Potential AUSFTA Trade Disputes over Off-Shore Constructions of Australian Pharmaceutical Policy

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Introduction
In the modern global economy, trade agreements, both multilateral and bilateral, have become increasingly important in shaping domestic health policies. The effect of trade agreements on medicines policy has been particularly stark, with the World Trade Organization’s (WTO’s) Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) achieving considerable notoriety for its supposed deleterious impact on the provision and affordability of essential medicines in developing nations. In addition, recent bilateral trade agreements pursued, and concluded, by the Office of the United States Trade Representative (USTR) contain provisions that strengthen and expand elements of what the authors prefer to term intellectual monopoly privileges (IMPs) that are restricted and contentious in the multilateral trading system (for example non-patent reward of innovation (anti-reference pricing), “linkage evergreening” and non-violation nullification of benefits (NVNB) provisions). The hypothesis explored here is that trade agreements are emerging as a new, and largely unexplored, tier of sovereignty in the construction of domestic health policy.
The medicines-related provisions of the *Australia-US Free Trade Agreement* (AUSFTA) provide a valuable case study in this respect. It is now some years since the AUSFTA entered into force. Whilst its domestic policy implications are still percolating through bureaucratic, industry and political dynamics, recent legislative changes to the Pharmaceutical Benefits Scheme (PBS) that appear to have evolved from the AUSFTA Medicines Working Group, make it important to examine whether the AUSFTA trade disputes mechanism constructs a new regulatory architecture supporting off-shore health policy development in Australia.

**Constructing the PBS**

The PBS has been operating for over 50 years as a federal government formulary. It specifically arose from legislation passed immediately after one of the few successful Constitutional referenda in Australian history (adding the new s 51xxiiiA in 1946). That legislation survived constitutional challenge in the High court of Australia (*Federal Council of the British Medical Association v Cth* (1949) 79 CLR 201). Since the 1990s the PBS has developed into a world-best-practice system for valuing pharmaceutical innovation what may be broadly described as a scientific process of cost-effectiveness analysis (established by s 101(3A) of the *National Health Act 1953* (Cth)) linked with a central government price negotiation and reimbursement system. Its aims fit with the principles of the Australian National Medicines Policy: that all Australians, regardless of health insurance status, benefit from timely and affordable access to quality medicines, well used, that offer the best therapeutic and fiscal value from a viable and responsible industry (Australian Government, 2000).

The PBS is popular with Australian citizens. This is partly because most citizens only have to pay a relatively low co-payment (currently approximately AUD$30) for most necessary medications. Public understanding of the cost-effectiveness analysis work of the Pharmaceutical Benefits Advisory Committee (PBAC) is increasing, as a result of the AUSFTA negotiations and also some recent PBAC decisions to list highly
priced “innovator” medications that received a high media profile.

The main success of the PBS system in terms of global medicines policy has been in developing an expert-supervised evidence-based system that uses federal government monopsony buying power to price a newly submitted brand-name, patented medicine in terms of the community value of its “health innovation” (in terms of its objectively demonstrated therapeutic significance) (Aristides and Mitchell, 1994; Henry, 1992; Henry and Lopert, 1999; Sansom, 2004; Pharmaceutical Benefits Pricing Authority, 2005; Australian Government Productivity Commission, 2001).

The PBS process does not restrict multinational pharmaceutical manufacturers’ access to the Australian market, or to set whatever price they wish for their product. If the PBAC recommends against PBS listing, for example, a manufacturer can still market its product at any price, although patients purchasing that product will have to pay a higher out-of-pocket price than would have been facing them if PBS listing had been achieved. This is why the PBS has never been formally recognised, under international trade law, as constituting a so-called “non tariff barrier to trade” (Faunce, 2006a; Senate Select Committee on the FTA Between Australia and the USA, 2004; Birkett, Mitchell and McManus, 2001).

From March 2003 to March 2004, $4.89 billion was spent by the Australian federal government and $0.91 billion by patients (through co-payments) for drugs “listed” on the PBS (Australian Government Department of Health and Ageing, 2004). The above considerations confirm the Australian Government has a legitimate and clearly articulated political interest in sustaining the operation of the PBS in accordance with the National Medicines Policy (Harvey, 2005).

