CSIRO Submission 10/403

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

Senate Legal and Constitutional Affairs Committee

February 2011

Executive Summary

This submission outlines CSIRO's view of the proposed amendment to the *Patents Act 1990*, and discusses the following points:

- CSIRO is Australia's leading patent filing enterprise and holds over 3,900 granted or pending patents or other forms of intellectual property (trademarks, designs and plant breeders rights) across a broad range of technologies;
- Many of these patents cover genes from animal, plant and human sources;
- The proposed amendment to the *Patents Act 1990* introduces potential ambiguity into the definition of patentable subject matter, which may potentially inhibit future investment in research and development in Australia;
- Assessing patentable differences is at the heart of patent law. The requirements for validity of novelty, inventive step and manner of manufacture each involve different aspects of patentable difference between an alleged invention and the prior art. Each of these requirements has been the subject of significant legislative and judicial development over many years. Introducing a new and unrelated test for patentable difference will introduce significant uncertainty, is likely to cause unintended effects and will likely increase the complexity, cost and uncertainty of patent litigation;
- The proposed amendment risks contravening Article 27 of the Trade-Related Intellectual Property (TRIPS) Agreement by limiting patent protection in a way that discriminates as to the field of technology;
- The impact that the amendment is likely to have on patents already granted and/or undergoing commercial exploitation is currently unclear;
- To address concerns regarding the impact of patent protection on research, CSIRO supports the introduction of a broad research exemption to patent infringement over the proposal to exclude biological materials from patentability;
- To address concerns regarding the impact of patent protection on access to beneficial technologies, CSIRO supports the use of measures to clarify compulsory licensing and crown use provisions over excluding biological materials from patentability;
- CSIRO supports recommendations to patent reform made in the Senate Community Affairs References Committee Report on Gene Patents (Senate Report), published in November 2010.

Introduction

Innovation is critical for a successful economy. CSIRO conducts research and development (R&D) in key areas of national priority for the benefit of Australia. CSIRO's ability to generate real impact and value for the nation is dependent upon effective and efficient disciplines of technology transfer, including the sale or licensing of intellectual property (IP).

CSIRO is Australia's leading patent filing enterprise and holds over 3,900 granted or pending patents or other forms of intellectual property (trademarks, designs and plant breeders rights) across a broad range of technologies.

Through the provision of a variety of licensing and equity opportunities we seek to ensure that the results of our scientific research deliver:

- Innovative and competitive industries;
- Healthy environments and lifestyles; and
- A technologically advanced society.

CSIRO is active across an extremely broad range of technologies, with extensive participation in the agricultural and biomedical sphere. CSIRO has a large patent portfolio in these technology areas, including several hundred patents and patent applications worldwide, covering genes from animal, plant and human sources.

CSIRO has a significant licensing portfolio in technology that provides new ways of treating disease and impacts upon numerous areas such as therapeutics, biopharmaceuticals, transgenics, disease resistance, bioremediation and food technologies.

CSIRO provides this submission for consideration by the Senate Legal and Constitutional Affairs Committee to assist in its Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the *Bill*).

The *Bill* proposes to amend the *Patents Act 1990* by introducing an exclusion of specific subject matter from patentability. The proposed subject matter is as follows: *'biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to, such materials as they exist in nature'.*

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

CSIRO's position

CSIRO is in the position of both carrying out research and protecting the results of this research via the patent system, and also utilising the knowledge created by other innovators via their intellectual property. CSIRO uses the patent system to facilitate technology transfer from the research environment to create impact for Australia. Accordingly, CSIRO is interested in the integrity of the patent system.

CSIRO believes that, for reasons explored in this submission, the introduction of the proposed amendment to the *Patents Act 1990* could diminish CSIRO's ability to attract R&D investment in important areas. The scope of the adverse effects on CSIRO's existing licensing portfolio is currently unclear.

CSIRO is more aligned with the recommendations of the Senate Community Affairs References Committee Report on Gene Patents (Senate Report), published in November 2010, and the final report of the Advisory Council on Intellectual Property (ACIP) on Patentable Subject Matter, December 2010, than the exclusion of subject matter proposed by the *Bill.*

CSIRO supports the following approaches to patent reform:

- To address concerns regarding the impact of patent protection on research, the technologically neutral measure of adding a broad research exemption is preferred over excluding biological materials from patentability;

- Similarly, to address concerns regarding the impact of patent protection on access to beneficial technologies, the technologically neutral measures of clarifying the compulsory licensing and crown use provisions are preferred over excluding biological materials from patentability.

The discussion below covers aspects of the proposed amendment, in particular, potential ambiguity of the proposed wording, the impact on granted patents and/or investment in them and compliance with our International obligations.

