

Submission to the Advisory Council for Intellectual Property (ACIP) on the Issue of Patentable Subject Matter In Australia

My interest in making this submission to the ACIP stems from my experience as a former diplomat and ambassador representing Australia's interests in a variety of forums which involved developing policy and negotiating Australia's position on intellectual property rights (IPR). I represented Australia's interests at the WTO TRIPS Council and also the FAO negotiations that developed the Plant and Genetic Resources for Food and Agriculture Treaty (to manage the World Seed Banks). I was the Lead Negotiator for Electronic Commerce in the US/AUS Free Trade Agreement negotiations, which included participation in several intellectual property policy negotiations. These assignments involved substantive discussions with the various IPR stakeholders. I am also familiar with Australia's broad interagency IPR enforcement procedures and processes as well as our active and constructive role in other international forums working on IPR and enforcement issues.

Since leaving the Department of Foreign Affairs and Trade (DFAT) my interest in IP has continued and I have presented papers, for example, covering issues such as the role of Foreign Direct Investment and TRIPS and Biosecurity aspects of IP. Contributed to developing collaborative mechanism to enhance dissemination of IP policy and trade policy development.

Regarding the questions posed in the ACRL Issues Paper, I will not be making a detailed submission to your Council as I have consulted and commented upon the submission put forward by Dr Luigi Palombi. I would like to register that **I strongly support all aspects of his submission**. Dr Palombi's Submission provides a level of expertise on these issues that should facilitate the deliberations of the Council. It is a well-argued case addressing all aspects of the questions posed and the broader role of the intellectual property regime and the importance of the Courts in maintaining the credibility of such a significant public policy issue.

As the Government's Report on the National Innovation Strategy – *venturousaustralia* – has been released since many of the respondents to ACIP's call for comments, I consider it would be appropriate for the ACIP's Report to support the IP recommendations particularly in relation to Recommendation 7.2, 7.3 and 7.4. I have submitted comments below that touch and expand these points and consider that 7.3 should be further expanded to include a much broader range of key stakeholders.

From my own level of expertise in IPR policy implementation and negotiations, the specific contribution I would like to make to the Council is to comment on some aspects of IPR governance and related transparency issues. I will be claiming that there is a general lack of good governance practice that negatively impacts on the management and implementation of IPR, both domestically and internationally. These broad 'governance' issues provide arguments for

Opening the policy debate up to non-IP experts and for ensuring that the structure of policy and consultative committees represent not only the IP industry and its clients but also a much broader base of consumer input than is currently the case.

The role of the Courts is essential to maintaining a forum for reviewing and resolving these complex IP issues. A more 'informed' Parliament is also essential but to date parliament and the relevant machinery of government is still catching up along with the rest of the community with the fast developing role and reach of IP rights.¹

1. Governance and Transparency Issues:

To examine the governance framework I will not be directly questioning arguments in favour of IPR - 'free-rider problems', 'inventors rights', contribution to research and the inherent flexibility contained within the TRIPS Agreement or that awarding monopoly control is balanced by its positive effect on innovation and technology transfer etc. Instead, I want to put the spotlight on some of the economic and social effects of IPR. For example, when stripped down to its basics including the issue of 'ownership', intellectual property rights represent a significant and broad-based *private tax*² both on production and consumption across the economy. The extraction of IPR from all levels of production draws on government resources – financial, commercial, legal and judicial and a significant investment in human resources. Its implementation requires complex public policy solutions to maintain the financial stream of intangible resources³.

¹ See the discussion on IP and the recommendations from the Report of the National Innovation Strategy - venturousaustralia.com.au/recommendations

² I have purposely used this term because it describes much more accurately the economic impact on the economy. All other broad-based embedded payments that consumers are faced with, voluntary or otherwise have several levels of democratic scrutiny applied (even products such as voluntary health insurance are recognised as requiring public and governmental scrutiny). This is not the case with IPR. The Copyright Tribunal provides one form of public comment but I would argue that the basic lack of understanding of the scope and effect of IPR in general do not enable fundamental understanding or scrutiny of these decisions.

³ The costs imbedded in goods and services from the complex range of IPRs (patents and copyright) is only beginning to be scrutinised. In 2006, for example, Bird & Bird the international legal company in a 2006 report calculated "...that 'royalty stackings' – the cumulative cost of all the licences involved – may amount to as much as 30 percent of the sales value of a product such as a mobile phone or a personal computer".

