Sidley, Kristine (REPS)

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Subject: Aus-US FTA Submission

Committee Secretary
Joint Standing Committee on Treaties
Department of House of Representatives
Parliament House
CANBERRA ACT 2600
AUSTRALIA

Please find attached a Submission re the Australia - US Free Trade Agreement

Regards

Mike Willis

April 19, 2004

Committee Secretary
Joint Standing Committee on Treaties
Department of House of Representatives
Parliament House
CANBERRA ACT 2600
AUSTRALIA

Dear Committee Secretary

Inquiry into the Australia – United States Free Trade Agreement

This Submission is directed at the Intellectual Property Rights Chapter [Chapter 17] of the Australia – United States Free Trade Agreement [AUSFTA]. Several commentators have already remarked on the likely impact on the Pharmaceutical Benefit Scheme from those provisions in the AUSFTA requiring procedural changes to the way the Pharmaceutical Benefits Advisory Committee operates. However, little attention has been paid to the intellectual property (IP) Chapter generally or the likely impact of its patent provisions on health related issues and the PBS in particular.

Such is the complexity of patent law generally and the relevant AUSFTA provisions in particular, only a sampling of provisions has been touched on within this Submission. Nevertheless, if the Committee so desired, I am available for further discussion or clarification regarding the issues covered.

Regards

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Introductory Comment

- The linkage between the Pharmaceutical Benefit Scheme and IP law has much to do with generic medicines. The entry of generic products as less-costly substitutes for brand name ones at the end of the statutory period of patent protection is characteristic of the pharmaceutical market in many countries. How Australia chooses to frame its patent law regime and particularly the way those laws serve to restrict or delay the availability of generic medicines will have significant implications for health costs and especially those related to the. However, even a cursory look at several of the AUSFTA provisions is suggestive of concern at the extent to which they may potentially lead to unjustified patent extensions, the denying of approval to generic manufacturers and delays in access to lower-priced equally effective, generic medicines. One remains extremely sceptical as to whether the PBS has been effectively quarantined from the likely costs associated with Australia's obligations under the Agreement.

- The Chapter 17 IP provisions within the AUSFTA are contentious and complex to interpret. While some of the more extravagant demands of US IP-based industries have been resisted, the IP proposals are significant and take much further the ongoing alignment of Australian patent law with that of the US. Importantly, this applies not just with substantive US patent law but also with US patent practice and procedure. The deeper alignment now proposed by the AUSFTA very *clearly marks out Australia's compliance with US versions of interpretation, clarification, definition and improvement of contentious patent law terminology.* This is very likely to have major implications both domestically and internationally for Australia.

- IP protection is viewed as crucial to investment in research and development and artistic creativity. However, it is not usually the need *per se* for such protection which attracts contestation, criticism and debate. What is contentious is the precise nature and extent of the protection afforded IP owners. In circumstances where increased protection is not self-evidently a good thing, getting the balance right is crucial.

AUSFTA Intellectual Property Overview

- Chapter 17 within the AUSFTA, dedicated to intellectual property (IP), is the largest substantive chapter in the Agreement. It spans some 29 pages consisting of 12 Articles and 96 subsections. This does not include an additional 3 side letters impacting on IP concerns. This compares with chapters of 23 pages on government procurement, 16 on financial services, 14 on investment and 12 pages on telecommunications. Some 8 pages only are given over to the specific chapter on agriculture.

- The IP provisions in AUSFTA are extensive and complex to interpret. However, in the absence of any demonstrated rationale for their formulation or of some 'due diligence' analysis of implications likely to flow from them, it is exceedingly difficult

to make a measured judgement about whether the provisions will serve Australia's interest. Nevertheless, they are significant to the extent they take further and deeper the current ongoing alignment of much of Australian IP law with that of the US.

This apparent desire by Australia for further uniformity and alignment with US patent law has passed the domain of substantive law and is intended to now apply at the level of US administrative process and practice. Under the AUSFTA, this extends to greater legalization of the way in which much of patent law, for example, is operationalised as well as the incorporation into Australian practice of US legal terminology. What is of concern is that the negotiation process has lacked real transparency and little public debate has taken place about the rationale or merits of such deeper alignment. What remains quite unclear is the precise effect - including judicial, cost and resource implications – Australia's agreement to these provisions will have over time.

