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Submission to the Senate Standing Committee on Legal and Constitutional Affairs

in relation to the

Patent Amendment (Human Genes and Biological Materials) Bill 2010

by

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Introduction

This submission is made in response to an invitation to comment on the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (referred to below as "the Bill") currently under review by the Senate Standing Committee on Legal and Constitutional Affairs.

Shelston IP is one of the largest and most respected specialist intellectual property (IP) firms in Australia. We have a highly-qualified and experienced team of scientists/patent attorneys practicing in the area of biotechnology and pharmaceuticals. We act for a range of Australian and international entities in relation to the prosecution of patent applications in the biotechnology and pharmaceutical fields before the Australian Patent Office. As a consequence, we have an interest in ensuring that amendments to the Australian *Patents Act 1990* (referred to below as "the Act) are, at the very least, clear and unambiguous.

The Bill

Currently Section 18(2) of the Act excludes human beings and the biological processes for their generation from patentability. The Bill proposes to amend Section 18(2) of the Act such that it will read as shown below - and hence provide an additional exclusion as expressed in paragraph (b).

(2) The following are not patentable inventions:

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

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

It appears that the purpose of the amendment (as stated in the Explanatory Memorandum) is to reinforce "the distinction between discovery and invention" and to apply that distinction by "expressly excluding from patentability biological materials which are identical or substantially identical to such materials as they exist in nature, however made".

According to proposed new Section 18(5) of the Bill, the term "biological materials" includes DNA, RNA, proteins, cells and fluids. As such, the proposed amendments relate to any material found in a living organism whether it be animal, plant, insect or microorganism.

These proposed amendments introduce significant and unnecessary ambiguity into the legislation. Further, the exclusion of genes and biological material from the patentability criteria (which the amendment purportedly codifies) is not recommended or supported by the numerous reports already conducted in relation to patentable subject matter. The amendments are unlikely to achieve the stated aim of the legislation and, in addition, create uncertainty in the biotechnology sector in Australia.

Clarity and breadth

The vague and ambiguous language utilised in the Bill would result in significant difficulty in establishing the types of inventions that are eligible for patent protection in Australia. This would have a significant effect on commercialisation of products from a broad range of technology areas including medical research, diagnostics, industrial processes and agriculture.

Specifically, the breadth of terms such as a "component" or "derivative" in the context of a biological material is not clear. Moreover, it is entirely unclear as to what is encompassed by

the term “substantially identical”. This lack of clarity as to the metes and bounds of these terms is extremely problematic in the science of biotechnology.

Even very small changes to, for example, a protein can have a substantial impact on its function. The precise location at which to modify or mutate a protein to elicit a change is often not easily recognised and identification of the relevant (desirable) mutation can require considerable ingenuity. Currently the Patent Office examines each patent application to determine whether the invention defined meets the patentability criteria i.e. is it new (“novel”) and inventive in view of what was known at the time the patent application was lodged? This provides a sufficient test to weed out, for example, a patent application for a new protein that would have been obvious to the person skilled in the relevant scientific field. However, the proposed legislation introduces another layer of complexity in order to determine whether a protein is patentable. By how much does a protein have to differ from a naturally-occurring material to fall outside the scope of the term “substantially identical” and/or “derivative”?

For example, the cervical cancer vaccine, Gardasil is made up of different proteins from the human papilloma virus. This vaccine was deemed to meet the criteria for novelty and inventive step. Would such a vaccine be considered a “derivative” or “component” of biological material under the proposed amendment? Similarly, would vaccines made up of parts of a protein be considered “components” of a biological material or “substantially identical” to naturally-occurring biological material? It is entirely unclear as to whether the proposed amendment would exclude Gardasil from the patentability criteria (even though it is presumably intended to do so on the basis that it would constitute a “discovery”). The proposed amendments, therefore, do not appear to provide any useful or meaningful distinction between a discovery and an invention as is the stated aim of the legislation.

As a further example, a bacterial enzyme (protein) mutated only in a very minor way may, as a result, acquire beneficial properties thereby making it suitable for use in a laundry powder intended to clean at lower temperatures. This might be considered a “derivative” of a biological material or “substantially identical” to a naturally-occurring biological material in the context of the Bill. If so, the invention would not be eligible for patent protection. However, this invention could never be confused with a “discovery” since the enzyme never existed in nature previously. As such, by excluding it from patentability, the amendments do nothing to distinguish between a discovery and an invention. Moreover, as students of the law and history of patents, we know that such advances in technology are precisely the sorts of innovation that the patent system is designed to encourage and protect.

In addition, it is unclear as to whether it is the intention of the legislation to exclude new compositions derived from biological materials such as wood, paper or rubber inventions. It is certainly arguable that as currently drafted these materials would fit within the exclusion to patentability.

Given our extensive experience in the prosecution of biotechnology patent applications, we have no doubt that the vague and ambiguous language of the Bill will require substantial judicial interpretation. As a result of the lack of clarity in the words of the proposed amendment, it is a real possibility that the Courts could interpret the legislation in a manner that is inconsistent with the objectives outlined in the Explanatory Memorandum referred to above. (Already we have evidence of the Courts seemingly taking obscure positions not intended by the legislation in other areas of patent law – most notably in the implementation of s70 relating to patent term extensions.)

