Australian Academy of Science

Submission to Senate Inquiry into

Patent Amendment (Human Genes and Biological Materials) Bill 2010

Introduction

The Australian Academy of Science welcomes the opportunity to provide a submission to the inquiry on this Bill.

This private members' Bill proposes amendments to the *Patents Act 1990* – which currently bans the patenting of human beings and the biological process for their generation – by extending this ban to include a much wider range of biological entities. The Bill proposes that the following should not be patentable:

> *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" are defined to include DNA, RNA, proteins, cells and fluids.

Many novel gene sequence patents with proven novelty and utility have resulted in a large number of beneficial therapeutics. The Academy acknowledges, however, that there is legitimate public concern about patenting gene sequences. It is unfortunate that during the period from 1976 to approximately 2000, when human and other genes were first obtained as cloned entities in bacterial viruses, patenting was permitted of many DNA sequences without further evidence of usefulness and of originality. This is no longer the case. The Academy supports a strict interpretation of the existing patent legislation, so that a DNA sequence on its own is not patentable. If it is necessary to amend the *Patents Act 1990* to make this clear, we would support such an amendment.

However, we believe the proposed amendments, as currently drafted, go too far. They are likely to hinder scientific progress and commercial utility in Australia and internationally.

Implications of the Bill

The proposed amendments, in their current form, will result in significant negative ramifications for biomedical research in Australia, and for the biotechnology industry, because the Bill seeks to change the *Patents Act 1990* by expressly excluding from patentability an extremely wide range of biological materials.

The definition of "biological materials" in the Bill is broad to a point where it would preclude patenting any biological entity found in nature in any form. It would cover DNA, RNA, proteins, secondary metabolites, natural compounds and cells from any source, including humans, plants, fungi, bacteria or viruses. The amendment would capture in the patent ban more than just DNA or RNA. Isolated proteins, including growth factors, antibodies and vaccines, proteins such as insulin, or pure cultures of cells such as stem cells, would not be patentable. Derivatives of biological molecules will also be included in the ban if they are 'identical or substantially identical to such materials as they exist in nature'.

This definition would exclude many of the new biological drugs that are proving so successful in treatment of cancer and other diseases.

The Academy also notes that there is confusion between the title of the Bill and the proposed amendments. The title refers to 'human genes and biological materials', which can be read to incorporate only human genes and human biological material. (Section 18(2) of the Act provides that 'human beings, and the biological processes for their generation, are not patentable inventions'.) However, the proposed amendment would apply to <u>all</u> (that is, human and non-human) genes and biological materials. Moreover, the fact that the precise meaning of words and phrases such as 'derivatives' and 'substantially identical' is unclear will in turn lead to further uncertainties and costs at the patent prosecution stage.

Finally, as a principle, the Academy urges Parliament to accept that Australia should endeavour to ensure our patent legislation, which is Commonwealth law and not State/Territory law, is harmonised internationally. This amendment would leave Australia with a very different set of criteria for patentability from most other countries. The patent system should remain a flexible international mechanism for promoting and rewarding scientific innovation.

Conclusions

The Australian Academy of Science acknowledges that there are legitimate public concerns about patenting human DNA sequences. We note that current international patent office practice is to disallow attempts to patent DNA sequences per se. We believe that this should remain the case and, if necessary, the *Patents Act 1990* should be modified to be clear on this point.

However, there needs to be more informed, evidence-based consideration of the breadth of the amendments, which are likely to create a legal environment that would disadvantage Australian research, particularly in the biomedical

area. As phrased, the amendment could stifle research and development to discover new diagnostic tests, therapies and vaccines.

The Australian Academy of Science holds that the proposed amendments are unnecessary. If law, they would expose Australia's research effort to foreseeable and serious negative consequences. Biological materials, diagnostics and therapeutics should remain patentable matter in Australia, subject to the provisions of the *Patents Act 1990.*