

# Australian Advisory Council on Intellectual Property Review of Patentable Subject Matter

## Submission from Cancer Council Australia

Cancer Council Australia is the nation's largest non-government cancer control organisation, representing the national interests of its eight state and territory members.

Responsibility for the content of this submission is taken by Cancer Council Australia Chief Executive Officer, Professor Ian Olver. Contact for further information is Paul Grogan, Director, Advocacy, c/o [paul.grogan@cancer.org.au](mailto:paul.grogan@cancer.org.au) or (02) 8063 4155. This submission consists of an overview and specific comment against the questions in ACIP's discussion paper.

### Overview

The content of this submission is drawn in part from a published Cancer Council submission to the Australian Law Reform Commission's (ALRC's) review of gene patenting, conducted from 2002 to 2004.

Due to the inconclusiveness of the ALRC's subsequent report, *Genes and Ingenuity: Gene Patenting and Human Health*, and the absence of ensuing legislative reform, the Cancer Council again makes the case that the patenting of isolated biological material, including genetic material, is not in the public interest.

Given the lack of progress since 2004, and the increasing use of genetic technology in cancer control, we emphasise throughout this submission that the key to resolution is to expressly exclude isolated human biological materials from patentable subject matter.

Furthermore, the development of DNA sequencing technology raises the question of whether the identification and isolation of biological materials involves an "inventive" step or an "innovative" step. In our view the nucleic and amino acid sequences of isolated biological materials represent neither an "innovation" nor an "invention", but a discovery of a fact of nature.

This submission focuses specifically on the cancer issues. We support, in-principle, the separate submissions provided by the Royal College of Pathologists of Australasia, and by Dr Luigi Palombi of Australian National University, the latter of which examines in detail the legal issues.

### Cancer and gene testing

Genetic science is rapidly advancing. Over the coming years our expanding knowledge of genetics will have a major impact on our ability to predict an individual's risk of developing cancer and on our ability to select treatments that are most effective. The genetic revolution may ultimately lead to ways of preventing cancer.

So far, medical genetics has largely been focused on single-gene diseases, with an increasing demand for genetic tests to detect pathogenic mutations in relevant genes – for example, BRCA1 and BRCA2 for breast and ovarian cancer, mismatch repair genes for colorectal cancer and HFE for hemochromatosis. While the list of genes and mutations will continue to expand, the current focus on individual genes may soon expand to genome-wide genetic profiling.

This global approach, where many genes are scanned simultaneously, has the power to predict the risk of developing common diseases whose aetiology (cause) is genetically complex. While there are uncertainties about the timing of these advances and the genetic-related therapies, it is expected that genetics will have a significantly increased impact on medical services within the next 10 years.

More research on, and planning for, the inevitable integration of genetics into clinical practice is urgently required. Ambiguity in the understanding and application of gene patents could restrict that research.

### **'Single-gene' disorders**

Currently most genetic testing is provided through state and territory genetic services and associated public sector laboratories.<sup>1</sup> Genetic testing is available in Australia through more than 40 laboratories, providing around 220 types of tests.<sup>2</sup> Not all of these laboratories provide a comprehensive surveillance service.

In Australia, private company Genetic Technologies Ltd offers a range of DNA tests for cancers, including breast and ovarian cancers, bowel cancer and a rare form of epilepsy. The company also has a commercial licensing agreement with Myriad Genetics Inc, which gives it the exclusive right to perform commercial DNA disease for the BRCA1 and BRCA2 genes linked to breast cancer.<sup>3</sup>

In June 2008, Genetic Technologies Ltd gave notice that it intends to enforce its patents in relation to BRCA1 and BRCA2. It is our understanding that the company expects all public and private laboratories in Australia to cease performing diagnostics for breast and ovarian cancer on or before October 6, 2008. Such a move presents a possible monopoly over an important public health service to Australians.

### **Cost issues**

Costs of genetic tests may vary depending on the type of test, from just over \$100 to more than \$2,500 per test. State health departments may provide limited funds for genetic testing from their budget allocations for non-MBS items. Specialised genetic testing is characterised by being generally complex with low throughput, may take up to six months and, in some cases, may be sent overseas for analysis at additional cost. Family cancer clinics (funded by state health departments) also receive small budget allocations for genetic testing, but this provides only for a limited application. In other cases, patients may be required to pay for their own testing.

