

MEDIA COVERAGE

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Page: 9

THE PROFIT STRAND

By Jane Lyons

What does it mean to have a private company own exclusive patents on human genes? Jane Lyons untangles the duelling strands of invention and discovery, ethics and enterprise.

MARKS on the wall remain silent testament to the first time 10-year-old Simon Field's heart stopped. In 2005, he had just arrived home from school when he suddenly lost consciousness, slamming against the wall before hitting the floor. His mother, a doctor, spent 10 minutes trying to resuscitate him as his siblings watched in horror.

An electrocardiogram pointed to the possibility of Long QT syndrome, an inherited cardiac arrhythmia condition, and a geneticist at the Women's and Children's Hospital in Adelaide sent his blood to a New Zealand geneticist to be tested for the genetic mutation linked to the syndrome.

The death of the geneticist, a rerouting of Simon's blood to a European laboratory, and years of waiting before an admission that the blood had been lost, eventually led his mother, Belinda Coyte, to Melbourne. By then, she discovered, the Victorian Clinical Genetic Services Pathology, a subsidiary of the Murdoch Children's Research Institute, had developed a Long QT gene test in 2006.

But the creation of this test by Dr Desiree du Sart and her team could easily have failed to come to pass because of a patent on the gene itself.

The Long QT patent is one of about 16,000 gene patents granted worldwide, covering the breadth of human affliction from breast cancer, epilepsy and hepatitis C to cystic fibrosis and hemochromatosis. Access to these genes, whether for research or diagnostics, is at the behest of the companies who hold the patents for about 20 years.

Such monopolies have raised concerns over the impediment to genetic research, as well as the higher cost for patients, who often find themselves with no alternatives except those set by the biotechnology company, and researchers who are forced to pay large licence fees if they want to proceed with their work — like du Sart.

A VCGS Pathology source says du Sart wrote to the scientists who had identified the gene mutations, hoping to gain some collegial insight when she struck some difficulties in her research. Instead, she received a letter from lawyers informing her that her team was infringing patent rights — an American biotechnology company, PGxHealth, held the Long QT patent. A licence was eventually negotiated for a large, undisclosed sum and the research continued.

In August, du Sart gave evidence to a Senate inquiry into gene patents. The Murdoch Children's Research Institute requested, and received, an in-camera hearing, with du Sart citing commercial-in-confidence concerns as the reason. The institute would not comment on the issue.

The inquiry, due to release its report in June, examined the effect of gene patents on the provision and cost of healthcare, training and accreditation of healthcare professionals and the progress of medical research.

However, the legal ramifications of a US court ruling on March 29, which invalidated the breast cancer gene patents (on BRCA1 and BRCA2) held by the biotechnology giant Myriad Genetics, may now give the inquiry something else to think about.

The chairman of the Cancer Council Australia, Professor Ian Olver, is hopeful.

"This [legal] result is not only significant to research and diagnostic uses of BRCA1 and BRCA2, it also sets a precedent for preventing the establishment of commercial monopolies over the use of many other genes and mutations that might hold the key to reducing cancer, death and disease," Olver says.

"It should send a message to Australian policymakers. We trust the Senate committee inquiring into this issue is watching with great interest."

He believes the trouble faced by du Sart over Long QT testing is a cautionary tale, as is the attempt in 2008 by an Australian biotech company, Genetic Technologies, to enforce its exclusive licence for testing breast cancer genes BRCA1 and BRCA2. The company, which tried to stop all other laboratories performing the cancer gene test, was forced to back down after a storm of public protest.

The test, which was government-subsidised when done by the public laboratories, would have cost patients about \$2100 through Genetic Technologies.

Olver dismisses inquiry submissions, such as that written by Melbourne University's Intellectual Property Research Institute of Australia, which point to a lack of empirical evidence or large survey samples to support claims that gene patents are affecting healthcare and medical research progress.

"I think it's early days, but if you can actually own [the rights to] a part of the genome, then you can restrict other people's access to it," he says. "What we're talking about here is framing laws so that all sorts of these potentially bad scenarios don't happen."

The question of whether the Patents Act 1990 should be amended to prohibit the patenting of genes is, arguably, the most contentious element of the inquiry. At the centre of the debate lies the standoff over the definition of what constitutes an invention, and is therefore patentable, and what is merely a discovery.

Professional bodies including the National Coalition of Public Pathologists, the Australian Medical Association, the Human Genetics Society of Australasia and the Royal College of Pathologists of Australasia, argue that genes and their mutations are natural phenomena that can only be discovered. They say intellectual property rights should only apply to related methods and processes.

