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SUBMISSION 2

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Ms Julie Dennett
Committee Secretary
Senate Standing Committee on Legal and Constitutional Affairs
Parliament House
CANBERRA 2600

Dear Ms Dennett

Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010

Further to my primary submission, I wish to make a second submission to address some of the issues raised in other submissions and by the ACIP Patentable Subject Matter Report (released on February 16, 2011). I do so, in my role as the author of the Bill, and with a view to bringing some clarity on the specific issues raised.

1) The the patenting of biological materials is a *special case* requiring *special legislation.*

The members of the Royal College of Pathologists Australasia (RPCA), rightfully I submit, hold "grave reservations with the stated position of IP Australia". They do so because as scientists, doctors and clinicians they know that IP Australia's position is untenable as a matter of scientific fact - naturally occurring biological materials, such as the genetic mutations in the human BRCA 1 and 2 genes, even when isolated (removed) from the human body, are not invented but are discovered.

Throughout the course of the Senate Community Affairs References Committee Gene Patent Inquiry, IP Australia vigorously defended a policy which has permitted (and which will continue doing so unless stopped by legislation or overruled by the Australian courts) the patenting of natural biological materials in an isolated form. This policy, IP Australia argued (and still does), was consistent with the decision of the High Court of Australia in *National Research Development Corporation v The Commissioner of Patents* (1959) 102 CLR 252 (NRDC).

However, I disagree with IP Australia's interpretation. Indeed, in my PhD thesis entitled *The Patenting of Biological Materials in the Context of TRIPS* I make the case that NRDC stands for no such thing. My doctoral thesis has since been published as a book, *Gene Cartels: Biotech Patents in the Age of Free Trade*. My position, as explained in both my thesis and book, has however been the subject of some criticism by those in academia and the patent attorney profession who have a adopted a pro-patent position in favour of the expansion of subject matter eligibility to almost anything. On the other hand my book has been praised by those in science or the law who are not serving the interests of others. These include Prof Sir John Sulston and Prof Baruch Blumberg, both Nobel prize winning scientists.

ACIP Patentable Subject Matter Report

The ACIP Patentable Subject Matter Report represents the zenith of the pro-patent position in Australia.

The key recommendation of ACIP's report is to replace the current test of patentable subject matter, which has stood for almost 400 years and which has had the benefit of hundreds of years of intense judicial scrutiny and interpretation, with a new test, one which the authors of the report suggest is consistent with NRDC and which will provide "a clear and contemporary definition of patentable subject matter". Specifically, the report recommends that anything which is "an artificially created state of affairs in the field of economic endeavour" [page 4 recommendation 4] should be patentable subject matter.

This new test of patentable subject matter, should it become law, will produce seismic effects on Australian patent law.

The recommendation is in sharp contrast to the 1984 IPAC Report into the Australian patent system and which culminated in the current *Patents Act, 1990.* That report recommended keeping the existing test (which is the current test) because of the "advantage of being underpinned by an extensive body of decided case law which facilitates its application in particular circumstances" [IPAC Report page 41]. A subsequent review of the Australian intellectual property systems and its impact on competition conducted under the chair of the eminent economist Prof Henry Ergas concluded in 2000 that "Australia has on the whole benefited from the adaptiveness and flexibility that has characterised the 'manner of manufacture' test" and recommended it "be retained".

This begs the question: If two significant reviews of the Australian patent system, the last conducted only a decade ago, supported the retention of the current test of patentable subject matter why was ACIP asked by the Minister to conduct a specific review of that same test in 2008?

The answer is to be found in the Australian Law Reform Commission's Gene Patent Report of 2004. One of the recommendations of that report, which supposedly focused on gene patents, was that the test, which also applies to all other kinds of innovations, be reviewed. In effect from an inquiry that was examining the impact of gene patents came a recommendation that was not specifically related to gene patents.

This begs another question: How did the ALRC come to make a recommendation beyond its terms of reference?

The true answer is not to be found by reading the ALRC's report. It is to be found by looking into the backgrounds of the people who oversaw the Inquiry, had a significant role in crafting its recommendations and authoring its report.

The umpire of this game is the Federal Court of Australia. Yet for 30 years, despite a few attempts, there has not been one single patent case dealing with the issue of patentable subject matter and isolated biological materials which has made it to judgment. Why not? IP Australia, formerly the Australian Patent Office, has never brought a test case on the issue before the Federal Court or participate in a test case that did. Surely, if it was so confident that its interpretation of NRDC was correct, a test case to confirm its interpretation would have been a logical step?

