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ATTACHMENT

Provides information and analysis to supplement the views put forward in my Submission.
(To assist in locating specific information, headings match the issues covered in the submission.)

For the reasons outlined in this Attachment, before considering ratifying ACTA a systematic review of the governance of intellectual property policy should be undertaken.

Many of the more complex effects from IP are now being reassessed and evaluated for *the actual effect* on the economy, innovation, health care, trade, security and development options. The non-government sectors are engaging, including some substantive analysis from the academic community. What appears to be missing is an active public policy debate to match and to assess the role and effect of IPRs. A Regulator should be appointed to undertake this function.

There remains a significant gap in policy coherence, within and between portfolios.
The bureaucracy has had to deal with major challenges resulting directly from IP policy and governance problems. Blocked foreign investment; bilateral agreements blocking health policy; pressure and legal challenges on PBS/TGA operations; national sovereignty challenged and taxpayers exposed to legal claims from IP policy. By now it should be obvious within and between key bureaucracies that leadership is needed to drive policy coherence across the public service – to coordinate an evaluation and analysis of IP policy in line with Australia's national interest and to ensure any vestige of regulatory capture is removed.

ANNA GEORGE

Overview: National Interest Analysis (NIA)

A National Interest Analysis (NIA) should represent a whole-of-government expression of the national interest. It is a powerful governance mechanism essential for maintaining accountability, transparency and should demonstrate policy coherence across government bureaucracies. These assessments inform and underpin democratic government. These NIA processes also provide a 'window' into the bureaucracy, to its intellectual and analytical policy capacity and to the level of policy coherence - both within and between Departments. A high degree of policy coherence is necessary to develop policy consistent with the national interest.

The key NIA assessment: "No new legislative measures are required to implement obligations under ACTA in Australia" - this is too narrow a basis, by itself, for assessing national interest.

- The NIA adopts a very blinkered approach to how IP - a rights-based economic monopoly - actually operates. Unlike other property rights, IP has a long tail of legal and financial consequences affecting economic and social policy and intrudes, in complex ways, into individuals' private lives.
- By actively supporting the development of ACTA, a particular policy position has been pursued. This IP policy has an effect on Australia's other foreign, trade and security priorities. Nowhere are these issues addressed in the NIA.

The NIA fails to acknowledge that Australia's IP laws in practice represent a non-static building block of complex legal commitments awarding economic private rights.

- These IP building blocks are underpinned by complex international treaties and overlaid by bilateral treaties such as the USFTA. And also related obligations such as investment agreements. <u>At this point in time</u> IP rights can already morph into many new areas of economic and social activity - through bureaucratic or court interpretations. This does not involve any parliamentary scrutiny.
- The NIA gives the impression that 'nothing will change' in the way IPRs operate. The ACTA Factsheet prepared for the public reflects this impression but what status does this document have in law? To simply iterate "ACTA does not require" Internet Service Providers to terminate users' connections … (the so-called 'three strikes')" – is this misleading in the simplicity of the analysis?

The NIA interpretation of ACTA is that it will have no effect on Australia, other than enabling the promotion of 'our' IP standards overseas. This will automatically benefit 'our' creators and

innovators. There will be no negative effects on the Australian public, other than they will be exposed to less counterfeit goods that could be potentially sub-standard or dangerous products.

Section A: National Interest Analysis: Major Elements Missing

ACTA obligations apply to **some but not all** products or services -physical and digital. This lack of clarification can lead to a misunderstanding of the public and consumer health and safety claims made in support of ACTA:

* **ACTA will not addresses products or services that are substandard, unsafe or make spurious claims:**
  (1) If they do not have IP rights attached to them; and also
  (2) **'Genuine' products that do have IP rights attached to them.**

1. The NIA provides descriptions of the ACTA text substantially condensed. Unfortunately, there are only three instances where a brief explanation of the **actual legal effect** in Australia is provided - Civil Enforcement (para 17) and Border Measures (paras18 and 20). This is not sufficient, particularly as the sections of ACTA likely to have the most consequences for Australian citizens and business would be the Criminal Enforcement provisions, including in the digital environment.