- A number of the obligations under the AUSFTA's Chapter 17 provisions that Australia is agreeing to undertake appear to pre-empt current inquiries and negotiations on several significant areas of possible patent law reform. These investigations are taking place both within Australia and at the international level. For example, at the domestic level, the Australian Law Reform Commission is currently examining the extent to which IP owners are unreasonably restricting the use of patented material or technology in Australia. Arguably, several provisions [Article 17.9.7(b)(iii) and Article 17.9.9, to name two] constrain the possible areas of patent law reform which may be identified by the Commission. Internationally, it is a concern that Australia's agreement under the AUSFTA to a deeper level of integration and harmonization with US patent law and practice appears likely to effectively reduce the strength and scope of Australia's negotiating position within international forums both currently and in the future. For example, within the World Intellectual Property Organisation currently, the issues of 'grace periods' [Article 17.9.9], patentability criteria and how the requirements for patentability are defined and applied [Article 17.9.13] are proving highly contentious.

- Article 17.10.5 is designed to link the market approval process, regulated by the pharmaceutical approval authority (TGA), with patent expiry which is administered by the patent regulatory body (IP Australia). There is no such linkage presently and PhRMA, the key US lobby group for the pharmaceutical industry, has pressed for it in all bilateral agreements entered into by the US. There already exists adequate remedy at law under the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) to prevent a generic company from marketing illegally a pharmaceutical under patent. PhRMA seeks such linkage as it protects brand-name companies beyond their existing intellectual property rights in that it serves to stay the approval of generic pharmaceuticals. Such a stay can have a significant impact on market entry by generic products. However, it's widely believed amongst health lobbyists that such linkage is likely to lead to unjustified patent extensions, the denying of approval to generic manufacturers and delays in access to lower-priced equally effective, generic medicines. In the US, the linkage has been the subject of

considerable abuse and investigation. Moreover, there's no requirement under TRIPs for any such linkage. The EU has no linkage.

- Australia has over recent years chosen to greatly reduce the flexibility available to it under TRIPs in implementing its international IP obligations. This has applied especially to patent law as it has impacted on pharmaceuticals. Other industrialised countries have chosen to preserve the flexibility permitted them under their international obligations. Decisions on increasing patent protection are highly contentious and require measured consideration and caution. One of Australia's recent efforts to confer greater patent protection to pharmaceutical companies has brought unintended consequences. A number of issues, ('grace periods' [Article 17.9.9], patentability criteria and how the requirements for patentability are defined and applied [Article 17.9.13]), now the subject of the AUSFTA, are currently being debated multilaterally and are viewed as best resolved multilaterally rather than bilaterally.

- From the viewpoint of the US, bilateral trade deals serve a strategic purpose. They promote the broader US trade agenda *by serving as models, breaking new negotiating ground and setting high standards.* Under US trade law, trade negotiators are mandated to ensure that the provisions of any bilateral agreement governing IP rights reflect a standard of protection *similar to that found in U.S. law.* Increasingly, bilateral deals are designed to institutionalise, globally, intellectual property standards beyond those which were agreed upon multilaterally under TRIPs. However, these bilateral deals are being used to scale up global IP standards to reflect not just the substantive standards of the US but also the letter of US administrative process and practice.

  This manner of interacting on IP protection has proved highly contentious and divisive. Many developing countries and numerous commentators believe that such bilateral trade deals allow the US to circumvent a multilateral approach to many of the more contentious aspects of IP law. Strong objection is being taken to the considerable efforts by the US, in conjunction with US industry, to *interpret, clarify and define, bilaterally*, much of the terminology within TRIPs which came out of a *multilateral* negotiation process. For the US, by building alliances, bilateralism helps to entrench prospective support for the global standards of IP protection it wishes to see in place. Such is the level of integration and uniformity with US substantive patent law and process reflected in the AUSFTA provisions that Australia must anticipate being seen as a very compliant actor in the process of the US achieving its goal. Arguably, that will constrain the limits of any future negotiating position that Australia may wish to formulate within international forums.