An essential element to achieving ‘compliance’ requires that the actions taken to extract these *private taxes* be perceived as legitimate. Regarding the cost of managing the effective delivery of these *private taxes* through the various channels – both private and public collections – this is also an aspect where there is little understanding or comprehension. These compliance costs represent a significant cost to production, distribution and consumption and is a factor that should always be integrated into any decisions being made to extend the scope of IPR.⁴

In relation to governance, this requires that all parties understand the scope of their responsibilities. Despite the elaborate investment in public policy and legal structures, there is a general lack of substantive knowledge of the role, scope and consequences of IP rights. Instead, the Australian public and more generally academic and economic actors, are generally ignorant of all but the most basic aspects of the role and consequences IPRs have in their daily life and expenditures. **This situation represents a significant governance failure.**

In summary: In the absence of sufficient understanding by the public of the role and importance of IPR in the Australian economy it is even more important the ‘machinery of government’ reflect and take account of the public and national interest aspects and be actively engaged in managing these governance issues appropriately. Some suggestions are included below:

Input to Policy: To fundamentally address governance issues it is important not to limit those involved in decision making to the IPR professions and industry or creators’ lobbying representatives. ‘Experts’ do not necessarily come with the full spectrum of knowledge needed to make assessments on behalf of the larger community. Instead a much broader spectrum of interests need to be actively brought into the debate. This would include analysis on the effects on: consumers; socio/economic consequences; public health considerations, and also any diminution of access to essential knowledge, goods or services.

To ensure that the public interest is protected it has been suggested in the *ventureaustralia* Report that Australia’s approach to competition policy be used as a basis for assessment. The role of other key economic department, Treasury, could also be expanded more fundamentally. While expanding the levels of responsibility for managing IPRs is a very useful first step, assessing ‘public good’ and ‘national interest’ is complex and should also be integrated into any analysis that defines the policy framework for IPR. (See also comments under transparency issues)

Belatedly, but still necessary is also the need to gain a more comprehensive understanding of the financial and social *consequences* flowing from IPR policy, practice and interpretation which has allowed new and expanded forms of IP rights to be legitimated.

⁴ A question that is worth pondering is how this can be possible when the IP Treaties are the oldest of the international trade treaties and it is almost 20 years since the WTO TRIPS globalised IP rights. It is only since the politically contentious case brought against the South African Government by the global pharmaceutical industry that the IPR regime registered as a significant issue worthy of broad academic interest outside of the legal mainstream. This lack of scholarship and scrutiny has meant that the public policy and private sector skill base and analytical capacity has been limited. Consumers remain largely unaware of the broadscope and economic effects of IPRs.

Role of the Courts: If the governance structures are not robust enough to ensure that the public interest is actively being promoted then it is imperative that the Courts continue to play a significant role. The legal profession itself should also become more open to understanding the impact and effects flowing from IPRs.

Dr Palombi's submission suggests, the existing Australian IP laws contain many checks and balances to assessing and implementing IP rights. What appears to be occurring is that the balance of these rights is out of kilter. By narrowing the interpretation of these important qualifying factors could be seen as institutionalising a bias towards pro-IP interpretations.

For example, if the scope and intention of the 'national interest' elements of IP laws (ie the subject of the ALRC's issues paper) had been taken more fully into account and more analytical rigor applied to consequences of awarding a significant IP patent monopoly over a unique gene sequence, the interpretive outcomes from the ARLC may be different. IP rights that can work to embed structural monopolies into the economy - that lead to the blocking of innovation as one effect and, in certain cases, to accessing lifesaving medicines – these are significant issues of national importance.

To have an active and informed debate on issues of significant social and economic public policy it is not sufficient to simply put out a discussion paper and call for comments. That process should be accompanied by actively seeking to involve broad participation and well informed representations from the community. Actively seeking views is not cost neutral but sanctioning policy approaches that could work against the interests of Australia or sectors of the Australian community is also costly. The time delay in addressing these important issues is also problematic as it facilitates the addition to the practice of IP law that the ARLC considered so important an element in making its judgement.

Analysis of benefits of IPR: With the development of new technologies across the spectrum of economic activity, interpretations of what legitimately falls under the IPR regime has expanded considerably. These new forms of technology have facilitated a massive financial increase in the payment of IP 'rights' and the TRIPS Agreement globalised these payments across borders. The obvious beneficiaries are those countries with high levels of IPR to work (US, EU, JAPAN). Australia does not fall into that category but rather is experiencing an increasing portion of national income going to fund these IPR imports⁵. Because of the hidden nature of these costs the public is largely unaware of the percentage of any purchase going to IP rightholders⁶. However, this lack of transparency also extends to most other areas and when considering the role of 'policy development' and 'governance' there are practical measures that could be developed to improve both the analytical and policy formulation process.

⁵ see footnote 3

⁶ The role of the copyright collecting societies should be of particular concern in this regard. The most obvious areas that are generally understood with regard to patents are the costs of medicines. The government has introduced systems that indicate to the public the cost difference between patented and off-patent drugs.

