

Ms Julie Dennett
Committee Secretary
Senate Legal and Constitutional Committees
PO Box 6100
Parliament House
Canberra ACT 2600

24 February 2011

Dear Ms. Dennett,

Re: The Patent Amendment (Human Genes and Biological Materials) Bill 2010

The Australian Reproductive Health Alliance (ARHA) works to promote policy and legislative frameworks that support reproductive and sexual health and the rights of women in Australia and the Asia-Pacific region.

Breast cancer, the most common cancer among Australian women, Indigenous and non-Indigenous, is the leading cancer cause of burden of disease for females in this country. In 2010, breast cancer accounted for 61,100 disability-adjusted life years (DALYs) or 40,600 years of life lost due to premature death and 20,500 years of healthy life lost due to disease and disability. The number of women diagnosed with breast cancer is increasing: by 2015, the number of new breast cancer cases is projected to be 22% higher than in 2006.

Demographic ageing is also seeing rising numbers of women succumbing to ovarian cancer. Because of difficulties in early detection, women who experience this, the most common form of gynaecological cancer, have lower survival rates than women with other cancers.

Like all women in Australia, these women have a right to timely and affordable access to the results of research that will enable accurate diagnosis and optimum treatment of these diseases. If the award of a patent is extended to biological materials which are identical or substantially close to materials as they exist in nature, however, this imposes financial and economic costs on development and innovation in this research. The recent Inquiry exposed shocking examples of patients, particularly in countries when gene sequences can be patented, unable to gain second opinions or have the tests they needed.

Some pertinent examples of restrictions on research and the costs involved when gene sequences are included in patent claims were outlined in the submission and evidence presented to the Inquiry by the Peter MacCallum Centre. This and other submissions illustrate the extent of the problem, and show that these delays and costs will increase exponentially as a greater understanding of the role and interaction between various genes is discovered.

We are therefore writing to ensure that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 is fully supported and passed in its current form. Only by doing this will the existing provisions in the Australian Patent Act be clarified and reinforced to give the clear message that 'scientific discoveries' should not be the subject of patents.

The Report from the Senate Community Affairs References Committee released on 26 November "strongly rejects" the approach that has allowed the patenting of 'isolated genetic material on the basis that they are 'inventions' rather than non-patentable products of nature or 'mere discoveries'. It notes that this is a matter of 'fundamental importance to the quality and accessibility of Australia's health system'. We are also aware, and ask the Committee on Legal and Constitutional Affairs to note, that the United States' Department of Justice recently filed an *amicus curiae* brief to the US Court of Appeals advocating the same position as expressed above.

The Bill, fully implemented, would have a positive impact that would help provide an environment where research, innovation and scientific endeavor can flourish. It will also reassure women experiencing breast or ovarian cancer, that samples given for research and/or diagnosis, which are an essential part of scientific discovery, will not be turned into 'patented produces' to be bought and sold in the market place.

The issue of patents on gene sequences is a technical and complex one and argumentation can be used to confuse or misrepresent the intention of the Bill. Stopping the patenting of biological materials, as defined in the Bill, will not prevent the use of these materials to create new inventions but instead will retain these important biological materials for continued use by the scientific community and industry. The Bill deals with sensitive and contentious issues, so we urge the Committee to demand that any claims arguing damage to research, innovation, access to medicines or breaches of international law or bilateral agreements be fully backed by objective evidence and considered in the context of their impact on women's health.

We wish to register our full support for the Patent Amendment (Human Genes and Biological Materials) Bill 2010 in its current form and request that the Committee prioritizes the rights of women and girls to timely and affordable access to research based information and services that can maintain their reproductive and sexual health.

Yours sincerely,

Susan Stratigos
President

Australian Reproductive Health Alliance www.arha.org.au

PO Box 140 Campbell ACT 2612 AUSTRALIA Ph: +61 2 6249 6566 Fax: +61 2 6247 0291

Secretariat for the All Party Parliamentary Group on Population and Development www.pgpd.asn.au

Member of ACFID & Signatory to the ACFID Code of Conduct

NGO Special Consultative Status with the Economic and Social Council of the United Nations

ARHA's mission is to promote public support for enhanced reproductive and sexual health in Australia and internationally, and to promote the advancement of the status of women and girls