Committee Secretary,
Senate Legal and Constitutional Committees
Parliament House
Canberra ACT 2600

**Inquiry: Patent Amendment (Human Genes and Biological Materials Bill) 2010**

Thank you for the opportunity to make a submission to this Inquiry. My submission should not be treated as confidential.

Statement of Interest:
The comments made in this submission are based upon experience as a former public servant and ambassador in the Department of Foreign Affairs and Trade (DFAT). My expertise extends to positions held in DFAT as director of the policy area responsible for intellectual policy - domestic and international negotiations - when the Myriad/Genetic Technologies issue was raised by the Dept of Health and as a Lead Negotiator for part of the Aust/US FTA negotiations. I have made formal submissions and attended the Hearings of the Senate Inquiry which informed the drafting of the Bill currently before your Committee. I have no financial interests in the subject matter covered by *The Bill*.

The experience outlined above has led me to the firm conclusion that *The Bill* before your Committee is the appropriate and most efficient way to address this contentious and sensitive issue. I therefore strongly urge the Committee to fully support *The Bill* in its current form.

The approach taken in *The Bill* provides the opportunity to bring the patent system back into line with national interest objectives. Thus creating an economic environment that serves the Australian public and provides a more conducive and efficient environment where research and innovation can thrive. Industry, innovators and researchers require confidence and surety that they can operate and in a patent environment that reflects such regulatory clarity.

More specifically, the public and the health community expect and require an environment that is free of 'legal desist or pay' letters claiming rights over naturally occurring biological material that are irrefutably 'discoveries'. Without the guidance and clarity provided in this *Bill*, costs to business and the public purse will continue to grow exponentially.

Views opposing this position will of course be put before your Committee. I will, therefore, take this opportunity to address some of the problems likely to be raised in the attachment to this submission.

Anna George
Adjunct Professor
Murdoch University
and
Associate Fellow
Chatham House
Centre for Global Health Security

**Analysis of some of the arguments put forward against the (Human Genes and Biological Materials Bill) 2010**

Much of the opposition to *The Bill* is likely to flow from the views already articulated by key Advisory Bodies - the ALRC and ACIP. Both these reports reject unreservedly the approach taken in *The Bill* and suggest other methods to resolve the 'problems' associated with the patenting of biological material that exist in nature.

The ALRC Report was released in 2003 so although it contains several useful administrative proposals (that have been supported in the Senate Report) many of its key findings are now significantly outdated.

Specifically, many of the reasons given for supporting the patenting of gene sequences in their naturally occurring form, have now been completely overtaken by legal and policy changes, in the US and also developments in Australia.

This is also the case in much of the rational behind the recommendations in ACIP's Report on Patentable Subject Matter: In particular, the Options Paper that prepared the groundwork for these recommendations was drafted to reflect the ALRC Report findings; Submissions received by ACIP, were also influenced and time-bound by the ALRC's dictum - that the proverbial horse had bolted (i.e. patents had already been awarded) so therefore no change to the status quo could be contemplated.[1]

I am aware that ACIP was under pressure to finalise its Report, partly because of the expectations raised in the Senate Inquiry - that ACIP would provide credible recommendations to address patenting of biological material. However, in the Report that was signed off on 23 December, ACIP did not even mention the path-breaking 29 October *amicus brief* from the US Government which articulated and spoke directly to the subject matter of ACIP's Report – Patentable Subject Matter.

Given the significance allocated to arguments put forward by ALRC and ACIP recommending 'harmonisation' with key parties, such as the US, the position articulated in the Amicus Brief is significant. It states *that "… the contention that a "purified" gene is patent-eligible merely because it does not occur in "pure" form in nature is essentially*

[1] How would the public and politicians have response if the Tax Commissioner had adopted the same hands-off approach, as the ALRC, to the infamous 'bottom of the harbour' schemes?

*indistinguishable from the "isolation" rationale, and fails for the same reasons. A product of nature is unpatentable because it is not the inventive work of humankind. That essential rule cannot be circumvented by drafting claims for the same natural product removed from its natural environment and proclaiming the result "pure".*[2]

For ACIP to produce its Report containing no reference at all to the significant decision, articulated in the US Government's *amicus brief*, and to only fleetingly acknowledge the earlier Judge Sweet decision (that defined Myriad's patent on BRCA gene sequences as invalid) does not make sense. It certainly does not make the recommendations put forward equate with developing good rigorous public policy

For these and other reasons outlined below, the ACIP Report lacks the necessary relevance required to have the recommendations related to this Inquiry taken into account at this point in time. Patent policy is now being scrutinised and more broadly questioned across a range of economic, health and innovation criteria.

