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**TRANS-PACIFIC PARTNERSHIP AGREEMENT: STATE OF
PLAY**
15th round, 3-12 December 2012, Auckland New Zealand

Handling Note: OTN to lead.

s 22 1(a)(ii)

What public consultation has Australia undertaken?

- The Government continues to take all available opportunities to engage with stakeholders and to meet with interested groups
 - we are always ready to receive written submissions
 - apart from regular public stakeholder consultations, DFAT's negotiators talk daily with stakeholders
 - : DFAT has provided over 330 stakeholder briefings since May 2011.
 - these interactions are very helpful in informing our approach to the TPP negotiations.

s 22 1(a)(ii)

s 22 1(a)(ii)

If raised: When will Australia release TPP texts to the public?

- Australia is committed to transparency in our FTA negotiations.
- As is normal practice in trade negotiations, the parties have agreed to keep negotiating documents (including text) confidential, though allowing for governmental consultation processes provided the documents remain confidential.
- At the request of some stakeholders, the TPP negotiating parties agreed to release the text of a letter the parties exchanged relating to confidentiality
 - the letter sets out an understanding among TPP countries on the handling of negotiating texts and other documents exchanged in the course of the negotiations
 - a model version of the letter has been made available on the DFAT website.
- Releasing text would require the agreement of all negotiating parties
 - text has no status until all parties agree to it.
- Much information that goes into Australia's negotiating positions is provided to the Government in confidence for the purpose of trade negotiations

s 22 1(a)(ii)

Once the text is agreed between parties it will be made public and subject to public and parliamentary scrutiny through a review by the Joint Standing Committee on Treaties (JSCOT)

- in accordance with the Government's treaty-making process, the TPP will be tabled in Parliament for twenty joint sitting days to facilitate public consultations and scrutiny by JSCOT
- the agreement will not be ratified by the Australian Government until this has taken place
- as part of the Joint Standing Committee review of the proposed agreement, the Committee invites public submissions and takes evidence at public hearings.

If raised: Text has been released in other trade negotiations such as the Anti-Counterfeiting Trade Agreement (ACTA) and in the WTO, so why won't the parties release the text in the TPP?

It has not been international practice to release negotiating text which covers sensitive individual market access positions

- market access is a key part of the TPP negotiations but was not included in ACTA
- WTO negotiating texts do not reveal individual country positions
- WTO texts are drafted by the Chairs of negotiating groups.

s'22 1(a)(i)

REDACTED

s 22 1(a)(ii)

REDACTED

s 22 1(a)(ii)

REDACTED

s 22 1(a)(ii)

If raised: Will the TPP mean Australia will be forced to re-visit sensitive areas from previous FTA negotiations (e.g. IP issues)?

s 22 1(a)(ii)

- Australia will need to respond to requests made by negotiating parties as they are made.
- Our negotiators are aware of Australian sensitivities and will defend them strongly in TPP negotiations

s 22 1(a)(ii)

- the Government would not accept any TPP outcomes which would undermine the integrity of Australian healthcare policy or constrain the Government's ability to regulate on legitimate social, environmental or other similar important public policy matters

[Briefing specific to IP/pharmaceuticals is provided separately in briefing no. 5.5]

s 22 1(a)(ii)

- Australia is pursuing strong commitments on Intellectual Property (IP) in the TPP that appropriately balance the interests of right holders, users and the Australian community.

If raised - Is Australia's position in the TPP seeking to prejudge the outcome of domestic IP reviews?

- No. Australia would not support provisions in the TPP that prejudged the outcomes of our own domestic reviews
 - nor which removed our present flexibility to respond to domestic developments.

s 22 1(a)(ii)

REDACTED

s 22 1(a)(i)

REDACTED

Background

s 22 1(a)(ii)

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Date: 12 February 2013	Date: 12 February 2013

T-11**FOREIGN AFFAIRS AND
TRADE****Free Trade Agreements: Trans-Pacific Partnership (TPP)**

s 22 1(a)(ii)

Transparency and stakeholder consultation

If raised: When will Australia release TPP texts to the public?

- Australia is committed to transparency in our FTA negotiations.
- As is normal practice in trade negotiations, the parties have agreed to keep negotiating documents (including text) confidential, though

allowing for governmental consultation processes which also ensure the documents remain confidential.

- Releasing text would require the agreement of all parties
 - even if it was possible, it would not assist informed public debate to release heavily bracketed negotiating texts that often include ambit claims and remain very much works in progress
 - text has no status until all parties agree to it.
- Once the text is agreed between parties it will be made public and subject to public and parliamentary scrutiny through a review by the Joint Standing Committee on Treaties
 - the agreement will not be ratified by the Australian Government until this has taken place
 - as part of the Joint Standing Committee review of a proposed agreement, the Committee invites public submissions and takes evidence at public hearings.

If raised: Text has been released in other trade negotiations such as the Anti-Counterfeiting Trade Agreement (ACTA) and in the WTO, so why won't the parties release the TPP text?

- It has not been international practice to release negotiating text which covers sensitive market access discussions
 - market access is a key part of the TPP negotiations but was not included in ACTA.
- WTO negotiating texts do not reveal individual country positions
 - as negotiating positions in texts can include ambit claims and evolve as negotiations progress, the current TPP text would not necessarily assist public understanding of the issues under negotiation, the dynamics of the negotiation, nor would it give any indication of the likely outcome.

s 22 1(a)(ii)

s 22 1(a)(ii)

REDACTED

s 22 1(a)(ii)

Copyright

- In the TPP negotiations, Australia supports strong and balanced commitments on copyright
 - that are consistent with current and emerging international standards, and Australia's existing laws and policy settings.

