

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

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PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

The National Coalition of Public Pathology (NCOPP) makes this submission to the inquiry into this bill to amend the *Patents Act 1990* to prevent the patenting of human genes and biological materials existing in nature.

About NCOPP

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. Members provide routine and complex 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. 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

The Bill

NCOPP supports a patent system that balances the promotion of innovation through a fair reward system to inventors and the public interest.

NCOPP's fundamental interest is ensuring that the issue of patents for human genes and biological materials is managed in such a way as to give a certain basis for the operation of Australia's genetic health system into the future, based on an agreed set of principles.

NCOPP welcomes and endorses the bill's intended purpose:

- "to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature".

It deals with a matter of profound public health importance. We urge the Committee to bring about this long sought reform.

We are opposed to the patenting of human genes, their mutations and biological materials themselves as they exist in the natural world. They 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 human gene or biological material or a pharmaceutical developed through use of genetic information may be invented and patented, just like the invention of a treatment for a disease may be patented.

We are also opposed to patenting a method or process that claims to provide exclusive access to a human gene or biological material, ties up a gene sequence or biological material and restricts use of knowledge and competition to define a naturally occurring variation in that gene or biological material. It represents poor public policy on research and development, transfer of knowledge, competition, access and choice, and cost grounds. It is to the detriment of public health.

NCOPP does not have the legal expertise to comment on the adequacy and effectiveness of the draft bill in achieving its intended purpose and in establishing a clear distinction between the discovery and invention principles or whether there are better ways of addressing these matters – e.g. through other legislative and administrative approaches and practices.

In terms of specifics, we are concerned with the proposed definition of biological materials in Amendment 4: Paragraph 18(4) – that “**biological materials**, in section 18, include DNA, RNA, proteins, cells and fluids”. We question whether including specific examples in a definition limits the range of biological materials covered under the Act. The list is not complete and may change over time in light of new knowledge and discoveries.

We note the various inquiries that have been undertaken or are occurring in relation to gene patents, intellectual property and Australia’s patent system. NCOPP is keen to have these matters resolved in a coherent, effective and timely way so that Australia is well placed for the future.

NCOPP thanks the Committee for the opportunity to comment on the draft legislation.

Yours sincerely

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President - NCOPP