I would like to make it clear that I am not contending that just because the US has altered its position, Australia should follow. Nevertheless, the factors behind such important changes to patenting practice are essential aspects of calculating where Australia's national interest lies within the context of **our own** economic, scientific and innovative capacities.[3] And particularly calculating best options for access to, and funding of, our health resources.

Both Reports, however, do provide significant information comparing Australia's policy to other jurisdictions (including the US). The survey approach reveals that Australia's patent regime is, as was claimed by the patent attorneys (IPTA) and IP Australia during the Senate Inquiry, extremely permissive in awarding low level patents or as described in the ACIP Report– lenient interpretations. This information should inject some transparency into future consideration and auditing of Australia's patent system as recommended by the Senate Report into the Patenting of Gene Sequences.

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[2] The US Amicus Brief fully acknowledges that the US Patent Office had been granting patents on such biological material but this situation now needed correcting. The logic informing its decision is clear –"… while isolated genomic DNA may have more potential applications than human genes in their natural context, the same is equally true of mined coal, separated cotton fibers, pure metallic lithium, ductile uranium, and other products of nature whose industrial value to mankind likewise arises when they are extracted from their naturally occurring environments."

[3] According to IP Australia, 92 percent of patents are overseas owned.

Submissions opposing The Bill before your Committee are also likely to refer specifically to the ACIP proposed 'fix' of the patent system. I will confine my comments to the two key options put forward by ACIP for judging what will be the 'Subject of Patents' and also how to address 'Public/Ethical Concerns':

**A. Defining patentable subject matter** would be premised on the approach - "*that an invention should be an artificially created state of affairs in the field of economic endeavour*". Drawing on this definition is problematic because it effectively skips over defining the invention threshold. Claims that, "…the boundaries around the subject matter that can be patentable would be maintained, because the recommendations propose a restatement of the law in the words that are currently applied by courts"[4]. So this is essentially recommending existing practice which enables and promotes the patenting of gene sequences (biological materials)

Even taking into account, the parallel recommendations/guidelines IP Australia is to develop – for internal guidance on patentable subject matter and training for patent lawyers - these recommendations essentially restate existing practice.

Instead, ACIP's proposed solutions retain the opportunity for endless esoteric '*patent-speak'* interpretations played out through the work of patent lawyers/IP Australia and the Courts.

- This approach would only continue to serve a system that thrives on ambiguity, that imposes large financial, administrative and opportunity costs onto the legal system, to business and on the scientific community, and, in particular onto Australia's health system.

**B.** The various 'for and against' arguments in the ACIP Report for patenting of these naturally occurring biological materials leads to the recommendation that **any public concerns** can be addressed by measures taken to amend the *Patent Act* to include:

- An 'Objectives' provision[5];

[4] ACIP Patentable Subject Matter – Key Points page 1

[5] "The purpose of the legislation as being to provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of patent right holders, the users of technological knowledge, and Australian society as a whole." Rec 2.

- A more limited, 'General Exclusion' provision to account for 'ethical concerns';
- Provide the Commissioner of Patents with an explicit power to seek advice, from any person the Commissioner considers 'appropriate'[6]; and.
- Let the Courts judge the validity of the ethical argument. According to their interpretation of *'where the commercial exploitation of the invention involves something which is wholly offensive to the ordinary reasonable and fully informed member of the Australian public*'

The Courts have always been capable of making such interpretations, although more recently they appear reluctant to do this. Ignored in this recommendation is that patent cases, more often than not, are settled out of court before the judgement is brought down, thus no case law developed. This of course would be less likely to be the case if a patent was challenged on the basis of 'ethics' rather than a commercial settlement.

There would, however, be significant consequences if so-called ethical arguments are to be addressed in this manner - formally within the patent system. It would leave highly contentious debates open for special interest groups to mount costly legal cases[7]. One only has to consider the differing ethical views held on the issues of reproductive health related patents to recall how difficult it would be to settle such ethical issues through litigation. Newer technologies may also provoke ethical question such as nano and regenerative technologies – all could be contestable by the *'ordinary reasonable and fully informed member of the Australian public'* having sufficient funds to contest the patent.

This ACIP recommendation simply actively promotes litigation: it is not good public policy; access to mounting a court case is inherently inequitable; and, it would not in the long run serve the interests of either business or the public.

