SENATE INQUIRY INTO THE IMPACT OF GENE PATENTS ON THE PROVISION OF HEALTHCARE IN AUSTRALIA

Submission to the

Senate Community Affairs Committee

Inquiry into Gene Patents

Submitted by: Anna George

INTRODUCTION

I have focused on the framework of '*governance*' to demonstrate to The Committee what I believe to be a subtle but nevertheless substantial pro-intellectual property rights bias in the management of these 'rights'. Intellectual property 'rights' (IPRs) are set in a social, economic and political framework which is governed by principles of competition to ensure the public good. The 'rights' are underpinned by a 'social compact' replete with expectations that there will be sharing of the benefits flowing from these 'rights' and importantly, the overall governance of IPRs will be effectively, efficiently and ethically managed through the machinery-of-government.

'Governance' of complex issues such as IPRs generally operate out of the sight of the public, involve disparate sets of individuals, professions and institutions and rarely is there an opportunity to illuminate and evaluate that process. This Senate Inquiry should make a substantive and significant contribution towards achieving good, appropriate and balanced governance of this very important public policy issue.

I will confine my comments specifically to human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, which will be referred to in the rest of this paper as *'gene sequences'*.

I will also draw The Committee's attention to situations where this issue impacts upon our strategic and national interest in relation to key international partners (including security aspects of possible health pandemics).

The Committee will be called upon to make judgments from arguments that will take opposing views on the legal interpretation of the current system of awarding patent rights. This Submission will argue the case that the current system is not working in a manner consistent with the rules defined in the AU Patent Act 1990 or the spirit and intention which underpinned the development of that Act. As in all cases, the interpretation of rights and obligations will be politically framed. I thank The Committee for enabling such a long-overdue Inquiry to be held on this very important public policy issue.

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19 March 2009

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Section 1: Statement of 'Interest' in the Subject Matter of this Inquiry:

Issue	I am putting forward this Submission to register that the current policy and implementation practice of awarding intellectual property rights (IPRs) fails to reflect the basic rules governing the awarding of patent rights. I also contend that political or social objectives underpinning the granting of these monopoly rights is generally ignored in the allocation and governance of IPRs. Any 'governance' approach that distorts decision-making to favour granting patents should be fully exposed, analysed and actively corrected otherwise the health and wellbeing of the Australian public is not being given due protection.
Argument	This Submission will argue that, particularly since the TRIPS agreement was signed, a pro-IPRs bias has been institutionalised incrementally into the governance framework that underpins Australia's patent policy. Reasons for this are many: lack of transparency in the system; strong corporate and legal vested interests; over-emphasis on trade-related factors; a general ignorance of the role and consequences of IPRs across whole-of-government decision making process, the media and public in general; and, also lack of sufficient parliamentary scrutiny.
Outcome	It will be important that this Senate Inquiry instigate a transparent and corrective **'re-calibration**' process that sets out clear checks and balances for the governance of IPRs. This is necessary to ensure that governance outcomes are consistent with Australia's national interest and the health and wellbeing of its citizens as opposed to a general bias towards IP claims of individuals/corporations.
Professional Experience and Interest in Subject Matter	I enter this Intellectual Property (IP) policy debate having had formal responsibility within the Department of Foreign Affairs and Trade (DFAT) for Australia's multilateral negotiations on intellectual property: I was Director of the area responsible for Australia's policy negotiations with the WTO TRIPS Council (the international body responsible for global IP policy) when the sensitive issue of 'access to medicines arose'; I was also involved in the final negotiations phase of the Food and Agricultural Organization (FAO) PGRFA Undertaking which dealt with the genetic resources of the World Seed Banks; and, AUST/US FTA Negotiations. I retired from DFAT following completion of my appointment as Ambassador to the Republic of Croatia in 2006 and since then have followed the intellectual property debate with keen interest. I have presenting papers on the FDI and TRIPS Agreement in the EU's GARNET program and the ANU Biosecurity Centre on the IP issue which has seen the blocking by Indonesia of Bird Flu virus samples to the WHO.
Supporting Argumentation and Transparency I am making this Submission as a private citizen. I am also a Consultant and A/Professor at Murdoch University.	Other Submissions received by the Committee will focus on legal interpretations commenting on the 'legitimacy' of the patenting of gene sequences. In particularly, I would like to state that I agree and fully support the interpretation and expert analysis put forward by, for example, Dr Luigi Palombi. The current interpretation[1] by IP Australia is I believe not grounded in either the spirit or the intention of Australia's Patent Law. I would also like to register that I see great value in the insightful and long overdue economic analysis that has been provided by Dr Hazel Moir. These two academics and patent experts provide a wealth of information for the Committee to apprise aspects that have hitherto been missing from the IP governance debates within Australia on the role, content and scope of intellectual property rights.

