



Australian Government Response

to

Senate Community Affairs References Committee

Gene Patents Report

November 2011

Introduction

On 11 November 2008 the Senate referred matters relating to the patenting of human genes and genetic materials to the Senate Community Affairs References Committee (the Senate Committee) for inquiry and report. The Senate Committee tabled its report (the Senate Gene Patents Report) on 24 November 2010.

The terms of reference for the inquiry directed the Senate Committee to inquire into:

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.

The Senate Gene Patents Report contains 16 recommendations directed, in part, to:

- establishing mechanisms for monitoring the implications of gene patents and the operation of the patent system;
- increasing legal requirements for the grant of a patent;
- improving patent law and practice concerning the exploitation of gene patents, including in relation to a new research defence to claims of patent infringement, Crown use, and compulsory licensing of patents; and
- introducing measures to assist in the interpretation and application of the *Patents Act 1990*.

Recommendation 4 of the Senate Gene Patents Report also recommended that the Government provide a combined response to:

- the Senate Gene Patents Report;
- the 2011 Advisory Council on Intellectual Property's Patentable Subject Matter Report (ACIP PSM Report);
- the 2004 Australian Law Reform Commission's Report No. 99, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99 Report); and
- the review of Australia's patent system by IP Australia.

The Government accepts this recommendation. This Government response addresses the recommendations of the above three reports. The review of Australia's patent system by IP Australia does not involve any public recommendations for Government response. However, the relevant outcomes of this review are outlined in the responses to the recommendations of the three reports.

ALRC 99 Report

On 17 December 2002 the then Australian Government Attorney-General, the Hon Daryl Williams MP, asked the Australian Law Reform Commission (ALRC) to inquire into and report on the laws and practices governing intellectual property rights over genetic materials and related technologies, with a particular focus on human health issues. The ALRC's report, *Genes and Ingenuity: Gene Patenting and Human Health*, (ALRC 99, 2004) was tabled on 31 August 2004.

The terms of reference for the inquiry directed the ALRC to consider – with a particular focus on human health issues – the impact of current patenting laws and practices related to genes and genetic and related technologies on:

- the conduct of research and its subsequent application and commercialisation;
- the Australian biotechnology sector; and
- the cost-effective provision of healthcare in Australia.

The terms of reference also requested the ALRC to consider what changes, if any, may be required to address any problems identified in current laws and practices with the aim of encouraging the creation and use of intellectual property to further the health and economic benefits of genetic research and genetic and related technologies.

The ALRC 99 report contains 50 recommendations directed to:

- improving patent law and practice concerning the patenting of genetic materials and technologies, including through amendments to the *Patents Act 1990* and changes in the practices and procedures of IP Australia, patent examiners and the courts;
- improving patent law and practice concerning the exploitation of gene patents, including in relation to a new research defence to claims of patent infringement, Crown use, and compulsory licensing of gene patents;
- ensuring that publicly funded research, where commercialised, results in appropriate public benefit, including through the adoption of appropriate patent practices;
- encouraging universities and other research organisations to raise the awareness of researchers about patenting issues and the commercialisation of research;
- ensuring that Australian research organisations and biotechnology companies are adequately skilled to deal with issues concerning commercialisation and the licensing of patented inventions;
- establishing mechanisms for monitoring the implications of gene patents for research and healthcare so that governments have the ability to intervene where gene patents are considered to have an adverse impact, either in specific cases or systemically;
- clarifying the application of competition law to the exploitation of intellectual property rights, including patented genetic materials and technologies; and

- clarifying the scope and practical application of exceptions to copyright infringement in relation to research.

ACIP PSM Report

In 2008 the Minister for Innovation, Industry, Science and Research, Senator the Hon Kim Carr, requested that the Advisory Council on Intellectual Property (ACIP) 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, and the historical requirement that an invention must not be ‘generally inconvenient’. Instigation of the review was informed by recommendation 6-2 of the ALRC 99 Report. ACIP released its report on patentable subject matter (ACIP PSM Report) on 16 February 2011.

The ACIP PSM Report contains 11 recommendations directed to various changes to the *Patents Act 1990* including:

- introducing a statement of objectives;
- defining patentable subject matter requirements using clear and contemporary language; and
- removing some of the current exclusions to patentable subject matter and introducing a morality exclusion.

The Government thanks the Senate Committee, the ALRC and ACIP for their reports. The Government’s response to the recommendations of these reports is set out below.

Government Response to Recommendations¹

Legend:

- The Senate Community Affairs Committee report, *Gene Patents* – November 2010 (**SGP Report**)
- The Advisory Council on Intellectual Property report, *Patentable Subject Matter* – December 2010 (**ACIP PSM Report**)
- The Australian Law Reform Commission report, *Genes and Ingenuity: Gene Patenting and Human Health*, (ALRC 99, 2004) – June 2004 (**ALRC 99 Report**)

SGP Report
Recommendation 1 3.156 The Committee recommends that the Government support and expand on the collection of data, research and analysis concerning genetic testing and treatment in Australia, in line with recommendation 19-1 of the 2004 Australia Law Reform Commission report <i>Genes and ingenuity</i> .
ALRC 99 Report
Recommendation 19–1 The Australian Health Ministers’ Advisory Council (AHMAC) should establish processes for: (a) economic evaluation of medical genetic testing and other new genetic medical technologies; and (b) examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

Response

The Government accepts these recommendations in principle.

The report and the Government response to the Review of Health Technology Assessment in Australia (HTA Review), which had been conducted as a Better Regulation Ministerial Partnership, were released by the Minister for Health and Ageing and the Minister for Finance and Deregulation in February 2010. In implementing the recommendations of the HTA Review that were accepted by Government, the Department of Health and Ageing has established the Health Technology Assessment Access Point to coordinate the provision of comprehensive advice to Government regarding co-dependent technologies, such as where the cost-effective use of a drug may be dependent on the result of a genetic test, and to determine the appropriate methodology for assessing such technologies.

The Government considers that the Medical Services Advisory Committee (MSAC) is the appropriate body to undertake evaluations of medical genetic tests (including their cost-effectiveness) based on available evidence. MSAC undertakes evaluations on eligible medical services on application from non-government bodies, on referral from Government, and as requested by the Australian Health Ministers’ Advisory Committee (AHMAC). The National Health and Medical Research Council

¹ Given the overlap and similar areas covered by many of the recommendations, the Government has provided a single response to multiple recommendations of the reports where appropriate.

(NHMRC) can also provide advice on technical or ethical aspects of genetic testing if requested by MSAC to assist in its deliberations.

The Government considers that there is insufficient need at this time to establish a specific process for examination of the financial impact of gene patents in the delivery of healthcare. The economic value and impact of patents continues to be an area of research interest both in Australia and internationally. A number of intellectual property organisations, including the World Intellectual Property Organization (WIPO), have recently included on their staff economists for this purpose. In Australia such research is undertaken by a number of universities and institutes including the Intellectual Property Research Institute of Australia (IPRIA). IP Australia also maintains a watching brief on developments in this regard.

SGP Report
Recommendation 2 3.157 The Committee recommends that the Government conduct a public consultation and feasibility study regarding establishing a transparency register for patent applications and other measures to track the use of patents dealing with genes and genetic materials.
ALRC 99 Report
Recommendation 9-1 IP Australia should develop and regularly update a searchable online database comprising patents and published patent applications. The database should: (a) be accessible to the public through IP Australia's website; (b) provide user-friendly access and search capabilities on a wide variety of bases; and (c) as soon as practicable, provide full-text searching of all complete specifications of published Australian patent applications and granted patents.