Without meaning to be flippant, but to public observers of this process, retaining technical complexities could serve only to conflate this particular issue. To introduce such complexity into an economic framework may be problematic. Why is it necessary or acceptable, to cut off or impede access - to biological materials existing in nature - when these materials have simply been replicated. It is rather ironic that the other

[6] Unless specifically defined in legislation to include broad community representation, this proposal can lead to the same limited groups of self-selecting experts being consulted.

[7] In ACIP's own words, "Over time, through case law, Australian courts will clarify the interpretation of the test. In this way, the courts will be the final arbiter about whether the commercial exploitation of an invention is wholly offensive to the ordinary reasonable and fully informed member of the Australian public." P19 ACIP Patentable Subject Matter Report.

main intellectual property expert - the copyright lawyer - would issue an infringement notice on such obvious copying practice.

In contrast, the approach taken in *The Bill* is simple, clear, and unambiguous. It is good policy and provides a level playing field for all engaged in developing an economy that is innovative, where scientific endeavour will be enhanced, where naturally occurring biological material can be used, reused and reused again – unimpeded by artificially constructed patent claims. *The Bill* is not retrospective but will curb excessive infringement claims.

Addressing this contentious issue by clarifying legislation would also demonstrate that Parliament and its Members are reasserting responsibility for managing Australia's national interest as it is articulated in patent policy and its implementation[8].

Enactment of *The Bill* – would provide an economic environment that promotes competition, minimises monopoly behaviour and would make the award of patents comply more with the interests of the Australian public – all important governance factors. For too long intellectual property policy deliberations have been driven almost exclusively by those with direct financial interests in promoting patents over naturally occurring biological materials.

The Committee has already receive submissions claiming that *The Bill* will not be consistent with Australia's international and bilateral commitments and that we must harmonise[9] our IP policy; that investment and access to medicines would be affected and that innovation opportunities would be damaged. These arguments, whether from powerful lobby groups or other interests, they should be asked to provide direct and specific evidence to back up such claims, and to call on independent experts, if necessary

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[8] The recent report from the Productivity Commission has helped to illustrate a little more clearly the costs and benefits and lack of adequate analysis of the financial consequences for Australia of expanding intellectual property rights.

[9] Those who argue that we cannot change because of commitments to harmonise in the AUSFTA should refer to the original text. The commitment is in the soft form – *"shall endeavour to reduce differences"* and applicable to both parties. The reference to 'harmonisation' is "*Each Party shall endeavour to participate in international patent harmonisation efforts…*" in international fora. Unfortunately, there has been a tendance to misquote this language and therefore misinterpret the level of Treaty commitment. (Article 17.9)

**International Issues:** Consideration of *The Bill* will be closely observed by the international community because of the landmark nature of the Australian Senate Inquiry and similar developments in the US (the Myriad case and the US Government's *amicus curiae* brief). The US developments may take some time to be resolved through the Courts but the significance of the change in the US position, with regard to the patenting of gene sequences, should not be underestimated.

There is now a new **'access to patent line'** that has been formally developed across the US Government bureaucracy - the worlds' strongest promoter of IP. This policy can be read as a strategic response[10] to enhance US innovation: to keep the basic biological materials free for use and reuse by the US industry; a recognition of opportunity costs; and, perhaps an evaluation of the old/new economy patent strategies, which have introduce a new set of dynamics into the market place:

- Global factors - patents and licencing rights are bought and sold on the global market that can alter access provisions, costs and IPR payment streams.
- Pharmaceutical and biotech companies are relying again on the natural occurring biological resources as future sources of new drugs, food, fertiliser, and oil replacement products.
- The new cost effective DNA technology enables easier access to the vast genetic resource pool (held by biologically mega-diverse countries like Australia).

In short, the US approach would reduce health and administration costs. It has evidence-based data to show that allowing the patenting of gene sequences has not brought the expected dividends or innovation. It is now moving to address specific market failures and ensure open access to the irreplaceable, naturally occurring biological materials which can be utilised in various new patentable innovations.

For too long Australia's patent system has operated to exclude simple and clear solutions that would serve to clarify and to define the line between open access and monopoly control. And, in this case, the line between public good and the exclusive use of these irreplaceable biological materials that exist in nature – that nobody invented. Members of Parliament have a responsibility to address these issues.

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[10] The interest of the US is expressed in the following terms "The extent to which basic discoveries in genetics may be patented is a question of great importance to the national economy, to medical science, and to the public health". Page 1 US DoJ Amicus Brief_Myriad