[1] By allowing the patenting of gene sequences such as BRAC Gene Mutations.

Section 2: Are the Institutions Responsible for the Management of IPRs Operating According to Australia's National Interest?

Public Expectations of Good Governance	The public rightly expects that government agencies perform to the highest ethical and administrative standard, particularly when they are tasked with the responsibility to assess and award monopoly rights that impose restrictions on research, provide twenty-years of significant market monopoly and open-ended financial rewards. The decisions made by these various Agencies require the highest level of scrutiny.
Problems with untested incremental adaptions to Policy	Given the basic rules governing patent law it is difficult to see how current practice of awarding IPRs is justified legally or ethically. The permissive approach, which has resulted in the patenting of gene sequences, lacks sufficient policy rigor in the awarding of IPRs. It represents a failure to monitor and assess according to public interest criteria. These governance failures, I believe can be tracked through the process of ***'policy incrementalism'***. The subtle favouring of administrative practice which privileges the 'extension' of intellectual property rights that has been underway for some years. This has worked to the detriment of the health and wellbeing of the Australian people.
Relying primarily on litigation to determine Australia's national interest or the health and wellbeing of citizens is: **-Costly** **-Inefficient** **-Ineffective**	Some basic questions raised to test the analytical rigor of the governance process are listed below : The various case studies that are being brought before this Committee will illustrate that, in general, Australia's Patent Office, IP Australia, appear to award patents on gene sequences according to criteria which draws more on interpretations of precedent related to similar 'products' without differentiating according to subject matter (human genes as opposed to known chemical substances in the NRDC Case) or selective approaches of key countries with strong IPR interests in patenting gene sequences. The following description illustrates the logic that underpins an approach that follows the comments above: ***'Permissive' granting of IPRs over the human gene sequence despite legal and ethical questions remaining on such patents*** **|** ***Assumption: that if this approach is proved to be problematic, a case against the decision will be tested in the Courts through active litigation by concerned interested parties*** **|** ***If not tested by the Courts the particular decision remains' valid' because the patent rights still apply*** **|** ***If tested by the Courts patent will either be validated or the patent broken: case outcome will assist IP Australia in its assessment process*** **|** ***If tested by the Courts but result is an 'out-of-court' settlement: the patent right stands and the analysis and logic and claims used to obtain the patent can continue to be replicated in similar applications*** **|** ***Highly questionable Case Law is developed and reinforced***

IP Australia has the Prime Bureaucratic Responsibility for Patent Policy

Exponential Growth of Patent Claims **Effect on Governing Patent Offices**	The comments above are not meant to be a cheap-shot at what is in fact a very difficult task that IP Australia has to perform. The role of Patent Offices around the world has never been more complex or difficult to manage in terms of workload; technical complex; the deluge of IP claims developed by teams of IP lawyers; the level of capital and financial reward at stake in these highly combative processes. It is not overstating the case to say that the whole process being pursued by the IP industry has got 'out of the control' of most Patent Offices. Acknowledging that position does not however, mean that any country can afford to have this situation negatively impact upon its people.
Need to instigate governance reforms:	It could be the case that if IP Offices were much more vigilant and managed the process more thoroughly in terms of achieving good governance outcomes then perhaps there would be less expansive and permissive patent claims. Bad governance procedures are not automatically corrected. There has to be a transparent and, if necessary, a costly bringing to account that will change behaviour or, at the very least, encourage those wishing to pursue expansive IP claims to carry much more of the costs that are currently borne by the taxpayer.
Testing the Existing Capacity to improve Governance :	Within the current mandate of IP Australia there are existing governance mechanisms that appear to be rarely utilised to test the effects of IP Australia's decisions. This is an area that the Senate Inquiry can assess and determine where governance practices can be improved in order to develop a much more efficient IP governance process. We should not have to rely on controversial events (such as the BRAC Gene Sequence case) to be able to assess whether IP policy practice is legally consistent, politically appropriate and aligned with Australia's national interest. I do not have access to the full range of administrative and governance process that can be initiated by IP Australia itself (or other government departments, including the Health Depts) but the Committee can avail itself of this information for this Inquiry. The questions detailed below relate to well-used governance processes that are applied across the Commonwealth policy frameworks. Aside of referring to case law on this matter IP Australia can initiate action to test the validity of Patents against public interest criteria: • What agency and interagency process took place before the decision to allow the patenting of GS was taken? • Was the Minister advised? • Was there a cost/benefit analysis conducted? • Was the issue of Australia's future health needs analysed? • Which stakeholders were consulted? Over time it has become clear that the decision to grant IPRs over gene sequences has raised important question related to Aust public health. Apart from the ARLC inquiry: • Has there been any attempt by IP Australia to clarify whether GS should be patented – by instigating a public interest court case? • Have Ministers been made aware of the problems and differing opinions globally on this issue and any consequences at the international level from the position taken by Australia?

