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SENATE COMMUNITY AFFAIRS COMMITTEE INQUIRY INTO GENE PATENTS

The National Coalition of Public Pathology (NCOPP) makes this submission to the Senate Community Affairs Committee Inquiry into Gene Patents.

NCOPP welcomes the establishment of the Inquiry and the opportunity to make a submission. The matters were examined by the Australian Law Reform Commission (ALRC) in its 2002-2004 review of intellectual property rights over genes and genetic and related technologies and final report *Genes and Ingenuity: Gene Patenting and Human Health*¹. NCOPP understands that a whole of government response to the report is being prepared by an interdepartmental committee, coordinated by Biotech Australia².

1. About Us

NCOPP is the organisation that represents the interests and values of public pathology services in Australia. Our members are the major publicly owned and operated pathology services in each State and Territory. They provide comprehensive diagnostic and consultative services to general practitioners (GPs), medical specialists, other clinicians and their patients in Australia's public hospitals and some private hospitals, in community care settings and in the wider community across urban, rural and remote parts of Australia.

Members provide routine and complex testing including genetic testing, health protection services, teaching at undergraduate and post graduate levels, training of pathologists, other clinicians and medical scientists and research. They take leading roles in many aspects of the clinical governance of Australia's public hospitals and health services.

The public sector provides the vast majority of medical genetic testing in Australia through State and Territory run clinical genetics services and the public laboratories associated with these services. Services are funded under the cost shared Australian Health Care Agreements (AHCAs) between the Commonwealth and States/Territories with tests provided free to patients and families following referral by a medical practitioner. A few tests are subsidised by the Commonwealth directly under the Medicare Benefits Schedule (MBS) with testing provided to private patients by private and public pathology services. Many public sector pathologists are practising clinicians and use genetic testing in providing direct clinical care to patients – e.g. in people with certain cancers, inherited blood disorders and infectious diseases in hospital and community based clinics.

Further information about NCOPP is available at our website at www.ncopp.org.au

¹ ALRC (2004) *Genes and Ingenuity: Gene Patenting and Human Health*. Australian Law Report Commission Report No.99, Commonwealth of Australia, Canberra.

² ALRC website information on implementation of ALRC99 accessed at www.alrc.gov.au

2. Gene Patents

Term of Reference (a)

The impact of granting gene patents in Australia over human genes and non-coding sequences, proteins and their derivatives, including those materials in an isolated form with particular reference to impact which the granting of patent monopolies over such materials has had, is having, and may have on:

- (i) provision and costs of health care**
- (ii) the provision of training and accreditation for healthcare professionals**
- (iii) the progress in medical research**
- (iv) the health and wellbeing of the Australian people.**

NCOPP supports a patent system that promotes innovation through a fair reward system to inventors. The patent system is well established across many fields of technology and medicine. Patents for inventions are in the public interest where they drive innovation, transfer results of research to the public and promote progress in exchange for exclusive rights.

The application of the patenting system to some areas of genetic materials, methods and products has proven to be problematic. Patents may be granted over:

- genetic material isolated from nature such as whole genes or the coding sequences of whole genes which are used in the diagnostic or predictive testing of genetic conditions, production of therapeutic proteins and gene therapy;
- methods or products used in testing for mutations in a gene or gene sequence; and
- general methods for identifying genetic sequences, mutations or deletions in an individual's genetic sequence. – e.g. polymerase chain reaction (PCR) to enable DNA from a genetic sample to be reproduced in large quantities.

Of key concern to NCOPP has been the patenting of the genes themselves.

NCOPP supports the position of the Royal College of Pathologists of Australasia (RCPA) and the Human Genetics Society of Australasia (HGSA) that genes and their mutations are naturally occurring substances that should not be patented³. They exist in the natural world and should not be owned just as a disease may be discovered, not owned. Intellectual property rights should only reside in the methods and processes by which its nature was ascertained where they satisfy patent requirements - namely, when they are novel, inventive, useful and fully disclosed. This means that a test for a gene may be invented and patented just like the invention of a treatment for a disease may be patented.

Moreover, NCOPP is opposed to patenting a method or process that claims to provide exclusive access to a gene. An example of this is the patent that the Australian biotechnology company Genetic Technologies Limited (GTG) holds for BRCA1 in Australia through an exclusive licensing arrangement with the US company, Myriad Genetics Inc. The patent covers both the BRCA1 gene and the test for predictive testing for breast cancer. A patent that gives exclusivity to a gene means that any method for checking mutations of this gene is in breach of the patent. This is in contrast to the situation where the patent only gives exclusivity to the method of testing, not the gene. For example, the PCR method is still under patent to Roche. Other methods have been developed to perform a similar function such as ligase chain reaction.

NCOPP considers that patenting a method or process that claims to provide exclusive access to a gene represents poor public policy on number of grounds. It stifles research into diseases and development of diagnostic, treatment and prevention tools. It drives up the costs of research, development and provision of health care. In Australia, with its largely publicly funded health care system, the public purse and taxpayers

³ RCPA Position Statement No. 3/2001 *Patenting of Human Genes*. Approval date 25 July 2001 and revised June 2006. Available from RCPA website at www.rcpa.edu.au. HGSA Position Statement No. 2000 PS01 *Patenting of Human Gene Sequences*, May 2001.

ultimately pay these additional costs. It impedes competition in innovation and ultimately constrains choice through the availability of and access to alternative and possibly more cost effective tests and treatments. It hinders the transfer of knowledge and expertise among health professionals in new areas of knowledge and professional development. It is to the detriment of public health.

The recent behaviour by GTG about whether it will assert its licence fee rights for BRCA1 testing in Australia is a salutary reminder of the precarious nature of the current arrangements and resulting uncertainty and vulnerability⁴. NCOPP believes that the basic DNA sequence of humans and other organisms should be placed in the public domain as soon as practical, without fees, patents, licences or limitations on use, giving free and equal access to all.

3. Measures to Ameliorate Adverse Impacts from Granting Patents Over Such Materials

Term of Reference (b)

Identifying measures that would ameliorate any adverse impacts arising from granting of patents over such materials including whether the Patents Act 1990 should be amended, in light of any matters identified by the inquiry.

The ALRC review recommended a set of improvements in the patent system in general including reforms directed at patent office practice as well as encouraging greater use of existing mechanisms within the *Patents Act 1990* and *Trade Practices Act 1974* to deal with appropriate use and exploitation of gene patents. They represented a practical and realistic way of addressing ambiguities and weaknesses with most of the recommendations not requiring legislative change. NCOPP considers that examination of amelioration strategies should be in the context of the Government's response to the ALRCs recommendations that is being coordinated by Biotech Australia. It is important to position Australia for the future transformation of health care that is expected to occur with the next wave of developments in genetic knowledge and technologies.

4. Amending the Patents Act 1990 to Expressly Prohibit Patent Monopolies over Such Material

Term of Reference (c)

Whether the Patents Act 1990 should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

NCOPP supports a patent system that balances the promotion of innovation through a fair reward system to inventors and the public interest. NCOPP considers that amendment of the *Patents Act 1990* to exclude genetic materials or technologies from patents should be considered after an assessment of whether the Government's response to the ALRCs recommendations is sufficient in addressing current ambiguities and weaknesses.

NCOPP would be pleased to discuss further the matters raised in the submission and assist the Committee's deliberations. Please contact Penny Rogers, our Chief Executive Officer, on 02 6247 9310 if you require any further information.

Yours sincerely



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President, NCOPP

⁴ Genetic Technologies ASX Announcement New Position re. BRCA Testing, 2 December 2008.