---

<sup>1</sup> Australian Law Reform Commission, *Genes and ingenuity – gene patenting and human health*, 2004

<sup>2</sup> Human Genetics Society of Australasia

<sup>3</sup> Genetic Technologies website

Once a pathogenic mutation in BRCA1, for example, is identified in an individual, it is a simple and relatively inexpensive matter to screen family members who already have a family history of breast cancer for this gene mutation. Mutation carriers identified in this way typically have a 20-fold higher risk of developing breast or ovarian cancer and are in need of ongoing and intense long-term surveillance. A genetically-based comprehensive program of surveillance for high-risk cancer families could save up to 800 lives in Australia each year, representing 20,000 life years saved annually at around \$2000 per life year.<sup>4</sup>

A licensing fee added to the current cost, of BRCA1 and BRCA2 testing could substantially increase the cost of the tests, both to the individuals and the governments that provide the tests. The establishment of a commercial monopoly over the tests would also risk reducing access to people whose lives could be saved through genetic testing and surveillance.

Given the rate of scientific innovation it is expected that pressure for the availability of genetic testing will increase. It is, however, difficult at this stage to accurately forecast the limits of these developments or the larger impact on health costs that will occur as the accuracy and reliability of genetic tests improve.

The development of automated “DNA chip” technology may yet enable testing for numerous genetic mutations that is both reliable and financially affordable. The scope for potential expansion of this technology emphasises the need to clarify patent law in relation to DNA sequencing.

### **Gene therapy/molecular pathology**

Genetic technology is rapidly developing, with the emergence of gene mapping, genetic testing tools and limited clinical trials of gene therapy over a relatively short time. The pace of innovation is likely to accelerate over the next five to 10 years, with wide-ranging implications in terms of health system infrastructure, costs and patient expectations.

Recent gene therapy (or “gene transfer”) trials have produced sufficient evidence to warrant further research. For example, the American Academy of Neurology has reported limited brain activity revival for gene therapy trials in Alzheimer’s patients; corrective genes have been implanted into foetal mice with the aim of developing the technique for humans; and the results of clinical trials into gene therapy to correct the abnormal gamma-c that causes X-linked severe combined immunodeficiency have encouraged further research.

Gene technology is expected to have an increasing impact on cancer treatment, with research currently being conducted into the potential role of genes, or drugs that could mimic genes, in slowing the growth of cancerous cells.

The problems of adapting to technological change in Australia (expressed throughout this submission) are also applicable to gene therapy. While gene therapy is now subject to preliminary clinical trials, its use as a mainstream treatment is expected to be up to a decade away. However, even conservative scientists accept that gene therapy as a medical technology for treating cancer will eventually become an essential part of the health system, generating a range of new and important considerations in terms of cost and infrastructure. Developments

---

<sup>4</sup> *Family Cancer Genetics Services in Victoria – A state-wide 5 year Plan 1999-2004*, Genetics Advisory Committee, 2004

should be closely monitored, and systems put in place to help facilitate a proactive and structured approach to introducing genetic technologies.

### **Molecular pathology**

An emerging example of the challenges of technological change is molecular pathology, a better targeted and more selective method than the empirical approach used in conventional pathology. Molecular pathology is expected to begin replacing conventional pathology over the next decade. It is likely to have a profound effect in both diagnostic and treatment services.

Again, the potential for technology based on DNA sequencing to radically change the profile of health and medical services demonstrates the need for clarity in patent law unavailable under current arrangements.

### *Addressing the questions in ACIP's Discussion Paper*

#### **Question 1 – Economic objectives of limiting patentable subject matter (Part 3)**

A) Can placing limits on inherently patentable subject matter be justified on economic grounds?

Yes. There is a real and present need to enforce the distinction between “discoveries” and “inventions”, particularly in relation to human biology and to exclude from patentability the obvious application of those discoveries per se in technical applications. The identification, isolation and sequencing of biological materials that are associated with a human condition or illness is not, or should not be, patentable subject matter, nor should such materials per se be taken into account in the assessment of “novelty” and “inventive step” of any invention which makes use of them.

If there is a need to encourage medical and scientific research, it is towards innovations in the technological platforms that will diagnose, treat or cure cancer, not merely towards the identification of biological materials that are associated with or causative of cancer, which is what is presently occurring. The mere application of these materials or their derivatives in technological platforms that are in use is obvious as should not be considered to be inventive.