If raised: Why is the Government locking in Australia's existing copyright system through the TPP?

- The Government is seeking provisions on copyright in the TPP that retain the flexibilities we currently have
 - this includes the ability to respond to domestic copyright developments and modify our copyright laws.
- There is no agreed position yet on copyright, and negotiations are ongoing.

s 22 1(a)(ii)

s 22 1(a)(ii)

Public policy issues

If raised: Impact of the TPP on Australia's public health system

- Australia is taking a clear position in the TPP negotiations that we will not accept any outcome that would adversely affect the integrity of the Pharmaceutical Benefits Scheme (PBS), or our health system more generally.
- Australia is conscious of the needs of developing countries in relation to access to medicines.

s 22 1(a)(ii)

Background

s 22 1(a)(ii)

US proposals on pharmaceuticals

s 22 1(a)(ii)

The US has also tabled a separate proposal in the intellectual property chapter covering pharmaceutical patents. The proposals are part of the Office of the United States Trade Representative's (USTR) 'Trade Enhancing Access to Medicines' initiative. USTR says the goals of the proposals include: promoting transparency and procedural fairness in the operation of national government health care reimbursement programs; expediting access to innovative and generic medicines; enhancing legal certainty for manufacturers of generic medicines; and minimizing unnecessary regulatory barriers. s 33(a)(iii)

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Intellectual Property/Pharmaceuticals

Handling Note: Issues relating to the Pharmaceutical Benefits Scheme are the portfolio responsibility of the Minister for Health & Ageing

Is Australia negotiating intellectual property provisions in free trade agreements that would affect the operation of the Pharmaceutical Benefits Scheme (PBS)?

- No, nothing in Australia's trade negotiations will impact on the integrity of the PBS.
- The PBS is an integral part of Australia's health system
 - retaining the ability to ensure access to quality, affordable medicines for Australian consumers is a priority.

Will the Trans-Pacific Partnership (TPP) undermine the PBS?

- Australia is taking a clear position in the TPP negotiations that we will not accept any outcome that would adversely affect the integrity of the PBS, or our health system more generally.

Will the TPP limit the government's ability to conduct its recently announced review of pharmaceutical patents?

- No. The TPP will not limit the government's flexibility to undertake its recently announced review of pharmaceutical patents in Australia.

A US NGO has leaked US TPP proposals relating to pharmaceuticals and the PBS. What position is Australia taking in relation to those proposals?

- The Government is aware that documents purporting to be leaked US TPP proposals on pharmaceutical and related issues have been made public.
- As is normal practice in trade negotiations, the parties have agreed to keep negotiating documents (including text) confidential, though allowing for governmental consultation processes with stakeholders.
- Releasing text would require the agreement of all parties
 - even if it was possible, it would not assist informed public debate to release heavily bracketed negotiating texts that often include ambit claims and remain very much works in progress
 - text has no status until all parties agree to it.
- The Government will not engage in a debate on the accuracy or otherwise of so-called 'leaked text'
 - the only thing that matters is the position the Australian Government is taking in the negotiations.

Is the US seeking TPP obligations on IP/pharmaceuticals that go beyond AUSFTA?

- There is no agreed position on IP between the TPP negotiating parties, and negotiations are ongoing.
- All countries will of course continue to pursue their own interests in the negotiations, but any final outcome would need to be agreed by all eleven negotiating parties.
- Australia is supportive of an outcome on pharmaceuticals that is consistent with our own strong and balanced IP system
 - and that provides flexibility in implementation.

s 22 1(a)(ii)

Background

Trans-Pacific Partnership (TPP), intellectual property (IP) and s 22 1(a)(ii)

The IP chapter and s 22 1(a)(ii) are sensitive areas of the TPP negotiations and of key interest to our stakeholders. The Government has made clear that it will not accept provisions in the TPP which undermine our Pharmaceutical Benefits Scheme (PBS) or our health system more generally.

s 22 1(a)(ii)

s 33(a)(iii), s 33(b)

5.5

The Office of the United States Trade Representative (USTR) describes the goals of the proposals as including: promoting transparency and procedural fairness; expediting access to innovative and generic medicines; enhancing legal certainty for manufacturers of generic medicines; and minimizing unnecessary regulatory barriers. s 33(a)(iii)

Review of Pharmaceutical Patents in Australia

On 15 October 2012, the Australian Government launched a review of pharmaceutical patents. The review will analyse the pharmaceutical extension of term provisions of the *Patents Act 1990* and whether there is evidence that the patent system is being used to extend pharmaceutical monopolies at the expense of new market entrants. The panel is due to provide a final report to Government in early 2013.

s 22 1(a)(ii)

s 22 1(a)(ii)

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s 22 1(a)(ii)	

Intellectual Property

- ▶ Comprehensive chapter covering many forms of IP
- ▶ Progressing steadily, significant technical work done
- ▶ Several key issues still to resolve
 - there is no agreed position on IP and new proposals have been tabled as recently as the last round
- ▶ Seeking strong commitments on IP consistent with our own IP regime
- ▶ Will not accept any outcome that would adversely affect the integrity of the PBS

**Trans-Pacific Partnership Agreement
Intellectual Property Stakeholder Meetings**

**14, 15, 16 & 19 November 2012
Sydney, Brisbane, Melbourne, Canberra**

Comprehensive chapter covering many forms of IP

- Proposals are under discussion on many forms of IP, including trade marks, geographical indications, copyright and related rights, patents, trade secrets, data required for the approval of certain regulated products, IP enforcement and genetic resources, traditional knowledge and traditional cultural expressions.