> The EU formally described the digital enforcement as the "…entire section is a novelty, without parallel in any plurilateral or multilateral agreement…[ACTA provides] innovative provisions on the way to enforce Internet infringements… Infringements in the digital world are not different from infringements in the physical world".

2. Criminal Offences (Art 23.1) 'commercial scale is not clarified but can be applied to **all IPRs** "…acts carried out on a commercial scale include *at least* those carried out **as commercial activities** for direct or *indirect economic advantage*". And f/n 9 "… by providing for *distribution*, sale or *offer for sale* of such goods**".**

- How does Australia define commercial scale, commercial activity, indirect economic advantage, offer of sale or distribution?
- Where is the line drawn between commercial and non-commercial, particularly on the internet, where one (infringing) shared download can be redistributed to XXX number of individuals?

3. The EU Memo provides some indication - commenting on the definition of 'commercial scale' claims "…ACTA wording… redresses the doubts created by the recent WTO panel against China,

which introduced high quantitative thresholds – 500 – fakes for penal measures to kick in. It also introduces the concept of "indirect" economic advantage which is valuable".

- Can we assume from these comments that ACTA members appear to disagree with the WTO dispute panel's decision and obviously the level of 500 fakes is considered far too high to qualify as an operational guideline?

- Will our customs, police or courts now have to assess somewhere between (1-499) qualifies as a counterfeit good if, *distributed, actually sold or offered for sale*? Is this EU comment consistent with Australia's interpretation?

- How will Australia respond to a EU request (or from any other ACTA member) to act on a shipment 'in transit' in Australia? 'In transit' is not in TRIPS obligations;

- 'Small consignments' especially over the internet have been brought within the scope of ACTA enforcement so how are these new obligations being managed - how will our shipping industry, transport and Australia Post deal with these new elements?

4. I am not trying to be flippant but so many aspects in ACTA require clarification. The answers should be available as the NIA advises that no new legislative measures are required to implement obligations under ACTA. If the agencies contributing to the NIA cannot assess such detail then Parliament should provide appropriate guidance. To simply leave this up to the Courts may mean that the Courts will not only look to precedents in Australia, but, **also to the actions of other ACTA members.** ACTA comes with legal obligations to promote enforcement and harmonization, recent decisions by the High Court should signal how wide ACTA obligations may be interpreted. JSCOT may wish in reporting on 'matters arising' to specifically provide guidance on these matters.

5. A National Interest Analysis, should address not just the legal framework but also the implementation effect and, if applicable, an informed analysis of other likely effects: For example, during briefings responding to questions about the effect of iiNET loosing its case currently before the High Court. We were advised the Court's decision would create a precedent for implementing 'graduated response or three strikes' policy. If necessary, government would introduce enacting legislation. Reporting sourced from US cables should leave no doubt of the intention behind the IINET case - to globally promote the three strikes policy.[1]

6. It is disappointing that such important elements were not touched upon in the NIA. The iiNET case is only one issue. To give the impression that absolutely nothing changes - that Australia

[1] See Crikey.com "Why big Copyright will continue to be a danger to basic rights, Bernard Keane (19 Jan 2011)

will not be encouraged to alter any of its practice (as opposed to laws) **is to ignore the inherent capacity of IP rights to extend into new areas (particularly with new technology) without changing current IP Law.**

7. ACTA has taken a large amount of public policy 'space' and effort over the last four years. As a 'framework' Agreement, the ACTA text has its share of 'flexible' interpretations, but an underlying rational is global harmonisation and enforcement. With the rest of the world is the strategic objective but **harmonisation with the enforcement practice of other ACTA members is the practical effect.**

- Would Australia's foreign and trade policy always align on IP related negotiations?

- Would this imply, for example, an expectation all ACTA members would be expected to take the same approach in international negotiations, in the WHO or FAO when IP issues on public health and food security are concerned, or the CBD? And what of the policies related to WTO, TRIPS and WIPO negotiations?

