Senate inquiry into gene patents

Cancer Council Australia, Clinical Oncological Society of Australia

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Cancer Council Australia is Australia's peak non-government national cancer control organisation. Its member bodies are the eight state and territory cancer councils, whose views and priorities it represents on a national level.

The Clinical Oncological Society of Australia is the peak multidisciplinary society for health professionals working in cancer research or the treatment, rehabilitation or palliation of cancer patients.

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Overview

We commend the Senate for inquiring into this important public health matter. While there has been significant interest in gene patents over recent years, Cancer Council Australia and the Clinical Oncological Society of Australia are concerned that some policy makers may not fully appreciate the flaws in current arrangements, particularly in view of the evolution in genetic science expected over the next 10-20 years.

Gene sequences (and genetic mutations linked to specific diseases) are not an invention, but rather the discovery and isolation of naturally occurring substances. As a fundamental part of human biology, gene sequences are increasingly pivotal to an extraordinarily important, burgeoning field of health science – and one that must not be restricted by measures ostensibly designed to reward invention which may lead to the establishment of commercial monopolies.

The fundamental problem of granting patents to biological material including gene sequences and related information is clearly exemplified by the risk that inadequate, anachronistic interpretation of patent law poses to healthcare professional development and accreditation.

While long-term resolution of this problem will in our view require legislative change, as independent, evidence-based health organisations motivated solely by population health concerns we assert that:

- Excluding gene sequences and related findings from the definition of patentable subject matter is in our view consistent with common law and the most effective, efficient way over the long term to resolve a potentially increasing raft of cost and access problems;

- A likely exponential evolution of genetic science means resolution of these problems must be achieved now, before they impose a more significant social and economic cost;
- Rather than rewarding innovation, gene patenting is contrary to patent law as developed by the courts and, if allowed, can actively discourage scientific research and discovery; and
- Allowing questionable legal practice regarding certain specific genes, which could become the status quo, is likely to have increasingly deleterious effects on health services, professional development and research as Australia's population ages.

Moreover, while amending the *Patents Act* is in our view the most appropriate legislative response to eliminate the monopolistic and anachronistic granting of patents over isolated biological materials, other measures would assist in effecting necessary change. These include:

- A more comprehensive *government* (as opposed to parliamentary) review of the problems of gene patenting, on a multidisciplinary level – i.e., formally involving economists, scientists, health professionals and consumers, as well as the patent lawyers and attorneys who have dominated previous studies;
- Recognition that a multidisciplinary approach to intellectual property arrangements in relation to science and technology will stimulate, rather than stymie, innovation – consistent with the Government's "Venturous Australia" report and recommendations;[1]
- Providing additional resources to enable the Australian Competition and Consumer Commission to challenge any claims regarding gene patents in relation to patentability and/or consumer protection;
- Consideration of the establishment of a patents court or a similar review body with formal representation of a range of stakeholders in addition to those with legal and commercial interests;
- Recognition that international precedents will not resolve problems in Australia. Canada, for example, is an entirely different prospect as its proximity and relationship with the US are very different to Australia's. The European Union is different again, as it has an enormous biotechnology sector; Australia does not. China has a different system of government etc; and
- An amendment of the *Patents Act 1990*, to ensure genes that have already been patented are exempt from licensing fees or monopolisation.

In addition, if systemic resolution cannot be achieved in the next five to 10 years, we recommend that open licences be introduced for genes and genetic testing – i.e., a fee is not required for non-commercial use of the gene or the test, but a fee can be charged to a commercial user (for example, a company using the gene or test to develop a product or test kit for other users). This system currently applies to testing for cystic fibrosis.

[1] Cutler & Company Pty Ltd 2008, Department of Innovation, Industry, Science and Research, 2008

Background

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 haemochromatosis. 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.

As the technology evolves, we expect to see the increasing use of genetic tests as markers of response to cancer therapy and indicators of treatment outcomes and prognosis. This use of genetic tests is expected to exceed usage for predicting cancer risk.

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 germ-line genetic testing is provided through state and territory genetic services and associated public sector laboratories.[2] Genetic testing is available in Australia through more than 40 laboratories, providing around 220 types of tests.[3]

In Australia, private company Genetic Technologies Ltd offers a range of DNA tests for germ-line cancer predisposition, including breast and ovarian cancers and bowel cancer. The company also has a commercial licensing agreement with Myriad Genetics Inc, which gives it the exclusive right to perform commercial DNA testing for the BRCA1 and BRCA2 genes linked to breast and ovarian cancer.[4]

In June 2008, Genetic Technologies Ltd gave notice that it intended to enforce its exclusive rights under the licensing agreement in relation to BRCA1 and BRCA2.[5] Our understanding was that the company expected all public and private laboratories in Australia to cease performing diagnostic tests for breast and ovarian cancer on or before October 6, 2008. (We understand

[2] Australian Law Reform Commission, Genes and ingenuity – gene patenting and human health, 2004

[3] Human Genetics Society of Australasia

[4] Genetic Technologies website

[5] GTG media release, statement to the Australian Stock Exchange, June 2008

this deadline was then extended to 6 November 2008 and later to an indeterminate date in 2009.)