Progressing steadily, significant technical work done

- Seven day IP meeting in Leesburg (14th round).
- Progress in the IP negotiations is steady, but slower than other chapters due to the length of the chapter and the complex nature of the issues; technical discussions are advancing well; we are gaining momentum with each round.
- The 15th round will be in Auckland from 3-12 December
 - registration for stakeholder participation closes Friday 16 November
 - the IP group will meet for seven days in Auckland.
- Provide summary of key areas to be discussed:
 - trade marks
 - geographical indications
 - enforcement
 - copyright and related rights.

Several key issues still to resolve

- There are a number of key issues outstanding that will require further discussion
 - some of these are sensitive and are likely to need political input – we expect these issues to be resolved during the latter stages of the negotiations.
- It is important to remember that the chapter has not been agreed
 - all parties are engaging in a negotiation process, and new text proposals have been tabled as recently as the last round in September 2012.
- Australia is working with TPP countries intersessionally to achieve as much progress as possible at the Auckland round.

Seeking strong commitments on IP consistent with our own IP regime

- IP is an integral part of international trade; strong and balanced IP settings, here and overseas, are important for our creative and innovative export industries, and for attracting investment in Australia.
- The TPP is an important opportunity for us to achieve greater consistency across the region in protecting and enforcing IP rights
 - which will provide more certainty for Australian exporters of IP-rich products including new technology, music, films and medicines, as well as companies investing in the region

- and reduce the volume of counterfeit products imported into Australia.
- The Government is aiming to develop a high-quality IP chapter that deals with recent developments in international IP, but does not go beyond Australia's existing domestic regime or require legislative change
 - we are seeking provisions that allow us to maintain the flexibilities in our IP system, and that strike an appropriate balance between the interests of right holders, users and the community.

Will not accept any outcome that would adversely affect the integrity of the PBS

- The Government sees the PBS as an integral part of Australia's health system
 - retaining the ability to ensure access to affordable medicines for Australian consumers is a priority, and the Government would not accept an outcome in the TPP that would adversely affect the integrity of the PBS.
- The Government's Trade Policy Statement also made clear that Australia will not support provisions in trade agreements that constrain our ability to regulate legitimately on important public policy matters such as public health.

If raised: Leaked text to date shows that the US is seeking more extensive and prescriptive commitments on IP than those in AUSFTA, and that would require us to change our laws. Leaked text also shows Australia presenting restrictive text on copyright limitations and exceptions.

- As is normal practice in trade negotiations, the parties have agreed to keep negotiating documents (including text) confidential, while still allowing for the necessary consultation processes with stakeholders.
- Releasing text would require the agreement of all parties
 - even if it was possible, it would not assist informed public debate to release heavily bracketed negotiating texts that often include ambit claims and remain very much works in progress
 - text has no status until all parties agree to it, and it can change significantly as parties search for outcomes acceptable to everyone.
- The Government will not engage in a debate on the accuracy or otherwise of the so-called 'leaked text'
 - the only thing that matters is the position the Australian Government is taking in the negotiations.
- Australia supports strong commitments on IP consistent with our existing domestic regime and international commitments.
- We are not presenting 'restrictive text' on copyright limitations and exceptions
 - we would not accept an outcome in the TPP that reduces the flexibilities we have to enact copyright limitations and exceptions.

If raised: Australia should be supporting developing countries to resist the TRIPS-plus provisions sought by the US, particularly on access to affordable medicines.

- The Government understands developing countries' need for access to affordable medicines, including through the exceptions and flexibilities in the

international IP system, for example under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

- we believe these exceptions and flexibilities are important to developing countries dealing with health crises including the HIV/AIDS epidemic
- and have made our views clear to other parties in the negotiations.

The Government supports each party's right to protect public health and promote access to medicines in accordance with TRIPS and the 2001 Doha Declaration on TRIPS and Public Health

- the Government has committed to implementing domestic measures consistent with the principles and terms of the Doha Declaration on TRIPS and Public Health.

TPP countries have agreed to reflect in the text a shared commitment to the Doha Declaration on TRIPS and Public Health

Ultimately, individual countries' negotiating positions are a matter for each government to determine.

T-23

**FOREIGN AFFAIRS AND
TRADE**

Trade: TPP: Copyright

Possible Question

What is the Government's position on copyright in the Trans-Pacific Partnership (TPP)?

Talking Points

- In the TPP negotiations, Australia supports strong and balanced commitments on copyright
 - that are consistent with current and emerging international standards, and Australia's existing laws and policy settings.

If asked: Is Australia presenting 'restrictive text' on copyright limitations and exceptions?

- No. Australia supports existing copyright limitations and exceptions under international agreements to which we are a party
 - in the TPP we would not accept an outcome that reduces the flexibilities we have to enact copyright limitations and exceptions
 - nor would we support provisions that prejudged the outcomes of our own domestic reviews.
- Copyright limitations and exceptions are still under negotiation
 - revised proposals on copyright limitations and exceptions have been tabled by different parties as recently as the last round in September 2012, and Australia will consider carefully any such proposals.
- Australia's positions in the intellectual property chapter have been, and continue to be, informed by a wide range of relevant stakeholder views and perspectives.

If asked: Is Australia supporting a 'three strikes' regime in the TPP?

- No. Australia does not support a three strikes regime for online copyright infringement in the TPP
 - Australia is seeking provisions that are consistent with our existing laws, and that preserve our policy flexibility in this area.

