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RCPA has Reservations about the Government's Response to the Gene Patent Report

The Royal College of Pathologists of Australasia (RCPA) has expressed concerns that in this Response (published November 2011), the Government has failed to address the very concerns that led to the establishment of the various inquiries into gene patents, as illustrated by two key outstanding issues.

In its response the Government has taken on board many of the recommendations on improving the process of patent applications that were identified in three major inquiries from 2004 to 2011.

The RCPA's newly elected president, Professor Yee Khong, applauds the Government for implementing these recommendations, however, he flags that two fundamental issues are not adequately addressed.

"These unaddressed issues inevitably stir uncertainty over the application of gene patents in the provision of equitable healthcare for Australians" says Khong.

"Firstly, the report fails to address the basic principle that human genes existed and functioned for hundreds of thousands of years before they were discovered, and as such cannot be construed as an invention and consequently cannot be patented," Khong says.

"The College is principally concerned about the impact of gene patents on medical tests. When a gene is tested for medical purposes, the gene has not been invented or altered by a patent holder, and the gene should not be patentable.

"However, laboratory modification of the gene or laboratory-modified products derived from a gene may be used for therapeutic purposes which lie outside the natural function of the gene in the human body.

"The College recognises that patent protection may be appropriate for therapeutic agents derived from naturally-occurring genes. But the genes themselves remain discoveries," said Khong.

Secondly, the report suggests that in practice there are mechanisms in place to protect patients from the adverse impacts of patenting on their healthcare, such as the Australian Competition and Consumer Commission (ACCC).

However, patenting of a gene gives the patent holder the right to restrict access to a product of nature and at the same time creates a monopoly on testing relating to that gene.

The key consequence of a patent-holder's monopoly on testing a gene is that there can be no competition. A competitor cannot find another gene to replace the one discovered by the patent holder, making ACCC powers of limited or no value.

Other monitoring recommendations have been made by the Australian Law Reform Commission to the Government to develop new processes to audit genetic testing in healthcare and the impact of gene patents.

However, the Government deferred this matter to the Medical Service Advisory Committee (MSAC), the Committee responsible for undertaking assessments of the cost-effectiveness of medical tests and making recommendations regarding Federal funding.

According to the RCPA, 98% of the types of genetic tests provided by Australian laboratories are currently not Federally funded, have not been assessed by MSAC, and neither Federal nor State governments have any data on the national usage of such tests, so that monitoring and auditing by MSAC is impractical and cannot be implemented.

The College remains hopeful that the Government recognises the importance of these issues and has welcomed the establishment of a national Genetic Working Party as part of the national Pathology Agreement to advise government on genetic testing in healthcare. However without addressing these basic issues there remains a risk that access to appropriate healthcare will be compromised for all Australians.

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