

AusSMC Briefing on gene patents

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Question and answer session

Transcript

Facilitator (Lyndal Gully)

I have a question. I'm interested about the relationship between the kind of international arena of these patents. If these genes are still patentable in the US, how will that actually work if Australia decides to make these genes not patentable?

Luigi Palombi

I might as well answer that question Lyndal. I mean the patents are, as you rightly point out, a nation by nation instrument so the law in the United States will cover the US and so forth. I think that if Australia simply makes it clear that you can't get patents on isolated genes and biological materials here, it's going to free our scientists up to be able to do a lot more research and do a lot more in terms of developing treatments and better diagnostics and cheaper diagnostics than their counterparts in the United States who are going to continue to have to work under the burden of having those sort of limitations that the US patents are granting.

Graeme Suthers

If I can just add to Luigi's comment. The acceptance of gene patents in international jurisdictions is sometimes used as an argument for accepting them here. But it's a one sided view on things. There is also strong opposition to the patenting of genes internationally. There is a slew of professional and expert bodies overseas in North America, in Europe, in the UK who are saying, "this should not happen". There is also opposition in the legislatures to the granting of gene patents, or the fact that gene patents have been accepted. So the fact that genes are currently accepted as being patentable in some jurisdictions does not of itself say that this a good or appropriate thing that Australia should do.

Facilitator

We've got a couple more questions online now. The first one from Elizabeth Finkle. She wants to know, what about the argument that patients will be worse off because companies won't have the incentive to develop tests?

Graeme Suthers

I'd like to counter that by saying that in fact medical research has made incredible progress without having to rely on these incentives. If we look at what advances have been made over the last fifty years in medical research, that was primarily driven by altruism public money. We did not need to have a lot of commercialisation of these discoveries to actually drive the discovery process. Now I recognise of course there's been a lot of investment in developing inventions, the various things that people put into your body, whether it be an artificial hip or something to prevent cardiac arrhythms and so on so that has clearly been an integral part of this whole process. But we have not had to rely on the patenting of discoveries to drive medical advances.

Ian Olver

I'd like to add that the competition, if the discovered gene is available to everyone, there's a deal of competition to create inventions that are patentable and we're not concerned about people patenting inventions of the treatments, if you like, but they won't even be able to develop them if they can't get at the core gene and its products.

Luigi Palombi

In a sense this whole idea that by limiting patents on genes that somehow it's going to remove the incentive to develop tests just doesn't hold water. The reality is that by granting patents on genes we are actually restricting development. By liberating the genes we are creating competition and ultimately the objective is to develop many, many different types of tests, more sensitive tests, more thorough tests, more accurate tests and cheaper tests. So in fact by removing the patents we are going to be encouraging innovation and really what we want is a paradigm shift in the technology of diagnostics. At the moment we're not getting that because the patents are being granted at too early and too low a standard in the development process.

Facilitator

We've got a couple more questions. Just a follow up question to that: Isn't basic research usually exempt from intellectual property and all genome data is on public data bases for instance?

Luigi Palombi

No. Basic research isn't exempt from IP. The problem is that the way you define your invention will define the scope of your monopoly and the way, as I said in my example, if the scope of monopoly is actually over the isolated genetic material or the isolated protein then the use of that material in any form at the present moment, even in a research environment, will be an infringement. But regardless of that, there is a need for the use of those materials in a clinical environment. Now the question of where do you draw the line, even if we introduced a research exemption, it's going to be very, very difficult to actually decide what activity is truly research and therefore subject to the exemption, or it isn't. And one might say that clinical use of the material, even though it would have perhaps a duality of purposes, could possibly not benefit from that sort of exemption, if we introduced it.

Facilitator

Okay. We've got another question. What is the argument for gene patents?

Graeme Suthers

I suspect that one of the prime arguments for gene patents is the one that was raised earlier, in terms of attracting capital into the business of finding genes and that companies need to have the assurance of a gene patent to justify the injection of capital into research. I don't accept that rationale but that is the rationale that is often presented. The intriguing thing is, there was a study a couple of years ago in Canada suggesting that in fact the return, the financial return to companies with gene patents has not primarily been in terms of licence fees but it's increased the stock value of the company. So it's been important for company to company type transactions, but actually hasn't been a principle money spinner for the company in terms of delivering the genetic testing. So I think the whole basis, the commercial basis on which gene patents might be justified needs to have further scrutiny to see whether in fact that basis is valid.

