DNA – battle lines drawn

A case to be heard in the US may clarify a grey area in the complex field of gene patents, Nyssa Skilton reports

An Australian genetic testing company has faced a patent infringement suit in the United States relating to its non-coding DNA technologies – methods that analyse part of the genetic code once referred to as "junk DNA", which is now known to play a critical role in the body.

The civil action comes just months before a Senate committee is due to report on the outcomes of the Gene Patents Inquiry.

The committee is expected to recommend some reforms to the processes associated with Australia’s patent system, but it is not likely to support ceasing registration of patents over human genetic material.

Genetic Technologies describes its patents covering non-coding DNA as "revolutionary" and its critics argue the company has defined them too far-reaching to be valid.

Every living thing more sophisticated than a bacterium contains this non-coding DNA, and its analysis takes place across diverse fields of science, including agriculture, the environment and medicine.

Australian genetic testing laboratories regularly analyse non-coding DNA to test for inherited diseases such as cystic fibrosis and types of cancer.

Austalian National University College of law senior lecturer Dr Matthew Rimmer says the big problem with the patent is that its validity has never been properly tested in court.

"There’s been these cut and run cases that have been going on in the shadow of courts in which Genetic Technologies threatened, and then negotiated settlements or licences with other parties," he says.

"I think this could be a good test case to clarify the validity and the scope of this particular patent and it would be a very meaningful challenge with Genetic Technologies having to battle some of the most prominent veterans of biotechnology litigation in the United States."

Genetic Technologies sparked controversy in Australia in 2001 when it ordered laboratories across the nation to stop testing on genetic tests for breast cancer, called BRCA1 and BRCA2. The test for mutations in these genes allows women at a family history of breast cancer to see if they have a higher risk of developing the disease.

After widespread protest, Genetic Technologies reversed its decision and government laboratories could continue testing.

But now the company has much bigger fish to fry. The parties it has targeted in the US District Court of the Western District of Wisconsin are Beckman Coulter, Orchard Biotechnology, Genmark, Gen-Probe, Interbeukin Genetics, Molecular Pathology Laboratory Network, Monteray, PIC USA, Sunsite Medical Laboratories and Pioneer Hi-Bred International.

Genetic Technologies chief executive officer Dr Paul Maclean says the patent has been described as a flimsy point, setting politicians into action with the Senate Gene Patents Inquiry.

The inquiry, which involved six public hearings last year, set out to examine the effects of granting gene patents on the provision and costs of health care, progress in medical research and training for health care professionals.

The inquiry heard two polarised arguments: one from some academic, scientific and medical researchers, who called for a moratorium on gene patents, and the other from companies such as Genetic Technologies, which argued Australia’s patent system is “unsound – does not need fixing”.

Rimmer says he hopes the inquiry results in some effort to reform the patent system to ensure the patents granted are of requisite quality and there is adequate protection for wider public interests, such as proper defence for experimental use.

"My hope is the politicians will be up to the challenge of tackling this thing," he says.

"My fear is that they would defer any decision or do nothing in the face of extreme fanatical positions on either side. Given the scientific and legal complexity of the area, my concern would be that policy makers would avoid trying to make sensible decisions or reconfigurations."

ACT Liberal senator Gary Humphries, who was part of the Senate committee, says there is a strong case for an overhaul of many aspects of Australia’s patent system.

"I would certainly think the case was made that many aspects of the patent system are creating a bit and need to be reviewed, and they prurtigate action and the sheer complexity of the patent registration process."

Patent applications can typically run into thousands of pages, involving detailed knowledge about aspects of scientific work which many of the patent readers at IP Australia, "you’d imagine would find challenging."

"We have a system which is, I think strainning somewhat under the complexity of the issues that are being dished up to us," Humphries says.

"There is a case for overhauling and dealing with a number of serious problems with the patent system, which have been the subject of recommendations now for a number of years."

"I think the pressure is mounting and I would hope that it occurs fairly soon, because there are some serious issues about that that need to be sorted out."

The Senate committee was due to report on its findings last week, but has extended the report time until June 17, 2010.