- Unlike trade concessions granted by Australia in other areas covered by the AUSFTA, the concessions afforded US IP owners and exporters cannot be confined merely to the US. Under TRIPs any advantage or favour with respect to the protection of intellectual property given by a WTO member to nationals of any other country, with limited exceptions, must be extended 'immediately and unconditionally' to the

nationals of all other members. The principle obliges Australia to extend any intellectual property benefits obtained under the AUSFTA by the US to all other WTO members. This is likely to have major cost implications well beyond the scope merely of the AUSFTA.

- Less well known is the fact that, in the five years to July 2004, Australia's patent law regime, which confers significant benefits on pharmaceutical companies, will have been supplemented by a pharmaceutical industry investment program delivering $300m to pharmaceutical companies. Moreover, the program was designed to compensate the pharmaceutical industry, in part, for the impact of the PBS. A new pharmaceutical grants program will commence on 1 July 2004 providing another $150 million over five years to pharmaceutical companies to encourage new R&D. The 'need for a fair return on investment in an expensive R&D process' is the very same rationale now used by pharmaceutical companies in justifying new patent concessions obtained under the AUSFTA. There is a strong connotation of 'double-dipping' in these circumstances.

Implications of Several Specific AUSFTA IP Provisions

- Domestically, it's a concern that one of Australia's obligations under AUSFTA [Article 17.9.7(b)(iii)] has pre-empted an area of possible patent law reform identified by the Australian Law Reform Commission in the Discussion Paper on its current inquiry into *Gene Patenting and Human Health*. The ALRC was considering the merit in permitting courts to require the transfer of the 'know-how' in a patentable invention. However, it declined to formulate a proposal for reform and instead opted to seek further submissions on the issue. AUSFTA [Article 17.9.7(b)(iii)] would appear to foreclose further discussion. Another AUSFTA obligation [Article 17.9.9] also appears to compromise a proposal [Proposal 15-3] by the ALRC that the relevant Minister ask the Government's Advisory Council on Intellectual Property to examine whether the patent law's 'grace period' provisions are having an adverse impact on the commercialisation of Australian research in Australia or overseas.

- At the international level, it's of concern that Australia's agreement under the AUSFTA to this level of integration and harmonization with US patent law and practice effectively reduces the strength of its negotiating position within international forums. Currently, negotiations are underway within the World Intellectual Property Organisation on a Substantive Patent Law Treaty (SPLT). In the context of the SPLT, issues concerning 'grace periods' [Article 17.9.9], patentability criteria and how the requirements for patentability are defined and applied [Article 17.9.13] have proved highly contentious. The negotiations are characterised by differences between the US and the EU and differences between industrialised and developing countries. The SPLT is likely to have significant implications for developing countries by reducing the relative flexibility available to them under the WTO's TRIPs Agreement to determine patent law policy and practice at the national level. However, under the AUSFTA, there is a real sense that Australia is aligning

itself with a US mission to re-shape all national intellectual property regimes to a standard of patent protection similar to that found in both US substantive law and US practice. Such a position is very likely to constrain Australia's negotiating options in circumstances, were they to arise later internationally, where Australia saw value in seeking to ensure that WTO multilateral rules on intellectual property took greater account of the interests of developing countries.

The Background Context

- It should come as no surprise that Chapter 17 of the AUSFTA is the largest substantive chapter. From a US perspective intellectual property was from the start one of the paramount issues on the negotiating table. IP protection is specifically stipulated for under US trade law and reflects the huge economic influence of US multinational (software, entertainment, pharmaceutical, publishing) interests. The US President's Advisory Committee on Intellectual Property Rights has very recently observed that copyright industries alone account for over 5% of US GDP. Indeed, the US is the world's largest producer and exporter of copyright materials. Moreover, the US Patent and Trademark Office emphasises that some 50% of US exports now depend on some form of IP protection.

- A comparison with Australia could not be more stark. Australia is a huge net importer of IP and more than 90% of all patents registered here are foreign owned. As the UK's Commission on Intellectual Property Rights recently cautioned, increased protection is not self-evidently a good thing. The Commission went on to assert that IP rights should best be regarded as *instruments of public policy*. Far from being mere items of tradeable property, they should most usefully be construed as *conferring economic privileges primarily for the purpose of contributing to greater public good.*

- The economics of IP protection in Australia has traditionally attracted little attention. At the time the TRIPs Agreement was finalized, no cost benefit analysis of its implementation was ever conducted. It has been observed that not one newspaper account at the time referred to costs that Australia was likely to bear as a result of the Agreement. Analysts from the (then) Industry Commission were later to argue that the direct cost to the Australian economy of retrospective protection for patents alone under TRIPs was likely to approach $4 billion. They estimated that two thirds of that cost went in the form of 'windfall gains' in respect of Australia's decision to extend the new patent term to patents then in force.