- No assessment is provided in the NIA on what other ACTA members are expecting to gain from ACTA enforcement and harmonisation processes. SOPA/PIP legislation in the US could have been reflected in the NIA as an indication of the type of harmonisation approach the US would likely bring to the ACTA Committee. The EU has just developed draft privacy laws to enable consumers take control over personal data held online. Yes ACTA is a framework agreement but **questions of national sovereignty are pertinent here if ACTA can facilitate de facto lobbying activities – or pressure exerted to 'pass an ACTA test'** before Australia acts, at the national level, on intellectual property **policies, governance or law.**

8. The Agencies involved in contributing to the NIA assessment are well aware that IP rights enforcement obligations have expanded into areas never envisaged when our current IP laws were passed. The monopoly rights structure underpinning IPRs and the capacity to interpret existing legal frameworks contribute to this pattern of **incremental expansion**. This on-going expansionism is promoted by an IP industry that thrives in an environment which, even when there are review mechanisms (i.e. to increase payments for copyright royalties) hardly anyone outside of the IP legal industry can understand anything about the esoteric IP arguments – including most politicians.

9. For example, how many members of the community are aware copyright enforcement has crept down to the level of the local hairdresser, café or garage having to pay an annual copyright

fee[2] for simply playing publicly funded radio or CDs already purchased? Or at the other end of the IP spectrum, patents are allowed to be placed over gene sequences e.g. the *isolated* breast/ovarian cancer BRCA genes. Over 20% of the human genome has now been patented so the original gene sequences cannot be used for other innovative products without permission and/or payment to the IP right-holder. Patents were extended to 'software' and traded - not for innovation purposes but to be used in what is described by the industry itself as 'patent wars'.[3] These infringement cases are being peddled globally through various jurisdictions, including Australia. Vast economic and social opportunity costs are attached to all of these IP incremental and interpretive decisions. It is naïve and at times misleading to expect IP boundaries will not be pushed further – particularly with new technology.

10. Data Provided in the NIA: Claims are made that the WTO enforcement obligations are not sufficient and the evidence cited is the OECD 2007 study claiming Aust$ 250 **billion**. In contrast, the US Government Accountability Office (GAO) more recent 2010 analysis (prepared for Congress) recorded actual seizure of goods (internet infringements not included). Counterfeit Goods for 2007 amounts to US$ 197 **million**.[4] The GAO comments are also relevant:

> "Three widely cited U.S. government estimates of economic losses resulting from counterfeiting cannot be substantiated due to the absence of underlying studies. Generally, the illicit nature of counterfeiting and piracy makes estimating the economic impact of IP infringements extremely difficult, so assumptions must be used to offset the lack of data. **Efforts to estimate losses involve assumptions such as the rate at which consumers would substitute counterfeit for legitimate products, which can have enormous impacts on the resulting estimates**. Because of the significant differences in types of counterfeited and pirated goods and industries involved, no single method can be used to develop estimates."

OECD Claim A$	**US GAO Actual seizures US$**	**Australia seizures A$**
2007 250 Billion	2007: 197 million	
	2009: 261 million *	2009: 26 million
	Total 2004-2009 (6 years) US$ 1.118 million	

* The US data also provides an interesting breakdown on the type of goods seized e.g. 2009: largest items being, 38% footwear, 12% consumer electronics. Pharmaceuticals accounted for 4%.

[2] Or provide a written guarantee that staff/customer numbers do not exceed a certain number, or, that no form of media is used on the premises.

[3] Apple and Microsoft paid USD 4.5Billion for Nortel's patents and Google US$ 12.5 billion for Motorola's patents. These figures are staggering and will be paid for by consumers.

[4] US Government Accountability Office (GAO) April 2010: Intellectual Property: Observation on Efforts to Quantify Economic Effects of Counterfeit and Pirated Goods accessed at http://www.gao.gov/new.items/d10423.pdf

Given that the US would no doubt be the largest importer of goods and has significant capacity to capture counterfeit imports, questions the efficacy of the OECD Report. This would leave an estimate of Aust$ 249 billion as the sum total of all other countries' counterfeit seizures and all internet infringements. Given the magnitude of difference, this would involve a stretch of the imagination.