Luigi Palombi

And just following from Graeme. I mean often you'll hear the argument of "if you don't have patents we're not going to have the incentive to do all this research". But in fact, as Graeme pointed out earlier, a lot of this research is done through publicly funded university research. And if you look at most of the gene patents, ultimately it all goes back to public funded research. Where the companies come in is usually somewhere later, when they can see that there's going to be an immediate application of that research. And diagnostics are usually the very first and obvious way to commercialise the identification of the gene and its particular function and so it's the easiest thing to do and that's where the patents come in. But unfortunately the patents aren't just limited to the gene in an isolated form or to their obvious uses, such as in a diagnostic. They usually make all sorts of claims. Claims that are quite speculative. And for instance in that example I gave you, there's a claim to gene therapy for epilepsy. Well the reality is there is no gene therapy for epilepsy and in fact there's no information disclosed in the patent which would enable a person of ordinary skill in the art to develop a gene therapy for epilepsy. It's a complete

and utter ridiculous claim but nevertheless because of this idea that if you identify a gene, you isolate it and you link it to a particular disease you're entitled to everything. This is what's been going on.

Facilitator

Okay. We've got about four more questions so I'll ask you to try and be as succinct as possible with your answers so we can get through them all. So Elizabeth Finkle wants to know, unlike drug discovery, are we saying there's no big development costs here in terms of developing these diagnostic tests?

Graeme Suthers

There are some big costs but they're not nearly as big as they are for drug discovery and implementation. It costs about a billion dollars to get a drug from concept into the pharmacy. It would be a thousand fold less, generally, to find a relevant gene.

Facilitator

Okay. We've got, the next question is from Leigh Dayton. She wants to know, please can you give us a checklist of specific recommendations you'd like to see out of the Senate Inquiry. And she'd like that from each of the panellists. So Luigi, would you like to start?

Luigi Palombi

The first thing I'd like to see is an amendment to the patents act to make it clear that you can't get a patent on an isolated gene that is identical or substantially identical to what exists in nature. That's the first thing. The second thing I'd like to see is, as Ian has said, a complete review of the patent system. A multidisciplinary review. And in that regard, what we've got to bear in mind is that at the present time the patent system only really functions because you have a patent office that grants patents and then it relies on private individuals to seek to revoke patents. We have no industry watchdog, we have no regulator for IP. So one of the things I'd like to see is the government establish an independent regulator for intellectual property that will in fact bring actions and try and invalidate patents that it sees are going to go over the line or which are detrimental for whatever reason to either the Australian economy or the Australian national interest. So they're the key things that I want to see come out.

Graeme Suthers

I'll do the College of Pathologists view. We think that there are two issues. One is the retrospective cases, the legacy as it were of gene patents and that needs to be addressed by perhaps at a regulatory level. We need to remove the prospect of monopolies for medical testing on the extant gene patents, the monopoly component, which is the real problem in terms of medical testing. Prospectively we have to somehow write into law that discoveries cannot be patented. Now how that is best achieved, whether it be by amending the legislation, whether it be by having an IP regulator, as suggested by Luigi, we're open on how that might be achieved, but we've got to nip this problem in the bud. There are 25,000 different human genes, there are 100,000 different human proteins, we've got to sort this out now or we're going to have an enormous problem translating the benefits of knowledge about genes and proteins into healthcare in this country.

Facilitator

Fabulous. And I think Ian made some fairly strong recommendations in his presentation anyway. So we'll move on to Danny Rose's question now. Can someone please summarise or estimate how many gene patents are held by Australian biotech companies currently and is there a consensus view on what should happen to those patents, if there is a change in laws to prevent them?

Graeme Suthers

That's a good question and it's actually quite a hard one to answer. Luigi will know more of the technical details but for the laboratories, they are required to do their own patent searches to see whether the gene test that they're wanting to implement potentially infringes some patent and that's no easy ask. IP Australia in its preliminary presentation to the Senate Inquiry back in March estimated that there are about 400 gene patents in operation in Australia, but even they were unable to determine whether this related to human genes or animal genes. Now if very simple stuff like this is hard to get for IP Australia, what hope has your busy medical scientist or pathologist going to have in trying to sort this out? So one key thing, this has already been recommended by the Australian Law Reform Commission, is there needs to be a much more transparent and a simpler method for working out what genes are in fact patented and what the patent covers. I'll perhaps hand over to Luigi for other elements of an answer to that question.