Response

The Government accepts Recommendation 9-1 of the ALRC 99 Report and notes that IP Australia has developed and implemented the AusPat search system to provide ready access to Australian patent information including full-text searching of complete specifications back to 1904 (commencement of the first Commonwealth Patents Act²). AusPat is a world standard database of patent applications enabling searches to be conducted across 28 different data fields including applicant/inventor name, technology, etc.. The functionality of the system caters for the novice to the advanced searcher including on-line support through a feedback mechanism.

In addition the system includes an 'eDossier' facility which means that the public will be able to readily see any objections raised by the patent examiner and the responses, amendments, etc. submitted by the patent applicant to overcome those and result in grant of a patent. This facility provides access to patent application files open to public inspection (which occurs 18 months from filing) from 2006.

² *Patents Act 1903* (Cth).

The Government will continue to explore web-based technology to make patent data more readily accessible and understood by the Australian community as part of continuous improvement of existing capabilities.

The Government accepts Recommendation 2 of the SGP Report as it relates to patent applications rather than how it relates to the 'use' of patents. The Government notes that the Intellectual Property Research Institute of Australia (IPRIA), which is partly funded by Government, has in the past and continues to conduct research on the use of patents. This includes research on patent enforcement and assignment.

SGP Report

Recommendation 3

4.137 The Committee recommends that the Senate refer the Patent Amendment (Human Genes and Biological Materials) Bill 2010 to the relevant Senate committee for inquiry and report.

Response

This recommendation is a matter for the Senate.

SGP Report

Recommendation 4

5.161 The Committee recommends that the Government provide a combined response addressing the Committee's inquiry into gene patents; the 2004 report on gene patents by the Australian Law Reform Commission; the review of patentable subject matter by the Australian Council on Intellectual Property (ACIP); and the review of Australia's patent system by IP Australia. The Committee recommends that the response be provided not later than mid-2011 or three months after the release of the findings of all reviews.
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Response

The Government accepts this recommendation.

SGP Report

Recommendation 5

5.162 The Committee recommends that, at an appropriate time following the release of the ACIP review of patentable subject matter and the IP Australia review of the patent system, the Community Affairs References Committee be tasked with inquiring into the Government's response to, and implementation of, the recommendations of those reviews, as well as the recommendations of the Committee's report on gene patents.

Response

This recommendation is a matter for the Senate.

SGP Report

Recommendation 6

5.172 The Committee recommends that the <i>Patents Act 1990</i> be amended so that the test for obviousness in determining inventive step is that a claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'.
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Response

The Government accepts this recommendation in principle.

The Government acknowledges the need to raise Australia's patent standard for inventive step (which is used to determine whether or not the claimed invention is obvious). The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 which has been the subject of extensive public consultations over a two year period provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will in combination strengthen the inventive step requirements and increase the quality of patents that are granted. The test "obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success" is but one of a number of legal tests which can be used by examiners and the courts to determine obviousness.

SGP Report

Recommendation 7

5.173 The Committee recommends that the <i>Patents Act 1990</i> be amended to remove the limitation that 'common general knowledge' be confined to that existing in Australia at the time a patent application is lodged (that is, that 'common general knowledge' anywhere in the world be considered).
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Response

The Government accepts this recommendation.

Amendments to implement this recommendation are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

SGP Report

Recommendation 8

5.174 The Committee recommends that the <i>Patents Act 1990</i> be amended to remove the requirement that 'prior art information' for the purposes of determining inventive step must be that which could reasonably have been expected to be 'ascertained' (that is, that the 'prior art base' against which inventive step is assessed not be restricted to information that a skilled person in the relevant field would have actually looked for and found (ascertained)).
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Response

The Government accepts this recommendation.

Amendments to implement this recommendation are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The proposed amendments would also remove the requirement that prior art for the purposes of assessing the inventive step of an invention is restricted to only that information that would be 'understood and regarded as relevant' by a skilled person in the art. The requirements that prior art be 'understood' and 'regarded as relevant' are implicit in the pre-existing tests for inventive step. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

SGP Report

Recommendation 9

5.175 The Committee recommends that the <i>Patents Act 1990</i> be amended to introduce descriptive support requirements, including that the whole scope of the claimed invention be enabled and that the description provide sufficient information to allow the skilled addressee to perform the invention without undue experimentation.

Response

The Government accepts this recommendation.

Amendments to implement this recommendation are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

SGP Report**Recommendation 10**

5.179 The Committee recommends that the *Patents Act 1990* be amended to provide that an invention will satisfy the requirement of 'usefulness' in section 18(1) only in such cases as a patent application discloses a 'specific, substantial and credible' use; the Committee recommends that such amendments incorporate the full set of recommendations on this issue from the Australian Law Reform Commission's 2004 report, *Genes and ingenuity* (Recommendations 6-3 to 6-4).

ACIP PSM Report**Recommendation 5**

Amend the *Patents Act 1990* (Cth) so that the requirement of usefulness in paragraphs 18(1)(c) and 18(1A)(c) encompasses the requirement for utility that is currently an aspect of the manner of manufacture requirement, and is a ground for examination of a standard patent and an innovation patent.

ALRC 99 Report**Recommendation 6-3**

The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to:

- (a) include 'usefulness' as a requirement in the examination of an application for a standard patent and in the certification of an innovation patent;
- (b) provide that an invention will satisfy the requirement of 'usefulness' only if the patent application discloses a specific, substantial and credible use;
- (c) require the Commissioner of Patents to be satisfied on the balance of probabilities that the requirement of 'usefulness' is made out in order to accept an application for a standard patent or to certify an innovation patent; and
- (d) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed, in addition to its current role as a ground for revocation. (See also Recommendation 8-3.)

Recommendation 6-4

IP Australia should develop guidelines, consistent with the *Patents Act*, the *Patents Regulations 1991* (Cth) and existing case law, to assist patent examiners in applying the 'usefulness' requirement. The guidelines should outline factors relevant to determining whether a use disclosed in a patent application is specific, substantial and credible to a person skilled in the relevant art.

Response

The Government accepts these recommendations.

With regard to Recommendation 6-3(d) of the ALRC 99 Report, the *Patents Act 1990* was amended in 2004 to include paragraphs 18(1)(c) and 18(1)(d) as grounds of opposition under section 59. The introduced grounds of opposition are that the claimed invention:

- must be useful (paragraph 18(1)(c)); and
- must not have been secretly used in Australia before the priority date of the claim by, or on behalf of, or with the authority of, the patentee or nominated person or the predecessor in title to the invention (paragraph 18(1)(d)).

With regard to Recommendation 6-4 of the ALRC 99 Report, IP Australia has commenced work in developing such guidelines. The date for completion of the guidelines to implement this recommendation will depend on the timing of the

legislative changes required to implement all other elements of these recommendations.

Amendments to implement all other elements of these recommendations are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

SGP Report
Recommendation 11 5.185 The Committee recommends that the <i>Patents Act 1990</i> be amended to clarify the circumstances in which the Crown use provisions may be employed; and that the Government develop clear policies for the use of the Crown use provisions. The Committee recommends that the Government adopt the Australian Law Reform Commission's recommendations on this issue from its 2004 report, <i>Genes and ingenuity</i> (Recommendations 26-1 to 26-3)
ALRC 99 Report
Recommendation 26-1 The Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the <i>Patents Act 1990</i> (Cth) (<i>Patents Act</i>) for the purposes of promoting human health. Similarly, the Department of Health and Ageing should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health. Decisions about Crown use in specific cases must be made on their individual merits.
Recommendation 26-2 The Commonwealth should amend the <i>Patents Act</i> to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or of a State' if the exploitation of the invention by a Commonwealth or State authority (or by an authorised person) is for the provision of healthcare services or products to members of the public.
Recommendation 26-3 The Commonwealth should amend the <i>Patents Act</i> to provide that, when a patent is exploited under the Crown use provisions, the remuneration that is to be paid by the relevant authority must be paid promptly and must be just and reasonable having regard to the economic value of the use. Similarly, the Act should be amended to provide that, when a patent is acquired under the Crown acquisition provisions, compensation must be paid promptly and must be just and reasonable having regard to the economic value of the patent.