Section B: Australia's Economic Opportunities Dashed – IP Blocks Hi-Tech Industry:

11. Raising this issue is relevant in order to demonstrate the damage that expansive pro-IP laws, or interpretation of these laws, can impose on Australia's economy, opportunities for hi-tech employment, and our balance of trade. Given the seriousness of this decision - not to allow this well-established generic industry to create a new industry in Australia - JSCOT may wish to seek a briefing on these events, examine the efficacy of the assessments and develop guidance to ensure nothing in ACTA would affect investment that is in the national interest. The broader issue of why this investment was blocked should be referred for parliamentary scrutiny, particularly as IP governance is currently under review in parliament.

- To understand some of the intricacies of this issue: patents tend to expire later in Australia than in many other countries (a) because Australia gives patent *extensions* of up to 5 years (a total of 25 years): (b) Patent owners apply for marketing approval later in Australia.[5]

12. There was some early ABC coverage of the issue but little follow up or exposure in the broader media. The circumstances that led to blocking a new multi-million high tech generic drug export industry are therefore not well understood. The assessment that this type of investment is not consistent with Australia's IP commitments was apparently derived from an *interpretation* but never tested in a court. Given the nature of IPRs this would all be highly contested territory.

13. The company involved, is the large US Generic Company, Hospira. Apparently there are no such IP barriers or reservations in Canada, India, New Zealand or Israel. So we can deduce from this that, neither TRIPS or NAFTA nor their bilateral FTAs block such export production.

14. The Government considered Hospira's proposal from late 2008 to July 2009 "the issue had been given very careful…consideration by relevant departments and agencies, including matters of economic impact, the system of intellectual property protection and Australia's international

[5] A reason cited is that the pharmaceutical companies come into our market later to preserve their bargaining position in other countries that do not have the benefit of our PBS which allows one purchaser – the Australian government.

trade obligations." [6] The outcome was negative for the US Generic Corporation, which has now established this multi-million high-tech industry in India. [7]

Section C: Claims that ACTA Enhances Security Policy - Implications of using this strategy

15. Claims that ACTA will enhance national security have been made, particularly in relation to linking counterfeiting to organised crime and funding of terrorism. Australia has tended not to actively promote this view but the security aspect was very much in the mix in justifying ACTA. To conflate management of private monopoly rights to the level of national and international security as some have done, is a dangerous tactic. Misuse of the 'security' label undermines other key areas of foreign and trade priorities, especially if targeted against particular regions or countries. Also there is one-dimensional approach to 'consumer safety issues' – ACTA is absolutely silent on unsafe products and services **with IPRs attached**.

16. JSCOT should also note that the ACTA Committee framework **replicates almost exactly** the consultative and collective action framework normally used only to promote national security. The Security Regimes operate to control proliferation of WMD such as, nuclear weapons (Nuclear Suppliers Group) and missile technology (Missile Technology Control Regime). In particular the ACTA Committee follows the form and operating structure of The Australia Group. This is not a coincidence.

- Australia acts as the Chair and Secretariat to the Chemical and Biological Weapons Export Control Regime known as *The Australia Group*. Key IP right-holders such as the pharmaceutical, defence and chemical industries are aware of how these export control regimes operate. Also their industry representatives are made aware of any changes to the CBW export control lists etc that might have occurred at the Meeting. They do not participate in the Australia Group Meetings. The institutional framework for the ACTA Committee takes this process further and provides 'in-house' dialogue opportunities for the IP right-holders who will be represented no doubt, among others, by the larger media and pharmaceutical IPR corporations/federations.

- ACTA draws on language normally associated with 'security' issues, for example, 'proliferation' of counterfeit goods. This is language which is not used in the TRIPS Agreement but has now crept into IP parlance – the US' 2010 Strategic Plan refers to

[6] See http://www.ipaanationalconference.org.au/past-conferences/2010-national-conference/papers-and-resources-2010/panel-session-2/item/136-dr-nicholas-gruen.html

[7] As the world leader in specialty generic injectable pharmaceuticals, Hospira offers one of the broadest portfolios of generic acute-care and oncology injectables, as well as integrated infusion therapy. The company is headquartered in Lake Forest, Ill., USA, and has approximately 13,500 employees. www.hospira.com. More recent acquisitions by Hospira include biotechnology business from Pliva-Croatia in 2009, the generic injectable pharmaceuticals business of Orchid Chemicals & Pharmaceuticals Ltd., a leading Indian pharmaceuticals company, for approximately $400 million, announced in late 2009 see http://en.wikipedia.org/wiki/Hospira

