Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

Mr Elton Humphery
Secretary
Senate Community Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Mr Humphery

Re: Senate Inquiry into Gene Patents

I am pleased to provide a submission to the Senate Community Affairs Committee regarding the *Inquiry into Gene Patents*.

Introduction

The purpose of the submission is to clarify any potential confusion between the patenting of genes and the regulation of gene technology under the Commonwealth *Gene Technology Act 2000* (the GT Act). The granting of patents over human and microbial genes, and the impact which the granting of patent monopolies may have, are matters which are outside the scope of the regulation of genetically modified organisms under the GT Act.

The regulation of gene technology in Australia

The regulation of the development and use of genetically modified organisms (GMOs) in Australia is achieved through a cooperative legislative framework which includes the Gene Technology Regulator (the Regulator) and a number of other regulatory authorities with complementary responsibilities and expertise.

The Commonwealth *Gene Technology Act 2000* (the Act), in conjunction with corresponding State and Territory legislation, underpins the national scheme for the regulation of live and viable GMOs in Australia. The implementation of the cooperative scheme is overseen by the Gene Technology Ministerial Council, which comprises representation from all Australian jurisdictions. The Regulator is an independent statutory office holder who administers the legislation and has extensive powers to monitor and enforce the legislation.

Intellectual property rights and patents are not issues for which the Regulator has any responsibility. The granting of patents over human and microbial genes, and the impact which the granting of patent monopolies may have, are matters which are outside the scope of the GT Act.

The object of the GT Act is "to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs". In drafting the gene technology legislation, Australian governments decided to confine the Regulator to the consideration of risks to human health, safety and the environment. This was due in part to feedback received during the consultation process on the legislation which identified strong

community concerns that a requirement to consider economic and marketing issues could compromise the regulatory system's focus upon the protection of people and the environment.

The GT Act regulates all dealings with live, viable organisms that have been modified by techniques of gene technology, including the progeny of such GMOs which have inherited a genetically modified trait. 'Dealing' is defined in the GT Act, and includes research, production, propagation, import, transport and disposal of a GMO. The legislation revolves around a system of prohibitions and approvals. All dealings with a GMO need to be licensed by the Regulator, unless the dealing is an exempt dealing, a Notifiable Low Risk Dealing (NLRD), on the GMO Register or specified in an Emergency Dealing Determination.

The Regulator may issue licences to deal with GMOs which, in effect, authorise dealings with a particular gene construct in association with a plant, animal or microorganism. A licence to deal with a GMO is issued to a specified licence holder and may confer some commercial exclusivity. A licence application involving the use of a patented gene sequence would be evaluated in the same way as any other application, using a science based process to assess risks to human health and safety or to the environment. The GT Act includes provisions to protect commercially valuable information, which may be declared Confidential Commercial Information (CCI) by the Regulator. Patents are in the public domain and patented information would not normally be regarded as CCI.

The 2006 *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement* considered whether there was merit in extending the scope of the GT Act to include consideration of marketing, economic and social factors in relation to the commercial release of GMOs. The Review concluded that the scope of the GT Act should not be extended and that the focus of the regulatory system should continue to be the protection of health and safety of people and the environment.

Yours sincerely

Ms Elizabeth Flynn
A/g Gene Technology Regulator

19 March 2009