Certain elements of the PBS (such as reference pricing), however, have long been a source of contention between Australia and both the USTR and the powerful US lobby group the Pharmaceutical Research and Manufacturers of America Association (PhRMA) (PhRMA, 2005; Van Maren, 2005).
Reconstructing the PBS Through the AUSFTA

The general US position in the medicines sector of the AUSFTA negotiations appeared to be that elements of Australia’s medicines regulatory system should be reformed. There was a legislated US agenda requiring its AUSFTA negotiators to seek to “eliminate” PBS reference pricing (Faunce, 2007; PhRMA 2003; Trade Promotion Authority Act, Public Law No 107-210 s 2102, 19 USC s 3801(2002)). The reasons related to inaccurate perceptions that the PBS was a “price control” mechanism that allowed Australian patients (termed “consumers” by industry lobbyists) to “free ride” on US R&D (Kyl, 2004; McClellan, 2003; Aldonas, 2004). This was part of a global US agenda on such issues, including raising pharmaceutical IMPs (Faunce, 2006b; PhRMA, 2005; US Department of Commerce, International Trade Administration, 2004; Ismail, 2005).

The final AUSFTA text in Annex 2C.1, however, made no explicit connection between “reward of pharmaceutical innovation” and either drug price rises, or changes in the PBS system. It provided two ways in which pharmaceutical “innovation” could be valued: competitive markets (the US position) and “objectively demonstrated therapeutic significance” (the Australian position) (Lopert, 2004). It did create a medicines working group of high-level officials from each nation to discuss medicines policy changes in non-public discussions (Faunce, 2007). Article 17.10.4 was equally ambiguous in requiring the Australian Therapeutic Goods Administration (TGA) “prevent” safety, quality and efficacy marketing approval wherever a pharmaceutical patent was “claimed”. This created a controversial pharmaceutical patent “linkage evergreening” mechanism that was the subject of specific amendments to Australian AUSFTA implementing legislation (Faunce and Lexchin, 2007).

Australia’s legitimate and unambiguously expressed expectations in the AUSFTA negotiations were that pharmaceutical prices in Australia would not rise as a result and, secondly, that no change would arise to the basic PBAC mechanisms, including reference pricing, for PBS listing and federal reimbursement (Marginson, 2006; DFAT, 2005; Deady, 2004; Lopert, 2004). Australian legislation passed in 2007
dividing the PBS into two formularies, F1 (for new patented medicines) and F2 (for generics), with limited reference pricing between them, appears to have been the outcome of a temporarily “soft” line on protecting these commitments (Faunce, 2007).

Yet, the high fiscal and public health stakes, coupled with divergent interpretations of deliberately ambiguous AUSFTA medicines’ obligations, however, raise the possibility (but not the certainty) of an eventual bilateral trade dispute in this area. If such a dispute could have a significant positive and beneficial influence on minimising AUSFTA-related off-shore construction of domestic Australian health policy.

One relevant factor in this regard may be that in May 2007, however, a deal between the USTR and US Democrat politicians on renewing “fast track” approval for bilateral trade deals required certain elements of the USTR–PhRMA agenda would no longer be pursued and would be removed from US bilateral trade agreements such as that with South Korea (Leuck, McKinnon, Hitt et al., 2007). As many of these provisions already applied under Annex 2C and Chapter 17 of the AUSFTA, a future Australian government perceiving their adverse impact, could well seek to challenge their continued application in trade agreement dispute resolution proceedings.

Covert Construction: Overview of AUSFTA Dispute Resolution

The PBS, as a well-established item of Australian public health policy with an impeccable democratic pedigree, represented a relatively novel inclusion in a free trade agreement (Irwin, 2006 [2005 in bib?]). In such circumstances, an Australian Government is entitled to require that any alleged AUSFTA-required alterations to PBS operations be explicit and detailed and be debated in a transparent and accountable manner in conformity with mechanisms that generally characterise the construction of health policy development in a parliamentary democracy. The Canadian Government, for example, ensured that its own universalist public healthcare system and policies were specifically excluded from most substantive obligations to
the US under the North American Free Trade Agreement (NAFTA) (Schwartz, 1997).