'proliferation' but specifically in relation to counterfeit medicines. Australia's NIA refers to proliferation as does the DFAT ACTA website. In the ACTA text '**proliferation' is broadened to include all intellectual property rights**:

> "*Noting* further the **proliferation** of counterfeit and pirated goods, as well as services that distribute infringing material...
> *Desiring* to combat such **proliferation** through enhanced international cooperation and more effective international enforcement" (my emphasis)

17. Given the more recent problems with WMD claims, I would not have considered that it would be in Australia's national interest to have a treaty such as ACTA attempt to gain legitimacy for its activities through *jumping onto the security bandwagon*. It also sends inappropriate signals to countries outside of ACTA and raises questions about what role ACTA and IP will play or be used in other international, regional and bilateral negotiations.

- The ACTA Committee when established will provide:
    - Built-in procedures, exposing Australian officials to counterfeit claims defined by other ACTA members and their right-holders (Ch IV Art 33-35)
    - Expectation Australia will act upon and formally respond to counterfeit/ infringement claims (Ch V.Art 38)
    - IP Right-holders (which includes a federation or an association having the legal standing to assert rights in IP Art 2.(l)) will be allowed to participate in the ACTA Committee work: in ad hoc committees or working groups (Art 36.3.(a) and provide advice/input *Art 36.3 (b)* share information and best practice, including techniques for identifying and monitoring piracy and counterfeiting (art 36.3.(d).

- One can be assured that major IP right-holders will use this privileged access to great effect to politically influence governments both on what they consider to be 'infringements and counterfeit' and fully employ and expect the legal frameworks of member states to address their IP concerns.

18. The National Interest Analysis does not consider any of these obligations or access issues to be of concern. ACTA provides treaty level status to enforcement mechanisms that enhance only the rights of a particular set of private national and global interests and, unlike governments, are not accountable to their citizens.

19. Another aspect requiring clarification is Article 37: Contact Points (see text below). To put this requirement into context, ACTA will be a Treaty status, intergovernmental negotiating body.

This status accords it a diplomatic government-to-government framework. For example, a Security Regime such as the Australia Group, uses export licences as a means of ensuring that it is not promoting, through its exports, proliferation of CBW (weapons of mass destruction). Only Governments are directly responsible for issuing export control licences to private companies.

20. The important point is that it is only formal government assessments and/or communications that are delivered through diplomatic channels (normally Embassy networks/Diplomatic Notes/cables).

21. If like the Australia Group, mentioned above, ACTA communication is passed at the level of formal diplomatic communication, will this include information on 'private claims to infringement'? If so, this would be a serious issue, as it would accord this information **a special status not appropriate for such claims.** Only Courts can make any judgement on the validity of IPRs. This may appear as an esoteric issue but it is one that I consider would be raising the private, and as yet unsubstantiated, claims of IP right holders to a level not appropriate. This is the ACTA obligation.

> 1. Each Party shall designate a contact point to facilitate communication between the Parties on any matter covered by this Agreement. (art.37)
>
> 2. On the request of another Party, A Party's contact point shall identify an appropriate official or official to whom the requesting Party's inquiry may be addressed and assist, as necessary, in facilitating communication between the office or official concerned and the requesting Party.

22. Japan is acting as Secretariat to ACTA. Japan is also engaged with the US and the EU to develop what is referred to as a Trilateral Initiative.[8] More recently work has been underway to promote 'mutual recognition of patents'. The goal is to create three global patent authorities capable of assessing and issuing global patents.[9] Japan and the US account for almost 80 of patents. Japan has been a key promoter of ACTA and shepherded the proposal from the industry second track process through to the finalisation of the ACTA Treaty. These activities filter into the broader political negotiating frameworks and create political discontent at the way the global IP industry is being carved up. Questions regarding where Australia's interest lies do not seem to have been the subject of broader informed debate, perhaps because few public policy experts are even aware of this complex mix of economic comparative advantage strategies being played out.

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[8] The USPTO, the EPO and the JPO formed the Trilateral Offices club in the 1980s to steer the system in ways that were responsive to the needs of the big business users …These three offices operate within international fora like WIPO to push patent treaty harmonization agendas that developing countries oppose.