Yet gene patent supporters say the isolation of the gene from the DNA sequence and its purification is enough to make it an invention.

Before 1980, life forms were considered a part of nature and not patentable. But a US Supreme Court case, *Diamond v Chakrabarty*, changed that by deciding genetically modified bacteria did not occur in nature and therefore could be considered inventions and patentable.

Following this decision, the patent offices in the US, Europe and Japan issued a practice memorandum in 1988, which declared the isolation of a gene from its DNA sequence was enough to differentiate it from its natural form and make it an invention. Australia followed suit.

However, it was the 2001 release of the Human Genome Project's draft map of the full human DNA sequence, and its constituent 20,000-25,000 genes, that signalled the race to lead medicine's next revolution.

The rush to stake a claim has been likened to the land grab of the gold-rush era, and most patents have been granted in the US, Europe and Japan. Intellectual Property Australia says less than 400 have been granted here, and most have been given to foreign companies.

But it seems the frontier mentality has not abated as thousands of gene patent claims remain pending, according to the World Intellectual Property Organisation.

And, with the next decade set to realise the full potential of the genetics revolution, the gene patent issue has never been more important for supporters and detractors.

The National Coalition of Public Pathologists says it is important to position Australia for the transformation of healthcare that is expected to occur with the next wave of developments in genetic knowledge and technologies.

"NCOPP believes that the basic DNA sequence of humans and other organisms should be placed in the public domain as soon as practical, without fees, patents, licences or limitations on use, giving free and equal access to all," it says in its inquiry submission.

Anna Lavelle, the head of biotechnology industry group **AusBiotech**, agrees that access is at the heart of the issue — but she believes a lack of gene patents would restrict access for the public.

"The absence or dilution of the certainty derived from patents is very likely to discourage investment and therefore jeopardise future . . . projects," Lavelle says.

She says attracting private investment is important as the public sector is incapable of financing the entire development process, but she denies that the desire for profits trumps consideration for social benefits. "The private and public interests are inextricably linked in a complex and somewhat co-dependent relationship. Access is an important issue and can be agreed without resorting to a ban on patents," Lavelle says.

But Professor Ian Frazer, the inventor of the cervical cancer vaccine, president of the Cancer Council Australia and a director of a start-up biotechnology company, says small companies, which make up 95 per cent of Australia's biotechnology industry, often cannot afford to be generous, and without regulation may take a harder line.

"It's no longer a case of the dollar back to shareholders as the main driver," Frazer says. "But if you don't regulate that, and you leave it up to the company to make up its own mind about what is responsible behaviour and what's not, some companies, and in particular the smaller, more vulnerable companies, are obviously going to draw a harder line about what's safe and what is not safe to do," Frazer says. "The question is whether patent law, or the application of the patent law [regarding genes], is correct. Fundamentally, I don't think it is."

Luigi Palombi, a patent lawyer and the director of the Australian National University's Genetic Sequence Right Project, agrees. He says the case law interpretation that led to isolated genes being considered inventions is invalid and, until the recent US case, had never been tested by the courts. "What we're looking to exclude is a very small part, which would not impact on the ability of industry to grow," he says.

Palombi says the attempt by Genetic Technologies to stop all laboratories testing in 2008 was not the first time; it had attempted to do the same thing in 2002 and 2003. He believes the company was emboldened to try again after a 2004 report by the Australian Law Reform Commission, which recommended the law not be changed because the horse had, in effect, bolted.

"If we go down this route all over again and we end up concluding what the [commission] did, that we just have to leave things as they are, we are just going to encourage a third attempt. And it may not be BRCA, but it will be some other gene."

The recent ruling by New York Federal Court judge Robert Sweet, which declared genes a discovery and not an invention, and an expected appeals process that may reach the US Supreme Court, could spell the end of gene patents in the US and send a message to Intellectual Property Australia, the local patent office.

Chris Hansen, the American Civil Liberties Union lawyer leading the charge, says despite the issue's complexity, the question is ultimately a simple one. "The question is: should it be permissible for a private company to own an exclusive patent on genes that appear in your body and my body and are essential to our health?"

"And almost anybody you ask that question of says, 'I don't know the law and I don't know the genetics, but that's wrong'. And it turns out that both the law and the genetics support that commonsense judgment."

What makes even more sense, Olver says, is bringing the debate back to where it really matters: people.

Five years on, Simon Field's heart and breathing have stopped many times, causing serious head injuries as he collapses. The Long QT test has finally come back negative and so his search for answers continues. But, because of the long delays in accessing the genetic test and its results, his health has suffered permanent damage and his heart is now dangerously enlarged.

"I don't know if he will be here in a year or not," his mother says.