

AusSMC Briefing on gene patents

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Transcript

Thank you Lyndal. I'm representing both the College of Pathologists but also as a member of the Clinical Oncology Society of Australasia. Pathologists are medical specialists who are the people responsible for overseeing medical testing. If you have a blood or urine sample sent off by your GP or specialist it's a pathologist who oversees that test and we have a very keen interest in this issue of gene patents.

As has been outlined by Ian and Luigi, we consider that gene patents are wrong in principle, as I've summarised on the slide there, and I won't dwell on that any further. One of the immediate downstream consequences of patents is that there is a monopoly provided by a company and this means that a company, although it may not own your genes, it can control access to your genes and we consider that to be an inappropriate restriction on personal freedom in our society and if the current patent legislation allows this state of affairs then the legislation must be changed.

But I'd like to concentrate today on some of the consequences that may not be so visible to consumers in terms of the medical testing. Pathologists are particularly concerned about the quality and sustainability of the test that they provide and these very issues are at stake if gene patents are accepted. The reason that this is a problem is that having a monopoly is the legitimate outcome of any patent, it gives the patent holder the right to be the sole provider or seller of the particular patented item or service. And monopolies in medical testing have a number of serious consequences.

The first is that they can limit training for laboratory staff. In 2006 we had about ten labs across Australia offering testing for familial breast cancer and in that year they tested about 1900 patients. Now the analysis for each patient requires analysis of 20,000 nucleotides, the ATGC that Luigi referred to in his presentation. And that obviously requires a very high level of skill and sophistication in the methods that are used and those skills can then be applied to the analysis of other genes. So the delivery of these BRCA genetic tests, the breast cancer genetic test, is a major factor in the training of staff in our genetic laboratories nation wide. And if there is a monopoly it will dramatically shrink the opportunities for training.

Secondly, monopolies in medical testing can preclude quality assurance. If you have a test arranged by your doctor, you'd like the result to be the correct one but monopolies can erode that. Laboratories who are doing the same sort of investigation share their problems, they share samples, they share solutions, both formally and informally there is a lot of interaction between the labs. If you have a monopoly you have limited diversity. There's limited opportunities for sharing and fewer drivers for quality and it really comes down to the crunch point that if a monopoly lab, a lab that is the only one providing a service makes a mistake, how would it know and who will it turn to to have those mistakes corrected?

Another problem is that monopolies in medical testing can stop the development of better tests. And this isn't just theoretical, it has happened. The monopoly lab for providing breast cancer genetic testing in the US missed mutations in 12% of the women they tested. Now a new method was developed and provided in Europe and the people who did that did so in defiance of the patents that were in operation at the time. Once they had developed this new method, which identified those 12% of women who had a mutation, the monopoly lab then picked up that new

method and used it. But you'll note that the improvement came in defiance of the patents, not because of the patents.

Monopolies in medical testing can block access to genetic data. Again, I'll use the example of the monopoly lab in the US which does all of the familial breast cancer testing for that population of 300 million. And that one laboratory holds all of the test data, that's 20,000 records per patient, and pharmaceutical companies and others very much value these data for drug development and testing. And it's the monopoly lab holding the data that decides the fate of the data, it is not in appropriately managed public arena. And so limiting access to that data is also going to limit quality assurance for other laboratories and also limit who can benefit from that data to develop better tests, methods and treatments or whatever.

Monopolies in medical testing dictate the security of health care. The College of Pathologists did a survey of genetic testing across Australia a couple of years ago and about 60% of all of the genetics labs operating were in the public sector and that means they had comparable funding and comparable governance as to who they were accountable to. And just under half of the tests were provided by two or more laboratories, the remaining tests were tests for very rare disorders and only provided by one laboratory nation wide. The key thing is here that for 45% of the tests, if one lab stopped testing for some reason there is back up within Australia to pick up that particular investigation at short notice and provide results back to clinicians.

But if you have a monopoly situation, if you have a laboratory who is the only provider of that particular genetic test because of the patent that it holds, then the monopoly lab can shift that monopoly to another provider, to an exclusive license holder, whenever it likes. And if a monopoly lab was to go bust or go under there is no back up in the system. So monopolies in medical testing erode the security of health care that we currently see in other areas of health care in Australia.

Monopolies in medical testing can dictate standards of care, the clear experience overseas was a patent enforcement in British Columbia lead to the cessation of breast cancer genetic testing and we had similar threats, as Ian Olver alluded to, in Australia, both in 2003 and then last year. On the other hand, in the US the same patent holder for the breast cancer genes encourages non-expert clinicians to request testing in settings that Australian clinicians would regard as inappropriate. So the monopoly can both limit appropriate testing and drive inappropriate testing.

Monopolies in medical testing can also impede research and there is clear evidence from the US that genetic researchers, for example 40% of genetic researchers withhold data from publication usually for patent related reasons and that has an immediate downstream consequence for the trainee researchers who feel that the withholding of data has indeed compromised their research and compromised the research of their own host laboratory.

So if gene patents can cause all these things, one has to ask why are gene patents regarded as legitimate.

Thank you.

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