Australian Government
National Health and Medical Research Council
NHMRC

Committee Secretary
Senate Legal and Constitutional Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Re: NHMRC Submission to the Senate Legal and Constitutional Affairs Legislation Committee's Patent Amendment (Human Genes and Biological Materials) Bill 2010 Inquiry

Dear Secretary,

Thank you for providing the National Health and Medical Research Council (NHMRC) with the opportunity to make a submission to the Senate Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill). As the Australian Government's key agency for managing investment in health and medical research, NHMRC is focused on encouraging excellence in health and medical research to improve the health of all Australians.

NHMRC understands the purpose of the Bill is to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease.[1] NHMRC has a number of concerns in relation to the proposed legislation, particularly its implications for research, which are highlighted in this submission. In developing this submission, NHMRC consulted its Committees and Council.

NHMRC is concerned that the proposed open definition of "biological materials" is not realistic and may prove problematic.[2] NHMRC is concerned that the breadth of the Bill, and lack of a definition of the term "substantially identical", has the potential to obstruct and suppress innovation and translation of the outcomes of biomedical research into products and/or treatments to improve the health and the wellbeing of Australians and people around the world. For example, the proposed amendments could have considerable intellectual property implications for the field of synthetic biology. Under the proposed amendments, a product of synthetic biology, while not a biological material, is modelled on biological material and therefore would appear to be excluded from being patentable by subsection 18(2)(2)(b).

Unless properly considered, the passing of the proposed legislation might disadvantage Australians working in a number of important new research fields, including discoveries in the broadly based and expanding "omics" fields, e.g. proteomics. This would impact on many in the health and medical

[1] Patent Amendment (Human Genes and Biological Materials) Bill 2010 – Explanatory Memorandum
[2] The definition does not specifically state what a 'biological material' is, and only what it does include, i.e. DNA, RNA, proteins, cells and fluids, including products that are "substantially identical" to the natural products. The list is not comprehensive, e.g. metabolites and carbohydrates are not mentioned, perhaps implying that they can be patented.

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research community as the patent system can provide useful incentives for investment in and translation of genetic research by conferring a commercially valuable right on inventors of genetic technologies for a specified period of time.

A comprehensive overview of gene patenting issues (most of which remain current in 2011) can be found in the 2004 Australian Law Reform Commission (ALRC) report *Genes and Ingenuity*[3], along with a number of recommendations that should be considered in the context of this current Inquiry and proposed legislative changes. The Attorney-General tasked the ALRC with examining the laws and practices governing intellectual property rights over genetic materials and related technologies, with a particular focus on human health issues, and the impact of current patenting laws and practices on research, industry and healthcare provision in Australia.

In NHMRC's submission to the ALRC inquiry, NHMRC emphasised the importance of ensuring that gene patents do not pose a hindrance to acquiring further knowledge through research. NHMRC supports the recommendation of the Senate Community Affairs Committee's Report on Gene Patents to amend the *Patents Act 1990* to include a broad research exemption[4]—a move that the ALRC also strongly recommended in its 2004 report.[5]

Access to genetic knowledge is critical for ongoing research and development of health applications and ultimately, to improve human health. As health and medical research innovations are translated into products and/or treatments to improve health care, it is also critical to ensure that the patents, where awarded to support and protect research, are not a hindrance to equitable and affordable access to genetic testing and appropriate health care. NHMRC considers that the necessity of patents to secure investment in research should be balanced with the likely benefits of amending the *Patents Act 1990*.

The widespread community concern regarding the patenting of naturally occurring gene sequences indicates a need for clarity. NHMRC supports the aim of the Bill, which is to clarify the existing law.[6] Because the *Patents Act 1990* does distinguish between discoveries and inventions, the ALRC did not recommend any amendment to this aspect of the Act.[7] However, NHMRC considers that greater clarity as to what constitutes a non-patentable discovery and a patentable invention in the context of human genes and biological materials will be of benefit to all stakeholders. Rather than through legislative amendments, this could be in the form of guidelines regarding intellectual property rights, competition law, and information and strategic capacity-building in relation to the existing provisions in the Patents Act, such as Crown use and compulsory licences, to access patented biological materials, as the ALRC recommended in 2004.[8]

In its inquiry and report on the proposed legislation, it is critical that the Senate Legal and Constitutional Affairs Legislation Committee does not lose sight of the broader issues for advancing health and medical research and ensuring affordable and equitable access to appropriate clinical services. For this reason, consideration beyond the legislative amendments as proposed by the Bill may also be warranted.