The use and abuse of patent practices has raised significant ethical questions	The deliberations of your Committee will make a significant contribution to bringing a level of accountability and transparency, particularly when the basic rules governing patenting have been 'stretched' to a level that has awarded patents, that I and many others consider, **do not conform to the basic patent test - invention**. IP Australia's decisions on this matter have not yet been formally contested in the courts. Also, the fact that the basis of this knowledge – the human genome program - has been at the highest political level deemed to belong to 'humanity' and that the elucidation of that knowledge was sourced from public funds - has been totally ignored by the key beneficiaries of the IP industry. This also raises major ethical questions[2]. Examining the basic governance fundamentals should throw light on the incremental policy decisions that have generally escaped scrutiny. Selectively focusing on specific aspects of a policy framework (such as 'following' so-called 'key' countries' IPR policies) can lead to substantively misinterpreting the broader political and national interest objectives that should underpin all policy decisions. The current approach to awarding IPRs on gene sequences also calls into questions issues of 'sovereignty' and 'security'. • Australia is vulnerable to excessive pricing on essential health and disease prevention produces; • IPRs block access to essential scientific information thus diminishing our capacity for research if appropriate checks and balances are not applied; and, • Intellectual Property Rights on genetic resources is damaging international collaboration. This could leave us unprepared to deal with security issues such as health pandemics - a situation that necessarily would have a significant impact on the health and wellbeing of Australians and our regional neighbours. To date, there are few cost/benefit analysis or economic benchmarks to analyse the effect of IPRs. Only when these issues are addressed fundamentally will costs and benefits be able to be discussed with any clarity and the concept of 'wellbeing' analysed. This will require vigorously opening up and tasking all related sources of information - within the health system and bureaucracies responsible for all the elements of IPR policy and analysis. Suffice to say that any approach that has a pro-IPR bias embedded in policy decisions, is fundamentally problematic and should be removed. More generally, governance processes can be fundamentally damaged or distorted through 'policy incrementalism' if that process is not grounded within sound political social, economic frameworks that serve the national interest. It can lead to situations where the general objective and purpose underpinning IP policy can be misinterpreted, systematically abused and even corrupted. Parliamentary scrutiny is an essential part of the ensuring the links between Government's policy objectives and implementation outcomes are delivered.

[2] The Joint Statement by President Clinton and PM Blair in March 2000. The information referred to is deemed to be 'prior art' – knowledge available to humanity to "…serve as the foundation of development of a new generation of effective treatments, preventions, and cures" …to be made freely available to scientist everywhere'.