Background

A number of stakeholder groups including the Australian Digital Alliance (ADA), Australian Fair Trade and Investment Network (AFTINET), academics and members of the public have raised concerns about Australia signing up to commitments on copyright in the Trans-Pacific Partnership Agreement (TPP) that go beyond Australia's domestic regime. These concerns have been raised during TPP stakeholder consultation meetings, in ministerial correspondence, in online blogs, twitter feeds and in the media.

Stakeholder concerns have been heightened by the recent release of alleged negotiating text on intellectual property showing US proposals that would exceed Australia's previous international commitments, including in AUSFTA. Australia is taking a clear position in the intellectual property negotiations: we are not seeking provisions that go beyond Australia's existing laws and policy settings.

On 3 August 2012, US-based NGO Knowledge Ecology International published leaked texts on copyright limitations and exceptions from the intellectual property chapter. s 33(a)(iii)

On the basis of the leak, several media outlets including the Sydney Morning Herald criticised Australian for presenting restrictive text on limitations and exceptions. Greens Senator Ludlam issued a press release on 7 August claiming that the Federal Government was 'hell-bent' on locking Australia into 'a dead-end copyright treaty'. s 33(a)(iii)

Australia is a party to several international treaties, including the Berne Convention, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and relevant WIPO treaties, which provide for copyright limitations and exceptions. Australia supports these provisions and is not proposing to reduce the capacity for copyright limitations and exceptions (including for the digital environment) in the TPP. We would not accept an outcome in the TPP that prejudged the outcome of our domestic reviews, including the Australian Law Reform Commission's Inquiry into Copyright and the Digital Economy.

Stakeholders in Australia are opposed to the introduction of a 'three-strikes' regime which would enable Internet Service Providers (ISPs) to disconnect users' accounts where they have been identified as repeatedly using their accounts to infringe copyright. This issue is currently the subject of industry negotiations in Australia.

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s 22 1(a)(ii)

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TRANS-PACIFIC PARTNERSHIP CONSULTATIONS
WA VISIT 29 AUGUST 2012
ELIZABETH WARD

Intellectual Property

- The TPP provides an opportunity for us to work with key trading partners in the region to develop effective and balanced IP standards that are in line with our own.
- The government is negotiating IP provisions that are consistent with current and emerging international standards, and our existing laws and policy settings
 - we are seeking commitments that support our innovative and creative industries and maintain an appropriate balance between the interests of right holders, users and the Australian community
 - it is important for us to retain the flexibilities we currently have (e.g. in relation to copyright limitations and exceptions), including for future IP reform in Australia (such as the outcome of the ALRC inquiry).
- The TPP negotiations involve nine countries with different IP systems, international commitments and objectives
 - we are working through these differences to develop an effective and balanced chapter that is appropriate for the region.
- We are engaging in a comprehensive consultation process to ensure Australia's positions in the IP chapter are informed by a wide range of relevant stakeholder views and perspectives.

s 22 1(a)(ii)

Background

Australia supports a comprehensive, high quality TPP that reflects the basic structure of the WTO Agreements, including TRIPS. Commitments on IP are important for Australia's innovative and creative exporters who have real commercial interests in accessible, transparent and strong IP protection and enforcement in our major trading partners. Australian consumers benefit through more access to legitimate products in the region. TPP countries have agreed to reinforce and develop existing TRIPS rights and obligations to ensure an effective and balanced approach to IP among the TPP countries.

TRANS-PACIFIC PARTNERSHIP CONSULTATIONS
WA VISIT 29 AUGUST 2012
ELIZABETH WARD

At the 14th round in Leesburg USA the IP group will discuss general provisions, trade marks, geographical indications, copyright and related rights and cooperation. There is still a way to go in the IP negotiations.

s 22 1(a)(ii)

~~FINAL CONFIDENTIAL~~

Meeting with public health NGOs August 2012 – Attachment A

Talking points

- The Australian Government is taking a clear position in the Trans-Pacific Partnership (TPP) negotiations that we will not accept an outcome that would adversely affect the integrity of the pharmaceutical benefits scheme (PBS) or our health system more generally.
- In the intellectual property negotiations, we are seeking an appropriate balance
 - which encourages the development of new, innovative drugs
 - and ensures access to affordable medicines, including generics.
- Australia is conscious of the needs of developing countries in the TPP in relation to access to medicines
 - AusAID provides regular input on the potential impact of TPP proposals on TPP developing countries and Australia's aid program
 - Australian trade policy officials meet with TPP developing countries, as required, to discuss text proposals and provide assistance regarding the implementation of their trade commitments.
- Australia is working to negotiate a TPP that supports each party's right to protect public health and promote access to medicines in accordance with the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and the 2001 Doha Declaration on TRIPS and Public Health.
- Ultimately each party must decide its own position in the negotiations.

If asked about TRIPS-plus provisions or an AUSFTA equivalent outcome:

- The Government would naturally be concerned about proposals that delayed the introduction of generic medicines, or increased the cost of medicines, for developing countries in the region
 - this could make it harder for developing countries to access necessary treatment
 - and limit the current reach of Australia's aid expenditure on medicines and vaccines.

If asked about the leaked US proposals (including the so-called 'access window'):

- As is normal practice in trade negotiations, the parties have agreed to keep negotiating documents (including text) confidential, while still allowing for the necessary consultation processes with stakeholders
 - even if it was possible, it would not assist informed public debate to release heavily bracketed negotiating texts that often include ambit claims and remain very much works in progress
 - text has no status until all parties agree to it, and it can change significantly as parties search for outcomes acceptable to everyone.
- There has been a lot of public commentary on so-called 'leaked text' of US proposals on pharmaceuticals.
- The Government will not engage in a debate on the accuracy or otherwise of the so-called 'leaked text'

~~THIS IS CONFIDENTIAL~~

- Australia is taking a clear position on these issues in the TPP and the only thing that matters is the position the Australian Government is taking in the negotiations.