As a result, in conducting their research and health activities, medical and scientific researchers and public laboratories in Australia face a labyrinth of pre-dominantly foreign owned Australian patents over physical and natural phenomena, such as genes and gene mutations or their derivatives, which have the potential to restrict or control the activities which they perform in Australia and for Australians. These patents have the effect of inhibiting early stage cancer research.

Gene technology is evolving in cancer medicine at a rapid pace, both for early detection, prognosis and treatment.

Capacity to identify cancer risk, as is currently done through testing for BRCA1 and BRCA2, is likely to increase as the technology improves. This is expected to lead to the development of new types of cancer therapies. In addition, molecular pathology is set to becoming an increasingly pivotal treatment modality as part of systemic therapy for cancer patients.

Unless patent law is clarified to exclude “discoveries” (as opposed to “inventions”) from patentable subject matter, technologies with the potential to significantly reduce cancer morbidity and mortality are at risk of becoming prohibitively expensive – both to governments and individuals. This risk applies both to the treatments themselves and the process of scientific innovation that leads to new technologies.

With cancer incidence in Australia likely to increase by around 30% each decade until population ageing peaks in 2047, unnecessary cost burdens on cancer research, detection and treatment imposed by anachronistic patent law could have a negative impact on the wider economy.

B) Should the subject matter of each individual invention be assessed to determine whether a patent is necessary to encourage innovation, or should such an assessment be done for entire fields of technology?

For the reasons outlined throughout this submission (and articulated in separate submissions from Dr Luigi Palombi and the College of Pathologists), patents should only apply to “inventions” Nor should patents be granted to the mere technical application of “discoveries” of the causes of cancer, such as genes and gene mutations or their derivatives, whether isolated or not.

**Question 2 – Economic effect of inherent patentability test.**

What would be the consequences on innovation of imposing or removing limits on patentable subject matter? Are you aware of any empirical data on such consequences?

Patenting isolated biological materials is, in our view, a far greater risk to innovation than abolishing patents.

More than \$130 million is invested in cancer research in Australia each year. Cancer research is, by definition, “innovation”. For instance, patents that give the exclusive power to exclude use of genetic material and coding sequences to any patentee simply increases the real cost of innovation in cancer research, without enhancing the outcome. Indeed, such patents act as a disincentive to cancer researchers because they give a patentee the ability to impose conditions on the use of these materials in the conduct of that research, including a requirement to share ownership of intellectual property that may result from that research.

**Question 3 – Ethical reasons for limiting patentable subject matter (Part 4)**

A) Can placing limits on inherently patentable subject matter be justified on ethical grounds?

Yes. In our view there are serious ethical considerations in relation to the patenting of subject matter such as DNA sequences. Gene patenting may lead to prohibitive licensing fees being applied to medical research and to cancer testing procedures. The risk of monopolies being established over the use of technology relating to human biology, such as DNA sequences, thus presents an ethical problem.

Clarifying that patents cannot apply to scientific innovation which does not involve an invention would pre-empt the potential ethical difficulties presented by gene patenting.

B) Is it appropriate for legislation to predetermine ethical limitations on patentable subject matter, or is it more appropriate for courts to determine such limitations on a case-by-case basis?

The fundamental principle underpinning our position is that public health (as advanced through cancer research, detection and treatment) must be given priority over commercial interests in relation to the patenting of isolated biological materials.

Ethical issues in relation to science can be complex. The ethical limitation on patentable subject matter should in our view be clarified by distinguishing between “inventions” and “discoveries”. Such a distinction could be a straightforward, definitive response to an otherwise complex issue.

Patenting discoveries such as DNA sequences is problematic for a number of reasons, and could contradict the ethos of scientific innovation as a cornerstone of improving human health and wellbeing. For example, discoveries in clinical fields such as surgery are not patented; conversely, they are encouraged through clinical training and the development and promotion of guidelines, without concern for individual or corporate commercial gain.

C) Is patent law an appropriate avenue for dealing with ethical issues? If not, what is an appropriate avenue?

Patent law would be an appropriate avenue for dealing with ethical issues in this context, by providing the arena to clarify and ensure that patents are applied only to “inventions” and not to “discoveries”. Public health is a matter of national security and as such the impact that patents may have on the ability of governments and health professionals to maintain the public health of Australians is paramount. Accordingly, patent policy must take into account ethical issues.