This in our view was an alarming development, presenting potential problems for breast and ovarian cancer testing and, as a precedent, for the future of freely available genetic testing (and related issues explored in this submission) in Australia.

On 20 November 2008, Genetic Technologies withdrew its enforcement notice[6] and stated a return to its position of 2003 – when it publicly asserted that it would not enforce its patents but rather bestowed free use of BRCA1 and BRCA2 genes and tests as a "gift to the people of Australia".

The actions of Genetic Technologies Ltd in our view averted a significant public health problem in Australia. It must be stressed that these actions were voluntary; there is nothing in the law to prevent a potential monopolisation of genetic testing under these circumstances. If, for example, Genetic Technologies Ltd withdraws from its agreement with Myriad, the company could simply sign an agreement with another company or (arguably) enforce its patents directly.

Gene therapy

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 set to accelerate over the next five to 10 years, with wide-ranging implications in terms of health system infrastructure, costs and patient/consumer 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 a decade or so away. Most scientists agree 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 should be closely monitored, and systems put in place to help facilitate a proactive and structured approach to introducing genetic technologies.

[6] 'Company relents on breast cancer gene test', The Australian newspaper, 20 November 2008

Molecular pathology

An emerging example of the challenges of technological change is molecular pathology, which is based on detection of changes in DNA and provides an individualised approach for determining the molecular make up of cancers. Molecular pathology is expected to comprise an increased proportion of all pathology and 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 to radically change the profile of health and medical services demonstrates the need for clarity in patent law unavailable under current arrangements.

As emphasised throughout this submission, the inadequacy and anachronism of current patent law in relation to genes will become increasingly problematic as the technology evolves.

Addressing the terms of reference...

The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

(a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:

(i) the provision and costs of healthcare,

Cancer Council Australia/COSA response

Cancer Council Australia/COSA's key concern in this context is the potential for monopolisation of genetic material through the granting of patents to:

- Reduce public access to predictive, diagnostic and therapeutic genetic technology in cancer control; and
- Increase the costs of genetic technology in cancer control to both government and community.

Current position

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 tests.

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.[7]

It is important to note that Australian laboratories have the capacity to tailor their own in-house genetic tests (this in itself demonstrates that there is no "inventive" step); monopolisation of the genes involved therefore could restrict the culture of competition, information sharing and quality improvement inherent in the technology.

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 for people whose lives could be saved through genetic testing and surveillance. Patent monopolies can also keep the costs of tests comparatively high, despite cost reductions generated by greater efficiency and technological advancements elsewhere in the system.

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.

It is important to note that inventive platforms such as "DNA chip" do not (and should not) extend to the basic biological materials contained within them.

Risk

Under current arrangements in Australia, there is no adequate legal protection to ensure genetic testing for cancer risk remains freely accessible and at reasonable cost to the health system and consumers. A potential problem was averted when Genetic Technologies Ltd abandoned plans to enforce its licensing fees and monopolise the tests in Australia late last year. As emphasised throughout this submission, the temporary resolution of this problem was brought about by an arbitrary decision by the company. There is no mandated protection from the problem re-emerging, in relation to breast and ovarian cancer, or for other important diagnostic procedures for which gene patents may be enforced. (Importantly, Genetic Technologies Group

[7] Family Cancer Genetics Services in Victoria – A state-wide 5 year Plan 1999-2004, Genetics Advisory Committee, 2004

is only the Australian licensee for BRCA1 and BRCA2 gene patents. The patent owner is a US company, Myriad, whose long-term plans are not disclosed.)

While we cannot speculate on claims from the company that its monopolisation of the tests would have had no impact on consumers, it should be noted that when BRCA1 and BRCA2 patents were enforced in Canada by Genetic Technologies Ltd's parent company, Myriad, costs increased and access was reduced.[8]

(a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:

(ii) the provision of training and accreditation for healthcare professionals,

Cancer Council Australia/COSA response

Patent monopolies over isolated biological materials are in our view problematic in the context of health professional training, development and accreditation.

