Breast Cancer Network Australia

Submission to the Senate Community Affairs Inquiry into Gene Patents

March 24, 2009

Giving a Voice to Australians Affected by Breast Cancer

About Breast Cancer Network Australia

Breast Cancer Network Australia (BCNA) is the peak national organisation for Australians personally affected by breast cancer. We empower, inform, represent and link together people whose lives have been affected by breast cancer.

BCNA represents more than 33,000 individual members and more than 200 Breast Cancer Member Groups from across Australia.

BCNA works to ensure that women diagnosed with breast cancer and their families receive the very best information, treatment, care and support possible – no matter who they are or where they live. BCNA is represented by the pink lady silhouette. The pink lady depicts the organisation's focus – women diagnosed with breast cancer.

Summary of BCNA's submission

Breast Cancer Network Australia welcomes the opportunity to provide a submission to the Senate Committee for Community Affairs Inquiry into Gene Patents and commends the Senate for establishing this process.

BCNA is particularly concerned that the granting of patents over human and microbial genes and non-coding sequences, proteins, and their derivatives may:

- have an adverse impact on the provision and cost of genetic testing
- limit the development of genetic research through an inability of researchers to access samples and data held by a private company
- adversely impact on women's ability to access timely, affordable and high quality genetic testing that is supported by genetic counselling
- increase the risk of personal genetic information being sold or made available to private companies who may use the information to discriminate against women with known genetic mutations

For these reasons, BCNA believes that the *Patents Act 1990* should be amended to expressly prohibit the granting of patent monopolies over such materials.

We believe that the views, opinions and experiences of women with a strong family history of breast cancer or known genetic mutation would add great value to the deliberations of the Committee's Inquiry, and we would welcome the opportunity to present in person to hearings that may be held as part of this Senate Inquiry.

Context

Breast cancer is the most common cancer experienced by women in Australia, and is the most common cause of cancer related death in Australian women. More than 13,000 women are diagnosed with breast cancer every year, with the numbers

293 Camberwell Road
Camberwell VIC 3124
ABN 16 087 937 531

Telephone: (03) 9805 2500
Facsimile: (03) 9805 2599
Email: beacon@bcna.org.au
Website: www.bcna.org.au
Toll Free 1800 500 258

expected to climb to approximately 14,800 by 2011[1]. There are currently two known gene mutations that can increase a woman's risk of developing breast cancer, the BRCA1 and BRCA2 gene mutations. Approximately 5-10% of all breast cancers in Australia are the result of an inherited gene mutation.

Through genetic testing, the presence of BRCA1 or BRCA2 gene mutations can be identified. A positive test result that indicates the presence of one of these gene mutations may mean that a woman begins regular medical surveillance for changes in her breasts through mammograms, Magnetic Resonance Imaging (MRI) and other methods, at a younger age than is otherwise recommended.

The Federal Government recently announced their support for young women with either a strong family history of breast cancer or the BRCA1 or BRCA2 gene mutation, through a new Medicare rebate for Magnetic Resonance Imaging (MRI) screening. This rebate has been warmly welcomed by BCNA and women as it will save high risk women many hundreds of dollars per MRI scan.

For women testing positive to BRCA1 or BRCA2, risk reducing surgery may also be an option. This may include the removal of a woman's breasts (mastectomy) and / or removal of her ovaries (oopherectomy). Both the adoption of early surveillance and risk reducing surgery have the potential to be life saving.

Women with a strong family history of breast cancer are also considered to be at higher risk for developing breast cancer. A strong family history includes those with three or more first or second degree relatives on the same side of the family with breast cancer. The risk is stronger again if two or more relatives have other characteristics associated with increased risk, such as being diagnosed before the age of 50 or being of Ashkenazi Jewish descent. A father's family history is just as important as a mother's family history.

Some women have a strong family history but test negative for the BRCA1 or BRCA2 gene mutation. It is thought that these families may in fact be carrying a gene mutation that has not yet been identified. Ongoing research in this area is therefore essential to enable us to increase our knowledge and understanding of the role of genetics in breast cancer.