Response

The Government notes these recommendations.

The Advisory Council on Intellectual Property (ACIP) investigated and reported on the Crown use provisions (see 2005 ACIP Report, *Review of Crown Use Provisions for Patents and Designs*).

The Government decided that there was insufficient evidence to support any legislative changes to the current provisions. As a result of the ACIP Review, the Minister for Innovation, Industry, Science and Research wrote to relevant Commonwealth, State and Territory Ministers in March 2009 to raise awareness of government rights and obligations under the provisions. IP Australia also developed a public information sheet highlighting the Crown's rights and obligations and the rights of intellectual property owners under the provisions.

The Government does not see a need at present to develop a health-specific policy on the circumstances in which Crown use provisions should be exploited as the provisions are available for all Commonwealth, State and Territory services. The Government agrees that the circumstances in which a patented invention should be exploited pursuant to the Crown use provisions should be considered on a case-by-case basis.

<p>SGP Report</p> <p>Recommendation 12</p> <p>5.190 The Committee recommends that the Government amend the <i>Patents Act 1990</i> to clarify the scope of the 'reasonable requirements of the public' test, taking into account the recommendation of the Australian Law Reform Commission on this issue in its 2004 report, <i>Genes and ingenuity</i> (Recommendation 27-1); the Committee recommends that the Government review the operation of the competition based test for the grant of a compulsory licence, with particular reference to its interaction with the <i>Trade Practices Act 1974</i>.</p>
<p>ALRC 99 Report</p> <p>Recommendation 27-1</p> <p>The Commonwealth should amend the provisions of the <i>Patents Act 1990</i> (Cth) relating to compulsory licences by:</p> <p>(a) inserting the competition-based test recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence; and</p> <p>(b) clarifying the scope of the 'reasonable requirements of the public test'.</p>

Response

The Government accepts these recommendations.

As the SGP Report notes, the Government introduced a competition-based test as an additional ground for the grant of a compulsory licence in the *Intellectual Property Laws Amendment Act 2006*. Specifically, the provision provides for a compulsory licence to be available as a remedy if a person has contravened any anti-competitive conduct provision under Part IV of the *Competition and Consumer Act 2010*. The Government will review the operation of the compulsory licence provisions of the *Patents Act 1990* including measures to raise awareness of these provisions.

SGP Report
Recommendation 13
5.195 The Committee recommends that the <i>Patents Act 1990</i> be amended to include a broad research exemption.
ALRC 99 Report
Recommendation 13–1
The Commonwealth should amend the <i>Patents Act 1990</i> (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.

Response

The Government accepts these recommendations.

Amendments to introduce an exemption from infringement for acts done for experimental purposes are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia’s patent law with global trends regarding standards for patentability. The proposed amendments include a broad research exemption as well as an exemption for acts connected with obtaining regulatory approval (such as the conduct of trials to provide data necessary for obtaining regulatory approval). The exemption is technology neutral applying to research in any technology field and regulatory approval of any technology. The various changes proposed under the Bill will in combination increase the quality of patents that are granted and provide the sought after certainty for researchers.

SGP Report
Recommendation 14
5.197 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the <i>Patents Act 1990</i> , the Government consider amending the Act to include anti-avoidance provisions.

Response

The Government does not accept this recommendation.

The Government has considered the submissions and examples put forward to the Senate inquiry and in the SGP Report relating to this recommendation.

The Government is of the view that existing measures including: the ability for third parties to make submissions during examination of a patent application (section 27 of the *Patents Act 1990*), pre-grant opposition (Chapter 5 and 9A Part 3 of the *Patents Act 1990*), re-examination (Chapter 9 and 9A Part 2 of the *Patents Act 1990*), internal quality audits, and external administrative and judicial processes, provide for compliance and quality.

These measures will be enhanced further with improved access to patent information through the new eDossier system. The eDossier provides on-line, free of charge, public access to relevant documents and correspondence on the patent application prosecution file. The improved access to this information will increase the transparency of the patent system and enable members of the public to address any concerns they may have about perceived misuse of the system through these existing measures.

Furthermore, the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 which has been the subject of extensive public consultations over a two year period provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. Specifically, the Bill seeks to change the burden of proof to 'balance of probabilities' for all patentability criteria which with the addition of a statement of objectives to the *Patents Act 1990* (in accordance with Recommendation 15 of the SGP Report and Recommendation 1 of the ACIP PSM Report) will further assist the courts and patent examiners with the interpretation and application of the *Patents Act 1990*. The various changes proposed under the Bill will in combination increase the quality of patents that are granted.

SGP Report
<p>Recommendation 15</p> <p>5.198 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the <i>Patents Act 1990</i>, the Government consider amending the Act to include objects provisions.</p>
ACIP PSM Report
<p>Recommendation 1</p> <p>Include a statement of objectives in the <i>Patents Act 1990</i> (Cth) describing the purposes of the legislation.</p> <p>Recommendation 2</p> <p>The statement of objectives to be included in the <i>Patents Act 1990</i> (Cth) should describe the purposes of the legislation as being to provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of patent rights holders, the users of technological knowledge, and Australian society as a whole.</p>

Response

The Government accepts these recommendations.

The Government recognises that a statement of objectives in the *Patents Act 1990* would provide a clear statement of legislative intent. The Government will develop legislation to give effect to these recommendations and its intention that patents should not lead to patients being denied reasonable access to healthcare. The legislation will be the subject of the same considered and comprehensive public consultation process as the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 including public exposure of the legislation drafting instructions and the draft legislative provisions.

SGP Report
Recommendation 16
5.202 The Committee recommends that the Government establish a patent audit committee.

Response

The Government notes this recommendation.

The Government notes that the objective of the patent audit committee is to provide assurance to Government that the patent system is working as intended. The Government notes that the Advisory Council on Intellectual Property (ACIP) which is comprised of expert members appointed by the Minister for Innovation, Industry Science and Research already has the powers to undertake quality reviews where directed by the Minister and to co-opt temporary members with expertise in the relevant subject area of a review. The Government will consider varying ACIP's membership to ensure industry, research and community/consumer interests are sufficiently represented. ACIP can be tasked with providing advice to the Minister on matters such as:

- whether the patent system appropriately balances economic considerations with the needs of the community (including benefits to the community);
- emerging technologies and access issues; and
- compulsory licensing.

The Government also notes that any such reviews would be in addition to existing avenues to assure the quality of individual patents in Australia including substantive patent examination, re-examination, pre-grant opposition procedures, third party notification under section 27 of the *Patents Act 1990*, the administrative and judicial review system, and IP Australia's internal quality audits and transparency in the prosecution of patent applications through the eDossier facility (which provides on-line, free of charge, public access to relevant documents and correspondence on the patent application prosecution file). The Intellectual Property Research Institute of Australia (IPRIA) also has an active and varied research program looking at various topical patent issues, including issues of quality.

ACIP PSM Report
Recommendation 3 Define patentable subject matter in the <i>Patents Act 1990</i> (Cth), for the purposes of both a standard patent and an innovation patent, using clear and contemporary language that embodies the principles of inherent patentability as developed by the High Court in the NRDC case and in subsequent Australian court decisions.
Recommendation 4 Amend the <i>Patents Act 1990</i> (Cth) to enhance the clarity of the patentability requirements, and to remove overlap of the patentable subject matter provision with the provisions on novelty, inventive step and usefulness.
ALRC 99 Report
Recommendation 6–2 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’.