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[3] Australian Law Reform Commission (2004). *Genes and Ingenuity: Gene Patenting and Human Health, (ALRC 99)*
[4] Report of the Senate Community Affairs References Committee on Gene Patents, November 2010.
[5] Australian Law Reform Commission (2004). *Genes and Ingenuity: Gene Patenting and Human Health, (ALRC 99)*
[6] Senator Bill Heffernan (New South Wales). Second Reading Speech on Wednesday 24 November 2010, Senate, p. 60.
[7] D. Weisbrot, President, Australian Law Reform Commission 1999-2009 (personal communication 19 January 2011).
[8] Australian Law Reform Commission (2004). *Genes and Ingenuity: Gene Patenting and Human Health, (ALRC 99)*

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Much of the controversy surrounding the patenting of biological materials has emerged due to the way in which exclusive licensing has been used. These issues could be addressed to ensure affordable and optimal clinical service delivery by measures that may not require amending the legislation. For example, with technological changes occurring rapidly in health and medical fields, appropriate support of patent examiners, including the ability to bring in advice from independent expert assessors may assist in the appropriate rewarding of intellectual property rights in areas that are new and not yet well understood advancements in science and technology.[9]

NHMRC considers it relevant to note that the focus of Inquiries to date has often been on affordable access to single-gene tests. It is now evident that many diseases and conditions require multiple gene expression analyses and that these are starting to impact on health care (e.g. microarray analysis of cancer tissue). As the costs of whole genome sequencing decrease rapidly, the goal of the "$1,000 whole genome sequence" will likely be realised in the not too distant future. This will allow patients to be assessed for a full range of conditions instead of conducting expensive tests for each condition separately. These rapid advancements in sequencing technology will present new challenges for the patent system as they become part of routine use. As such, the implications of patenting must be considered in an environment that will continue to change rapidly, so that the use of legislation alone to achieve the purpose of the Bill would be very challenging, particularly given the time required to amend legislation that is found to be outdated or problematic.

NHMRC through the expertise of its Human Genetics Advisory Committee (HGAC) is able to provide advice on high-level technical and strategic issues in human genetics, and on the social, ethical and legal implications of human genetics, genomics and related technologies. Details of HGAC's functions, membership and secretariat are provided at Attachment A for your information.

In summary, research into the human genome is already benefitting health care and health outcomes and the potential for future gains is immense. A balance between access to equitable, affordable, appropriate and high quality healthcare, and the need to support, maintain and nurture biomedical research and innovation is necessary. NHMRC commends the establishment of the Inquiry and trusts that in inquiring into and reporting on the specific terms of the proposed amendments, the Committee will consider the suggestions above and the possible implications of their implementation for human health, research and innovation.

I trust this submission is of use and assists the Committee in its Inquiry.

Yours sincerely

Professor Warwick Anderson
Chief Executive Officer

25 February 2011

[9] A recommendation of the Australian Law Reform Commission (2004). *Genes and Ingenuity: Gene Patenting and Human Health, (ALRC 99).*

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Human Genetics Advisory Committee (HGAC)

Functions

The functions of HGAC, as gazetted by the Minister on 25 March 2009, are:

- to advise NHMRC on current and emerging issues in human genetics and related technologies, particularly the expected impacts on human health and healthcare;
- to advise NHMRC on the ethical, legal and social implications arising from developments in human genetics and related technolgies;
- such other functions as the Minister from time to time determines in writing after consulting the CEO; and
- any other functions conferred on the Committee by the NHMRC Act, the regulations or any other law.

While the HGAC provides advice to Council on high-level technical and strategic issues in human genetics, and on the social, ethical and legal implications of human genetics and related technologies it is important to note that under the *National Health and Medical Research Council Act 1992* (NHMRC Act), AHEC has carriage of the development of Human Research Guidelines.

Membership

The composition of HGAC is not defined under the NHMRC Act. HGAC has 12 members for the 2009-12 triennium. The membership includes persons with expertise in human genetics; community representation; privacy, discrimination and health law; data management and information security; science communication; and the health needs of Aboriginal and Torres Strait Islanders.

A member of Australian Health Ethics Committee (AHEC) also sits on HGAC – this is a requirement under the NHMRC Act.

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