

Health Practitioners

Welcome to the Autumn edition of Maurice Blackburn's Health Practitioners newsletter. This quarterly newsletter is intended to keep you up-to-date with some of the recent cases and legal developments, as well as promote discussion around recent issues of relevance to your field.



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WHO OWNS OUR GENES?...A LEGAL UPDATE

The granting of patents over naturally occurring biological material has generated a great deal of controversy over the past few decades. There are strong philosophical, economic, scientific and religious objections to the commercialisation of the human body and its genetic material.

Large sections of the medical and scientific community believe that human gene patents can limit or extinguish the rights of other people and organisations to conduct research over a gene or develop new tests and treatments.

In Australia, the Federal Government's patents body, IP Australia has been granting patents over isolated human genes for some years - no laws have been passed to specifically allow this, and no Australian court has ever decided whether the practice is legal.

However recently there have been some significant legal developments in Australia and the US in this area.

In June 2010, Maurice Blackburn filed a challenge to determine the legal validity of Australian patent 686004 which covers mutations to the BRCA1 gene which are associated with breast and ovarian cancer. Myriad Genetics, a US company has held this patent since 1994 and licences its rights in Australia to Australian Company Genetic Technologies Ltd.

The application to the Federal Court of Australia in Sydney was made on behalf of Cancer Voices Australia, an advocacy group and Yvonne Darcy, a Brisbane woman who has twice survived breast cancer. The application also had the support of the Cancer Council Australia which is keen for law reform in this area.

The case went to trial over five days in February 2012. On Friday 15 February, 2013, the Federal Court of Australia in Sydney, handed down its decision.

The ruling by Justice Nicholas found that the isolation of the gene from the human body is the product of human intervention and isolated gene sequences are therefore patentable. Justice Nicholas stated that when the isolation of naturally occurring DNA and RNA results in an "artificial state of affairs with a discernable effect", it is longer a product of nature. The result is that the patent of Myriad Genetics Inc and the licence to the patent held in Australia by Genetic Technologies Limited remain in place.

There was widespread disappointment about this decision among doctors, researchers and health consumers, with Cancer Voices and Cancer Council of Australia saying "the law must be changed to protect the community from gene monopolies."

The case is now on appeal to the Full Court of the Federal Court.

Background – why is Maurice Blackburn involved in this issue?

Our firm has a long and proud tradition of representing groups and individuals pro bono in public interest litigation as part of its Social Justice Practice.

The firm acknowledges that many people in society cannot afford to take on powerful interests with deep pockets and that laws should work for community and consumer benefit. Monopolies granted patents are of enormous public interest when they relate to human genes.

Myriad Genetics' "invention" has been given the title of "In vivo mutations and polymorphisms in the 17q-linked breast and ovarian susceptibility gene." In simpler terms this means a mutated form of the gene known as BRCA1, with the patent covering the isolated form of the gene.



This means that Myriad Genetics and companies to which it sells licenses (such as Genetic Technologies in Australia) have the right to stop anyone else from studying and exploiting the isolated gene.

We believe that products of nature should be freely available for study and productive use - not private property.

Have these companies tried to enforce their gene monopolies?

Yes. On July 7 2008, Genetic Technologies announced to the Australian share market that it intended to enforce its exclusive rights. The CEO sent a letter to numerous

medical, pathology and cancer centers in Australia alleging that they had infringed and were continuing to infringe its exclusive patent rights, by testing patients for the BRCA1 genetic mutation. Genetic Technologies gave other testing facilities seven days to cease testing, and demanded that the facilities refer all of their patients to Genetic Technologies' services.

The letters caused a public backlash, and Genetic Technologies did not follow through on this threat; but they could still do so at any time until the patent expires.

In the US Myriad Genetics has taken legal action to enforce its patents in 1998, 1999 and 2000.

US LEGAL DEVELOPMENT

There is also a case relating to gene patents on foot in the US. In 2010, a US District Court ruled that the same patent which we are challenging was invalid because it was simply not a patentable invention. The US case was hailed as a 'major victory for medicine and science innovation'. In 2011 the decision was overturned by a 2:1 majority in the US Court of Appeals.

In November 2012, the American Civil Liberties Union filed a further suit alleging that patents on two human genes associated with breast and ovarian.

ASBESTOS AWARENESS UPDATE

Australia has one of the highest rates of asbestos related disease in the world. At the national and state level, various moves have been taken to improve awareness of the dangers of asbestos.

The Federal Government has set up an Office of Asbestos Management which may provide health professionals with information.

The office is currently seeking feedback to help shape a national strategic plan.

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For further information about the Office of Asbestos Safety or the National Strategic Plan, or to provide comment on the recommendations of the Asbestos Management Review, please email

OfficeofAsbestosSafety@deewr.gov.au.

The resources page has further information on the Office of Asbestos Safety and general information on asbestos

management, including publications released by the Office of Asbestos Safety.

deewr.gov.au/office-asbestos-safety?resource

Maurice Blackburn is a preferred legal adviser for Asbestoswise support group for people with asbestos related disease in Victoria.

asbestoswise.com.au



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