What ACIP's recommendation means, in effect, is that 'an invention' is no longer the threshold of patentability in Australia. Literally anything which is artificial or in an artificial state (because this is "an artificially created state of affairs") will be eligible for the grant of a 20 year patent monopoly. Make no mistake about what is being proposed here. It is an attempt, pure and simple, to circumvent 400 years of patent law so that *biological materials can continue to be patented*.

Like it or not, naturally occurring biological materials are, due to the misapplication of existing patent law and a lack of regulatory oversight, a special case and nothing but special corrective legislation, along the lines proposed by this Bill, is going to stop their continued patenting.

Not even the test case, being brought by Cancer Voices Australia and Mrs D'Arcy, a women suffering from breast cancer, in the Federal Court of Australia to test the validity of the biological material claims in one of the four Australian patents granted to Myriad Genetics over genetic mutations linked to breast and ovarian cancers, will be relevant if the ACIP recommendation becomes the law because the Court is interpreting and applying the old test and not the proposed new test.

Change the rules to get the desired outcome.

Under the proposed new ACIP test, even a biological material in an isolated form will be patentable subject matter because in that state it is "an artificially created state of affairs" regardless of the fact that no one invented it or that it is identical or substantially identical to what exists in nature. Moreover, the second limb to the proposed new ACIP test ("in the field of economic endeavour") is virtually meaningless because even an isolated biological material can have an economic purpose, for example, in a diagnostic test.

While it is true that the phrase "an artificially created state of affairs" and the word "economic" appear in the NRDC decision, the way which the authors of the ACIP report have interpreted the deci-

sion and then used that interpretation to fashion a new test of patentable subject matter is, regrettably, wrong.

NRDC

What were the patent claims in issue? They were claims to methods that used a known herbicide to kill weeds but not kill certain types of crops.

What was the legal issue? The legal issue was whether it was possible to claim such a method as an invention when the end result of that method was not a physical product but an effect. The effect was the destruction of certain kinds of weeds without killing certain kinds of crops.

Why were these patent claims controversial in the 1950s? The controversy was over the Commissioner of Patents' rejection of these method claims on the basis that (a) an effect was not 'vendible' nor a 'product' because it was simply an effect, and, (b) horticultural and agricultural processes were not 'manners of new manufacture'.

Why is NRDC the leading case on patentable subject matter some 50 years later despite the fact that technology today is not the same as it was in the 1950s? The court, on which sat some of Australia's most distinguished judges including the Chief Justice, Sir Owen Dixon, explained that the term 'manner of new manufacture', which is used in the current test of patentable subject matter, was not confined to a physical product but could include an effect, such as that produced by the methods claimed in the patent, because that effect was a 'product'. The decision made it clear that the test of patentable subject matter was not to be so narrowly construed as the Commissioner had.

In what context did the High Court use the term 'artificial state of affairs' and 'economic'? This is what the High Court actually held:

> The *effect* produced by the appellant's method exhibits the two essential qualities upon which "product" and "vendible" seem designed to insist. It is a "product" because it consists in an artificially created state of affairs, discernible by observing over a period the growth of weeds and crops respectively on sown land on which the method has been put into practice. And the significance of the product is economic; for it provides a remarkable advantage, indeed to the lay mind a sensational advantage, for one of the most elemental activities by which man has served his material needs, the cultivation of the soil for the production of its fruits.

The High Court did not, as is plainly obvious from this passage, hold that the sole indicia of 'invention' or 'manner of new manufacture' was "an artificially created state of affairs in the field of economic endeavour". If that were so it would have been so much easier for their Honours to have said just that instead of considering and explaining hundreds of years of judicial interpretation.

Their Honours were cognisant for the need of a non-literal interpretation of the term 'manner of new manufacture' just as they were cognisant that they could not open the flood gates to patentability so that just anything 'artifical' and 'economic' would be suitable subject matter. It is for this reason that they laboured over the judicial authorities, spanning hundreds of years, to craft a decision that would stand the test of time, knowing that technologies would evolve and advance. That limitation I refer to came in a passage which is often overlooked:

> The statement was that fruit and other growing crops, although the assistance of man may be invoked for their planting and cultivation, do not result from a process which is a "manner of manufacture". This may be agreed. However advantageously man may alter the conditions of growth, the fruit is still not produced by his action.