Response

The Government accepts these recommendations in principle, and will develop legislation to define patentable subject matter using clear and contemporary language. The Government recognises the important role of patents in commercialising health research and the need to provide industry with certainty within the patent system. The development of this legislation will be subject to considered and comprehensive public consultation. This will enable an opportunity to consider benefits and impacts on the health sector. The legislation drafting instructions and the draft legislative provisions will be subject to the same considered and comprehensive public consultation process as the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011.

The Government has already acted on Recommendation 6-2 of the ALRC 99 Report which has resulted in the ACIP PSM Report. The ‘manner of manufacture’ test has served the Australian intellectual property system well to date, but the Government recognised that as part of continuous improvement and international harmonisation it would be appropriate to review the test. However, due to the high degree of overlap between ‘manner of manufacture’ and other criteria for patentability, in order to be effective the scope of the review was broadened to encompass ‘patentable subject matter’. The terms of reference for the review were 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, and the historical requirement that an invention must not be ‘generally inconvenient’.

The ACIP PSM Report is the result of extensive public consultation over a two and a half year period including written submissions and public forums. The Government recognises the complexities of providing incentives for creating innovations, enabling further innovation and cost effective access to innovations. Any changes must therefore have full regard to all these. This is particularly important with respect to health-related innovations where understandably there is strong public concern about affordable access to healthcare.

It is also important to note that the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 which has also been the subject of extensive public consultations over a two year period provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The higher standards for demonstrating novelty, inventive step and usefulness will provide for patenting of inventions that demonstrate a more substantial level of inventiveness and thereby raise the overall quality of patents granted in Australia. In that regard the changes proposed under the Bill will deal directly with broad and speculative patents which are understandably of public concern. The Bill also has provisions to provide researchers and innovators with the freedom to undertake research and regulatory approval activities without fear of infringing patents. All these proposed changes to the *Patents Act 1990*, in combination with existing safeguards of Crown use and compulsory licences, increase clarity over patentability requirements, provide incentives for creating innovations and making them available and establish mechanisms for responding to anti-competitive behaviour.

The Government will also continue to monitor international developments through its membership of various fora including the World Intellectual Property Organization (WIPO) and World Health Organization (WHO), and international and domestic patent-related jurisprudence to ensure that the balance of interests continues to be maintained.

ACIP PSM Report

Recommendation 6

Retain the specific exclusions set out in sub-sections 18(2) and 18(3) of the <i>Patents Act 1990</i> (Cth).
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Response

The Government accepts this recommendation.

ACIP PSM Report

Recommendation 7

Repeal section 50 of the <i>Patents Act 1990</i> (Cth), and the corresponding grounds for revocation of an innovation patent contained in section 101B of the <i>Patents Act 1990</i> (Cth).
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Response

The Government accepts this recommendation having regard to the response in relation to Recommendations 8, 9 and 10 of the ACIP PSM Report.

ACIP PSM Report**Recommendation 8**

Include in the *Patents Act 1990 (Cth)* a patentability exclusion as permitted by Article 27(2) of the TRIPS Agreement.

Recommendation 9

Amend the *Patents Act 1990 (Cth)* so as to exclude from patentability an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.

Recommendation 10

Amend the *Patents Act 1990 (Cth)* to provide the Commissioner of Patents with an explicit power to seek advice, from any person the Commissioner considers appropriate, to assist the Commissioner in applying the general patentability exclusion proposed in ACIP Recommendation 8 and in ACIP Recommendation 9.

ALRC 99 Report**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 patentable 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.

Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of a patented invention.

Response

The Government accepts Recommendation 7-1 (a) in principle and (b) in full but not (c) of the ALRC 99 Report in recognition of the more recent proposals in the ACIP PSM Report.

The Government recognises the need for the patent system to reflect contemporary community expectations and therefore accepts Recommendations 8, 9 and 10 of the ACIP PSM Report but notes that the specific amendments to the *Patents Act 1990* will need to be consistent with Australia's international obligations. The Government will develop legislation to give effect to these recommendations. The legislation will be subject of the same considered and comprehensive public consultation process as the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 including public exposure of the legislation drafting instructions and the draft legislative provisions.

ACIP PSM Report

Recommendation 11

Amend the <i>Patents Act 1990</i> (Cth) to require the Commissioner of Patents to be satisfied that an invention is a patentable invention before accepting an application for a standard patent or certifying an innovation patent.
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ALRC 99 Report

Recommendation 8–3

The Commonwealth should amend the <i>Patents Act</i> to require patent examiners to be satisfied on the balance of probabilities when assessing all statutory requirements for patentability that are relevant at the stage of examination. (See also Recommendation 6–3.)
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Response

The Government accepts these recommendations.

The amendments to give effect to these recommendations are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill has been the subject of extensive public consultations over a two year period and provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia’s patent law with global trends regarding standards for patentability. The various changes in combination will increase the quality of patents granted in Australia.

ALRC 99 Report

Recommendation 5–1

IP Australia should:

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| (a) assess the impact of patent fees on the actual term of Australian patents; and
(b) periodically review the structure and quantum of patent fees to ensure that fees are set at levels appropriate to discourage patent holders from maintaining patents that lack real commercial value. |
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Response

The Government accepts this recommendation.

IP Australia sets fees consistent with:

- achievement of the following agency Outcome as agreed with Government:
Increased innovation, investment and trade in Australia, and by Australians overseas, through the administration of the registrable intellectual property rights system, promoting public awareness and industry engagement, and advising Government;
- the *Australian Government Cost Recovery Guidelines 2005*;
- the *Financial Management and Accountability Act 1997*; and
- other Government policies and international obligations.

IP Australia employs a fee schedule structure where the renewal fees increase with the age of the patent and thereby discourage renewal of patents with no or little remaining commercial value. In developing the fee schedules, IP Australia takes into consideration a range of issues including the mean age of Australian patents, consistency in cost of like services across other intellectual property rights, international benchmarking and equality of access for patent holders of different

economic means. IP Australia completed a review of its fee structure in July 2010, having last reviewed its fees in 2006. It will continue to conduct regular reviews of its fee structure and will take all the relevant issues into account including assessing the impact of fees over the period of Australian patents as well as the need to consider disincentives for behaviour that could reduce innovation.

ALRC 99 Report

Recommendation 6-1

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.
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Response

The Government accepts this recommendation noting Australia's obligation under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to maintain technology-neutral patentability criteria.

The Government is pursuing a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. These changes are contained in the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 which has been the subject of extensive public consultations over a two year period. The various changes proposed under the Bill will require more evidence that the invention can do what it claims to do and increase quality of the patents granted in Australia.

ALRC 99 Report

Recommendation 8-1

To ensure the ongoing competence of Australian patent examiners in examining patent applications, IP Australia should enhance its efforts to provide examiners with education and training in areas of technology relevant to their particular specialty. IP Australia should review and update its education and training programs regularly so that new developments can be incorporated as required.

Response

The Government accepts this recommendation.

The Government recognises the importance of the skills of patent examiners in ensuring quality of decision making in the grant of Australian patents. To that end IP Australia has an active program of continuing professional training and development. Opportunities are available for examiners in the form of internal and external training courses, part-time university study and attendance at seminars, conferences (including international conferences), industrial visits and placements. The programs are subject to periodic reviews and improvements. In the 2009-10 financial year, IP Australia spent 3.4% of its expense budget on staff training and development. On average, \$5,900 was spent per patent examiner on training and development.

IP Australia also continues to recruit new staff with knowledge and experience in developing technologies. IP Australia requires all patent examiners to have tertiary qualifications. As at early 2010, 53% of patent examiners employed by IP Australia had postgraduate tertiary qualifications with 80% of these being science-based.