- As indicated above, an economic and cost-benefit analysis is essential for public policy analysis of IP rights. The *inventaustralia* report touches on this issue mentioning the role of ‘competition policy’. Other important policy areas that should be more actively engaged include the ACCC and Treasury, Health, Industry, Communications etc. DFAT has responsibility for multilateral trade negotiations and other Agencies have standard setting responsibilities. There are some specific coordination bodies that currently consult on an ad-hoc basis but there is a need for a ‘whole-of-government’ approach that would help to integrate a broader IP knowledge base into the bureaucracy. For example, DFAT’s trade negotiating role should be based on policy fully cognisant of the economic, competitive and innovation implications of IP. Bringing together the various consumer focused areas in the range of Ministries would be a challenge but entirely achievable.

Transparency in decision taking: Following on from the points made above, as a public policy practitioner and multilateral negotiator, one of the major problems I encountered with IPR was the inherent lack of understanding and comprehension of the legal consequences of IP ‘rights’ across the broad spectrum of Australian society and economy. This was most clearly demonstrated during the US/Aust and other FTA negotiations. If the effects of IPR only impacted on a small portion of the Australian population this might not be problematic but the economic, technological, financial and innovation and access issues are substantial and on-going. Only the stakeholders with strong claims to promote IPR were represented in any meaningful way during these important negotiations⁷.

While it could be argued that this might also be the case with many of the other areas being negotiated in bilateral and international forums, I would maintain that the very intrusive nature of the IP regime across the economy puts it into an entirely different category from other trade related issues.

Public Scrutiny: For example, the imposition of federal or state taxes, changes in tariffs, local rates and charges are scrutinised through a political and democratic process. **The expansion to categories of goods and services subject to IPR payments do not face that same level of scrutiny.** Furthermore in the ALRC’s report, which underpins the ACIP’s process, from a policy perspective is problematic. The Report recognises the problem of patenting biological material “...that such materials should not have been treated as patentable subject matter” but then goes on to pronounce that “...However, the time for ...[changing this situation] has long since passed”. Placed in the context of another taxation issue, it would be interesting to see the response if the tax commissioner made a similar that sort of statement regarding, for example, dealing with bottom of the harbour schemes.

This ACIP interpretive approach does nothing to assure the public that the governance of IP policy is being analysed from a national interest perspective. If ‘time and

⁷ It is a matter of public record that the key stakeholders from the copyright collecting societies and the profession associations were of course concerned about the effect of a US/AUST FTA on maintaining the Australian content policy but in terms of the US position to alter Australian law to harmonise with the US on IPR these groups were all happy to extend considerably the timeframes for collecting IP payments. This was a prime example of the vested interests of the owners of IP being in a privileged position to extend the reach and payments to IP. There are now several publicly available critiques of the US/FTA’s effect on management of patents, particularly as it affects public health policy.

existing practice' were the determinants of IP policy then we would not have experienced the ever-extending scope of IPR. From a governance perspective, if expansion of rights is legitimate then so also is contraction of IP rights through the appropriate legal mechanisms.

International Issues:

It is also important to note that at the international level it is the placing of IPRs on the broadscope of genetic resources that promotes the most angst among countries not able to flex their IPR muscle (litigation costs or not being able to take advantage of economic possibilities). Many of these genetic resources come under the category of non-patentable material as they are discoveries or occur in nature but this has not prevented the key IP countries from ignoring the right under TRIPS to make national decisions about aspects of its patent laws. Australian should take account of not only the effect that interpretations of Australia's IP laws have on the Australian public but also the effect on the international environment beyond simply following US/Jap/EU.

The issue of patenting gene sequences is one of the most contentious in international negotiations and increasingly because of the lack of resolve and leadership on this issue (other than the demand that genetic resources be patentable) the debate on IPR is leading to a breakdown in the longstanding global collaborating mechanisms that contribute to Australia's security interests, particularly in the Asia Pacific Region⁸.

Those promoting extending IPRs generally argue that Australia needs to comply with its international obligations. These views need to be scrutinised carefully. Australia already fully complies with TRIPS. With regard to our FTA negotiations, too often there is a failure to examine the arguments being put and the actual position taken domestically by the country proposing them. The 'harmonisation' mentioned in the US/Aust FTA, it is not mandatory for Australia to adapt to US standards. The US like many other countries blocks or adopts positions internationally that are in its national interest and it will be happy to utilise domestically. Other countries such as India are registering strongly their interpretation of IP rules both in law and practice. These developments need to be well understood by Australian policy practitioners because increasingly Australia will be sourcing patented technology from different markets

I will be happy to provide further comment on the issues above and would wish to be kept informed of developments. I will also be happy to participate in any further consultations the Council may be conducting.

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⁸ Blocking the sharing of avian influenza viruses by Indonesia is only one of the areas where international collaboration in health and food production has broken down or damaged by bitter debates on the issue of patenting of genetic material/gene sequences and also the failure to move ahead on developing effective access and benefit sharing agreements. The policy position taken by Australia on this issue will have ramifications in other areas where we require collaboration or access to these resources.