AUSFTA Chapter 21 outlines a process for the resolution of disputes, which the Australian chief negotiator of the AUSFTA stated that he regarded as little different in substance to that applying in other WTO and bilateral trade agreements (Deady, 2004). In general terms, it requires that the parties initially attempt to resolve a dispute through consultations initiated by delivering written notification to the other Party’s designated office (AUSFTA, art 21.5). If these initial consultations do not resolve the matter within 60 days, it may be referred by the same written notification process to the Joint Committee supervising implementation of the AUSFTA, composed of government officials of each Party (AUSFTA, art 21.2.1(c) and art 21.6). If the Joint Committee has not resolved the dispute within 60 days of that notification, the complaining Party, by like written notification, may refer it to a dispute settlement panel (AUSFTA, art 21.7.1).

Article 21.7 describes the establishment of such an AUSFTA dispute settlement panel. Each Party is to appoint one panellist, in consultation with the other Party (AUSFTA, art 21.7.3 (b)). The third member (the Chair) is to be selected by agreement of the Parties, or, failing that, by lot from amongst a contingent list of 10 individuals established by the Parties before the entry into force of the AUSFTA (AUSFTA, art 21.7.3(c) and (d)). The criteria for selection of panellists, outlined in art 21.7.5, specify “objectivity, reliability, and sound judgment” with “expertise or experience in law, international trade, or the resolution of disputes arising under international trade agreements”. Such panellists must also be “independent of, and not be affiliated with or take instructions from, either Party and not have a conflict of interest or appearance thereof, as set forth in a code of conduct to be established by the Joint Committee” (AUSFTA, art 21.7.5(c) and (d)). The identity of the panellists on the contingent list has not been made public. The AUSFTA provisions regarding the appointment of panel members resemble, but are not identical to, those found in the NAFTA and the Dispute Settlement Understanding (DSU) of the WTO.

Under NAFTA, on the other hand, ad hoc Panels comprise five members and are chosen on a reverse selection process by
the Parties (a disputing Party selects citizens of the other or another disputing Party, rather than its own citizens). There is no appeals process. Only federal governments have standing. Under the WTO DSU, ad hoc Panels of three (or by agreement five) are chosen by the Director General of the WTO in consultation with the Parties. Panel decisions may be appealed. Only federal governments have standing. Under the WTO DSU, panellists are usually non-Party members of WTO delegations or academics and not nationals of the Parties, unless by specific agreement (WTO, 2003, Dispute Settlement Understanding, art 8.3). They are generally expected to have expertise relevant to the dispute (Palmeter and Mayroidis, 2004).

If the determinations and recommendations of the AUSFTA dispute resolution panel are not implemented within 45 days, negotiations about mutually acceptable compensation shall commence (AUSFTA, art 21.11.1). If, after another 30 days, such agreement is not reached, the complaining party may supply written notice that it intends to suspend benefits under the AUSFTA (not necessarily in the same area as that of the dispute) (AUSFTA, art 21.11.2). If the other Party considers that the level of suspended benefits is manifestly excessive, or that it has, in fact, “eliminated the non-conformity or the nullification or impairment that the panel has found” it may request the panel be reconvened (AUSFTA, art 21.11.3). If the complained-of party decides it does not wish to suffer any suspension of benefits, it may pay an annual monetary assessment to the complaining party (AUSFTA, art 21.11.5). Thus, a major structural difference between the AUSFTA and WTO dispute settlement processes is that the AUSFTA does not have a mechanism of appeal from the report of a dispute resolution panel.