ALRC 99 Report**Recommendation 8–2**

IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth) (*Patents Act*), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.

Response

The Government accepts this recommendation.

The Government agrees that there should be clear examination guidelines for how the criteria for patentability apply to inventions for all technologies, including genetic materials. IP Australia has examination guidelines to give effect to this recommendation and these are contained in the publicly available *Australian Patent Office Manual of Practice and Procedure*³ which is a controlled document under its externally certified ISO 9001 quality management system. The Government believes the current examination guidelines provide appropriate guidance on how these criteria apply to inventions involving genetic materials and technologies. IP Australia will continue to provide appropriate guidance as the law develops, and will update the examination guidelines as appropriate in consultation with stakeholders.

ALRC 99 Report**Recommendation 9–2**

Information about patent litigation should be readily accessible to the public.

To this end:

- (a) the Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to require courts exercising jurisdiction under the Act to give written notice to the Commissioner of Patents when a legal proceeding to challenge or enforce a patent is commenced, and when a decision or judgment is given in any such proceeding;
- (b) the Commissioner of Patents should include information about any such notice in the file of a patent and make the information readily available, for example in the Official Journal of Patents and in the patents database on IP Australia’s website; and
- (c) courts exercising jurisdiction under the Patents Act should amend their Rules of Court, as necessary, to give effect to this Recommendation.

Response

The Government accepts this recommendation noting however that a change to the *Patents Act 1990* is not necessary.

Section 139 of the *Patents Act 1990* and provisions contained in Rule 34.42 of the Federal Court Rules already require parties to provide information to the Commissioner of Patents. The Commissioner places this information on the file for the patent in question and this information is accessible using the e-Dossier facility in AusPat which allows online, public access to patent files.

Also, the Federal Court has implemented an internet inquiry system called ‘Federal Law Search’ which provides this information for patent-related proceedings. IP Australia will continue to work with the Federal Court to improve the existing

³ Available at http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm

notification process and visibility of proceedings via AusPat and the Federal Court's Federal Law Search system.

ALRC 99 Report

Recommendation 10-1

Courts exercising jurisdiction under the <i>Patents Act 1990</i> (Cth) (<i>Patents Act</i>) should continue to develop their practices and procedures for dealing with patent matters in order to promote the just, efficient and cost effective resolution of patent disputes.

Response

This recommendation is a matter for courts exercising jurisdiction under the *Patents Act 1990*.

ALRC 99 Report

Recommendation 10-2

Courts exercising jurisdiction under the <i>Patents Act</i> should continue to develop procedures and arrangements to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving patents over genetic materials and technologies.
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Response

This recommendation is a matter for courts exercising jurisdiction under the *Patents Act 1990*.

ALRC 99 Report

Recommendation 11-1

The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) should review the <i>National Principles of Intellectual Property Management for Publicly Funded Research</i> (National Principles) to ensure that publicly funded research, where commercialised, results in appropriate public benefit. (See also Recommendations 12-1 and 17-2.)
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Response

The Government accepts this recommendation.

The National Health and Medical Research Council (NHMRC), in collaboration with the Australian Research Council (ARC) are convening a review of the *Principles of Intellectual Property Management for Publicly Funded Research*. The review will include consultation with interested stakeholders.

ALRC 99 Report

Recommendation 11–2

The ARC and NHMRC should develop guidelines to assist organisations receiving public funding for research in complying with the National Principles. The guidelines should, among other things:

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| (a) provide guidance on what is meant by ‘public benefit’; |
| (b) assist organisations in determining whether it is appropriate for particular research results to be commercialised; and |
| (c) identify a range of approaches to the exploitation of intellectual property and the circumstances in which they might be used. |

Response

The Government accepts this recommendation.

The Government supports the development of guidelines to assist organisations receiving public funding for research in complying with the *Principles of Intellectual Property Management for Publicly Funded Research* (National Principles), and supports such guidelines including the elements in the recommendation. The guidelines will be developed in consultation with interested stakeholders.

The Government notes that both the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) require compliance with the National Principles as an integral part of receiving ARC and NHMRC funding. Until December 2010 for the ARC this was facilitated through the Funding Agreement signed between the ARC and the Administering Organisation, and was required as part of any Multi-Institutional or Collaborative Agreement signed by the Administering Organisation with other parties involved with ARC funded research. From January 2011 compliance continues to be required and will be included in both the Funding Rules and the Funding Agreement. Currently for NHMRC, compliance is facilitated through the Deeds of Agreement signed between NHMRC and the Administering Institution. It is the responsibility of the Administering Organisation or Institution to provide further guidance and facilitate the mechanics of protecting intellectual property and/or commercialising research where appropriate.

ALRC 99 Report

Recommendation 11–3

In exceptional circumstances, where the public benefit would clearly be served by broad dissemination of the results of publicly funded research, the ARC and the NHMRC should consider attaching conditions to the grant of funding. These conditions might include a requirement that research results be placed in the public domain, or that a patented invention be widely licensed.

Response

The Government accepts the recommendation in principle.

The Government notes that the *Australian Code for the Responsible Conduct of Research* and the *National Principles of Intellectual Property Management for Publicly Funded Research* include guidance on the dissemination of research findings and management of intellectual property. Compliance is a condition under which ARC and NHMRC funding is awarded. Where suitable, strategies for achieving

impact from publicly funded research should be assessed on a case by case basis and publication should be consistent with appropriate IP management. Cooperative Research Centres (CRCs) are also required to comply with this code.

NHMRC believes that the results of government-supported health and medical research should be made widely available so that both the research community and the public are able to derive maximum benefit from these outputs. The ARC has always been supportive of the broad dissemination of research and in 2011 has introduced a new component to Funding Rules which will allow up to two per cent of awarded ARC funding (total or non-salary) to be used for publication and dissemination of Project outputs and outreach activity costs.

NHMRC has introduced a policy that requires all published outputs arising from NHMRC-supported research projects to be deposited in an open access institutional repository within 12 months of the date of publication. Similarly, the ARC strongly encourages publication in publicly accessible outlets and the depositing of data and any publications arising from a Project in an appropriate subject and/or institutional repository.

In addition, the ARC has introduced from 2011 new guidelines against which Final Reports will be evaluated including the need to justify why any publications from a Project have not been deposited in appropriate repositories within 12 months of publication, and the need to outline how data arising from the Project has been made publicly accessible where appropriate.

ALRC 99 Report

Recommendation 11–4

Research organisations should ensure that their policies on intellectual property ownership cover research undertaken by visiting researchers, students and staff—whether undertaken solely within the organisation or jointly with other bodies. (See also Recommendation 17–4.)

Response

The Government accepts this recommendation in principle noting that its implementation is a matter for research organisations.

ALRC 99 Report

Recommendation 12–1

The Australian Research Council and the National Health and Medical Research Council, in implementing Recommendations 11–1 to 11–3, should recognise the public benefit in ensuring the wide dissemination of research tools.

Response

The Government accepts the recommendation in principle.

The Government notes that the *Australian Code for the Responsible Conduct of Research*, jointly published by the ARC, the NHMRC and Universities Australia, includes guidance on the dissemination of research findings including manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and

how to manage conflicts of interest to promote integrity in research, and manage intellectual property. Compliance with the Code is a condition under which the ARC and the NHMRC funding is awarded. As noted, the ARC has a number of guidelines, requirements and funding opportunities available to support wide dissemination of research outputs.

ALRC 99 Report

Recommendation 14–1

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.
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Response

The Government accepts this recommendation in principle noting that its implementation is a matter for research organisations.