Governance Case Study: BRCA1 and BRCA2 gene sequence

Only when the BRCA's test rights were again enforced – prompting complaints from the Cancer Council and public anger - did the Commonwealth Health Department respond.	I have included a Timeline Chart below that tracks some, but not all, of the processes that came into play when health professionals within the bureaucracy first raised the warning of the problems associated with awarding IPRs over the BRCA gene sequence. This triggered a hive of initial activity that appears to have dissipated without resolving the major problem then encountered – the questionable patenting of gene sequences and health and public interest concerns to access such resources. All these issues are still of great concern and almost a decade later the situation has deteriorated further. The whole scenario is replete with political and corporate governance implications. The players involved - including the high-profile non-executive directors previously involved in government and governance at the highest political and economic levels in Australia[3] - is astounding. Also astounding to the mere observer is the way that the decision to enforce its BRCA testing rights has altered according to the 'political heat' that these decisions have caused. These events are serious. They demonstrate the 'political' nature of the problem, they also clearly demonstrate how the issue of awarding patent rights over gene sequences is generally kept well under the political radar. A key question for the Committee to examine is to find out is why it is only through the miscalculation or greed or perhaps political or public relations stupidity of this particular company that the issue is now being questioned – again • Is this the way to conduct good public policy? • Why did the key bureaucracies, including health departments, fail to act on behalf of the public **before** such a 'soap-opera of events unfolded? The Committee should be uncovering why existing governance mechanisms have not been brought into play; why gene sequences over essential health issues continue to be given away by IP Australia; Why Health Departments have not brought this issue to the attention of State and Federal Governments. Failure to look after the governance of such important resources when the issues are totally within the remit of both the Commonwealth and States represents a collective failure inherent in the governance of all of the entities involved – including Parliament.

[3] The decision made last year to enforce the BRCA test rights eventually prompted a response from the Commonwealth Health Department to have the Australian Competition and Consumer Commission examine the issue. It is to say the least, ironic, that Henry Bosch AO was at that time was the Chairman of Genetic Technologies - In his former life he was the Head of the ACCC. John Dawkins AO was also a non-Executive Director of Genetic Technologies and his political legacy has been the reform of the Australian Universities which included re-introducing fees, and promoting business practices such as ensuring IP is maximised within the university – an outcome that has been questioned in the latest Report on the National Innovation Strategy - VentuousAustralia

Timeline of Events – Public Policy Debates within Governance Structures

Concern raised formally within Government in 2001	**2001:** The Commonwealth and State Dept of Health and other professions raised concern about access to breast and ovarian cancer gene sequences that were controlled by Genetic Technologies, which held the Australian exclusive licence for testing the BRCA1 and BRCA2 gene sequence. Several inter-agency meetings were held to discuss the issue.
Backflip by Genetic Technologies	**2002:** Genetic Technologies pulls back from enforcing its exclusive licence thus enabling State/Com Laboratories to conduct tests, exchange research data unencumbered by potential patent litigation.
Issue shifted to the ARLC for 'expert' consideration.	**2003:** Politically and technically the issue gets shifted to the Australian Law Reform Commission (ARLC) to consider. The ARLC is tasked to include in its Review of gene patenting and human health - *Genes and Ingenuity* the impact of patent laws and practices regarding genes and genetic technologies. **2004:** Recommendations by the ARLC raise some concerns but did not fundamentally question the 'right' to patent gene sequences (see separate section dealing with the ARLC decision). **August 2004**: The ARLC Report was tabled in Parliament. I am not aware of the outcomes from this debate
Australia relies again on the 'generosity' of a private company to enable access to vital gene sequences.	**2008 (Oct)** Genetic Technologies announces enforcement of its BRCA 1 and 2 testing rights. Cancer Council raises concern and media covers issue **2008 (Dec)** Genetic Technologies reversed its decision.

The ARLC made Recommendations[4] to address issues affected by the patenting of gene sequences – has this been actioned? **These important options have always been available to be activated – why have they not been utilised?** ***Crown Use Provisions and Compulsory Licencing*** **Are these measures being interpreted within the bureaucracy as a 'political' issue as opposed to a policy issue?**	**2001 – 2004** Since the tabling of the ARLC Report in Parliament there appears to have been no active policy debate questioning Australia's position to allow IP to be placed on gene sequences. IP Australia has continued to award patents on gene sequences. **2004-2009** – Policy / Governance Vacuum? While the BRCA1 and 2 Gene sequence have been accessible for Commonwealth and State Laboratories other gene sequences have not**.** **The Committee will only be able to make an assessment of the financial, health, research and public interest aspects of this Inquiry if it can obtain all relevant and factual data on the access limitations placed on other important gene sequences.** There has always been the legal possibility for action to be taken – either through Crown Use Provisions or Compulsory Licencing. That this action does not appear to be a policy consideration by any of the areas involved in the government's health or scientific community indicates that it is an area considered 'out of bounds'. The Committee could question why these options do not seem to be available when 'public interest' is at stake. If the commonwealth and State Health Departments have been silent when faced with financial or access restrictions because of the gene patents then they have effectively chosen not to act on behalf of the Australian public. This is another failure of governance and would illustrate just how imbedded the notion of patent 'rights' has become in these key Departments. This factor alone should be investigated in a forensic manner.