A brief examination of the dispute resolution experience under NAFTA suggests that the process of appointing panel members can be protracted and susceptible to diplomatic pressure (Hansen, 2003). In the 10 years between the ratification of NAFTA in 1993 and 2003, the NAFTA countries were unable to fully agree on the roster of pre-approved panelists (Hansen, 2003). In the first two disputes to require the establishment of a panel under the NAFTA, the process of selecting a panel chair took six months (Agricultural Products Tarification (US v Canada) and Safeguards on Brooms (Mexico v US); see Gantz,
Law professors seem to dominate amongst persons chosen to be NAFTA panelists. If a dispute concerned medicines policy, it is reasonable to assume that such persons would also have expertise in relevant health policy (Gantz, 1999).

If an aspect of Australian domestic medicines policy becomes unacceptable and pressure for change is applied through mechanisms in the AUSFTA, then any Australian opposition in resultant consultations and panel decisions, will rely on interpretive provisions of the *Vienna Convention on the Law of Treaties* (VCLT).¹

General principles of international law will *prima facie* apply to interpretation of such AUSFTA medicines provisions, as they do to all bilateral treaties and WTO agreements (Jennings and Watts, 1996; WTO Appellate Body, 1996). Article 21.9.2 of the AUSFTA clarifies this in a particular respect, by providing:

> The panel shall consider this Agreement in accordance with applicable rules of interpretation under international law as reflected in Articles 31 and 32 of the *Vienna Convention on the Law of Treaties* (1969). It shall base its report on the relevant provisions of the Agreement and the submissions and arguments of the Parties. The panel may, at the request of the Parties, make recommendations for the resolution of the dispute.

Articles 31 and 32 of the VCLT establish the requirements of good faith treaty interpretation and use of supplementary materials in that task.

There is a textual link to the VCLT in Art 3.2 of the DSU. Article 31 of the VCLT essentially outlines a rule-based approach to interpretation, giving primacy to the intent objectively expressed in the treaty (Lennard, 2002). In past WTO dispute resolution cases, the US has attempted to argue that the requirement in art 31 to interpret a treaty in good faith includes an obligation to protect the legitimate expectations of the parties as covered by an NVNB (non-violation nullification of benefits) provision (WTO Appellate Body, 1998a). This position has been rejected by multiple WTO Appellate Body decisions (WTO Appellate Body, 1998a; WTO Appellate Body, 1998b).

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Subparagraph (c) of AUSFTA art 21.2 establishes the potential application of a non-violation nullification of benefits (NVNB) claim to unambiguous and clearly defined obligations in Annex 2C (Chapter 2) and Chapter 17 (intellectual property) of the AUSFTA. It is now well accepted under international trade law, that NVNB claims are concerned with enforcing clearly defined, explicit and unambiguous promises or concessions made during good faith negotiations to secure treaty provisions, not with interpreting constructive ambiguities (deliberately vague textual outcomes of negotiating truces) in their final documentary expression (WTO Appellate Body, 2000). To otherwise allow allegations of the “legitimate expectations” by one party to reshape the meaning of a treaty provision is inconsistent with the requirement of good faith and objectivity contained in art 31 of the VCLT and would create considerable commercial and government uncertainty in international trade relations (WTO Appellate Body, 1998b; Cameron and Gray, 2001).

Article 32 of the VCLT provides that to confirm a textual interpretation under art 31, or to resolve an interpretation that is ambiguous, obscure, manifestly absurd or unreasonable, “supplementary means of interpretation” may be considered. Such “supplementary means” have been given a very broad meaning (Sinclair, 1984).

Article 31.3(c) of the VCLT provides that for the purposes of interpreting the text of a treaty, any relevant rules of international law applicable in the relations between the parties must also be taken into account. Thus, the VCLT specifically imports the principles of treaty interpretation that exist in customary international law.

The Appellate Body in EC – Measures Concerning Meat and Meat Products (Hormones) for example held that it could not be assumed that sovereign States intended to impose upon themselves a more onerous obligation, rather than the less burdensome one that least interferes with a state’s territorial supremacy over well established domestic policy (WTO Appellate Body, 1998c). This is not a universally held view. However, an interpretation of the AUSFTA text that allows a Party to apply democratically endorsed public health policy concerning medicines is *prima facie*, in the absence of strong
contrary evidence, to be preferred over an interpretation inhibiting such national sovereignty.