If asked about enforcement provisions on the seizure of generic medicines:

- . . . We are not considering any provisions in the TPP that would change our current policies on generic medicines, or limit the availability of generic medicines in Australia.

s 22 1(a)(ii)

~~CONFIDENTIAL~~**Background***Correspondence from coalition of public health NGOs*

A coalition of Australian and international public health NGOs wrote to you on 17 July 2012 seeking an assurance that Australia would support proposals in the Trans-Pacific Partnership (TPP) that 'provide maximum flexibility to developing countries' in preserving access to medicines for their populations. The coalition of NGOs includes Médecins Sans Frontières Australia (MSF), the Public Health Association of Australia (PHAA) and the Australian Fair Trade and Investment Network (AFTINET). In their letter, the NGOs refer to so-called 'leaked text' of US proposals on pharmaceuticals and intellectual property, s 22 1(a)(ii)

and claims that these proposals would reduce access to affordable medicines for developing countries.

An earlier letter from the NGOs to the Prime Minister on 27 February 2012 claimed that US proposals threatened to (i) undermine access to medicines by delaying production of generic medicines and increasing costs to health systems and (ii) place greater restrictions on governments to regulate the price of medicines.

Background to the US proposals on pharmaceuticals

s 22 1(a)(ii)

On 12 September 2011 the US tabled a detailed additional proposal covering pharmaceutical provisions as part of a new 'Trade Enhancing Access to Medicines' initiative. s 33(a)(iii), s 33(b)

s 22 1(a)(ii)

s 33(a)(iii), s 33(b)

The proposals were last discussed at the 11th round in March 2012, s 33(a)(iii), s 33(b)
s 33(a)(iii), s 33(b)

~~TOP SECRET~~

Development concerns with US proposals

AusAID is concerned that the US proposals may increase the cost of medicines, and delay the introduction of generic medicines, for developing countries in the region. AusAID works through the Global Fund to Fight Aids, Tuberculosis and Malaria, the GAVI Alliance, NGOs and other multilateral organisations, to ensure that life-saving medicines reach people in developing countries in the region. These organisations often use generic medicines as they are commonly much more affordable than patented products. Several NGOs have raised concerns with AusAID about the need to ensure access to affordable medicines.

Access window in leaked US proposal

The NGOs urge Australia to reject the so-called 'access window', s 33(a)(iii), s 33(b)

s 22 1(a)(ii)

What is the Australian Government's position on health issues in the TPP?

- The Australian Government would favourably consider proposals in the TPP that promote access to quality, affordable medicines in the TPP region.
- The Australian Government's Trade Policy Statement, released in April 2011, made clear that Australia will not support provisions in trade agreements that constrain our ability to regulate legitimately on public policy matters, such as health.

Would the Australian Government agree to provisions that impact the PBS?

- The Pharmaceutical Benefits Scheme (PBS) is an integral part of Australia's health system
 - and the ability to ensure access to quality, affordable medicines for Australian consumers is a priority.
- The Australian Government would not accept an outcome in the TPP that would adversely affect the integrity of the PBS, limit the availability of generic drugs, or compromise Australia's health system more generally.

Proposed US text on pharmaceutical patents

- Australia provides strong and balanced IP protection for pharmaceuticals.
- We support the stated US objectives (in the Trade Enhancing Access to Medicines White Paper), of reducing barriers to trade, promoting transparency and procedural fairness and expediting access to both innovative and generic medicines.
- However, the current US proposal on pharmaceutical patents raises significant concerns for Australia
 - we are not convinced that provisions s 33(a)(iii), s 33(b)
 - would result in benefits to Australia and the TPP region
 - : we have seen no evidence to support this proposition
 - : to the contrary, our research suggests that such changes would likely result in costs to the Australian government and consumers, as well as the region
 - : and delays in generic drugs reaching the market.

s 22 1(a)(ii)

s 22 1(a)(ii)

Possible "development" impact of the US proposals

The Australian government, and our stakeholders, are also concerned that the US proposals may increase the cost of medicines, and delay the introduction of generic medicines, for developing countries in the region

- this could make it harder for the poorest in developing countries to access necessary treatment
- and limit the current reach of Australia's aid expenditure on medicines and vaccines.

s 33(a)(iii), s 33(b)

REDACTED

~~CONFIDENTIAL~~

ROUNDTABLE ON HEALTH ISSUES AND THE TRANS-PACIFIC PARTNERSHIP AGREEMENT
26 July 2012

Item 1: Welcome and introductions

- We are pleased to welcome the US delegation to Canberra, led by Joseph Damond, Senior Vice President, Biotechnology Industry Association (BIO), and Richard Kjeldgaard, Association Vice President (IP), Pharmaceutical Research and Manufacturers of America (PhRMA) to discuss health issues and the Trans-Pacific Partnership Agreement. The delegation also includes industry participants:
 - David (Dj) Wolff, C&M International (advisor to BIO and PhRMA)
 - Dr Brendan Shaw, Chief Executive, Medicines Australia
 - Donna Edman, Executive Director, Public Affairs, Medicines Australia
 - Lorraine Chiroiu, Communications, Media and Policy Manager, AusBiotech Ltd.