[9] See Peter Drahos Submission 60
http://www.aph.gov.au/Senate/committee/clac_ctte/gene_patents/submissions/sublist.htm

Section D: ACTA: Is it getting in the way of existing counterfeit measures?

23. NIA claims *"As ACTA obligations are directly aligned with Australia's IP enforcement standards, any expansion in ACTA membership would bring more countries into conformity with Australian standards. As an ACTA Party, Australia could advocate the benefits of participation in ACTA to improve enforcement in our region." (emphasis mine)*

24. Firstly, that statement does not acknowledge that the many countries, including in our region, do not support ACTA particularly TRIPS-Plus provision that are embedded in ACTA. They will also understand the political economy strategies underpinnings of ACTA. Including that Australia is not a major benefactor or holder of IP assets so may question Australia's motives in taking a leading role to promote ACTA, especially if IPRs are used as a bargaining tool in FTA/TPPA negotiations with our region. Also ignored are the political problems and sensitivities IPRs create, both within the WTO, WHO and several other international organisations. Is it in our broader national interests to actively advocating ACTA, without recognising the political resistance to it and effect it has on Australia's other foreign, trade and security priorities?

25. Secondly, a plethora of established measures operate to address 'counterfeiting'. They include UN international organizations, WTO, WIPO etc and global collaborative mechanisms operating and interacting with national/regional enforcement agencies: Interpol, Europol and the International Customs Organization (ICO) and several regional groups, including in APEC.

26. With regard to 'counterfeit drugs' (an issue used to justify developing ACTA) it should be of interest to JSCOT that ACTA is not considered by many key players to be a legitimate vehicle to address this issue. **International collaboration to combat counterfeit medicines is blocked.**

27. Currently most Asian and Latin American counties are refusing to participate in *The International Medical Products Anti-Counterfeiting Taskforce* IMPACT because of claims of aggressive IP enforcement methods. This quote from a Chatham House Background Briefing Paper[10] provides information on the IMPACT initiative, which Australia formally participates in.

> "The global community has a longstanding interest in combating counterfeit, falsified and substandard medicines dating from the 1988 World Health Assembly (WHA) Resolution 41.16 and culminating in the launch of the *International Medical Products Anti-Counterfeiting Taskforce (IMPACT)* in 2006. But the issue of counterfeit medicines has now become extremely controversial. The definition of counterfeit medicines that WHO first developed in 1992, and that IMPACT subsequently revised in 2008, has generated continuing controversy by conflating the concept of counterfeiting - which has a specific

[10] Chatham house Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward Briefing Paper Charles Clift, November 2010 http://www.chathamhouse.org/publications/papers/view/109566

meaning in relation to intellectual property - with issues concerned with the quality, safety and efficacy of medicines.

In particular, concerns have been raised that this definition might lead to threats to the legitimate trade in generic drugs. These concerns have been exacerbated by the detention in the European Union in 2008 of generic versions of brand name drugs in transit from India to other developing country markets on the grounds that they were infringing European patents; and by **suspicions over the possible impact of the Anti-Counterfeiting Trade Agreement (ACTA)** being negotiated between developed countries and some emerging economies to establish higher international standards for intellectual property rights enforcement. (Emphasis mine)

Section E: Scope of the Treaty – Trade – Geographic Indications (GIs)

28. During the ACTA negotiations, and in some of the earlier drafts, there were references to one of the very 'creative' areas of intellectual property - **Geographic Indications (GI**). Ensuring IP rights are fully recognised and applied to geographic indications is the EU's prime objective. It is a highly contentious area but can be compared to the US position in guarding and promoting its 'Hollywood' media industries.

29. As background, after the WTO came into force, Australia traded away its right to use specific wine descriptions such as Champagne, Burgundy, Port, and Sherry etc for access into the EU wine market. This negotiated outcome is generally seen as successful. The EU has another active GI agenda in the WTO attached to a much broader set of GIs which relate to terms used by our food industry – generic terms such as feta, kalamanta. [11].