The Senate Inquiry into Gene Patents is particularly pertinent for women at high risk of breast cancer as a private company, Genetic Technologies Ltd, currently holds an exclusive licence over testing for the BRCA1 and BRCA2 gene mutations. Genetic Technologies Ltd was granted the Australian licence in 2003. At the time Genetic Technologies Ltd announced that they would not enforce their licence rights, thereby allowing all the existing public and private laboratories to continue to conduct BRCA1 and BRCA2 tests.

However in 2008 Genetic Technologies reversed this decision, writing to all the laboratories in Australia conducting BRCA1 and BRCA2 tests asking them to cease testing by a specified date. While the company eventually reneged on their decision to enforce their licence, and returned to their initial position, there was considerable uncertainty and alarm generated as a result.

[1] AIHW, AACR & NCSG: Ian McDermid 2005. Cancer Incidence projections, Australia 2002 – 2011. Canberra: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries (AACR), and the National Cancer Strategies Group (NCSG).

BCNA was deeply concerned by the actions of Genetic Technologies Ltd in 2008. In particular we were worried that women's access to genetic testing would be significantly compromised.

We are contributing a submission to the Senate Inquiry in support of proposed changes to the *Patents Act 1990* to prohibit the grant of patent monopolies over human and microbial genes and non-coding sequences, proteins and their derivatives, as we believe this would provide certainty for Australian women in relation to BRCA1 and BRCA2 gene testing, and the future of gene research and technology in relation to breast cancer.

Addressing the Terms of Reference

In this submission we have limited our comments to four key aspects of the Community Affairs Committee Terms of Reference as outlined below. Our submission reflects BCNA's key areas of expertise and interest, the women with breast cancer, and those women at high risk of developing breast cancer and their families.

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 or may have on:

(i) the provision and costs of healthcare

"I'm so thankful that I was tested for the gene. My breast cancer was picked up early due to surveillance which otherwise would not have commenced until I turned 40. By then, it would have been too late." Kerrie

BCNA is concerned that the granting of patents over human and microbial genes and non-coding sequences, proteins and their derivatives could restrict women's access to genetic testing – a key aspect of the health care of many women at high risk of breast cancer – due to the commercial monopoly over genetic material and testing that the issuing of a patent grants to a company.

In particular we are concerned that a private company holding a gene patent could limit access to genetic testing for women by insisting that tests are only conducted through specified laboratories, or that the cost of the test could be increased in order to increase the profitability of the testing process for the company.

In Australia the private company Genetic Technologies Ltd has been granted a licence for the testing for BRCA1 and BRCA2 gene mutations. While they originally chose not to enforce their licence monopoly, the company changed their mind in 2008, and wrote to laboratories across the country who were conducting testing for BRCA1 and BRCA2 gene mutations, insisting that they cease doing so by a specified date. While the company eventually reneged on that decision, there is no mechanism that we are aware of that could prevent the company from enforcing their licence in this way again.

We are concerned that any restriction in the number of laboratories conducting testing for BRCA1 and BRCA2 could limit women's access to the test and could increase waiting times for test results.

In addition there is a risk that Genetic Technologies Ltd could start forcing women to pay for the genetic test that they currently can access at no cost. In Canada, the parent company of Genetic Technologies Ltd, Myriad, have a patent over BRCA1 and BRCA2 gene testing and we understand that under this arrangement the cost of testing has increased and access to testing by high risk families has decreased.

We are very concerned that any increase in the cost of genetic testing may mean that some women will not be able to undergo a genetic test, the results of which can, quite simply, save her life.

BCNA believes that the granting of patent monopolies over human genetic and other material could adversely impact on the provision and cost of health care for women with breast cancer and those at high risk of breast cancer and we therefore do not support such an initiative.

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

(iii) the progress in medical research

"My sister also decided to go with the genetic test. She doesn't carry the gene mutation. I remember the day she got her results. She cried because she felt so guilty for not having the gene, but I was so happy for her. I feel so lucky and privileged to have had the option of a genetic test available to me." Christine

Research innovation in the area of breast cancer is vital in improving outcomes for women with breast cancer and their families now, and into the future. This is particularly important to families who may have a strong family history of breast cancer, but who test negative for the BRCA1 or BRCA2 gene mutation. It is thought that these families may be carrying an as yet unknown gene mutation which may be responsible for their high risk of breast cancer.