- I understand BIO and PhRMA are visiting Australia to share their perspectives on biopharmaceutical issues in the TPP (including challenges to innovation and the role of IP) and to discuss the US proposals s 33(a)(iii), s 33(b) s 33(a)(iii), s 33(b)

- We welcome your visit, which is very timely
 - as you are aware, the current US proposals raise some major concerns for Australia
 - : and are the focus of significant stakeholder interest
 - our main concerns are that the proposals s 33(a)(iii) and would alter finely balanced elements of our PBS
 - : and it is not clear to us how the proposals are in Australia's overall interests, and the broader interests of the region.

- We are particularly interested to hear your views on how the matters covered by the US proposals would promote access to quality, affordable medicines in the TPP region.

- We would like to use some of our time today to provide information on the government's perspectives on these issues and the TPP, and welcome any questions you have for us. The Australian agencies participating today are the Department of Foreign Affairs and Trade, the Australian Agency for International Development (AusAID), the Departments of Health and Ageing, and Industry, Innovation, Science, Research and Tertiary Education, and IP Australia.

- The agenda for today provides a simple framework for the discussion:
 1. Welcome and introductions
 2. Industry representatives' perspectives on health issues and the TPP
 3. Comments from government representatives and general discussion
 4. Closing remarks

- I again welcome you to Canberra and hope this roundtable provides some helpful insights for all of us.

~~For Official Use~~**Political brief***What is the Australian Government's position on health issues in the TPP?*

- The Australian Government would favourably consider proposals in the TPP that promote access to quality, affordable medicines in the TPP region.
- The Australian Government's Trade Policy Statement, released in April 2011, made clear that Australia will not support provisions in trade agreements that constrain our ability to regulate legitimately on public policy matters, such as health.

Would the Australian Government agree to provisions that impact the PBS?

- The Pharmaceutical Benefits Scheme (PBS) is an integral part of Australia's health system
 - and the ability to ensure access to quality, affordable medicines for Australian consumers is a priority.
- The Australian Government would not accept an outcome in the TPP that would adversely affect the integrity of the PBS, limit the availability of generic drugs, or compromise Australia's health system more generally.

Proposed US text on pharmaceutical patents

- Australia provides strong and balanced IP protection for pharmaceuticals.
- We support the stated US objectives (in the Trade Enhancing Access to Medicines White Paper), of reducing barriers to trade, promoting transparency and procedural fairness and expediting access to both innovative and generic medicines.
- However, the current US proposal on pharmaceutical patents raises significant concerns for Australia
 - we are not convinced that provisions s 33(a)(iii) would result in benefits to Australia and the TPP region
 - : we have seen no evidence to support this proposition
 - : to the contrary, our research suggests that such changes would likely result in costs to the Australian government and consumers, as well as the region
 - : and delays in generic drugs reaching the market.

s 22 1(a)(ii)

~~For Official Use~~

s 22 1(a)(ii)

Possible "development" impact of the US proposals

- The Australian government, and our stakeholders, are also concerned that the US proposals may increase the cost of medicines, and delay the introduction of generic medicines, for developing countries in the region
 - this could make it harder for the poorest in developing countries to access necessary treatment
 - and limit the current reach of Australia's aid expenditure on medicines and vaccines.

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Australia's concerns with the US proposed text on pharmaceutical patents

State of play

s 33(a)(iii), s 33(b)

In a blog posted on 20 July 2012, USTR Ambassador Ron Kirk stated 'we have heard a great deal of feedback on our early proposals – including on the treatment of lesser-developed countries, such as Vietnam – and are carefully reflecting upon that feedback. We want to get the balance right and to work with the public and with our trading partners to get there. This process will take some time and, as we work over the course of the next several months, we will be very interested in additional input'.

s 33(a)(iii), s 33(b)

s 33(a)(iii), s 33(b)

REDACTED

[REDACTED]

s 33(a)(iii), s 33(b)

s 22 1(a)(ii)

s 22 1(a)(ii)

REDACTED

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s 22 1(a)(ii)

s 33(a)(iii), s 33(b)

~~For Official Use~~**Background***Intellectual Property, s 22 1(a)(ii)*

The TPP Intellectual Property (IP) Chapter and s 22 1(a)(ii) are sensitive areas of the negotiations and of key interest to our stakeholders. The Government has made clear that it will not accept provisions in the TPP that adversely affect the integrity of the PBS, limit the availability of generic drugs, or compromise Australia's health system.

s 22 1(a)(ii)

On 12 September the US tabled a s 33(a)(iii), s 33(b) proposal for discussions by the TPP IP group covering pharmaceutical provisions as part of a new 'Trade Enhancing Access to Medicines' initiative. The USTR describes the goals of the proposal as promoting transparency and procedural fairness in the operation of national government health care reimbursement programs, promoting access to medicines, eliminating tariffs on medicines and curbing the trade in counterfeit medicines, s 33(a)(iii)

Australian stakeholder response

A number of stakeholders, including the Australian Fair Trade and Investment Network (AFTINET) and the Public Health Association of Australia, have raised concerns about the US proposals on pharmaceuticals and s 22 1(a)(ii). A letter sent to the Prime Minister on 27 February 2012, on behalf of these and other health organisations, stated that the proposals threaten to (i) undermine access to medicines by delaying production of generic medicines, adding to the costs of the PBS and (ii) place greater restrictions on the rights of governments to regulate the price of medicines through schemes like the PBS. A subsequent letter to Dr Emerson, dated 17 July 2012, seeks an assurance that Australia will support proposals in the TPP to 'provide maximum flexibility to developing countries in preserving access to medicines for their populations'.

s 22 1(a)(ii)

s 22-1(a)(ii)