Another important source of structural pressure on the impact of the AUSFTA on Australian domestic medicines policy may be the WTO Declaration on the TRIPS Agreement and Public Health (Doha Declaration). US trade negotiators had a legal obligation to ensure that respect for the Doha Declaration was a “principal negotiating objective” (Trade Authority Promotion Act (US) Pub L No 107-210; 19 USC § 3802 (b)(4)(C)). This being the case, Australia is entitled to a legitimate expectation (for the purposes of an NVNB claim under AUSFTA art 21.2 (c)) that any benefits flowing from the Doha Declaration were included as an important context of the TRIPS affirming provisions in Ch 17 of the AUSFTA (AUSFTA, art 17.1.3).

At the WTO Ministerial meeting in Hong Kong at the end of 2005, the so-called paragraph 6 solution to art 31(f) of TRIPS for countries with low domestic manufacturing capacity, was agreed to be incorporated into an amendment to the TRIPS agreement in such a way that it could not be derogated from in an FTA (WTO, 2005). Where the AUSFTA text attempted to restrict this obligation, a WTO-based cause of action on the part other affected member would arise (Abbott, 2005). This TRIPS amendment would constitute important subsequent practice involving the formal agreement of both Australia and the US.

**Potential AUSFTA Health Policy Disputes**

We will now analyse some of the most likely areas in which Australian government utilisation of AUSFTA dispute resolution proceedings may lead to push-back against AUSFTA-related off-shore reconstructions of Australian medicines policy.

**Independent PBAC review**

Prior to 2004, the patented pharmaceutical industry’s problems with the PBAC had manifested in two major failed appeals to the Australian Federal Court (*Pfizer Pty Ltd v Birkett* (2001) 112 FCR 305 and *GlaxoSmithKline Australia Pty Ltd v Anderson* [2003] FCA 617). One possible area of lobbying and dispute, given this
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background, may involve the review mechanism established to fulfil Australia’s obligations under AUSFTA Annex 2C.2 (f).

This Australian mechanism requires an independent expert to review existing evidence and report back to the PBAC. The US may see this has not done enough to create the required “independent review process”. If US lobbying proved unsuccessful and the matter resulted in an AUSFTA dispute, this would involve a fairly straightforward application of Articles 31 and 32 of the VCLT (under AUSFTA 21.9.2). Contextual evidence will suggest that Australia clearly did not intend to agree to any interpretation of the words “independent review process” that would allow a PBAC decision to be overturned. Before the special Senate roundtable on the PBS in the AUSFTA Australia’s senior negotiator, Mr Deady stated (2004):

If this ever did come up – and I do not believe it would ever get to a dispute, but even if it did – the panel would look at the very structure of the agreement in this area. In fact we have a very specific commitment in Annex 2C which refers to this review mechanism. It is then elaborated in a side letter and narrowed by that side letter to identify that Australia in implementing this part of the agreement, will look at just negative findings. That is the extent of the language … There is no capacity for the US to challenge a particular ruling or decision of the review or of the PBAC. (Deady, 2004)

Reference pricing and “innovation”

Annex 2C.1, as mentioned, states two competing mechanisms for valuing pharmaceutical innovation as set out as subsidiary to the overarching and primary objective of “high quality health care and continued improvements in public health”.

The AUSFTA Medicines Working Group (MWG) met for the first time in Washington on 13 January 2006. Dr William R. Steiger, Special Assistant to the Secretary for International Affairs at the US Department of Health and Human Services, and Ms Jane Halton, Secretary of the Australian Department of Health and Ageing, chaired the meeting. The stated objective of the group was stated to be “to promote discussion and mutual understanding of issues related to the importance of innovation and pharmaceutical research and development to continued improvement of healthcare outcomes in both countries” (US
Department of Health and Human Services, 2006). No minutes were published, but a freedom of information Act application revealed that a document proposing a blueprint for reforming the PBS so that innovator drugs were less easily reference priced against generics was discussed (Faunce, 2007). The MWG also met in April 2007 and discussed the new F1-F2 PBS legislative which substantially implemented the US agenda against reference pricing by limiting it between innovator and generic classes of medications (Faunce, 2007). A related policy has controversially placed Medicines Australia (along with the Department of Health and Ageing) in charge of fine tuning the new policy on innovative medicines.