And just as an inventive process can mass produce a synthetic version of a naturally occurring thing, whether that thing be a natural dye (such as alizarine), or a human protein (such as human insulin), it makes no difference to the end product's patentability. The process may be an 'invention' and patented but the *product* of that process is not, because no matter how "advantageously man may alter the conditions of growth, *the fruit is still not produced by his action".*

The Royal College of Pathologists Australasia Submission

The College members submitted that while they "support the intent" of the Bill they do not not agree that the Bill is the solution because they maintain "it should not be necessary to make a 'special case' of naturally occurring biological materials by deeming them non-patentable on societal grounds".

Their concerns are understandable from a layman's or non-expert point of view, and this they readily acknowledge by professing not to have "expertise of intellectual property and law". They do, however, have expertise in the relevant science. They know, therefore, that merely isolating a naturally occurring biological material is not the act of true invention and this they readily admit. We are grateful to them.

That said, I would like to point out to this Committee that the problem is not about societal values but about patent law. And the law, at least as it presently stands, provides that only 'inventions' can be the proper subject of a patent monopoly.

What becomes clear as one fully digests their submission is their inherent mistrust of the legal system and those that know their way around it, namely, lawyers. This mistrust, I might agree, is reasonable in view of the way the patent system has been so deplorably distorted by the collective actions of IP Australia, the patent attorney profession and the lack of an independent regulatory oversight in the case of biological materials. But even so, as I have explained there are very good *legal* reasons to treat biological materials as a special case and pass this Bill into law.

The Bill, however, is not all that will be required to be done if all of the concerns expressed by the College members in their excellent submission are to be addressed. But it is, nonetheless, one small step in the right direction.

2) A modification to the proposed section 18(2)(b) in the Bill

The proposed prohibition, it has been pointed out to me, may achieve the same objective but be more simply expressed. After giving this some considerable thought and having met with Prof Ian Olver AM, CEO, Cancer Council Australia to explore how this objective might be achieved, I am pleased to advise the Committee that together we have formulated an alternative prohibition. I invite the Committee to consider this in lieu of the present prohibition contained in the proposed section 18(2)(b).

Subsection 18(2)

Repeal the subsection, substitute:

(2) The following are not patentable inventions:

(a) human beings, and the biological processes for their generation; and

(b) biological materials ~~including their components and derivatives~~,whether isolated or purified or not and however made, which are identical ~~or substantially identical~~ to such materials as they exist in nature.

After subsection 18(4)

Insert:

(5) In this section:

biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids and their components.

identical, in section 18, means a biological material which is structurally and functionally identical and where any structural change or difference is immaterial to its function.

The modifications are:

1) the deletion of the word ‘components’ in section 18(2)(b) and inserting it in section 18(5) in the definition of ‘biological materials’;

2) the deletion of the word ‘derivatives’ in section 18(2)(b);

3) the deletion of the term ‘substantially identical’; and

4) the insertion of a definition of ‘identical’.

The word ‘derivatives’ becomes redundant because the word ‘components’ (now in the definition of biological materials) will capture such components which have been modified (and are derivatives as a result) and biological materials which have been modified (and are derivatives as a result) but which are nevertheless ‘identical’ within the meaning of the word as defined in section 18(5).

The word ‘components’ is included in the definition of ‘biological materials’.

The word ‘identical’ is defined in section 18(5) so that any structural modification performed on a naturally occurring biological material which is immaterial to its function (as in its natural function) will be excluded from patentability. This will have the same scope as the term ‘substantially identical’ but overcomes, we believe, concerns about over its possible misinterpretation.

3) Conclusion

It will be a matter for the Committee to decide between the two versions of the prohibition. It is possible, I accept, that it may prefer neither. Whatever the recommendation, I ask the Committee to support the intent of the Bill even if at the end of the day the implementation of that intent is achieved using different words and/or other legislation.

4) Declaration of Interest

Finally, I wish to declare to the Committee that I have no interest, direct or indirect, financial or otherwise, in the subject of this Inquiry or in its results. Neither I, nor any member of my direct family, nor any corporate vehicle in which my direct family owns or controls, has any shares in any biotechnology company or has any interest in any organisation that may directly or indirectly benefit from patents of the kind which may be impacted by the Bill (should it become law). I am not a member of a patent attorney firm nor do I have any interest, actual or contingent, of any kind in such firms. Indeed, I have nothing to fear nor favour from the Bill nor the outcome of this Inquiry.

Yours sincerely,

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