**Question 4 – Ethical effect of inherent patentability test.**

A) What would be the ethical consequences of imposing or removing limits on patentable subject matter?

It is our view that isolated biological materials and other scientific discoveries relating to human biology are NOT patentable subject matter and to the extent that patents are being granted, should be expressly excluded from patentability. The ethical consequences of imposing such a limit would, in our view, be positive: life-saving research, surveillance and treatment innovations in cancer control could proceed without risk of paying prohibitive licensing fees based on flawed legislation.

B) Are you aware of any examples of such consequences?

A salient example of an ethical problem caused by ambiguity in patent law is the current use of BRCA1 and BRCA2 testing in public familial cancer centres in Australia.

While the Australian Government commissioned the Australian Law Reform Commission to explore this issue in 2004, the subsequent inquiry and its findings were inconclusive. As a result, public health professionals remain concerned that the imposition of a licensing fee, or the establishment of a monopoly, on the tests would make them less accessible to the community and/or increase taxpayer healthcare cost burden with no advance in public health outcomes.

If this is not resolved, the consequences for the Australian Government and community are likely to be of considerably more concern as the scope of genetic cancer technology grows and our population ages.

**Question 5 – Other reasons for limiting patentable subject matter.**

Other than economics, ethics and national security, can placing limits on inherently patentable subject matter be justified on any other grounds?

Cancer Council Australia's main concern is the long-term health of the nation. While the ethics, economics and security issues relating to patentable subject matter may continue to be debated, we remain concerned that cancer control technology in Australia may be compromised by delays in resolving this issue.

Australians have a one-in-two lifetime risk of developing cancer. Any restriction to the use of genetic technology could lead to inferior outcomes for the millions of Australians who will be diagnosed with cancer over the next four decades.

**Question 6 – Content and structure of current Australian law (Part 7)**

A) Does the content of current Australian law meet the objectives of the system? Are decision makers focusing on the appropriate principles?

At present it does not. As outlined throughout this submission, patenting human genes and other biological material as patentable subject matter is likely to restrict innovation in medical science.

B) Is the legislative structure of current law appropriate for the content?

It is apparent that the antiquated and ambiguous structure of current patent law is inappropriate in relation to the important, emerging field of genetic technology. Ensuring “patentable subject matter” does not apply to “discovery” nor to the obvious technical application of discoveries would provide long-term legal protection for medical and scientific innovation.

C) Is the current law clear to decision makers and users of the system?

No. Uncertainty surrounding the future of genetic testing for BRCA1 and BRCA2 is an important example of how unclear the current law is to decision makers and to “users of the system”. (Note that if patents were not awarded to scientific discoveries, genetic scientists and counsellors would not need to be “users of the system” in this respect.)

D) Does the content or structure of the current test cause you any significant problems?

Yes.

According to ACIP’s Discussion Paper, consideration of whether patentable subject matter represents a innovation or an invention with utility is “incorporated in the flexible concept of manner of manufacture ...” (p56).

It is in our view entirely inappropriate that such a fundamental principle be described as part of a “flexible concept”. The distinction between “discovery” and “invention” should never be flexible and it must be the case that patents be granted only for “inventions”, which must exclude obvious technical applications of discoveries.

### **Question 7– Issues with current Australian law**

In response to this question, Cancer Council Australia supports in principle the position articulated in the separate submission from Dr Luigi Palombi.

### **Question 8 – International integration**

Is it more important to achieve best practice or to harmonise with a major jurisdiction? Are any jurisdictions preferable over others?

It is, in our view, most important to achieve best practice in a way that protects the best interests of Australians – by ensuring that patent law is under no circumstances a threat to health services delivery, research and innovation.

### **Question 10 – Preferred patentable subject matter**

According to what you believe are the appropriate objectives and constraints of the patent system, what sorts of subject matters do you think should be inherently patentable and what should not?

Would your preferred content be compliant with Australia’s international obligations?

As emphasised throughout this submission, scientific discoveries (as opposed to specific inventions), should not be inherently patentable, nor should the obvious technical application of scientific discoveries be sufficient to render an invention, patentable. The use of DNA sequences in testing for genetic cancer risk, and the potential problems of patenting such sequences, is an ideal example of why.