The litmus test as to whether the AUSFTA MWG has become a new, off-shore means of constructing Australian health policy may be whether the USTR decides to challenge in AUSFTA dispute resolution proceedings (as not valuing pharmaceutical “innovation” on the US “competitive markets” test), any subsequent Australian federal legislation abolishing the new F1 PBS category.

The crucial issue may become how to comprehensively and precisely define pharmaceutical “innovation” in the AUSFTA, given that there is no express definition in Annex 2C, indeed, the ambiguity resulting from different positions by the US and Australia is here inherent and deliberate (Lopert, 2004).

Textually, the principles in Annex 2C.1, are presented as subsidiary to the overarching aim of pursuing the objectives of “high quality health care and continued improvements in public health”. Annex 2C.1(c) links innovation to timely and “affordable” access. Annex 2C.1(d) specifically provides for the alternative of valuing innovation through the adoption of procedures that assess a pharmaceutical’s “objectively demonstrated therapeutic significance”. Another important point is that Annex 2C.1, unlike Annex 2C.2, does not specifically refer to the PBS and so Australia is not obligated to make changes to the PBS to recognise pharmaceutical innovation, but can do so through a variety of other, extra-PBS schemes, perhaps expanding or developing creatively on those already existing.

In the absence of a clear and explicit definition of “innovation” in Annex 2C.1, the NVNB provision cannot apply
to any related obligation, as to do so would fundamentally undermine good faith treaty interpretation and consequently certainty in international trade relations.

AUSFTA art 21.9.2 (incorporating arts 31 and 32 of the VCLT) “supplementary means” of interpretation in this context could conceivably include particular statements by senior government officials during the negotiations, before a Senate Committee on the issue, at the signing of the agreement, or during the passage of the implementing legislation through each parties’ legislature (second reading speeches and explanatory memoranda or the text of the legislation itself). Statements made during the AUSFTA MWG meetings are unlikely to be accorded the status of such “supplementary means” as this body has no official role in interpreting the AUSFTA text or constructing medicines policy in either nation (Deady, 2004). Media statements by key government officials in response to specific developments concerning medicines policy under the AUSFTA could also be relevant. An important aspect here is the absence of any objection by the US to the omission from the Australian implementing legislation of any amendment changing the cost-effectiveness criterion in the National Health Act 1953 (Cth).

**Linkage evergreening**

Article 17.10.4 of the AUSFTA is the “linkage evergreening” provision, so-called because it requires a link for the first time in Australia the marketing approval regulatory process for pharmaceuticals (on clinical quality, safety and efficacy grounds), with their patent status. This linkage is analogous to the Hatch-Waxman legislation introduced in the US in the 1980s in an attempt to encourage the entry of generics into the market, and that introduced to Canada under NAFTA in 1994 (United States Federal Trade Commission, 2002; Office of Patented Medicines and Liaison, Health Canada, 2004). The effect in either case was to provide patent holders with a mechanism for using the judicial system to extend the life of their patent (Faunce and Lexchin, 2007). Article 17.10.4(a) of the AUSFTA was designed to have this effect because its obligation is to “prevent” generic manufacturers from obtaining marketing
approval for a pharmaceutical whenever a patent is “claimed”. The provision does not define either “prevent” or “claimed”. In addition, AUSFTA 17.10.4(b) requires that the patent holder be notified of any generic marketing approval application.

To fulfill the obligation created by this provision of the AUSFTA, Australia had to enact amendments to the *Therapeutic Goods Act 1989* (Cth). The amendments inserted a new s 26B which requires applicants for marketing approval to certify that their product will not infringe a valid patent claim or that the patent holder has been notified of the application.