[4] Crown Use: The ARLC recommended using these provisions in specific cases where gene patents are adversely affecting research or healthcare.
Compulsory Licencing: The ARLC proposed a competition-based test be introduced into this provision to deal with circumstances in which there is a public interest in enhancing competition in the market.

Section 3: Governance – international linkages:

Globalisation of IPRs has extended the concept and scope of IPRs.	Although this Senate Inquiry is focused almost exclusively on the Australia's domestic health environment, it is not possible to exclude the international nature of IPRs. The globalisation of IPRs changed the patent landscape. Globalisation provided an even stronger emphasis on the seeking of and the protection of IPRs. More than any other impetus globalisation has extended the concept and scope of IPRs to levels unthinkable in previous eras. A very important part of gaining the political agreement for this transformation has been the rhetoric surrounding the benefits of IPRs. In Australia the political rational that underpins decisions to award patents rights reflects this view of a 'balance of interests' that include 'rights and obligations'. These are managed through a political process, which includes a governance structure with sets of checks and balances. There are rules, tests, interpretations and guidelines both political and national interest to consider.
TRIPS Agreement sets out minimum standards and Australia is in full compliance with our International and bilateral obligations.	Australia's international obligations flowing from the WTO TRIPS Agreement provide a set of 'minimum standards' implemented according to domestic policies. Australia is in full compliance with the WTO TRIPS Agreement. There are also bilateral Free Trade Agreements that contain IPR provisions, the most well known is the Aust/US FTA which extended some IP provisions, particularly in the area of copyright. The view is likely to be put forward in some Submissions that because of the bilateral Free Trade Agreement with the US, specifically Article 17.9, Australia should now harmonise with US IP policy. This is not/not the case. Australia did not give up its sovereignty on these or any other matters. The level of commitment made in that text is not absolute and the 'obligation' in the 'soft' form it takes is as incumbent upon the US as it is on Australia. **I wish to place this particular aspect clearly on the Senate Inquiry Record and have it noted for this Inquiry and any subsequent Inquiry.**
There is no legal reason for Australia's IP Policies to be 'harmonised' with any other country unless a sovereign decision is made to do so.	The example that I wish to illustrate below indicates how lack of clarity or misinformation can be used and biased in favour of extending patent rights. This is particularly reprehensible when it concerns the development of government's policy and the governance mechanisms designed to provide balanced views representing the broad scope of interests in Australia – which in this case I would include the health and wellbeing of the Australian people The subject matter of this Senate Inquiry - gene sequences - is the new and highly lucrative frontier of global IP claims. How Australia's Patent System is managed and adapted is having an impact on the 'health and wellbeing' of Australian people.

Case Study: Interpretation of Australia's Obligations

The outcome of the ACIP Report will make a recommendation to maintain or amend fundamentally the operation of Australia's Patent System.	The Advisory Council on Intellectual Property (ACIP) in 2008 put out an Issues Paper to take forward the issues identified by the ALRC Report i.e. Patentable Subject Matter, Recommendation 6.4 (which will be discussed in more detail in the Second Case Study). Essentially the outcome of the ACIP Report will be Recommendations to maintain or amend fundamentally the operation of Australia's Patent System. The ACIP Issues Paper provided a detailed description of Australia's Patent System and posed many questions to be answered in Submissions from interested parties. Of particular interest to this Senate Inquiry should be the following excerpt: "8.2 AUSFTA [5] The Australian United States Free Trade Agreement mostly mirrors the TRIPS provisions. The main differences are:
A debate that is being tested and unfortunately through this process credence - that Australia must harmonise to US policy - is factually flawed and should be corrected.	▪ Plants and animals, and essentially biologically processes for their generation, may not be excluded from patentability, and ▪ Each party **must endeavour** to reduce differences in law and practice between their respective systems and **shall participate** in international patent harmonisation efforts The correct AUSFTA language which is included in an Annex to the ARLC Issues Paper is as follows: "Each Party **shall endeavour** to reduce differences in law and practice between their respective systems, including in respect of differences in determining the rights of an invention, the prior art effect of applications for patents, and the division of an application containing multiple inventions. In addition, each Party **shall endeavour to participate** in international patent harmonisation efforts, including the WIPO, fora addressing reform and development of the international patent system." (emphasis mine) Of all professions, lawyers are well aware of the value of each word and the importance of where that word is placed. Tracing the language and the use made of the language through the text in the ARLC Issues Paper conveys the view (particularly to those not familiar with international negotiations) that the default position is that Australia **'must endeavour' to harmonise** with the US IP Policy. *Must* and *Shall* convey entirely different levels of commitment. The notion of 'harmonisation' in the AUSFTA is not even linked to Australia and US domestic IP policies it is actually linked to harmonising efforts' (i.e. 'shall endeavour to participate' which implies working collaboratively in a multilateral environment to addressing reform and development of the international patent system – that process is so distinctly different from the notion of 'harmonising bilateral IP Policy. That some IP proponents would prefer for the benefit of their profession and their clients that the Australian IP system mimic certain aspects of the US patent law is not an issue of policy or substance it only reflects a preference to make their work easier and financially more lucrative.