REDACTED

**Trans-Pacific Partnership Agreement
Intellectual Property Stakeholder Meeting**

**Thursday 24 May 9.30am-11.30am
Treaties Room, DFAT, Canberra**

Agenda

- Welcome and introductions
- Update on IP negotiations from the 12th round, Dallas
- Overview of IP schedule for the 13th round, San Diego
- Other issues
 - US proposal relating to pharmaceuticals
- Future TPP IP Stakeholder Meetings

**Trans-Pacific Partnership Agreement
Intellectual Property Stakeholder Meeting**

**Thursday 24 May 9.30am-11.30am
Treaties Room, DFAT, Canberra**

Update on IP negotiations from the 12th round, Dallas

- Seven day IP meeting in Dallas.
- Progress in the IP chapter is good but slower than other chapters
 - text comprehensive, long, covers complex, sensitive, technical issues.
- Several Parties attributed positions on text, which allowed the group to narrow and isolate differences, identify consensus language.
- Provide summary of key areas discussed:
 - enforcement
 - patents
 - traditional knowledge, traditional cultural expressions and genetic resources.
- We are analysing all proposals closely, and working with relevant government agencies including IP Australia, Health, Innovation, AusAID, AGD, Customs, Environment.
- The Government is aiming to develop a high-quality IP chapter that deals with recent developments in international IP, but does not go beyond Australia's existing domestic regime or require legislative change
 - we are seeking provisions that allow us to maintain the flexibilities in our IP system, and that strike an appropriate balance between the interests of right holders, users and the community.

Overview of IP schedule for the 13th round, San Diego

- Dates for 13th round in San Diego: 2-10 July 2012.
- Formal stakeholder consultations: Monday 2 July.
- Provide summary of key areas to be discussed:
 - copyright and related rights
 - general provisions
 - cooperation
 - (not pharmaceuticals).

Other issues

US proposal relating to pharmaceuticals

- The IP group discussed the US proposal on pharmaceuticals at the 11th round in March 2012, and all delegations put forward views on the proposal
 - Australia raised concerns about the potential impact on generic entry and likelihood for delayed access to affordable medicines.
- We are analysing the proposal closely, and working with relevant government agencies including IP Australia, Health, Innovation, AusAID.
- The Government sees the PBS as an integral part of Australia's health system

- retaining the ability to ensure access to quality, affordable medicines for Australian consumers is a priority. The Government would not accept an outcome in the TPP that would adversely affect the integrity of the PBS.
- The Government's Trade Policy Statement also made clear that Australia will not support provisions in trade agreements that constrain our ability to regulate legitimately on important public policy matters such as public health.
- We are conscious of the needs of developing countries in the TPP in relation to access to medicines.
- We are working to negotiate a TPP that supports each party's right to protect public health and promote access to medicines, in accordance with TRIPS and the 2001 Doha Declaration on TRIPS and Public Health.
- Ultimately each party must decide its own position in the negotiations.

Future TPP IP Stakeholder Meetings

- Further stakeholder consultation to be held within six months
 - likely to be Canberra, Sydney, Melbourne, Brisbane.

**TPP IP Chapter
Stakeholder Talking Points
February 2012**

If raised: What position is Australia taking on intellectual property in the TPP?

- We are aiming to develop a high-quality Intellectual Property chapter that deals with developments in international IP since TRIPS, but does not go beyond Australia's existing domestic regime or require legislative change

s 33(a)(iii)

If raised: What is the current status of the IP negotiations?

- Progress has been slow, but extensive bracketing has been undertaken and we hope that we can now move ahead in negotiations
 - although we anticipate that there will be several areas of the text that will be difficult to reconcile.
- It is important to remember that the Chapter has not been agreed
 - all parties are engaging in a negotiation process
 - ∴ it is not a given that any particular piece of text currently on the table will be included in the final agreement

If raised: Leaked text to date shows that the US is seeking more extensive and prescriptive commitments on IP than those in AUSFTA, and that would require us to change our laws. These include copyright (term based on periods other than life of the author), enforcement (statutory and triple damages, coverage of in-transit merchandise), and a requirement to allow patents for surgical, therapeutic and diagnostic methods for the treatment of humans or animals.

- We can't comment on allegedly leaked text, however Australia supports the development of a comprehensive, high-standard IP chapter in the TPP.

s 33(a)(iii)

If raised: If the US gets it way in the IP chapter, the pricing of pharmaceuticals and the cost of the PBS will escalate hugely.

- The Government sees the PBS as an integral part of Australia's health system
 - retaining the ability to ensure access to quality, affordable medicines for Australian consumers is a priority. The Government would not accept an outcome in the TPP that would adversely affect the integrity of the PBS.
- The Government's Trade Policy Statement also made clear that Australia will not support provisions in trade agreements that constrain our ability to regulate legitimately on important public policy matters such as public health.

If raised: Australia must ensure that other negotiating parties are not bound by IP provisions such as those proposed by the US. For example, US proposals on IP and patents would have a significant and detrimental impact on timely access to affordable medicines in Vietnam.

- We have explained to all negotiating partners our stance on these issues, but individual countries' negotiating positions are a matter for each government to determine.

TPP: Talking points on Pharmaceuticals and Copyright Meeting with AFTINET

Pharmaceuticals

- Our negotiators are working with relevant experts, stakeholders and other parties in the negotiations to develop robust and balanced positions on pharmaceuticals in the TPP.
- Australia is taking a clear position in the TPP negotiations that we will not accept any outcome that would adversely affect the integrity of the Pharmaceutical Benefits Scheme (PBS), or our health system more generally.
- Australia is conscious of the needs of developing countries in relation to access to medicines.
- All countries will of course continue to pursue their own interests in the negotiations, but any final outcome would need to be agreed by all eleven negotiating parties.