However, after vigorous public debate, the implementing legislation went further and also introduced a new s 26C which provides that where a certificate has been given under s 26B by a generic manufacturer and the patent holder wishes to claim a patent and institute infringement proceedings, the patent holder must first certify that the proceedings are being commenced in good faith, have reasonable prospects of success (as defined in s 26C(4)) and will be conducted without unreasonable delay. If the certificate is found to be false or misleading, fines of up to $10 million apply and the Commonwealth Attorney General is permitted to join the action to recoup losses to the PBS. Section 26D provides that a patent holder who seeks an interlocutory injunction to prevent the marketing of the generic pharmaceutical must obtain leave from the government to do. Sections 26C and 26D are the so-called “anti-evergreening” provisions designed to prevent patent holders from manipulating the court system to lengthen the term of the patent and delay the entry of generic pharmaceuticals into the market. They are a strong statement of Australia’s “legitimate expectations” on benefit (freedom from pharmaceutical price rises due to “evergreening”) in this area. As Australia’s chief AUSFTA negotiator stated before the special Senate roundtable on the PBS and the AUSFTA (Deady, 2004):

We are not importing the Hatch-Waxman legislation into Australian law as a result of the free trade agreement … [Article 17.10.4] … does not add or provide any additional rights to the patent holders in that process …

The US, nevertheless, has expressly signalled their disapproval of Australia’s implementation of art 17.10.4 in an exchange of letters between the Australian Minister for Trade and the USTR
on the implementation of the AUSFTA, in which the USTR stated (Zoellick, 2004):

If Australia’s law is not sufficient to prevent the marketing of a product, or a product for an approved use, where the produce or use is covered by a patent, Australia will have acted inconsistently with the Agreement. We will be monitoring the matter closely, and reserve all rights and remedies as discussed below.

We also remain concerned about recent amendments to sections 26B(1)(a), 26C and 26D of the Therapeutic Goods Act of 1989. Under these amendments, pharmaceutical patents owners risk incurring significant penalties when they seek to enforce their patent rights. These provisions impose a potentially significant, unjustifiable, and discriminatory burden on the enjoyment of patent rights, specifically on owners of pharmaceutical patents. I urge the Australian Government to review this matter, particularly in light of Australia’s international legal obligations. The United States reserves its rights to challenge the consistency of these amendments with such obligations.

This is a clear statement of US intent to challenge Australia’s implementing legislation. Yet such interpretations of the relevant AUSFTA obligations will be contradicted by recent supplementary materials such as any statement of the USTR permitting nations to have greater “flexibilities” in implementing such provisions.

Conclusion

The PBS, through its unquestioned democratic legitimacy in mode of development and its evidence-based best practice and fiscal significance, would qualify as an important item of domestic health policy under most rule-of-law based approaches to construction of health policy (Hart, 1997; Schauer, 1991; Sartorius, 1987; MacCormick and Weinberger, 1986). Yet, as the Sutherland Report of the WTO notes: “there is clearly a political dynamic towards establishing the means of pursuing non-trade, geo-political objectives through offering the carrot of preferential trade deals” (Sutherland, 2005).

It may ultimately be in AUSFTA dispute resolution proceedings that the proposition is finally tested as to whether trade law departments of corporate multinationals, the USTR
and MWG primarily have become profit constructing centres at the expense of the Australian public and its health (Hoekman and Newfarmer, 2005).

While ambiguities in controversial areas of the trade agreement may allow the negotiating process to move forward, eventually the obligations contained in the agreement must be defined. Ultimately, if the world trading system wishes to be seen as being committed to constructing a world trading order sustainable because of its manifest linkage with fundamental social virtues (such as justice and equality and those expressed in the international human rights agenda), it needs to resolve the problems surrounding the use of bilateral trade agreements to drive changes in domestic health policy, particularly by using NVNB provisions and constructive ambiguities to facilitate lobbying of Australian government health officials by private interest groups such as Medicines Australia and through extra-parliamentary, non-transparent and non-accountable agencies such as the AUSFTA MWG.