AusSMC Briefing on gene patents

Thursday 30 July 2009 - Online

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Transcript

Thanks very much. Right, well there's my little introduction. You know who I am. What's this gene patent Inquiry all about? Well it's about whether or not we should be granting patents over – and it's really important you understand this – isolated genes and biological materials, which are the products of those genes. What's isolated? Isolated is something that has been removed from the human body or its natural environment. That's essentially the distinction which is being made here. So the Inquiry is going to examine whether these patents should be granted and the impact that they're having on the Australian health community and the health system.

So should there be patents on genes will be one question. Should there be patents on proteins? Should there be patents on natural biological materials? These materials are essentially identical to those that already exist in nature. So we're not talking about materials that have been genetically modified significantly to either enhance their performance or to function in a way which they are not designed to function in a natural environment.

This was acknowledged way back in 2000, that raw fundamental data must be made freely available to scientists everywhere. This is the reason why both US President Clinton and British Prime Minister Blair, at the time that the human genome was decoded, made this statement. They understood that fundamentally we need to enable scientists to have free access to this knowledge and to this information. And it is information because the genes essentially are repositories of information, it's just a biological system rather than say a system such as we would understand in a video machine or a DVD. But it's essentially a repository of biological information which contains blueprints that the body will then use, or that other organisms will then use, in order to manufacture or produce proteins.

Patents are about inventions and this is one of the fundamental things that we have to understand. They're about discoveries, we're not here to reward discoverers with monopolies for twenty years, and that's what a patent monopoly does. It grants exclusive rights to an inventor for a period of twenty years, that's a very significant amount of time. So unless you have something that is an invention you don't get to the point of having a patent.

And I want to explain to you very, very quickly by giving you an example of what I'm talking about. Now this is an epilepsy gene mutation patent. This is typically what an Australian patent looks like. And you'll see that there is a title. This one is titled, A Diagnostic for Epilepsy. One would think, that seems something that would be an invention, because it's a diagnostic method for epilepsy. But there's more to it than that, as I will show you.

You will see that there is the owner of the patent, a company by the name of Bionomics Limited. This is an Australian company. You'll also see that the patent filing date was 2004, that means that for twenty years from that date that patent has life, which means it doesn't expire until the 10th of March, 2024. That's a significant period of time, as I said. But what is this patent all about? The patent will also contain a section called a Specification in which it describes in detail, essentially what the invention is. But what do we find out here? We find out an awful lot about epilepsy. So there's a lot of background information about what epilepsy is, how it manifests itself on an individual, what the implications to that individual are and the fact that they have identified a gene that is linked to a specific form of epilepsy.

But all of a sudden we also note that this patent is not just about a method for the diagnosis, it's also about a method for the treatment of epilepsy. Now how did those words just suddenly appear in this document? And then we have a section in the patent called the Claims. Now the Claims are a bit like the title, they set out the boundaries of the monopoly. And you'll see that Claim 1 talks about a method, so again you'll say, "well this is the sort of thing that is going to be capable of invention". But if you have a very, very close look at what is disclosed in that claim you will see that it's nothing more than what you would expect a pathologist to do if they're actually undertaking a genetic test. There is no technology disclosed in that Claim which actually points the way to a new diagnostic test. It's really nothing more than a claim to any method for testing for the SCN1A gene.

But then at Claim 27, which is a few pages down through the Claims, you will see there are some very sneaky claims. And here we go. "27. An isolated nucleic acidic molecule…" Now that is nothing more than a claim to the DNA, to the actual structure of the molecule that causes these particular problems in the human.

Further on we see a Claim to isolated polypeptide. That's a protein, essentially it's the end result of the gene mutation. It's what ultimately is the defect in the human, how it's manifested and why this individual is going to have epilepsy or suffer from this particular form of epilepsy. And then we know that genetic mutations are the key because the patent says it. And we see here that it says, "…the nature of the alterations in the SCN1A gene may encompass all forms of gene mutation, including deletions, insertions, rearrangements and point mutation…". Very clearly this is not a patent about something that anyone invented. This is about a particular gene.

And we also know this because right at the end of this very long patent, which I think it's something like 522 pages long, we have this incredible appendix and it starts with page 1 and you'll notice that this is a series of letters, A, T, C and G. Now that's essentially the genetic code and the alphabet for the genetic code consists of four letters. Now it might look like gibberish but that's not actually gibberish, it is the code for this particular gene mutation. And you'll see that it's significant – page 1, page 2 and page 416, it's all genetic code and not one letter of that genetic code was invented, conceived or created by any of the people that are named on the patent as the inventors.

So just summing up, patents are about invention. Genes and proteins are not inventions. Isolation of genes does not change what they are. Isolation of genes merely changes where they are. Purification of genes does not change what they are, purification of genes merely concentrates them. Patenting genes, as Graeme has said, is like patenting the moon. And the US Supreme Court has repeatedly held that natural phenomena, like genes and proteins, are free to all men and reserved exclusively for none.

Thank you.

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