- Australia did not come to the AUSFTA negotiations with sub-standard IP protection credentials. The additional concessions within the AUSFTA have come at a time when Australia's existing patent laws go well beyond its international obligations under TRIPs.

- Australia's current patent law regime for pharmaceuticals confers one of the highest levels of protection to pharmaceutical companies in the world. It permits patent term

extensions for pharmaceuticals to a total of 25 years while there's a standard patent term of 20 years for other products. However, there's no requirement under Australia's international IP obligations to have any such extension scheme. Canada, for example, has no extension scheme. The scheme itself has resulted in a majority of patents expiring later in Australia than they do in the US and Europe. The scheme has been of clear benefit to foreign pharmaceutical companies, added significantly to PBS costs and, according to the Productivity Commission, constituted a costly barrier to Australian exports of generic products. Australia patent law also includes so-called 'spring-boarding' provisions. These allow generic manufacturers to work on the pharmaceutical substance before the patent expires for the purpose of obtaining regulatory approval. However, the way these provisions are framed in Australia restricts generic manufacturers more so than similar provisions in both the US and Canada. Finally, Australia also has, what are called, 'data exclusivity' provisions for pharmaceuticals which exceed our international requirements, are weighted in favour of pharmaceutical companies and delay the entry of generic products onto the market.

- *All of the above characteristics refer only to Australia's present patent regime.* This provides an elevated level of IP protection which is of our own choosing. It is well in excess of Australia's international obligations. Indeed, there has been persistent economic and legal advice in the past that raising IP standards beyond accepted international norms will not be in Australia's national interest. Other industrialised countries have been more selective in retaining permitted elements of flexibility. While the total cost to the PBS of Australia's present high patent protection level for pharmaceuticals has never been quantified, it is clearly significant.

- *What now must be factored in are the additional commitments given by Australia under the AUSFTA.* To the extent that major US pharmaceutical interests have applauded the IP provisions within the AUSFTA it approaches an absurdity to conclude anything else but that further delays in the entry of generic pharmaceuticals onto the Australian pharmaceutical market will occur. This is again likely to have significant cost implications for the PBS.

- It is not well known that IP concessions within so-called free trade agreements have their own frame of reference. Unlike trade concessions granted by Australia in other areas covered by the AUSFTA, the concessions afforded US IP owners and exporters cannot be confined merely to the US. Under TRIPs any advantage or favour with respect to the protection of IP given by a WTO member to nationals of any other country, with limited exceptions, must be extended 'immediately and unconditionally' to the nationals of all other members. The principle obliges Australia to extend any IP benefits obtained under the AUSFTA by the US to all other WTO members. This is likely to have major cost implications well beyond the scope merely of the AUSFTA.

- Perhaps even less well known is the fact that, in the five years to July 2004, Australia's patent law regime, which confers significant benefits on pharmaceutical companies, will have been supplemented by a pharmaceutical industry investment

program delivering $300m to pharmaceutical companies. Moreover, the program was designed to compensate the pharmaceutical industry, in part, for the impact of the PBS. A new pharmaceutical grants program will commence on 1 July 2004 providing another $150 million over five years to pharmaceutical companies to encourage new R&D. The 'need for a fair return on investment in an expensive R&D process' is the very same rationale now used by pharmaceutical companies in justifying new patent concessions obtained under the AUSFTA. There is a strong connotation of 'double-dipping' in these circumstances.

Concluding Comment

- As mentioned earlier, a number of the AUSFTA provisions give every appearance of potentially leading to unjustified patent extensions, the denying of approval to generic manufacturers and delays in access to lower-priced equally effective, generic medicines. Moreover, one remains extremely sceptical as to whether the PBS has been effectively quarantined from the likely costs associated with Australia's obligations under the Agreement.

Michael Willis