

## **Human Gene Patents: wrong in principle, wrong in practice**

Representatives of the Royal College of Pathologists of Australasia (RCPA) will be presenting to Senate Committee Inquiry into Gene Patents today in Melbourne to stress that human genes should not be patentable under existing patent law.

Being held amid considerable controversy, the Senate Committee Inquiry is addressing the impact of gene patents on the provision of healthcare in Australia.

The peak professional body in pathology in Australasia, the RCPA contends that human genes don't adequately fulfil patent criteria, and the granting of human gene patents can have a stifling effect on the delivery of accessible, quality assured genetic tests. It may also stop the development of better tests, limit training for laboratory staff and has the potential to result in increasingly restrictive monopolies.

The President of the RCPA, Dr Bev Rowbotham says gene patents are wrong in principle.

"The patenting of human genes has been erroneously accepted by IP Australia," says Dr Rowbotham.

"The granting of patents for genes appears to be inconsistent with current patentability requirements, however if current legislation allows human genes to be patented as 'inventions', then the law must be changed to highlight the distinction between discoveries and inventions."

According to patent law, to be patentable, an item must meet five criteria. Arguably the most pivotal among these is that it must be an invention.

"But a human gene is not an invention, it is a discovery. DNA is a chemical and an information source that has been widespread for thousands of years, and existed before any patent applicant was born," says Dr Rowbotham.

Dr Graeme Suthers, Chair of the RCPA's Genetics Advisory Committee, says gene patenting is also wrong in practice.

"Whilst the RCPA recognises the importance of patents in medical research, and strongly supports the notion of patenting a novel treatment based on genetic knowledge or patenting a new technique for genetic analysis, it is our firm belief that the current propensity to grant patents for actual human genes will have an increasingly detrimental effect on our healthcare system in Australia," says Dr Suthers.

"There is clear evidence that patent monopolies could potentially lead to restrictions in the provision of healthcare, and increased healthcare costs, through (for example):

- not permitting testing outside a particular laboratory, which in turn limits training opportunities and precludes effective quality assurance,

- not permitting modification of a test to address ethnic differences or to enable development of better tests, and
- requiring that a commercial test kit be used that is more expensive than an in-house equivalent, which may limit a patient's access to the test.

“Alarming, when we consider that there are approximately 25,000 human genes and 100,000 proteins that could be covered by patents, we begin to understand the scope of red tape, restrictions to access, inflated healthcare costs and missed opportunities we will be facing in the future.”

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The RCPA is the leading organisation representing pathologists in Australasia. Its mission is to train and support pathologists and to improve the use of pathology testing to achieve better healthcare.

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