Scope of proposed amendment and its impact

The scope of the subject matter proposed to be excluded in the *Bill* is unclear in a number of respects:

"Biological"
The interpretation of what is "biological and/or exists in nature" is not at all clear. Synthetic molecules often not thought to be biological can turn out to be present in nature as analytical methods become more powerful (e.g. it has been found that the chemical nitric oxide, a free radical is made in the endothelial cells of vessels). As biological knowledge is continually expanding, use of the potentially very broad expression "biological materials" will introduce significant uncertainty into the law. Significant litigation may be necessary to clarify such uncertainty.

"Substantially identical"

- It is unclear how "substantially identical" should be interpreted. Such language introduces significant legal uncertainty unless there is more guidance provided as to how the degree of difference should be determined. The principle by which to assess the required degree of difference would be welcomed. If not, and it is left to the courts to develop an interpretation, this will take many years, and as there are very few patent cases in this technology area that have reached the courts, this is likely to mean uncertainty for a long period of time, potentially resulting in increased complexity and cost of resolving patent disputes.

- Such uncertainty can impact in many areas including potentially negatively affecting investment in Australian research. This is because investors look to invest in research with the prospect of protecting any innovation resulting from the research via the patent system, thus affording them a way of obtaining a return for their investment. If there is uncertainty as to the scope of patent protection that can be obtained in Australia, it is likely to become less attractive to invest in Australian R&D. This is even more acute if there is more certainty in the scope of patent protection in other countries, investors are likely to choose these countries to invest in R&D.

- The expression "substantially identical" implies that some particular degree of difference to "identical" will not be sufficient to confer patentability, while some greater degree of difference will avoid characterisation as "substantially identical".

- We would welcome the introduction of further definition to the proposed legislative amendment, or further guidance as to the principle by which to assess the required degree of difference. Some possible bases for assessing "substantially identical" could potentially be: informational quality, physical characteristics, or functionality. However, on analysis each of these is problematic (apart from the fact that there is no basis provided for selecting any of these or other possible criteria).

- For example, assessing "substantially identical" by reference to the *informational quality* of molecules could be potentially meaningful for molecules such as DNA and RNA, but would not be applicable to biological materials that are not generally regarded as information carriers (eg. proteins, cells and certain fluids). Even if informational quality were to be regarded as a basis for assessing "substantially identical", guidance would still be required on what level of difference confers patentability.

- If *physical characteristics* or *functionality* are to be considered in assessing difference, guidance would be required as to which physical or functional characteristics may be considered, or how the test is to be applied.

- Further, pharmacology is centrally concerned with biological mimicry. A large number of materials derived from molecules in one kingdom (e.g. plants), can confer benefits on another (e.g. animal/human) and much research investment is made in this area. The proposed legislative amendment takes

no account of the inventiveness of applying knowledge from one branch of biology to another.

- Assessing patentable differences is at the heart of patent law. The requirements for validity of novelty, inventive step and manner of manufacture involve different aspects of patentable difference between an alleged invention and the prior art. Each of these requirements has been the subject of significant legislative and judicial development over many years. Introducing a new and unrelated test for patentable difference will introduce significant uncertainty, is likely to cause unintended effects and will likely increase the complexity, cost and uncertainty of patent litigation.

Breadth of "biological materials"

The proposed amendment goes significantly further than excluding from patentability genetic sequences that are identical to those found in nature, and extends to all manner of "biological materials". This blanket exclusion appears to prejudge the patentability of whole categories of inventions before the facts relating to those inventions are even known.

- For example, the expression "biological materials" would include enzymes identified or extracted from a range of organisms and microorganisms that can be put to a vast range of industrial uses, such as in food processing, manufacturing industries, and bioremediation, just to name a few.

- We recommend a study of the impact of the proposed amendment on innovation and R&D investment in these industries or in the medical and healthcare sector. We refer to a report by the House of Representatives Science and Innovation Committee on the Inquiry into Business Commitment to Research and Development in Australia, tabled in 2003. In chapter 6 of this report, the considerations by which major international corporations site their R&D investment are discussed and the following comments made:

  'International companies like a legal system that does not act as 'a disincentive for bigger companies and other players overseas to want to do business or make an alliance with us'. The international corporations look for a legal system that can 'harmonise' with the legal system they are most familiar with. An important aspect of the legal system is the adequacy of the IP regime which, in Australia's case, was said to be 'the fourth best country in the world in terms of its IP protection… [and] that gives us an element of security about IP'.18

  In its current form, with the potential ambiguity of the proposed wording, the 'blanket' nature of the proposed excluded subject matter, the potential legal uncertainty, the *Bill* may lead *to* questions around the adequacy of the IP regime, which, as explored by the above mentioned report is likely to act as a dicincentive for overseas companies to want to invest in Australian R&D.