The Government notes that the *Australian Code for the Responsible Conduct of Research*, jointly published by the Australian Research Council (ARC), the National Health and Medical Research Council (NHMRC) and Universities Australia, includes guidance on the responsibilities of institutions. This includes the promotion of responsible conduct of research, the establishment of good governance and management practices, provision of training for researchers, promotion of mentoring and ensuring researchers have a safe working environment, and management of intellectual property. Compliance with the Code is a condition under which the ARC and the NHMRC funding are awarded.

ALRC 99 Report

Recommendation 14–2

Universities should ensure that students undertaking degrees in health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research.

Response

The Government accepts this recommendation in principle noting that its implementation is a matter for individual universities.

ALRC 99 Report

Recommendation 14–3

The responsible Minister should initiate a review of the grace period provisions in the <i>Patents Regulations 1991</i> (Cth) (<i>Patents Regulations</i>) to examine: (a) whether they are well understood by the research community; and (b) how they have affected the commercialisation of Australian research in Australia or overseas.
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Response

The Government accepts this recommendation.

IP Australia completed a review of the grace period provisions and the final report was published (*Review of Patent Grace Period*, August 2005). This review was in

response to a Government commitment to review the grace period provisions two years after they were introduced (on 1 April 2002). The report recommended that no changes to the grace period provisions were required.

Since this review, the Government has identified some aspects of the drafting of the current grace period provisions that create uncertainty as to the requirements for use and scope of these provisions. Relevant amendments to remove this uncertainty are being pursued through the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. The Bill which has been the subject of extensive public consultations over a two year period provides for a number of changes to raise the standards for grant of a patent thereby realigning Australia's patent law with global trends regarding standards for patentability. The various changes proposed under the Bill will require more evidence that the invention can do what it claims to do and increase quality of the patents granted in Australia. The Government continues to engage in international fora in relation to a harmonised approach to grace periods. The Government will continue to monitor national and international developments and jurisprudence to ensure the grace period provision continues to serve the needs of the public and innovators.

ALRC 99 Report

Recommendation 14–4

Research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions in the Patents Regulations, particularly in relation to:
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| (a) the effect of publication before filing a patent application; and |
| (b) the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions. |

Response

The Government accepts this recommendation in principle noting that its implementation is a matter for research organisations.

ALRC 99 Report

Recommendation 15–1

IP Australia should develop examination guidelines, consistent with the <i>Patents Act 1990</i> (Cth), the <i>Patents Regulations 1991</i> (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cells and related technologies.
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Response

The Government accepts this recommendation.

IP Australia has developed examination guidelines to give effect to this recommendation and these are contained in the publicly available *Australian Patent Office Manual of Practice and Procedure* (available at http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm) which is a controlled document under its externally certified ISO 9001 quality management system. These guidelines will need to take account of any outcomes from the 2010 review of the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002*.

ALRC 99 Report

Recommendation 15–2

As part of the independent reviews to be conducted under the <i>Research Involving Human Embryos Act 2002</i> (Cth) and the <i>Prohibition of Human Cloning Act 2002</i> (Cth), the responsible Minister and the National Health and Medical Research Council should require an examination of the exploitation of intellectual property rights over stem cells when considering the establishment of a National Stem Cell Bank.
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Response

This recommendation is no longer relevant.

The 2005 Legislation Review of the *Research Involving Human Embryos Act 2002* (and the *Prohibition of Human Cloning Act 2002*) recommended the establishment of a National Stem Cell Bank. The Government subsequently rejected this recommendation after commissioning a Report on Options for the Establishment of a National Stem Cell Bank (2007) and deciding that such a bank could not be justified for a number of reasons, including because the science is at an early stage and it would duplicate resources available overseas e.g. UK Stem Cell Bank. The National Health and Medical Research Council (NHMRC) will maintain a watching brief on developments in this area.

ALRC 99 Report

Recommendation 17–1

Biotechnology Australia, in conjunction with its member departments, should collaborate with the peak national bodies with an interest in technology transfer from the public sector:

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| (a) to further develop and implement programs to assist technology transfer offices in research organisations in commercialising inventions involving genetic materials and technologies; and |
| (b) to develop strategies to ensure widespread participation of technology transfer offices in these programs. |

Response

The Government accepts this recommendation in principle, noting that Biotechnology Australia no longer exists.

The Advisory Council on Intellectual Property (ACIP) is currently conducting a review, titled *Collaborations between the Public and Private Sectors: The Role of Intellectual Property*, into how intellectual property acts as an enabler or disabler in collaborations between the public and private sectors. The Government will respond to the recommendations of this review in due course. The Australian Government has facilitated a number of collaborations between public and private entities such as through Commercialisation Australia, the Australian Research Council (ARC), the National Health and Medical Research Council (NHMRC) and Cooperative Research Centres (CRCs) and will monitor this issue.

ALRC 99 Report
Recommendation 17–2
The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC), in implementing Recommendation 11–1, should recognise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research.

Response

The Government accepts this recommendation and recognises the importance of clear ownership of intellectual property resulting from jointly funded research.

The Government notes that: the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) funding agreements currently require that institutions have policies and procedures in place for the management of intellectual property; and, where there is a requirement for matching funding by partner organisations, ARC funding agreements require that institutions not allow a research project to commence, nor funding to be expended, until the institutions and their collaborating partner organisations have entered into a written agreement that, among other things, includes arrangements for managing intellectual property. Within the relevant ARC Funding Rules and Funding Agreement documentation, the ARC is explicit that the ARC does not claim ownership of any intellectual property in a Proposal or a funded Project.

The Government agrees that the ARC, the NHMRC and Cooperative Research Centres (CRCs) should review those requirements in the light of the outcomes of the review of the *National Principles of Intellectual Property Management for Publicly Funded Research* which is currently being scoped. The review will include consultation with stakeholders.

The Government notes that the *Australian Code for the Responsible Conduct of Research*, jointly published by the ARC, the NHMRC and Universities Australia, includes guidance on establishing agreements for collaborations, managing conflicts of interest, access to research materials and intellectual property.

In implementing Recommendation 11-1 of the ALRC 99 Report, review of the National Principles, the Principles currently state that, ‘The ARC and the NHMRC do not wish to hold a stake in direct ownership of IP nor do they intend to benefit directly from commercial outcomes of the research funded through their financial support’ and ‘Recognising the Common Law rights of research institutions as employers, the ownership and the associated rights of all IP generated by the NHMRC and the ARC supported research will initially be vested in the research institutions administering the grants’.

ALRC 99 Report

Recommendation 17–3

The ARC and NHMRC, in implementing Recommendation 11–2, should: (a) provide guidance on ensuring clear ownership of intellectual property resulting from collaborative or jointly funded research; and (b) identify a range of approaches to ensuring clarity of ownership.

Response

The Government accepts this recommendation in principle, noting that while it is not appropriate for the Government to provide legal advice to third parties, it is common for issues of intellectual property ownership to be negotiated as part of contractual processes.

However, the Government notes that the *Australian Code for the Responsible Conduct of Research*, jointly published by the Australian Research Council (ARC), the National Health and Medical Research Council (NHMRC) and Universities Australia, recommends that organisations involved in joint research projects ensure that an agreement is reached with the partners on the management of the research including issues relating to intellectual property.

The Government also notes that with regard to Recommendation 11-2 of the ALRC 99 Report, the ARC continues to require compliance with the *National Principles of Intellectual Property Management for Publicly Funded Research* (National Principles) as an integral part of receiving ARC funding through Funding Rules and Funding Agreements. As noted above, this includes the requirement that compliance with the National Principles must be part of any Multi-Institutional or Collaborative Agreement signed by the Administering Organisation with other parties involved with ARC funded research.

The Government also notes that the Australian Council on Intellectual Property (ACIP) is currently conducting a review entitled *Collaborations between the Public and Private Sectors: The Role of Intellectual Property*.

