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Genetic conflict

Medical institutions are demanding Australian gene patent holders hand over their technologies for a token payment. The biotech players are anxious. **Olga Galacho** reports

A GROUP of senators meeting around the country will soon have to exercise the wisdom of Solomon in a highly charged debate on whether public access should come before private profits in the complex business of gene patents.

The Senate committee inquiry led by Liberal Bill Heffernan this week heard passionate arguments from organisations such as the Peter MacCallum Cancer Centre that patent protection for genes would damage public health outcomes.

The inquiry follows growing public concern that since the human genome was mapped, commercial interests are increasingly staking claims to individual genes integral to their technologies.

Those businesses argue that patenting certain genes is the only way they can protect investments and stop taxpayer funded laboratories from using the same technologies for their own commercial benefit.

Last year, Fitzroy biotech Genetic Technologies found itself at the centre of a storm when it sought to stop publicly funded laboratories from using its licensed breast cancer screening tests BRCA1 and BRCA2 without paying.

Opponents of gene patents succeeded in forcing Genetic Technologies to back down, arguing that patients should be able to choose whether they had their tests conducted by Genetic Technologies or other laboratories chosen by their oncologists.

In the damaging fallout, the company's board was disbanded and earlier this year, Dr Paul MacLeman was appointed chief executive.

As the patenting of genes was publicly aired again during the Senate hearings this week, Dr MacLeman spoke to *BusinessDaily* about the company's frustration over public institutions conducting the cancer tests at close to the commercial rates Genetic charges and refusing to pay licence fees.

DR MacLeman said Genetic itself paid tens of thousands of dollars in royalties to Myriad, the US owner of screening technologies that analyse genetic mutations which can indicate predisposition to breast cancer.

The Victorian Department of Health's Kylie Mayo and Peter MacCallum familial cancer centre director Dr Gillian Mitchell say the patent laws are anti-competitive.

Dr Mitchell told the Senate inquiry that existing gene patent laws discouraged licensed owners from improving their technologies and reducing their costs.

In her submission she proposed that "the government should strongly consider requiring all existing Australian gene patent holders to grant compulsory licences to government-funded laboratories and research institutions engaged in providing a service to the public and to exempt them from paying more than a token annual licence fee".

When contacted by *BusinessDaily*, spokespeople for the clinic and the department said they could not comment on whether they were actively avoiding paying licence fees to Genetic Technologies.

But several biotech companies have claimed that unless their years of research and development are rewarded through royalties collected on patented products, there is no incentive for investors to support them and no incentive for them to continue to research new therapies.

AusBiotech chief executive Anna Lavelle believes that unless these intellectual properties are protected, it could lead to companies making pirated copies of the technologies.

"Australia risks becoming the new counterfeit capital of Asia if anyone is allowed to take these products and make a home brew of their own," Ms Lavelle said.

"Imagine how enthusiastic global companies would be if Australia were to flout their patents.

"It would be a very brave government that banned genes from being patented because it would put us in conflict with free trade agreements and invite international wrath."

Enforcement of patent laws is high on the list of prerequisites for potential investors, according to Scoresby DNA diagnostic company Genera Biosystems.

"How well protected are your technologies?" is the first question we get asked by American financiers," Genera chief executive Allen Bolands told *BusinessDaily*.

"They spend a lot of time doing due diligence on your IP (intellectual property) and they simply would not put cash into a venture if its not ironclad," he said.

While Genera selects gene markers for its test platforms which are not

patented, Mr Bolands said the company did collect royalties for the diagnostic products it developed for the pathology sector.

"As a company that relies on patent protection for its revenues I would be very disgruntled if someone was trying to rip me off and I would definitely go after them," Mr Bolands said.

"If your business doesn't have robust IP safeguards, then development of products will not occur."

DR Robin Craig, managing director of GeneSearch, a private biotech that imports and develops gene-based diagnostic products, said his future investments would be dictated by the outcome of the Senate inquiry.

"Gene patents don't affect us now but in the longer term as the genetic engineering sector grows, we are likely to make investments in other companies in a "business angel" type of capacity," Dr Craig said.

"If those companies' revenues are dependent on patented genes and the IP laws change, then naturally we will have to look somewhere else to invest."

Dr Craig said opponents of royalties should ask themselves whether a product or a medicine would exist at all if there hadn't been some patent protection in place at some point in its development.

AusBiotech's Ms Lavelle said the genes-based biologics sector was about to explode as therapies became more personalised for individuals and moved away from the present one-size-fits-all medical treatments.

"Over the next 10 years, we will see these personalised therapies increasingly enter the market here and overseas," she said.

"To guarantee their development, however, we need a system that incentivises the private sector to expect a reward for investing in the research.

"Without patent protection governments through the public sector would have to find the billions of dollars that the private sector now spends on inventing new drugs and diagnostics."

Genetic Technologies Mr MacLeman said he wants to see a return to business certainty for biotechs.

"It is really no skin off my nose whether the government allows genes to be patented or not," he said.

"What we need is a law one way or

the other and for it to be enforced.

“Currently, we are acting within the law but we object to these other institutions saying they don't like the law and choosing to ignore it.”

The Senate Community Affairs Committee Inquiry into Gene Patents is due to issue its report in November.