Even if eventually the Courts clarified to some degree the meaning of the relevant terms within the context of the Act, innovators in the biotechnology sector will have no certainty in

the intervening years as to whether they can expect to recuperate their (often very significant) investment through the monopoly currently afforded by the patent system. This is likely to have a negative impact on investment in this sector of the economy which already struggles to attract funds.

Reports into patentable subject matter

A number of reports in relation to the types of inventions that constitute suitable subject matter for a patent have been conducted. Most notably, in December 2002, the Federal Attorney-General asked the Australian Law Reform Commission (ALRC) to examine the laws and practices governing intellectual property rights over genetic materials and related technologies, with a particular focus on human health issues. As a result, two reports were generated, namely:

- Genes and Ingenuity: Gene patenting and human health (ALRC Report 2004)[1]; and
- Gene Patenting and Human Health (DP 68 March 2004, the second consultation document to be produced during this ALRC inquiry)[2];

Neither of these reports made any recommendation to amend the Act to expressly prohibit the patenting of genes or biological material.

Following the 2004 ALRC reports on gene patenting and human health, the Minister for Innovation, Industry, Science and Research asked the Advisory Council on Intellectual Property (ACIP) to conduct a review into the appropriateness and adequacy of the "manner of manufacture" (patentable subject matter) test. The terms of reference for the review asked the ACIP to inquire, report and make recommendations to the Australian Government on patentable subject matter. The ACIP Report was released on 16 February 2011. Significantly, the report states "... we do not recommend the introduction of a specific exclusion to prevent the patenting of human genes and genetic products".

In November 2010, the Senate Standing Committee on Community Affairs released its report on gene patents[3] and, despite a majority of submissions that appeared to support "gene patent reform", this report also made no recommendation to amend the Act to prohibit the patenting of genes or biological material.

Thus, despite (and perhaps even as a result of) close scrutiny, enquiries into the patentability of genes and genetic/biological products have consistently reached the same conclusion: there is no requirement to exclude this subject matter by amendment of the patentability criteria.

The proposed amendment will not achieve the stated aim

As illustrated in the examples provided above, the amendments will make no meaningful distinction between a discovery and an invention by excluding biological materials of the types specified from patentability.

It would appear that the current gene patent debate was re-ignited or at least fuelled by public anxiety raised in 2008 when a Melbourne-based company, Genetic Technologies (that

[1] http://www.alrc.gov.au/sites/default/files/pdfs/publications/ALRC99.pdf
[2] http://www.alrc.gov.au/sites/default/files/pdfs/publications/DP68.pdf
[3] http://www.aph.gov.au/Senate/committee/clac_ctte/gene_patents_43/report/index.htm

held an exclusive license to conduct tests for determining susceptibility to breast cancer based on mutations in BRCA-1 and BRCA-2 genes) decided to assert their rights and charge those using the genes for diagnostic testing in Australia. The perceived potential increase in breast cancer testing costs resulted in the Inquiry by the Senate into the patentability of genes and other biological material mentioned above.

Previously, the proponents of gene patent reform have argued that the use of genetic material in a diagnostic assay is elementary and non-inventive and thus does not meet patentability requirements. This is misleading because it is based on the assumption that the test already exists and the genetic material is merely used in such a test. It also fails to recognise that a minute percentage of the genome needs to be identified and associated with a particular disease state in order to develop a diagnostic tool. This task is tantamount to searching for a needle in a haystack, when there is no guarantee that the needle actually exists.

Moreover, there are a number of questions that need to be considered during the development of a gene-based diagnostic test including: Which disease states out of the thousands that are known are associated with a gene? If a disease state is associated with a gene which gene is it associated with? Is the disease state associated with more than one gene? What mutations in the gene(s), if any, lead to a predisposition of individuals to develop the identified disease state? What is the extent of the predisposition to developing the disease state? Does a greater predisposition to developing the disease state require a number of particular mutations in a gene or indeed a number of genes? To what extent is a person predisposed to developing the disease state if they only exhibit a limited number of possible mutations in the gene or genes in question? To provide answers to these questions often requires a great deal of ingenuity and, moreover, the genes used in the diagnostic test are not the genes as they exist in nature. These diagnostic tests, therefore, cannot be deemed to be mere discoveries or obvious extensions of discoveries.

We emphasise also that the proposed amendment to the Act does not exclude the use of "biological materials" in, for example, diagnostic tests. It relates only to the biological materials *per se* and not their use. New uses of the "excluded" materials would still remain patentable.

Discoveries are currently not patentable. The proposed amendment makes no useful contribution over and above the criteria currently available to us to distinguish between a discovery and an invention. If diagnostic tests are to be excluded from patentability, the proposed amendment is not the appropriate means by which to do so.

Summary

In conclusion, we submit that the Bill should be rejected because the proposed amendments *inter alia*:

- lack clarity;
- are at odds with the substance and recommendations of the Reports on patentable subject matter discussed above;
- are unlikely to achieve the stated aim of the legislation; and
- introduce unnecessary uncertainty into an already fragile area of the Australian economy, the biotechnology sector.