ALRC 99 Report

Recommendation 17–4

Research organisations should ensure that their policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research. (See also Recommendation 11–4.)
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Response

The Government accepts this recommendation in principle noting that its implementation is a matter for individual research organisations.

The Government further notes that the *National Principles of Intellectual Property Management for Publicly Funded Research* would apply to research organisations where their research is government funded.

ALRC 99 Report**Recommendation 17–5**

Biotechnology Australia, in conjunction with its member departments, should collaborate with the peak national bodies with an interest in technology transfer from the public sector to develop model materials transfer agreements for use by research organisations, along the lines of the models developed by the United States Association of University Technology Managers. (See also Recommendation 22–2.)

Response

The Government accepts this recommendation in principle, noting that Biotechnology Australia no longer exists.

The Government will investigate options for developing model materials transfer agreements for use by research organisations. A proposed process for developing model agreements will involve stakeholder consultation.

ALRC 99 Report**Recommendation 18–1**

Biotechnology Australia, in conjunction with its member departments, and in consultation with state and territory governments and other stakeholders, should:

- (a) develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies; and
- (b) develop strategies to ensure widespread participation of biotechnology companies in these programs.

Response

The Government accepts this recommendation in principle.

Although not specifically directed at biotechnology, these initiatives are available to biotechnology companies:

- Australia's Innovation Agenda, *Powering Ideas: an Innovation Agenda for the 21st Century*, was released on 12 May 2009. It sets a 10-year reform agenda to make Australia more productive and more competitive. *Powering Ideas* takes a holistic approach to developing a 10-year vision for the national innovation system (NIS) as it builds on the review of the NIS, other reviews, and investigation and policy work undertaken throughout 2008-09. *Powering Ideas* outlines actions taken to boost Australia's innovation system, as well as new proposals to improve innovation within the research, business and public sectors including reforms to the governance of the innovation system. It sets innovation priorities and strengthens coordination: to improve skills and expand research capacity; to increase incentives for innovation in business, government and the community sector; and to boost domestic and international collaboration over the next 10 years.;
- The R&D Tax Credit, which replaces the R&D Tax Concession from income years starting on or after 1 July 2011, supports business R&D and targets small innovative firms, including in the biotechnology sector. Legislation implementing the new program passed the Australian Parliament on 24 August 2011. The legislation awaits Royal Assent. The new R&D Tax Credit has two key components: (i) a 45 per cent refundable tax credit (equivalent to a 150 per cent

concession) will be available to firms with an aggregated turnover of \$20 million per annum; and (ii) a 40 per cent non-refundable tax credit (equivalent to a 133 per cent concession) will be available to all other firms. The new R&D Tax Credit is a broad-based and market-driven package. It increases the base rate of government assistance for R&D conducted by businesses of all sizes, with no limit to the amount of R&D expenditure for support. The new measure is simple, predictable and adopts the international practice of using a well-understood tax credit to support business R&D. To be available from 1 January 2014, a new element to the R&D Tax Credit, Quarterly Credits, will be open for small and medium enterprises (SMEs) in anticipation of receiving a tax offset under the R&D Tax Credit. Quarterly credits will further improve cash flow of SMEs and provide an added incentive to invest in R&D;

- Commercialisation Australia is a competitive, merit-based assistance program offering funding and resources to accelerate the business building process for Australian companies, entrepreneurs, researchers and inventors. Commercialisation Australia offers not only a range of funding options, but multi-layered networking opportunities to help applicants achieve business success; and
- The Innovation Investment Fund program targets new companies at the seed, start-up and early expansion stages of development to assist them to grow rapidly and to build upon their research and development capability. This is achieved by providing capital and business assistance from venture capital fund managers. Of the 13 current fund managers, three are specifically targeted at biotechnology while another six have an interest in the sector.

ALRC 99 Report

Recommendation 19–2

AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.
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Response

The Government does not accept this recommendation

The Government does not see a need at present for additional mechanisms to address the cost of medical goods and services. The Government has existing funding mechanisms, the Medicare Benefits and Pharmaceutical Benefits Schemes, which are aimed at providing Australians with access to appropriate and affordable and cost-effective medical services and medicines.

ALRC 99 Report

Recommendation 19–3

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 Commission 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).

Response

The Government accepts this recommendation in principle and notes that the National Health and Medical Research Council (NHMRC) has the capability to provide technical advice on the expected impact of patents and patent practices on medical research and the provision of healthcare. In line with the responses to Recommendations 19-1 of the ALRC 99 Report, the Government considers that the Medical Services Advisory Committee (MSAC) is the appropriate body to undertake economic evaluation of new health-related technologies.

With regard to Recommendation 19-3(c), the Advisory Council on Intellectual Property (ACIP) undertook a review of the use of Crown use provisions (see ACIP Report *Review of Crown Use Provisions for Patents and Designs*), following which the Minister for Innovation, Industry, Science and Research wrote to relevant Commonwealth and State Ministers in March 2009 to raise awareness of government rights and obligations under the provisions. IP Australia also developed a public information sheet highlighting the Crown's rights and obligations and the intellectual property owners' rights under the provision.

ALRC 99 Report**Recommendation 19–4**

The proposed Human Genetics Commission of Australia (HGCA) should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. The HGCA should liaise with and provide advice to AHMAC, health departments, and other stakeholders about ways to facilitate access to inventions, in accordance with Recommendation 19–3. Pending the establishment of the HGCA, AHMAC should establish a mechanism to perform these functions.

Response

The Government notes this recommendation.

In response to the Human Genetics Commission of Australia (HGCA) recommendation in the Australian Law Reform Commission/Australian Health Ethics Committee Report, *Essentially Yours: The Protection of Human Genetic Information*, the Human Genetics Advisory Committee (HGAC) has been established as a principal committee of the National Health and Medical Research Council (NHMRC). HGAC advises the CEO of the NHMRC on high-level technical and strategic issues in human genetics, and on the broad social, ethical and legal implications of human genetics and related technologies. The Australian Health Ministers' Advisory Council (AHMAC) and other government stakeholders can request advice from HGAC via the NHMRC CEO. However, detailed monitoring of the application of intellectual property laws to genetic materials and technologies is outside HGAC's Terms of Reference and the *National Health and Medical Research Council Act 1992*.

The Crown use provisions were reviewed by the Advisory Council on Intellectual Property (ACIP) and their report issued in 2005 (see 2005 ACIP Report, *Review of Crown Use Provisions for Patents and Designs*), following which the Minister for Innovation, Industry, Science and Research wrote to relevant Commonwealth and State Ministers in March 2009 to raise awareness of government rights and obligations under the provisions. IP Australia also developed a public information sheet highlighting the Crown's rights and obligations and the intellectual property owners' rights under the provisions.

The Government also supports a review of the operation of the compulsory licensing provisions of the *Patents Act 1990* (see response to Recommendation 12 of the SGP Report and Recommendation 27-1 of the ALRC 99 Report) to ensure that the provisions are achieving their intended purpose as a safeguard to facilitate access to innovations where the reasonable requirements of the public are not being met. The review will also include measures to raise awareness of these provisions.

ALRC 99 Report**Recommendation 22–1**

Biotechnology Australia, in conjunction with its member departments, should develop and implement programs to assist research organisations and biotechnology companies in licensing and commercialising inventions involving genetic materials and technologies. The programs should be developed in collaboration with state and territory governments, peak national bodies with an interest in licensing and commercialisation of intellectual property, and other relevant stakeholders. (See also Recommendations 17–1 and 18–1.)

Response

The Government accepts this recommendation in principle, noting that Biotechnology Australia no longer exists.

