploitation

As soon as practicable after an invention has been exploited under subsection 163(1), the relevant authority must inform the applicant and the nominated person, or the patentee, of the exploitation and give him or her any information about the exploitation that he or she from time to time reasonably requires, unless it appears to the relevant authority that it would be contrary to the public interest to do so.

#### 165 Remuneration and terms for exploitation

(2) The terms for the exploitation of the invention (including terms concerning the remuneration payable to the nominated person or the patentee) are such terms as are agreed, or determined by a method agreed, between the relevant authority and the nominated person or the patentee or, in the absence of agreement, as are determined by a prescribed court on the application of either party.

(3) For the purposes of subsection (2), the terms, or the method, may be agreed before, during or after the exploitation.

(4) When fixing the terms, the court may take into account any compensation that a person interested in the invention or the patent has received, directly or indirectly, for the invention from the relevant authority.

#### 165A Exploitation of invention to cease under court order

(1) A prescribed court may, on the application of the nominated person or the patentee, declare that the exploitation of the invention by the Commonwealth or the State is not, or is no longer, necessary for the proper provision of services of the Commonwealth or of the State if the court is satisfied that, in all the circumstances of the case, it is fair and reasonable to make the declaration.

(2) The court may further order that the Commonwealth or the State is to cease to exploit the invention:

- (a) on and from the day specified in the order; and
- (b) subject to any conditions specified in the order.

In making the order, the court is to ensure that the legitimate interests of the Commonwealth or of the State are not adversely affected by the order.

#### 166 Previous agreements inoperative

An agreement or licence (whether made or given before or after the commencement of this Act) fixing the terms on which a person other than the Commonwealth or a State may exploit an invention is inoperative with respect to the exploitation, after the commencement of this Act, of the invention under subsection 163(1), unless the agreement or licence has been approved:

- (a) if the relevant authority is the Commonwealth—by the Minister; or
- (b) if the relevant authority is a State—by the Attorney-General of the State.

## 167 Sale of products

(1) The right to exploit an invention under subsection 163(1) includes the right to sell products made in exercise of that right.

(2) Where under subsection 163(1) the sale of products is not an infringement of:

- (a) a patent; or
- (b) a nominated person's rights in the products;

the buyer, and any person claiming through the buyer, is entitled to deal with the products as if the relevant authority were the patentee or the nominated person.

## 168 Supply of products by Commonwealth to foreign countries

Where the Commonwealth has made an agreement with a foreign country to supply to that country products required for the defence of the country:

(a) the use of a product or process by the Commonwealth, or by a person authorised in writing by the Commonwealth, for the supply of that product is to be taken, for the purposes of this Chapter, to be use of the product or process by the Commonwealth for the services of the Commonwealth; and

(b) the Commonwealth or the authorised person may sell those products to the country under the agreement; and

(c) the Commonwealth or the authorised person may sell to any person any of the products that are not required for the purpose for which they were made.

## 169 Declarations that inventions have been exploited

(1) Subject to subsection (4), a patentee who considers that the patented invention has been exploited under subsection 163(1) may apply to a prescribed court for a declaration to that effect.

(2) In proceedings under subsection (1):

(a) the alleged relevant authority is the defendant; and

(b) the alleged relevant authority may apply by way of counter-claim in the proceedings, for the revocation of the patent.

(3) The provisions of this Act relating to the revocation of patents apply, with the necessary changes, to a counter-claim.

(4) An application under subsection (1) in respect of an innovation patent cannot be made unless the patent has been certified.

## 170 Sale of forfeited articles

Nothing in this Chapter affects the right of the Commonwealth or a State, or of a person deriving title directly or indirectly from the Commonwealth or a State, to sell or use an article forfeited under a law of the Commonwealth or the State.

## **ACQUISITION BY THE CROWN**

### Part 3—Acquisitions by and assignments to the Crown

## 171 Acquisition of inventions or patents by Commonwealth

(1) The Governor-General may direct that a patent, or an invention that is the subject of a patent application, be acquired by the Commonwealth.

(2) When a direction is given, all rights in respect of the patent or the invention are, by force of this subsection, transferred to and vested in the Commonwealth.

(3) Notice of the acquisition must be:

(a) given to the applicant and the nominated person, or the patentee; and

(b) published in the Official Journal and the Gazette unless, in the case of the acquisition of an invention that is the subject of an application for a patent, a prohibition order, or an order under section 152, is in force in respect of the application.

(4) The Commonwealth must pay a compensable person such compensation as is agreed between the Commonwealth and the person or, in the absence of agreement, as is determined by a prescribed court on the application of either of them.

#### 172 Assignment of invention to Commonwealth

(1) An inventor, or an inventor's successor in title, may assign the invention, and any patent granted or to be granted for the invention, to the Commonwealth.

(2) The assignment and all covenants and agreements in the assignment are valid and effectual, even if valuable consideration has not been given for the assignment, and may be enforced by proceedings in the name of the Minister.