[5] ARLC's Patentable subject matter Issues Paper at 8.3 (page 39)

Case Study: ARLC – Outcome Based on Precedent – Legitimate?

Rec 6.2 "However, the time for taking this approach to the patenting of products and material as long since passed. For decades, naturally occurring chemicals have been regarded by patent offices in many jurisdictions as patentable subject matter, when they are isolated and purified. This principle has been applied by analogy to biological materials, including genetic sequences, on the basis that they are merely complex organic compounds. This development was certainly not foreseen when the modern patent system was established, and a different approach might have been available when the issue first arose for consideration". Rec 6.3 Nonetheless, the ARLC considers that a new approach to the patentability of genetic materials is not warranted at this stage in the development of the patent system , for the following reasons: It would represent a significant and undesirable departure from accepted international practice with respect to genetic inventions, and may adversely affect investment in the Australian biotechnology industry…" …….	I have laboured the points above because all too often 'wrong impressions' or misleading interpretations are carried from Report to Report, this is an important inquiry and the ARLC are appointed by Government as one of the main areas for scrutinising and making recommendations that take on a particular level of authority when policy and governance issues are being developed and monitored. Also of concern is that there have only been 38 Submissions put forward into this very important Inquiry. In terms of developing democratic outcomes, this should be an issue of great concern to all. **To summarise**, within the current legal frameworks 'IP Policy' should not be guided and informed simply by reference to: ▪ 'Keeping-up' with the IP policies of our industrial partners' by adopting their standards[6]; ▪ Analysis based on the proposition that if we don't award IP rights then the pharmaceutical companies will not allow their products to be accessed by Australia. ▪ That patents have been granted (legally untested) and the simple fact of them being granted (whether or not they have fulfilled the essential criteria of patentability) is reason for continuing with this approach. The Committee should note that the points above was used in the ARLC Report as the rational for continuing to support the approach taken by IP Australia which allows the patenting of gene sequences such as BRCA (*Recommendation 6.1*) ▪ The ARLC Report recognises the problem in its *Recommendation 6.1* "…there are attractive arguments for the view that such materials should not have been treated as patentable subject matter". ▪ Unfortunately, that logic is compromised by *Recommendation 6.2* "However, the time for taking this approach to the patenting of products and material as long since passed... and *Recommendation 6.3* effectively closed the issue. "Nonetheless, the ALRC considers that a new approach to the patentability of genetic materials is not warranted at this stage in the development of the patent system…". It should be noted that the direct question of '**whether gene sequences should be patented?' has been halted.** ▪ Instead, the question of whether the patenting of gene sequences was transposed into *Recommendation 6.4* questioning aspects of the patent law. By 'passing-the-political-ball' and asking the ACIP[7] to examine issues that address the entire patent system with no distinct or specific mandate to examine the patenting of gene sequences.

[6] The view may be put forward by some commentators that this is the case with the AUS/US FTA – it is wrong.

[7] From a governance perspective, it is interesting to note that The ACIP Inquiry has attracted only 38 submissions. This indicates in itself a governance failure to engage the broader community to consider the implications of a system that allocates monopoly power over the entire economy. More problematic is that with this very small number of submissions how can the outcomes reflect the national interest consultations.

