

PBS in the Shadow of USFTA Dispute Mechanism

Dr Thomas Faunce, Senior Lecturer ANU Medical School
Lecturer ANU Law Faculty

Professor Peter Drahos, RegNet ANU.

Soon after the release of the free trade agreement (FTA) between Australia and the US, members of the US Congress congratulated the US Trade Representative Bob Zoellick on securing a deal that made Australians pay a greater proportion of research and development (R&D) costs for US drugs. Meanwhile, Australian negotiators were assuring the public that no fundamental changes had been made to the Pharmaceutical Benefits Scheme (PBS) and its capacity to ensure that essential medicines remain affordable. So who was right?

In any trade negotiation there will be intractable issues arising from conflicts between the respective domestic interest groups. To resolve these, negotiators customarily agree to items of text that are 'constructively ambiguous'. This is a well-known technique and allows both sides to claim victory.

Eventually, of course, these constructive textual ambiguities have to be sorted out. In the case of the US-Australia FTA, this may involve resort to the dispute settlement chapter, which has received little attention to date. Under chapter 21 the fate of Australia's PBS could be decided by a three person trade panel (one nominated by the US, one by Australia and the third jointly agreed), composed of experts with a background in international trade and intellectual property law.

Should we risk exposing the PBS to the nuances of such a dispute resolution process, especially against an experienced and well-resourced opponent such as the US? To illustrate the problem, let's consider the possible resolution of some constructive ambiguities in Annex 2-C, the Annex in the FTA that deals with pharmaceuticals.

Imagine that in five years time an “innovative” US drug with high R&D costs is rejected for PBS listing. The drug’s manufacturer wants this decision reviewed. The FTA specifies an ‘independent review process’ for decisions that relate to the listing of new pharmaceuticals or their reimbursement. The meaning of “independent review” is undefined. Currently, decisions of the Pharmaceutical Benefits Advisory Committee (PBAC) may be appealed in the Federal Court, though recent attempts by pharmaceutical companies have there proved unsuccessful. Assume that the “review process” eventually established under the FTA (probably by its Medicines Working Group) allows for drug manufacturers as applicants, but not bodies such as the Public Health Association of Australia, or the Australian Consumer’s Association. Assume also that Australian representatives have made sure it cannot overturn a PBAC decision. The US, however, buoyed by recommendations from the committee monitoring the FTA, now claims this “review mechanism” is inadequate. It threatens and then moves to invoke the dispute resolution mechanism.

Article 1 of the FTA’s Pharmaceutical Annex outlines ‘agreed principles’ utilized by the dispute panel in interpreting the text. These emphasize “innovation”, the importance of R&D and “competitive markets.” Missing, however, is an unambiguous and unqualified statement of Australia’s right to make a priority of “protecting public health” and, in particular, facilitating “access to medicines for all.” These are the words that public health groups fought for and won in the WTO’s *Doha Declaration* under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), but which the US is now circumventing through more restrictive bilateral FTAs.

A case that illustrates the likely outcome is the litigation between India and the US over India’s obligation under TRIPS to create a temporary “mailbox” system for pharmaceutical patents before it moved to full protection in 2005. The need for cheap generic drugs to aid the health of its vast population makes pharmaceutical patents a deeply controversial issue in India. Indian negotiators had made sure the provision contained a constructive ambiguity. The US, however, disputed the adequacy of India’s implementation. The US took the matter to WTO dispute resolution and prevailed.

The overall US threat is that if this FTA panel decides that Australia is in breach of its obligations, then chapter 21 permits a “suspension of benefits” or “cross-

retaliation” in other trade areas such as beef, or lamb, or manufacturing. In order to prevent this, the party found to be non-compliant may have to pay large amounts of monetary compensation.

The large US pharmaceutical industry argues that the agreement will make innovative medicines more readily available in Australia. Yet, does mere incremental improvement of drugs in existing lucrative developed nation disease markets truly constitute innovation? Responding to innovation has never been a basic principle of our PBS. Instead, of utmost importance has been the capacity of drugs to offer significant therapeutic gain to the whole community at a reasonable price. The PBS represents world’s best practice on access to medicines. If our PBS remains part of this FTA the PBAC will have to work in the shadow of US trade enforcement tools and its fundamental principles may be irrevocably altered.