AusSMC Briefing on gene patents

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Transcript

Thank you very much. I want to talk a little bit about the implications of patenting genes, or the problem that we've got, and that is brought to the public attention with the attempt by genetic technologies last year to enforce their patents over two of the genes known to be responsible for breast cancer. And what that would have done, it would have restricted the testing to one commercial laboratory where there was at least one, and sometimes two laboratories in every state that were doing this, and that potentially as a monopoly could have increased the cost and restricted the availability. It could have restricted research and any invention based on the gene to one company because of the twenty year patent that Luigi has just talked about. And whereas we have no issue with the fact that an invention that comes from a gene could be patented, just the discovery and isolation doesn't involve any inventive step.

But what I wanted to show you, that this is really only the tip of the iceberg. This was about a test for one cancer. But what we've seen in cancer treatment is a paradigm shift away from conventional chemotherapy to targeted therapies and we're just seeing the first of these enter the market. And these are drugs that target the products of genes, they often target the proteins that the genes make. The reason they're an advance over chemotherapy is chemotherapy essentially kills any cell that's dividing and makes use of the fact that the body will recover and the cancer won't. These targeted therapies target gene products that are responsible for the growth of cancers that are not necessarily found in any great extent in normal tissue. And so you get less side effects because it leaves the normal tissue alone and you get better cancer kill.

And we've got some drugs on the market, and I've used the commercial names because they're more familiar, but Mabthera is an antibody that's directed against a particular protein and lymphomas. Herceptin, very well known for its effect in breast cancer as long as the target is over expressed. And then there are small molecules that have been useful in the treatment of chronic myeloid leukaemia and kidney cancer, that are all part of this new wave of targeted therapies.

And so restricting research is not only going to restrict a diagnostic test, it's going to restrict the ability of scientists who actually develop new treatment as depending on what they discover about the gene and its ability to alter the growth of tumours. What we're going to see over the next decade is a flood of these such treatments, and we're going to see drugs targeted at these various gene products.

The genetic make up of a cancer is going to be important for a whole lot of other things as well. It will actually tell us what type of cancer it is and it will be far more accurate than currently looking down a microscope at a pattern of cells. By the pattern of gene changes it may well tell us how aggressive the tumour is and therefore the prognosis of the patient, how likely they are to die of the tumour, how likely it is to come back if it's removed surgically. And as I've said, it will actually tell us by the pattern of genes what specific treatment the cancer is likely to respond to. And so one of the implications of patenting genes would be to stymie this research and restrict it to the one company who was fortunate enough to get the patent just on a discovery.

So what solutions are we going to put forward? Well following the senate inquiry we clearly want governments to review the gene patenting laws but in a multidisciplinary way. Previously it's been patent lawyers but clearly economists, researchers, health professionals and cancer

consumers and consumers in other diseases as well have opinions on the commonsense of whether you can patent a discovery rather than an invention.

Can we look internationally? Well international precedents may not resolve these issues since they're often decided on technicalities rather than the principle of whether the mere discovery of a gene can be patented. What we're suggesting, however, is that it's early enough in the process of developing all these new treatments, to draw a line and not allow further gene patenting, and then we don't have to get into arguments about retrospectivity. Because the flood of these things is about to happen, we've just seen the first few shots. We're not suggesting though that it mightn't be helpful to amend the patents act in Australia to exempt already patented genes from license fees.

So in the short term, open licenses for genes or genetic tests so a fee is not required for non-commercial use would be useful, and resourcing the ACCC to be able to challenge any of these gene patent claims as part of its consumer protection activity.

So in conclusion, the mere act of isolating a gene from the human body should not be patentable. Australia needs to ensure that the patent system is not exploited by cooperations who want to hold a twenty year exclusivity over a gene and our patent law system needs to be overhauled now. It's a short of a watershed time, to ensure that we will have an equitable health system and that we'll have the best opportunity to develop new treatments for a range of diseases that will be treated by targeting gene products.

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