However BCNA is concerned that the granting of patents over human and microbial genes and non-coding sequences, proteins and their derivatives may result in private companies using their commercial monopoly to restrict the use of gene materials in research, thereby limiting research innovation and development.

Alternatively gene patent holders may choose to charge a fee for access to data and samples, which could be prohibitive for publically funded researchers, or which could place considerable additional burdens on their research budgets.

BCNA supports the position of the Cancer Council Australia and the Clinical Oncology Society of Australia (COSA) on this issue and agree that excluding gene patents in Australia is the most effective strategy to ensure that medical research is not compromised or restricted.

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

(iv) the health and wellbeing of the Australian people

As we have outlined previously in this submission, genetic testing is essential to the health and wellbeing of many women at high risk of breast cancer. BCNA is concerned that the commercial monopoly created by the granting of a gene patent to a private company may result in negative changes to the current genetic testing

process. We are also worried about an increased risk of discrimination on the basis of genetic status.

Genetic testing

"I've spoken to my surgeon about genetic counselling and have completed consent forms. I'm waiting to participate in the next stage. I have two daughters and a son and I want them to know about their genetic background so they can manage their health." Angela

Genetic testing is currently offered in Australia through Familial Cancer Centres. These Centres provide not only genetic testing, but the support and information necessary for high risk families to feel confident about their decision to undergo the test, and any subsequent consequences of the test results.

In order to effectively meet the health and well-being needs of the Australian people genetic testing should be:

- **accurate** so that women feel confident in their test results, particularly where women may be considering undergoing risk reducing surgery such as mastectomy or removal of their ovaries on the basis of their test results
- providing test results to women in a **timely** manner
- supported by **genetic counselling** prior to, and after testing takes place, to ensure women are supported to make informed decisions about undergoing testing, and any further medical procedures that may be required
- **affordable** so that a woman's decision to undergo genetic testing is not limited by her ability to meet the financial cost
- **accessible** to ensure that women can undergo genetic testing regardless of where they live in Australia

The granting of a patent over human and microbial genes and non-coding sequences, proteins, and their derivatives to a private company could see control of genetic testing pass to a private company as part of the patent. Under this arrangement there are no guarantees that the genetic testing process as outlined above would or could remain in place.

In particular BCNA is concerned that the genetic counselling component of the current genetic testing process could be lost, in favour of a more streamlined and commercially cheaper approach, where a woman sends the relevant samples to a laboratory, with the results of the test sent directly to her. Without adequate communication, information and support for women, the results of a genetic test can be highly distressing and confronting. Appropriate information and strategies to assist women to manage their personal health and wellbeing on the basis of the test results may also not be provided, creating further uncertainty for women.

We therefore urge the Senate Community Affairs Committee to prohibit the grant of patent monopolies over human and microbial genes and non-coding sequences, proteins, and their derivatives including those materials in isolated form.

Discrimination

"We've also seen a genetic counsellor and discussed the option of a genetic test. I was booked in but then decided against it because of the negative impact it could have on my two younger sisters (aged eight and 12). If a gene mutation was discovered, it might be difficult to get life insurance. Mum decided against it too. We may choose to have it done later on but for now it's not our choice". Vanessa

BCNA is equally concerned that the granting of gene patents could increase the risk of discrimination against women and men who test positive to a genetic mutation such as the BRCA 1 or BRCA 2 gene mutation. We are concerned that a company that holds the sole right to test for the presence of a gene or gene mutation would also hold a significant amount of personal genetic information.

Without adequate protections in place there is a risk that a private company could on-sell an individual's personal genetic information to other private companies or organisations. BCNA is concerned that this may result in discrimination against individuals in relation to a range of areas such as employment or access to finance or loans.

Strict rules need to be in place to ensure that genetic data is not a commodity and the privacy of women using a genetic testing service for example, is upheld.

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

BCNA believes, for the reasons outlined throughout this submission, that the *Patents Act 1990* should be amended to expressly prohibit the grant of patent monopolies over human and microbial genes and non-coding sequences, proteins, and their derivatives including those materials in an isolated form.