Copyright

- In the TPP negotiations, Australia supports strong and balanced commitments on copyright
 - that are consistent with Australia's existing IP laws and policy settings
 - and that retain the flexibilities we currently have to respond to domestic developments in IP.
- There is no agreed position yet on copyright, and negotiations are ongoing.

Talking points for Director, NSWSO – Speech to AmCham on Intellectual Property
 s 22 1(a)(ii) in the Trans-Pacific Partnership

Intellectual Property

- The TPP IP chapter is ambitious and wide ranging. Progress is being made at every round and we are looking forward to moving the negotiations towards completion this year.
- In the TPP Australia is seeking strong and balanced commitments on IP that:
 - are in line with our own strong and balanced IP laws, and
 - are consistent with current and emerging international standards.
- Australia already has IP commitments with a number of TPP parties through FTAs and other agreements including under the WTO and WIPO
 - we consider many of these standards to be international best practice and would like to see them reflected in the TPP
 - but, we recognise some of these are not appropriate for the TPP
 - and we are working through these areas with the other parties.
- It is an important time for IP in Australia
 - many domestic IP reviews are underway including on copyright and the online environment, and on pharmaceutical patents and the patent system
 - these reviews have a bearing on Australia's position in the TPP negotiations.
- The challenge for our negotiators is achieving flexible outcomes that provide policy space to address emerging IP issues
 - while ensuring effective and transparent standards so we can tackle the challenges we face in the region.

s 33(a)(iii)

If raised, how is Australia managing the IP negotiations with so many domestic IP reviews?

- We are closely monitoring these reviews
 - the government agencies overseeing them – IP Australia and the Attorney-General's Department – are actively involved in the TPP negotiations and provide us with regular updates on the status of reviews
 - we are also consulting with other stakeholders with an interest in these matters, including government agencies, industry and interest groups and members of the public.
- In the negotiations, we are taking positions to give us flexibility. What this means depends on the issue and what is being negotiated
 - it is important to remember that the need for 'flexibility' must be balanced with the goal of effective and transparent commitments on IP
 - this is vital if we are to achieve greater certainty and opportunities for IP exporters and importers in the region.

s 22 1(a)(ii)

If raised, will Australia support strong provisions on pharmaceutical patents in the TPP, like in AUSFTA?

- This is an important and sensitive area for all parties, including Australia, and we are working with relevant agencies, stakeholders and international partners to develop our position.
- Australia is seeking an outcome on pharmaceutical patents that is consistent with our strong and balanced system
 - and that provides flexibility in implementation.
- We are seeking an outcome in TPP:
 - that balances the promotion of innovation and new innovative medicines on one hand, and the need for access to information and follow-on entry on the other
 - that ensures reliable access to affordable medicines for our consumers
 - that recognises the different levels of development of TPP countries, and
 - that facilitates regional coherence.
- All countries will of course continue to pursue their own interests in the negotiations, but any final outcome would need to be agreed by all parties.

If raised, will Australia agree to more than five years data exclusivity (or protection) for biologics in TPP?

- Australia currently provides five years data exclusivity for biologics.
- The question of data exclusivity is currently under consideration in the review of *Pharmaceutical Patents in Australia* launched by the Government in October 2012
 - we are not seeking to drive changes to our domestic regime in the TPP
 - and would support an outcome in this area that retains our present flexibility.

Background on IP reviews

Several major IP reviews are underway in Australia, including an ALRC inquiry into *Copyright and the Digital Economy* (due to report November 2013) and the IP Australia / Committee (Tony Harris, Dianne Nicol, Nicholas Gruen) review of *Pharmaceutical Patents in Australia* (due to report around April 2013).

The ALRC is considering whether exceptions and statutory licences in the *Copyright Act 1968* are adequate and appropriate in the digital environment and whether further exceptions should be recommended. Copyright exceptions provide a balance between the interests of right holders and the larger public interest in permitting uses of copyright works in particular cases without having to obtain the authorisation of the owner of the copyright. Australia provides copyright exceptions for a wide range of uses including education, libraries and archives, government functions, assisting people with disabilities, fair dealings for specified purposes as well as for radio and television broadcasting. In TPP, some Australian stakeholders have raised concerns that restrictive provisions on copyright exceptions would limit the ALRC's ability to make recommendations for reform.

The pharmaceutical patent review is analysing the pharmaceutical extension of term provisions of the *Patents Act 1990* and whether there is evidence that the patent system is being used to extend pharmaceutical monopolies at the expense of new market entrants. In TPP, some Australian stakeholders have said that Australia's approach on pharmaceutical patents needs to be consistent with the review and its recommendations. Many stakeholders are strongly against AUSFTA-plus provisions. Our pharmaceutical industry body, Medicines Australia, supports AUSFTA-consistent provisions but is not pushing for an AUSFTA-plus outcome, other than on data exclusivity for biologic drugs. A biologic drug is a 'large molecule' drug created by biologic processes, rather than being chemically synthesized. Examples are vaccines, blood and gene therapy. Data exclusivity refers to protection granted to the originator of a drug for the data used to develop the drug. The right is granted under the regulatory (also known as 'marketing') approval process and is separate from patent rights. The protected data is the data submitted to the regulatory agency to prove the safety and efficacy of a new drug (e.g. clinical data). Data protection prevents generic drug manufacturers from accessing the originator's data for their own applications (without consent) until after the protection has expired. In return, generic manufacturers can rely on the originator's data in seeking regulatory approval.