Governance – Machinery of Government **What would be the response if the Tax Commissioner used the same logic as the ARLC?** **ARLC Did not question the patenting of gene sequences but made other recommendations that are of direct concern to the Senate Inquiry*.** **How these 'recommendations' have been implemented should be of interest to all concerned**.	The outcome from the ARLC's deliberations is even more problematic when you consider that the mandate to assess such issues is meant to represent one of the few 'unbiased' consultative mechanisms where governance processes, outcomes and public interest can be tested against government policy. The rational behind the Recommendation 6 is significantly flawed. If, for example, the ARLC's view is placed in the context of the mandate of the Tax Department it clearly illustrates the fundamental governance problem associated with the implementation of IP policy. Both IP Australia and the Taxation Office are mandated to develop and implement policies that confer considerable financial benefits to individuals and business according to Commonwealth Law. IP Australia assesses and awards IP Rights providing 20 years of monopoly control over inventions and open-ended rights over trade marks Taxation Department assesses and awards a series of exemptions to taxable income etc. It would be interesting to see the political and public response if the Tax Commissioner adopted the approach taken by the ARLC to the patenting of Gene Sequences with regard to, for example, dealing with the infamous 'bottom of the harbour' schemes: That the time for making those who benefited from the 'bottom of the harbour' tax evasions schemes accountable has long since passed, so we will therefore allow them to continue to use such methods to continue to evade their tax obligations to the Australian community. My comments above are not meant to be trite. The ARLC raised some very useful points in relation to other aspects of IP Policy (see below) but the patenting of gene sequences has for many years been highly contentious. Is was a very 'live' policy issue that had been 'kicked around' within Commonwealth and State public policy circles for some time. The Commonwealth Health Department in 2001 held several important inter-agency meetings to examine the BRCA breast and ovarian cancer gene sequence and the issue was then taken up by the ARLC Inquiry. This was a significant issue for the ARLC to consider particularly given the concerns raised within the policy community. The ARLC limited its response to suggested how to ameliorate the **effects flowing from the patenting of gene sequences**: *Any social and ethical concerns should be dealt with through regulation of the use or exploitation of these patents, and expressed concern that gene patents may make the provision of healthcare more expensive…Also if a gene patent is adversely affecting healthcare, health departments should examine legal options to open up access to the invention eg challenging the patent or reporting anti-competitive conduct to the ACCC. ▪ To date, apart from the recent referral of the actions by Genetec Technologies to the ACCC (which were reversed) all of these recommendations have yet to be actioned.

International Negotiations: Interpretations of Australia's Position on The Patenting of Gene Sequences

The default negotiating position in all international forums is IP Australia's current approach. **Australia allows a very broad interpretation to the patenting of gene sequences** **Developing countries are reacting and developing their negotiating positions taking their lead from the aggressive behaviour of the intellectual property industry.** **It is to say the least gratuitous to expect developing countries to take account of the 'global interest' in accessing such vital genetic resources when we are entirely promoting that approach domestically.**	The issues raised above are also relevant and have consequences as Australia interacts at the international level in the various forums where intellectual property rights are being actively raised. These include areas related to trade, health, agriculture, biological diversity and also enforcement of IP (WTO, WIPO, WHO, FAO, WCU, CBD). The current interpretation by IP Australia - that the patenting of gene sequences is allowed - means that Australia then adopts a particular negotiating stance these international forums. This may not currently or subsequently serve our national interest, particularly with regard to the issue of health pandemics. The Committee should be made aware of the political debates and problems resulting from permissive interpretations of IPRs. For example, Indonesia stopped sending its bird flu samples to WHO Collaborating Centres (Melbourne has one of the four major WHO Collaborating Centres). Indonesia was concerned that what it considers as its genetic resources (bird flu virus) was being taken and commercially used by pharmaceutical companies without its permission. That Indonesia would not be able to afford or access bird flu vaccines and that its genetic resources would be locked away in patent claims privately owned. Indonesia's concerns of cost and access are valid. The Committee will be recall the difficulty all countries had in accessing and the cost to health services of purchasing the patented 'tamiflu' product. The patenting of gene sequences is highly contentious and is prompting the breakdown of global collaboration mechanisms that have served the international community for the last 60 years in areas of human and animal health and essential plant seed sharing. All of these negotiations are still underway and will take some time to work through. While Australia's IP governance system **actively promotes and condone the broadscope patenting of gene sequences** Australia negotiating position is locked into that assumption and our position internationally interpreted that way, including by other countries. The Committee should be briefed on these important issues. IP Australia's current policy on the broad-scope patenting of gene sequences takes on 'a life' outside of the narrower domestic policy debate and is not in any way scrutinized by those Agencies negotiating on behalf of Australia in the various international forums outlined above.