Academic excellence and continuous quality improvement in medicine have been built on generations of collegiate information sharing. The potential to impose prohibitive costs on the use of genetic material could restrict continuous improvement and reduce collaboration between institutions. The result could be a significant diminution of the capacity of longstanding academic institutions to maintain internationally competitive standards, particularly at a time of medical workforce pressure and when the scope of genetic medicine is on the threshold of significantly widening.

Imposing licensing fees on the use of biological materials is also in our view contradictory to the ethos of progress in healthcare and scientific innovation as cornerstones of improving human health and wellbeing. By comparisons, 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.

The fundamental problem of granting patents to biological material including genes is clearly exemplified by the risk inadequate, anachronistic patent law poses to healthcare professional development and accreditation.

In terms of accrediting gene testing laboratories, the monopolisation of genes eliminates competition and carries the risk of sole providers having no incentive to find more efficient and affordable ways to undertake tests and make other use of the genetic information they control.

[8] Gold R, Caulfield A, Ray P, Gene patents and the standard of care, Canadian Medical Association Journal, 2002

(a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:

(iii) the progress in medical research,

Cancer Council Australia/COSA response

Our concerns about gene patents in relation to healthcare professional training and accreditation apply equally to medical research.

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 increase 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.

Therefore, while patents were ostensibly introduced (hundreds of years before genes were discovered) to encourage and reward innovation, in medical research there is a significant risk that their granting could have the opposite effect.

Genes (and genetic mutations linked to specific diseases) are not an invention, but rather the discovery and isolation of naturally occurring substances. As a fundamental part of human biology, genes are increasingly pivotal to an extraordinarily important, burgeoning field of health science – and one that must not be hamstrung by monopolies.

While we commend the Advisory Council on Intellectual Property and the Australian Law Reform Commission for proposing an experimental use exemption for patented genes in some medical research,[9] in our view the recommendations are not sufficiently extensive. For example, exemption should also apply to research on the patented tests for identifying certain genes, to encourage continuous improvement; just because a commercial interest discovered a particularly gene or developed a test for its isolation does not mean that the test could not be improved (e.g. made more accessible and affordable) by a separate research entity. There are numerous other examples where exemption for experimental use would not be sufficient. Applying for the exemption could also impose administrative burden for not-for-profit and academic institutions involved in medical research.

As emphasised throughout this submission, excluding genes from patentable subject matter would be the most efficient way to ensure medical research and resultant public health outcomes are not compromised by the current anachronistic patent arrangements.

[9] Advisory Council on Intellectual Property, Patents and experimental use, 2005

(a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:

(iv) the health and wellbeing of the Australian people;

Cancer Council Australia/COSA response

There is in our view significant potential for the health and wellbeing of the Australian people to be compromised by the inadequate, anachronistic patent arrangements currently in place.

That we do not currently have major problems with cost or access to life-saving genetic tests is, in our view, a matter of good fortune rather than design. As we saw with Genetic Technologies Ltd last year planning to enforce its monopoly over tests for two very important cancers in Australia, the current legal framework cannot adequately protect the community from the many potential problems of sole providers controlling diagnostic testing and other uses of genetic technology.

The 'Background' section of this submission (pages 1&2) provides a summary of the current relevance of gene technology to the health of Australians in a cancer context, along with research, training/accreditation and the many other fields of healthcare increasingly linked to genetics. These are likely to be compounded, particularly if you consider that:

- Gene patents could potentially compromise the cost and accessibility of all these procedures;
- Genetic science is in its infancy – and occasional concerns (such as the 2008 concern around BRCA1 and BRCA2 patents) could become enormous legal challenges as the technology evolves; and
- Australia's cancer patient base should increase by around 30% each decade until population ageing peaks in 2047[10,11] – and patient expectations are likely to increase with the advent of new predictive, diagnostic and therapeutic interventions.

We strongly assert, therefore, that the current patent arrangements pose a serious threat to the health and wellbeing of the Australian people, particularly in light of expected developments in the technology and the population mix.

[10] Australian Institute of Health and Welfare, Cancer incidence projections 2001-2011, 2005

[11] Australian Bureau of Statistics, population ageing projections 2004-2101, 2004.

(b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the Patents Act 1990 should be amended, in light of the any matters identified by the inquiry; and

Cancer Council Australia/COSA response

Beginning with the Australian Law Reform Commission consultation in 2003, we have consistently asserted that the only efficient, permanent way to ameliorate the numerous adverse impacts around gene patenting before the technology evolves further is to exclude genes from the definition of patentable material.

Ultimately amending the *Patents Act 1990* to invalidate patents on biological material may be the only course of action to permanently resolve the potential problems explored in this submission.

We believe our rationale for this view is clearly articulated in this submission and from a number of other submitters whose core concern is population health outcomes.

(c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

Cancer Council Australia/COSA response

See above.