The Government notes that there are existing government and private sector initiatives that encourage the commercialisation of innovations from public sector research and biotechnology companies, as set out in the responses to Recommendations 17-1, 17-2 and 18-1 of the ALRC 99 Report.

ALRC 99 Report**Recommendation 22–2**

AusBiotech Ltd, as the peak industry body in the biotechnology sector, should develop model agreements and interpretative guidelines for patent licences involving genetic materials and technologies. The model agreements should be developed in collaboration with Biotechnology Australia, state and territory governments, and other relevant stakeholders as a non-binding model of desirable licensing practices. (See also Recommendation 17–5.)

Response

The Government accepts this recommendation in principle, noting that Biotechnology Australia no longer exists.

The Government will investigate options for developing model agreements and interpretative guidelines for patent licences. A proposed process for undertaking these investigations will involve stakeholder consultation.

ALRC 99 Report**Recommendation 22–3**

AusBiotech Ltd should consider whether additional industry initiatives are necessary or desirable to facilitate the licensing of patent rights over genetic materials and technologies.

Response

This recommendation is a matter for AusBiotech Ltd.

ALRC 99 Report**Recommendation 24–1**

The Commonwealth should amend s 51(3) of the *Trade Practices Act 1974* (Cth) (*Trade Practices Act*) to clarify the relationship between Part IV of the Act and intellectual property rights.

Recommendation 24–2

The Australian Competition and Consumer Commission (ACCC) should develop guidelines to clarify the relationship between Part IV of the *Trade Practices Act* and intellectual property rights. The guidelines should address:

(a) when the licensing or assignment of intellectual property might be exempted under s 51(3) or might breach Part IV; and

(b) when conduct that would otherwise breach Part IV might be authorised under Part VII of the *Trade Practices Act*.

The guidelines should extend to the exploitation of intellectual property rights in genetic materials and technologies, including patent pools and cross-licensing.

Response

The Government notes the recommendations to amend section 51(3) of the *Competition and Consumer Act 2010* (CCA) and for the Australian Competition and Consumer Commission (ACCC) to subsequently produce guidance material.

As the agency responsible for the enforcement of the provisions of the CCA, the ACCC produces a wide range of publications that deal with its functions and the legislation for which it is responsible.

If subsection 51(3) of the CCA is amended to change the application of the competition laws to intellectual property in the future, the Government will ask the ACCC to consider issuing relevant guidance.

ALRC 99 Report**Recommendation 24–3**

As the need arises, the ACCC should review the conduct of firms dealing with genetic materials and technologies protected by intellectual property rights, to determine whether their conduct is anti-competitive within the meaning of Part IV of the *Trade Practices Act*.

Response

The Government notes this recommendation.

The Australian Competition and Consumer Commission (ACCC) is an independent statutory authority charged with the responsibility for enforcing the *Competition and Consumer Act 2010* (CCA). Relevantly, subsection 29(1A) of the CCA prohibits the Minister giving directions to the ACCC about its performance of functions or exercise of powers under Part IV (prohibition of anti-competitive conduct) of the CCA.

The ACCC publishes guidelines on its enforcement and compliance policies, which are available on its website – www.accc.gov.au. The Government expects that if any concerns arise, the ACCC will consider these issues in the same way as it would all suspected breaches of the CCA.

ALRC 99 Report**Recommendation 24–4**

Commonwealth, state and territory health departments, and other stakeholders, should make use of existing complaint procedures under the *Trade Practices Act* where evidence arises of conduct that may breach Part IV and have an adverse impact on medical research or the cost-effective provision of healthcare.

Response

The Government accepts this recommendation in principle.

The Government notes that concerned parties should use the Australian Competition and Consumer Commission's (ACCC's) existing complaints mechanisms to raise any concerns that conduct is occurring which may breach the competition provisions of the *Competition and Consumer Act 2010*.

ALRC 99 Report**Recommendation 25–1**

If evidence arises that the prices of patented genetic materials and technologies have adversely affected access to healthcare services in Australia, the responsible Minister should consider whether to:

(a) refer the matter to the Productivity Commission for a study or inquiry pursuant to the *Productivity Commission Act 1998* (Cth); or

(b) direct the Australian Competition and Consumer Commission, or another body, to conduct an inquiry pursuant to Part VIIA of the *Trade Practices Act 1974* (Cth).

Response

The Government notes this recommendation.

Part VIIA of the *Competition and Consumer Act 2010* provides for price inquiries where, in the view of the Minister, competitive pressures are not sufficient to achieve efficient prices and protect consumers. The Government will consider the need for such an inquiry if this evidence arises.

ALRC 99 Report**Recommendation 28–1**

The Commonwealth should amend the *Copyright Act 1968* (Cth) (*Copyright Act*) to provide that research with a commercial purpose or objective is 'research' in the context of fair dealing for the purpose of research or study.

Response

The Government does not accept this recommendation.

The issue of whether the term 'research' in sections 40 and 103C of the *Copyright Act 1968* can include a commercial purpose has not been specifically considered by the courts. The wording in the provisions does not currently exclude research with a commercial purpose from the scope of the fair dealing exception. The reasoning of cases examining these provisions confirms that the terms 'research' and 'study' should be interpreted with their ordinary meanings. The ordinary meaning of

‘research’ connotes a broad meaning that does not distinguish whether the purpose is of a commercial or private nature.

The current wording of the *Copyright Act 1968* does not exclude research with a commercial purpose from falling under the fair dealing exception. Until a contrary finding is made under case law the Government sees no need for legislative amendments to be made to the *Copyright Act 1968*.

ALRC 99 Report

Recommendation 28–2

The Commonwealth should amend the <i>Copyright Act</i> to provide that, in relation to databases protected by copyright, the operation of the provisions relating to fair dealing for the purpose of research or study cannot be excluded or modified by contract.
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Response

The Government does not accept this recommendation.

The operation of the provisions relating to fair dealing for the purpose of research or study in relation to databases protected by copyright is a subset of the broader issue of the exclusion or modification by contract of the fair dealing exceptions. The views of the Australian Law Reform Commission (ALRC) are noted and provide valuable assistance to the Government. However, the Government does not propose to examine this broader issue at this time.

ALRC 99 Report

Recommendation 28–3

Prior to the implementation of art 17.4.7 of the Australia–United States Free Trade Agreement—which includes a prohibition on the circumvention of access control measures—the Australian Government should assess the need for an exception for researchers engaging in fair dealing for the purpose of research or study in relation to databases protected by copyright. Once the prohibition has been implemented, the Australian Government should periodically review the impact of the anti-circumvention provisions on the practical exercise of fair dealing for the purpose of research or study in copyright works.
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Response

The Government notes this recommendation.

The Government notes the views expressed by the Australian Law Reform Commission (ALRC) that the Government should assess the need for an exception to circumvention for researchers engaging in fair dealing for the purpose of research and study in relation to databases. However, the ALRC indicated that there did not appear to be any significant problems being experienced by Australian researchers in this regard.

The then Australian Government Attorney-General, the Hon Philip Ruddock MP, gave a reference to the House of Representatives Standing Committee on Legal and Constitutional Affairs to inquire into, and report on, possible additional exceptions to the technological protection measures liability scheme. The Committee concluded its

inquiry in March 2006. The Committee did not recommend an exception to allow circumvention by researchers engaging in fair dealing for the purpose of research and study in relation to databases.

In accordance with the Australia-United States Free Trade Agreement, amendments to the *Copyright Act 1968* set out the criteria for determining additional exceptions. Amongst other matters, proponents of an exception must credibly demonstrate that there is an actual or likely adverse impact on their non-infringing activities. Future reviews to determine the need for any additional exceptions will provide the opportunity for those affected by the liability scheme to demonstrate that the need exists for an exception to allow circumvention of technological protection measures for research and study in relation to databases.