30. During ACTA negotiations, the GI issue was in the EU Negotiator's own words, a 'red line' issue. Strangely, when the final ACTA Text was released, no reference to GIs could be found in the text. Nevertheless, what did come into the public domain were two EU internal Memos. These Memos provided a very insightful and instructive guide to how and what the EU negotiators' considered they managed to politically and 'legally' embed into the ACTA Text.

31. Some questions were raised during consultations on what this might mean for Australia. No formal answers have been provided. We have been left with the impression that either, the EU allowed the distribution of the internal memo to bolster its case - that GIs **are** embedded in ACTA, or, there is no legitimacy in the EU claims of GI's inclusion. Creative ambiguity is not an

[11] This site provides the history of negotiations on GIs http://www.wto.org/english/tratop_e/trips_e/gi_background_e.htm and Australia's formal negotiating position on GIs remains on the negotiating table under A "**joint proposal**", document TN/IP/W/10/Rev.2,
This site provides some information interpreting a WTO Dispute with the EU but broader agreement within the WTO has yet to be finalised. http://www.dfat.gov.au/trade/negotiations/disputes/290_protection_of_trademarks_q_a.htm

appropriate strategy in an IP enforcement treaty, particularly as the GIs (descriptions/marks) are claimed to be applicable also on the Internet.

- Is the Australian food industry fully aware of how ACTA will operate in both their domestic and overseas markets and on the internet? [12]

Section F: Foreign and Trade Policy and National Interest

32. In several multilateral organizations intellectual property - policy and governance - is an area of foreign and trade policy that remains highly contentious. The operations of successful global collaboration mechanisms - in areas vital to public health and food security - have been damaged by IP related political agendas. The global dynamics associated with IP trade and comparative advantage are also under challenge. Foreign and trade policy strategy must reflect these sensitivities.

33. To advocate the benefits of ACTA, in other multilateral or regional forums is to do the work of the major global IP asset holders (US, Japan and the EU). The level of our IP assets, innovation status, and the management of the sovereign rights we hold over Australia's mega-diverse genetic resources - should factor in analysis and drive policy. This mix of national interests needs to be tested against strategies that promote higher levels of IP harmonization and enforcement to other countries. **Do we serve our national interest** in these forums if there is the perception that Australia is acting as the 'stalking horse' for a policy that is being actively resisted by many in our region and elsewhere: regarded as undermining the WTO; affecting public health policy; and, innovation opportunities?

34. The statements made in the WTO TRIPS Council by the major countries critical of ACTA are insightful. They provide an important analysis. The Chinese statement carefully lays down some political 'red lines' that could have ramifications in other areas of national interest. India's statement also provides a strong analytical assessment of ACTA and reports 'illegal' seizure of some generic pharmaceutical shipments currently under discussion at the WTO. [13]

35. Intellectual property rights should be understood in terms of their political and economic effect. The ownership and control over IPRs are determined by trading decisions made by private corporations. The stock of IP global assets currently reside mainly in the US, Japan, some

[12] Ironically, the agreement in the US FTA which privileges trademarks over GIs could assist Australia's food industry to be prepared in advance of ACTA or WTO action on GIs but this would require an active stance being taken by the bureaucracies to explain to the food industry and other areas of the economy how trademarks might be employed for this task.
[13] Chinese statement. http://keionline.org/node/883 and India's statement to the WTO. http://keionli2e.org/node/1300

EU and Switzerland, but this does not in any way guarantee they will remain there. IPRs are traded on global stock markets; they can easily be separated from their production source and managed as tradable assets and useful hedge fund acquisitions. Their structure does not guarantee that the stream of IP payments will flow into the taxation systems where the IP right is 'defended'.

36. Global production is also a factor. China and India currently provide 80% of the generics to developing countries. Most of the global brand pharmaceutical drug trials are conducted in India. China supplies India with much of the raw pharmaceutical material, and its research is focused on becoming a leader in next generation of health care - regenerative health.

37. Recent media coverage of Medicine Australia's complaints about Australia's high costs of conducting drug trials and claims that our tax rate was too high - totally missed the point. This type of analysis ignores the global transformation of the pharmaceutical industry (and the media industry). Australia can produce impressive IP, but with a few of exceptions, mostly sells it off early and cheap thus failing to extract sufficient long-term income streams. The structural inefficiencies/opportunities foregone with this scenario go well beyond IPRs.

