

Local pathologists keeping close watch on US gene patent decision

Australian and New Zealand pathologists are keeping a close eye on the evolving issue of gene patents, following the lodgement of a statement by the United States government in the US Federal Court. The US government move is part of the preparation for an appeal against an earlier US District Court decision banning gene patents.

A gene patent means that the patent owner is potentially able to restrict pathologists from using the gene sequence to perform a genetic test.

Dr Graeme Suthers, Chair of the Genetics Advisory Committee of the [Royal College of Pathologists Australasia \(RCPA\)](#), says the US government action has world-wide ramifications.

“This isn’t something that only medical researchers need to be aware of; it has important consequences for everyone who provides or uses healthcare,” says Dr Suthers.

The issue of who, if anyone, should have the right to control a doctor’s ability to make a genetic diagnosis has been a source of debate in the medical profession and wider community for several years. The recent statement by the US government, along with the precedent-setting District Court decision to ban patenting of genetic material, has revived the debate.

Dr Suthers says the US government statement makes distinctions between different types of DNA.

“The new statement draws a distinction between two forms of DNA that occur naturally: the raw unprocessed genetic code or genomic DNA, and the processed DNA of a gene that is called cDNA. The US Government’s stance regarding genomic DNA has changed dramatically because it now regards genomic DNA as unpatentable. However, it has retained the view that cDNA is potentially patentable.

“This is a new direction that may have an impact on a current Australian Senate inquiry into gene patenting in this country. Some laboratories rely on cDNA for diagnostic genetic testing, while others rely on genomic DNA.”

Dr Suthers says that the granting of patents on human genes is problematic because of the broader ramifications.

“It may have far reaching consequences in the provision of health care through limiting the development and eventual use of genetic tests. Efforts to commercialise this information should be focused on developing products and applications, rather than restricting use of the genetic information.

“It is essential that appropriate public policy regarding gene patents is developed and implemented before restrictive genetic testing through patents becomes widespread,” says Dr Suthers.

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