Methods/processes

Finally, on the issue of clarity of the proposed amendment, it appears to only affect compositions of matter *per se,* leaving methods/processes unaffected. It appears

that the issues giving rise to the recent political controversy regarding gene patents, namely the potential for patent protection to limit access to genetic diagnostic testing, which would be covered by method/process claims, would be entirely unaffected by the proposed amendment.

Impact on granted patents and/or investment in them

It is difficult to ascertain the impact the amendment is likely to have on patents already granted and/or undergoing commercial exploitation. At present, it appears the proposed amendment will affect patents granted prior to the date of the amendment as well as patents granted after the date of the amendment. How this will affect investments already made on the basis of granted patents and the scope of protection currently afforded to them is uncertain and needs careful exploration.

Relative position with countries that do not exclude such subject matter

Introduction of this amendment to the *Patents Act 1990* means the scope of protection available in Australia will be less than in those countries where such subject matter is not excluded. As mentioned above in reference to the report tabled in 2003 by the Science and Innovation Committee on the Inquiry into Business Commitment to Research and Development in Australia, security of the IP regime of a country is one determining factor when comparing countries into which R&D investment may be made. The potential uncertainty posed by the introduction of the *Bill* has the further potential of disadvantaging Australia in terms of investment in R&D and in product introductions in Australia by both Australian companies and offshore interests.

Scope of protection achievable in a territory is also a key selection criteria for companies to seek patent protection in a particular territory and consequently to introduce products to that market. Reducing the scope of patentable subject matter as proposed by the *Bill* is likely to result in Australia being viewed as a less attractive proposition compared with countries that currently do not exclude such subject matter, for example, US, China, Japan.

Compliance with the agreement on trade-related aspects of intellectual property rights (TRIPS)

- The TRIPS Agreement provides minimum standards of IP protection with members having flexibility to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. The TRIPS Agreement is administered by the WTO and all WTO members are contracting parties. Australia has been a signatory since the agreement came into force in 1995.

- Article 27 of the TRIPS Agreement requires that (amongst other things) patents be available for inventions in all fields of technology (provided they are new, involve an inventive step and are capable of industrial application)

and that, subject to certain exceptions, patents be available and patent rights enjoyable without discrimination as to the field of technology.

- The explanatory memorandum for the *Bill* seeks to characterise the amendment as an application of the distinction between discovery and invention. However, without clarity on the meaning of "substantially identical" (discussed above), it is not possible to be confident that the amendment would only exclude "discoveries" from patentability. All fields of technology necessarily rely upon harnessing natural phenomena to some extent. As noted in the Senate Report on Gene Patents, the distinction between unpatentable discovery and patentable invention can be extremely fine, and the invention/discovery distinction can be imprecise and misleading.

- The proposed amendment risks prejudging the novelty and inventive step of whole classes of inventions before the facts relating to such inventions are known.

- We consider that as currently drafted the *Bill* risks contravening Article 27 of the TRIPS Agreement for limiting patent protection in a way that discriminates as to the field of technology.

Senate Report and ACIP Recommendations

- The Senate Community Affairs References Committee Report, published in November 2010, contains many recommendations in relation to patent reform, and in particular reforms which improve the operation of the patent system generally rather than reforms limited to genetic sequences or even to biological materials. Some of its recommendations include reforming the already existing mechanisms of compulsory licensing and crown use. It also recommends the introduction of a broad research exemption.

- CSIRO supports the following approaches to reform recommended by the Senate Report:

    - To address concerns regarding the impact of patent protection on research, the technologically neutral measure of adding a broad research exemption is preferred over excluding biological materials from patentability;

    - Similarly, to address concerns regarding the impact of patent protection on access to beneficial technologies, the technologically neutral measures of clarifying the compulsory licensing and crown use provisions are preferred over excluding biological materials from patentability.

- Similarly, the Advisory Council on Intellectual Property (ACIP) in its final report on Patentable Subject Matter of December 2010, considers that improving access to beneficial patented technology is better dealt with through mechanisms other than the test for patentable subject matter, such as compulsory licensing, crown use, or pricing mechanisms (such as the way the Pharmaceutical Benefits Scheme provides a mechanism to access expensive patented pharmaceuticals).

We agree that matters concerning access are better dealt with through alternative mechanisms, rather than imposing specific patentability exclusions.

- Both the Senate Report and ACIP considered that an exclusion should only be introduced if there is a very clear case, and a significant social and political consensus on the need for such a change. Both concluded that no persuasive case has been made to introduce the proposed exclusion, and CSIRO agrees with those conclusions.