



## GENE PATENTS AMENDMENT, PLEASE

### Presentation to Coalition Backbench Policy Committee

24 June 2013, Parliament House, Canberra

Sally Crossing AM

Thank you for inviting me to talk about the pressing need to make an amendment to Australia's Patents Act (1990) - to *clearly exclude the ability to grant patents over human genetic material*. We need this to improve and save lives by freeing research from this encumbrance.

My name is Sally Crossing and I am speaking on behalf of Cancer Voices, the independent volunteer voice, since 2000, of people affected by cancer.

I will talk about how the American Supreme Court decision ten days ago makes an amendment even more pressing. In the US naturally occurring human genetic materials that have been 'isolated' from their natural environments are no longer patentable. They now have certainty of freedom to use human genetic material - which we in Australia do not have. This has major short and long term impacts for health consumers and researchers.

That decision has overturned an interpretation which the Australian community finds abhorrent. Ask anyone if they reckon bits of their bodies, inside or outside them, should be patentable. The unequivocal, usually unbelieving, answer is always NO. We are encouraged to note that most MPs of all parties are of a similar mind, and in fact have made numerous attempts - since 1996, to amend our Patent Act.

Removing the ability to patent biological materials that have simply been removed from their natural environment is enormously important - ethically and economically - and in the areas of diagnosis, treatment and research.

We think the stars are now in alignment for a commitment by the next Australian Government to make such an amendment one of its first legislative acts.

### Why is Cancer Voices Australia concerned about this issue - and what are we doing?

We were concerned enough to have been a plaintiff in the single judge Federal Court case which gave a negative decision in February this year. Concerned enough to launch a **Say NO to Gene Patents campaign**, to continue talking to MPs (you've probably all had letters from us), talking to the media, by raising a formal Petition - to doing anything we can to gain your attention to the mounting public concern over this very big issue.

AND it's bigger than a couple of breast cancer genetic mutations - it's even bigger than cancer - which itself now annually causes more Australians deaths than any other disease.

Diagnostic testing and treatment of all kinds of disease and conditions increasingly rely on genetic profiling - this is the necessary step before we can benefit from true personalised medicine.

We people with cancer are hoping we live long enough so that more of us will benefit from treatment which directly addresses our own particular genetic profiles. This coming era is recognised by the clinical and research worlds as the next big advance in medicine. And we consumers of their services recognise it too!



**A little history** – and I can give you a more detailed chronology if you'd like.

- 2002 Genetic Technologies' first threat to enforce its breast cancer gene patents caused media and community outcry
- 2003 Genetic Technologies "gifts" its patent rights to the Australian people
- 2008 Genetic Technologies threatens to sue Australian laboratories using BrCa tests and calls for transfer of all genetic material to them. Further public outcry and another withdrawal of threat / ie more "gifts" to us of our own DNA
- 2009 Senate Community Affairs Committee holds an Inquiry into gene patents
- 2010 Cancer Voices Australia & Yvonne D'Arcy challenge Myriad's patent over isolated Br Ca 1 DNA
- 2010 Bill to ban gene patents introduced to Parliament and referred to a Senate Committee
- 2013 Australian Federal Court decides patent claims on isolated DNA are patentable (Feb)
- 2013 US Supreme Court decides they are not patentable (June) on Appeal
- 2013 Full Federal Court of Aust. of 5 judges will hear an Appeal re the Feb decision (Aug)

You can see that 2013 has proved to be a stellar year for the debate, with a little help from Angelina Jolie ("*Court wipes patent on Jolie genes*" The Austn 15 /06). Hopefully your decision soon will turn sustained, thoughtful debate into positive history via a one and a half page amendment to the Patents Act.

#### **How does the US decision impact on Australia? Now & future**

On 13 June, the US Supreme Court of the United States delivered its decision on patenting genetic testing for breast cancer and ovarian cancer. In the lead judgment, Justice Thomas commented: "*Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention*".

Informed commentators, including Cancer Voices, have welcomed the example of the US decision and recognise it will have a far-reaching impact. A 15 June SMH Editorial summed it up like this: "the new parliament should revive the lapsed 2010 proposals – this time without timidity and with a clear understanding that people's lives can be saved without crueing biotech research".

The US decision gives our legislators the impetus to ensure we in Australia have certainty regardless of the reading of present patent law by Australian courts. If Parliament acts soon, this will ensure certainty is gained quite quickly. Australia needs to be aligned on such a fundamental issue as this, with the US - one of our major trading and research partners - or we will lose out to a freer market.

Free, unencumbered access to genetic information cannot be achieved when patents are used to suppress competition, innovation, research and testing – and treatment as well.

#### **What do we want?**

***Cancer Voices Australia and the many people living with cancer today are calling for an Amendment to the Patents Act 1990 which would, as a minimum, clearly exclude the ability to grant patents over any human genetic material. We now seek your commitment to this in the lead up to the Federal Election.***

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#### **POSSIBLE QUESTIONS**

##### **Q: Haven't we addressed this in 2011?**

"Raising the Bar" legislation was limited to pure research, not to commercial or clinical use, hence did not address the main problem – the patentability of biological materials that no one invented.

##### **Q: How will industry react?**

Industry argued they need patents on human genetic material protect their investment. This was the argument put vigorously by the US biotechs to their Supreme Court. It was not upheld by the Court, although synthetic DNA (cDNA patents) remains so – the basis of much of their business. Interestingly, Myriad itself is not complaining. In the few hours after the decision, the price of testing fell by 2/3 as competitors moved in. Share prices fluctuated up and down – and that small part of the industry became competitive again. In Australia we can expect more dire warnings of the end of the biotech industry, but watching events in America will show otherwise.

**Q: Why is CVA interested?**

We care because personalised treatment depends on access to genetic profiling.

We also think the moral issue is an important one for the community.

It's not just for one gene or one disease – it's a public good

Cancer patients and their health professionals also want full certainty of access, quality of testing and interpretation, appropriate counselling and ability to gain second opinions.

**Q: Aren't patents expiring anyway?**

Thousands (40%) of our genes have patents on them, patents expiring at different times – but more can be applied for at any time. We are entering a new era of personalised medicine which depends on easy, fast and free access, to be able to target a range of genetic mutations and their combinations.

**Q: Why not wait for Australian Federal Court decision?**

Could be a long wait and may again be negative. The biotech industry lobbyists will be very active about impending, but unsubstantiated doom. But mainly, we need certainty ASAP

**Q: Who else supports your position?**

Cancer Council Australia, Royal College of Pathologists, Human Genetics Society of Australia, Ian Frazer and other eminent researchers, Australian Medical Association, National Breast Cancer Foundation of Australia – for starters.

I feel confident we can add "the people of Australia" to that list.

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Cancer Voices Australia is the independent, 100% volunteer voice of people affected by cancer, working to improve the cancer experience for Australians, their families and friends. We are active in the areas around diagnosis, information, treatment, research, support, care, survivorship and policy. To achieve this we work with decision-makers, ensuring the patient perspective is heard.

Cancer Voices has led the cancer consumer movement in Australia since 2000. The CVA network across Australia shares objectives and works together on national issues identified as important by their members, with consumers working to help others affected by cancer.

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