Luigi Palombi

I completely agree with everything Graeme has just said. There's a complete lack of real effective transparency in the patent system. It's almost impossible to get accurate data from IP Australia, they don't know themselves. The other problem is they use a classification system that really just isn't adequate nor specific enough. I mean they say there's only 400 gene patents but look, there are a whole stack of patents that are coming through as so-called method patents, but they're actually gene patents, they're just called method patents because everyone has twigged to the idea that isolation is going to be an area of attack, of vulnerability. So they're just shifting the goal posts and now calling them method patents. Now effectively they're still gene patents. Do IP Australia classify those patents as gene patents? I don't know. Nobody knows. So to cut a long story short, it's just impossible to get accurate data and we do need accurate data desperately. In terms of what happens if there's a change of law to prevent new patents? Well you know, effectively I think it will send a message that these patents are of dubious validity or some of the claims within these patents are of dubious validity. Remember, a patent is a complex document, it consists of many, many claims as I showed and claims of the kind that we are discussing here that are going to be declared invalid as a result of legislation will mean that they will disappear. I mean that they will not have an effective recognition in the marketplace. The market will quickly appreciate that there's been a shift in the ground. Now that might lead to litigation ultimately to resolve these things but no patent is guaranteed validity and this is very clear, it's in the legislation. Every patent that's granted by IP Australia can be challenged at any stage during its life. So if ultimately it's declared invalid and its one patent and it has a ripple effect, well then that's just the risk that you take when you apply for a patent. There are going to be ramifications, there's no question that a change in the legislation will send a signal.

Facilitator

Okay. We've got one more question. Elizabeth Finkle wants to know, can you just go over again the current US and European stance on gene patenting?

Graeme Suthers

Can we make that plural? Because it's stances on gene patenting. In both Europe and the US there is provision for genes to be patented and they are patented, but that's not to suggest that everyone in those regions is happy with that. If we go to America the American College of Medical Genetics, the American Medical Association and the College of American Pathologists all say, "don't do this, it is bad". If you go to Europe where again genes can be patented, we have the European Society of Human Genetics, we have the Nuffield Council in Bioethics, we have the British Society of Human Genetics saying, "don't do this". So the very fact that these things can be done does not mean that there is acceptance of that. I think it is striking that the European community legislated that genes should be patented, they must be patentable and made that a directive that had to be applied across the member states. Now the very fact that they felt they had to legislate that something was patentable strikes me as rather bizarre and almost absurd. And the very fact that it was directed to the member states generated a lot of heat in a number of legislators across the European Union. So listen, there's no one stance that we can put up and say, "this is the North American or European view".

Luigi Palombi

And just following on from what Graeme has just said in terms of Europe, when the European directive came into effect in 2000, at that time there was a deadline of July 2000, seven of the fifteen countries that are members of the European Union had not actually complied with the directive. It actually took the European Commission – they actually took some of the countries to court, including the Netherlands, in order to force them to comply. And two of the countries that have since complied, France and Germany, strictly speaking haven't complied with the directive because they've created certain loopholes. In other words, it's not really that you can isolate the gene, there is a requirement under their laws that you also establish a function. Now that may not be significant but it strictly does not comply with the directive. So this confirms what Graeme is saying. There is enormous unhappiness within Europe over the situation. In Sweden they are currently revisiting the directive as well and I think that scientists within Sweden are pushing their government to revisit the directive and have the European [0:18:23.4] revisit the directive. In the United States it's merely a matter of practice. The US patent office has been granting patents but the US Supreme Court has yet to rule on it. And so we just do not have a clear position in terms of what the US courts will do. Hopefully we will soon but there's no guarantee and it's the same in Australia, we have no court decision whatsoever on whether or not it is possible to patent genes. It's just merely been a matter of practice.

Facilitator

Fabulous. Well thank you to all of our speakers. We'll leave the question/answer session there. Those of you who have joined us today, an audio copy of today's presentations will be posted on the website at www.aussmc.org, along with all the PowerPoints that you saw today. I want to thank again all of our speakers for the fabulous presentations. If you have any questions please feel free to contact us at the Australian Science Media Centre, we're on (08) 8207 7415. So thank you again and thanks for being part of this briefing.

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