Lack of Transparency and Appropriate Expertise:

Complex subject matter Managed by a very small group of policy experts. **Limited stakeholder consultations with the broader community.**	The complex array of legal and technological issues that overlay the management of intellectual property has obscured much of the process from public scrutiny. However, the process is essentially administrative and technically there is a set of criteria that must be met, the most basic one being that the product must be an 'invention'. More difficult is the analysis of whether the IP claim is justified and this is where all countries' patent offices are struggling with the management task and generally lack the basic tools and skills to make these assessments. This is a systemic issue that the Committee may wish to bring to the attention of Parliament**.** Lack of expertise is a major 'Governance failure'. I would venture to say that one of the reasons we are in this position is because there has been a substantial lag in developing the economic, legal and governance 'knowledge base' in the twenty years since agreement was reached to globally harmonise to a set of minimum IPR standards.
Institutional lag in comprehending role and functions of IPRs	I would include in this critique the general failure of academic institutions to respond in a timely way to provide appropriately skilled graduates across all disciplines and to contribute to a rich analytical debate on the role and cost/benefit analysis of IPRs. The role of the legal profession, however, is another matter. Intellectual Property has been protected and managed through some of the oldest of the trade treaties. In academia the legal profession has acted as 'gatekeepers' to IP knowledge by providing until fairly recently very narrow specialists in IP.[8] The role of the legal professions have single-handedly managed IP processes and have done so in a manner that has generally failed to make the issue transparent to the public at large. At one level this is understandable given the lucrative nature of the business but this has worked to the detriment of society in general. The tendency to legally complicate the claims, to seek ways to tie up vital information in a manner that excludes access, to reduce any amelioration of such practices to extremely costly litigation process and to engage in actively attempting to block scientific research sometimes simply by discharging letters that 'warn' of possible litigation does not serve broader societies interest. In essence, the claims for IPRs have far outstripped and moved ahead of the capacity of bureaucracies to make informed policy based on legal obligations, interpreted and assessed through an informed, knowledgably and proactive national interest governance framework. This is partly the reason for a pro-IPR bias in the governance system. Faced with an active and highly specialised profession prepared to push the IPRs 'envelope' as far as possible it is the role of Government's to actively remind bureaucracies and to make the machinery-of-government serve the national interest.

[8] The case brought against the Government of South Africa by 37 international pharmaceutical corporations and their subsequent back-down, when the basic premise of their arguments were exposed to scrutiny, was a watershed in opening up academic interest in the still very controversial patent system and access to medicines debate.

Conclusion:

I have focused on the framework of '*governance*' to bring to The Committee's attention what I believe to be a subtle but nevertheless substantial pro-intellectual property rights bias in the management of these monopoly rights.

The 'balance of intellectual property 'rights' is fundamentally out of kilter and the patenting of gene sequences is a symptom of that problem. This is situation that many countries are struggling with. Until there is a political re-calibration to ensure that the institutions of governance apply the rules in a manner consistent with Australia's national interest, the rights and wellbeing of the Australian people will continue to be diminished.

If the current practice of granting patents over gene sequences (discoveries) continues through the permissive interpretation of 'invention' and Australia's Patent Office continues to allow broad scope patents - that lock into the patent rights aspects that do not pass the essential tests for patent rights – if this situation is left unchallenged then the financial and political consequences of will continue and grow.

The financial costs to the health budget (both of governments and to private citizens) will unnecessarily increase. Access of scientists and researches will be made more complex, costly and in the worse case scenario, vital data will not be available. Access to ongoing research will continue to be privatised and unavailable for on-going research.

I have not directly addressed the issue of the contribution that intellectual property makes to technological innovation. Inherent in my comments above I have worked from the premise that if the rights to gain a patent are applied in a manner that respects the underlying spirit and intent of the patent rules all parties will be in a position to gain. That intellectual property rights form part of the current economic system and should always be seen as the exception to the rule. When such important monopolies get out of kilter with national interest then the public good is not served

I have also touched upon how our current policy position impacts on international negotiations that affect issues that go to the centre of Australia's strategic and national interest. This is an issue that deserves much greater attention than simply negotiating from a default position that has not yet even been formally challenged in the Australian courts.

Thank you for the opportunity to put my views forward to your Committee.
Anna George