- It could also be argued that the 'market for IP' almost provides a perverse incentive that innovations developed (primarily in our university system) will not be developed in Australia because of the easier pickings had by simply on-selling the IP or invention at an early stage before the investment costs kick-in.

38. I have indicated that ACTA has generated negative responses in the WHO's IMPACT programs. Also in May 2011 United Nations Special Rapporteur report on freedom and expression addressed ACTA, noting that, "while the provision to disconnect individuals from Internet access for violating the treaty have been removed from the final text of December 2010, the Special Rapporteur remains watchful about the treaty's eventual implications for intermediary liability and the right to freedom of expression."

39. Brazil has indicated it will pass legislation to protect its citizens against the type of activity that ACTA will be promoting. The Mexican Congress … approved a resolution rejecting the Anti-Counterfeiting Trade Agreement (ACTA)… The resolution, which specifically asks Mexican President Felipe Calderón not to sign the treaty on Mexico's behalf, reflects the ongoing controversy regarding the agreement's potential impact on intellectual property rights [14] Directly following the EU's deposit of 22 signatures to ACTA the EU Parliament's Rapporteur to ACTA, Kader Arif, resigned that over the process behind getting the EU to sign onto ACTA. He stated "… *I want to denounce in the strongest possible manner the entire process that led to the*

[14] See. http://ictsd.org/i/news/bridgesweekly/109704/

signature of this agreement: no inclusion of civil society organisations, a lack of transparency from the start of the negotiations, repeated postponing of the signature of the text without an explanation being ever given, exclusion of the EU Parliament's demands that were expressed on several occasions in our assembly. [15]

40. ACTA is by no means a completed political deal in the EU, more signatures are required, including Netherlands and Germany, and will have to go to the EU Parliament before ratification.

41. This recent, rather sobering comment, made by the Director General of the WTO, Pascal Lamy, is relevant. It signals frustration at developments such as ACTA. The forum shifting practices undermining multilateral systems and the political division created by ever-expanding IPRs. Lamy comments on this lack of policy coherence and fends off criticism of the WTO TRIPS:

> " …the main responsibility for ensuring coherence is within national governments, including how intellectual property is handled in bilateral or regional free trade agreements. If governments accept tougher standards for intellectual property protection than required in the TRIPS Agreement (known as "TRIPS-plus), *then governments are accountable to their critics not to the WTO.*[16] *(Emphasis mine)*

42. The role or value of IPRs in terms of Australia's national interest is rarely questioned. This reflects the legal 'rights' based framework and underlying assumption that IP adds to societies wellbeing. It is time for a reassessment to bring the governance framework up to date to reflect growth of IPR into many new areas of the economy and global developments. Voluntary self-correction is rare, partly because of the complex rights-based framework but also there are few incentives to moderate behaviour or stop some of the more egregious IP practices that are creating barriers to innovation. **Lax or biased governance** in any area of the economy is problematic but when attached to private monopoly rights this can be a particular toxic mix.

There is a need to appoint a Regulator to assess the role and effect of IP in the economy. Many of the more complex effects from IP are now being reassessed and reevaluated for *the actual effect* on the economy, innovation, health care, trade, security and development options. The non-government sectors are engaging, including some substantive analysis from the academic community. What appears to be missing is an active public policy debate to match and to assess the role and effect of IPRs.

There remains a significant gap in policy coherence, within and between portfolios.

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[15] http://www.techdirt.com/articles/20120126/11014317553/european-parliament-official-charge-acta-quits-denounces-masquerade-behind-acta.shtml

[16] http://www.wto.org/english/news_e/news11_e/trip_23nov11_e.htm

The bureaucracy has had to deal with major challenges resulting directly from IP policy and governance problems. Blocked foreign investment; bilateral agreements blocking health policy; pressure and legal challenges on the PBS/TGA operations; national sovereignty challenged and taxpayers exposed to legal claims from IP policy. By now it should be obvious within and between key bureaucracies that **leadership is needed to drive policy coherence across the public service – to coordinate an evaluation and analysis of IP policy in line with Australia's national interest and to ensure any vestige of regulatory capture is removed.**