Challenges to Australia's national health policy from trade and investment agreements

Recent federal trade policy commitments could protect Australia's tobacco control legislation and the Pharmaceutical Benefits Scheme in the Trans-Pacific Partnership Agreement negotiations

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In its Trade Policy Statement of April 2011, the Australian Government committed to "preserve the right of Australian governments to make laws in important public policy areas" and to reject provisions in trade agreements that could "limit its capacity to put health warnings or plain packaging requirements on tobacco products or its ability to continue the Pharmaceutical Benefits Scheme".[1] One forum in which this resolve is likely to be tested is the Trans-Pacific Partnership Agreement (TPPA) negotiations. The TPPA is a proposed regional free trade agreement between Australia, Brunei, Chile, Malaysia, Peru, Singapore, New Zealand, the United States and Vietnam — a diverse assortment of countries from several continents around the Pacific rim. The TPPA differs from existing bilateral and regional free trade agreements in its sheer size and geographic diversity. It has the potential to restrict national policy space — "the freedom, scope and mechanisms that governments have to choose, design and implement public policies to fulfil their aims"[2] — on an unprecedented scale.

This article explores the potential for the TPPA to constrain Australia's national health policy space through two illustrative case studies: tobacco plain packaging and the Pharmaceutical Benefits Scheme (PBS).

Investor–state dispute settlement and plain packaging of tobacco products

During 2011, the Australian Government introduced legislation requiring tobacco products to be packaged in plain paper (with graphic health warnings, but minimal branding). This represents an important assault on one of the last bastions of tobacco marketing — the appeal to personal identity.[3] Strong tobacco control policies such as Australia's tobacco plain packaging laws are consistent with a substantial body of scientific literature and the World Health Organization's Framework Convention on Tobacco Control, but they can be challenged under international trade and investment agreements, which are driven by economic rather than public health goals.

Philip Morris Asia (PMA) — a subsidiary of Philip Morris International (PMI) — has launched an investor–state dispute against the Australian Government over its tobacco plain packaging legislation. While several tobacco companies have taken their complaints to the High Court, PMA has also been able to pursue its case in international arbitration (where it has a greater chance of success) through an investor–state dispute settlement (ISDS) clause in a bilateral investment treaty signed between Australia and Hong Kong in the early 1990s. This is the second investor–state dispute to arise over tobacco labelling; PMI is bringing a similar case against Uruguay through a Swiss subsidiary.[4] PMI has also been prominent in calling for an ISDS provision in the TPPA.[4,5]

Ironically, the corporate restructuring that has allowed PMI to access the Hong Kong bilateral investment treaty (PMA was made the sole shareholder in Philip Morris Australia in February 2011) has also significantly weakened its claims. This is because the investment was made with the company's full knowledge that the plain packaging legislation was being developed.[6] The government has a strong case. Nevertheless, the dispute with PMA highlights broader problems of including ISDS provisions in trade treaties, and demonstrates why it is important that they be excluded from the TPPA.

The arbitration rules that govern PMA's dispute with the Australian Government are those of the United Nations Commission on International Trade Law. The case will be decided by a tribunal made up of three members: one chosen by PMA, one chosen by Australia, and a third, mutually agreed upon, which will act as president. This method of appointing arbitrators has been described as neither independent nor impartial.[7] In sharp contrast to domestic forms of adjudication, individuals can serve as a legal representative in one ISDS case and an arbitrator in another, further undermining their ability to act without bias. Furthermore, although the arbitrators will be experts in international investment law, they may have little or no experience with specific fields of public policy such as tobacco control.

While the public has a stake in investor–state disputes, confidentiality is a dominant principle in investment arbitration. Hearings are rarely opened to the public unless both parties agree, and investors have opted for closed hearings in several recent cases concerning public policy. In this regard, it is commendable that the Australian Government has adopted a high standard of transparency in advance of the commencement of formal proceedings by posting PMA's claims and their response on a public website.[8]

The arbitration will be expensive for Australian taxpayers, although the government may be able to recoup some

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1 Leaked United States demands for changes to schemes such as Australia's Pharmaceutical Benefits Scheme

- Pharmaceutical Benefits Advisory Committee (PBAC) recommendations to be based on competitively derived market forces or systems that appropriately value patented pharmaceuticals (no mention of "objectively derived therapeutic significance" as in the Australia–United States Free Trade Agreement)
- Appeals process able to challenge PBAC recommendations
- Heightened capacity for direct-to-patient pharmaceutical advertising ◆

of the costs if it prevails. In several investor–state disputes to date, legal fees alone have amounted to over US$4 million and in one case have exceeded US$13 million.[9] There are also arbitrator's fees, administration fees and additional costs for involving experts and witnesses. Even more significant are the awards in investor–state cases, which are widely enforceable.[7] The Czech Republic was obliged to pay more than US$350 million in compensation to a Dutch investor, which according to one report meant a near doubling of the country's public sector deficit.[10]

It can readily be seen how insertion of a TPPA ISDS mechanism into Australia's national health policy space might skew legislation away from the public interest towards supranational corporate interests. This is why it is significant that the government has vowed to no longer include provisions on ISDS in the bilateral and regional trade agreements that it signs.[1]

Australia's refusal to consent to ISDS in the TPPA is a significant step towards limiting the encroachment of international trade agreements into our national health policy space and retaining our sovereign right to regulate significant areas of public health policy.

US proposals for medicines policy in the TPPA

Challenges to Pharmaceutical Benefits Advisory Committee processes

The PBS is another area of domestic health policy that the Australian Government has committed to protect in international trade agreements. However, US TPPA negotiators are seeking substantial changes to Australia's laws and administrative processes. Certain draft TPPA provisions relate to the PBS directly and also indirectly, by seeking to prolong pharmaceutical patents and minimise exceptions to them made in the public interest. We examine these proposals as another instance of how the TPPA may promote incursions into our national health policy space.

In October 2011, a draft annex to the transparency chapter of the TPPA was leaked.[11] Under the rubric of transparency and procedural fairness, this TPPA annex seeks to impose new restrictions on the operation of national pharmaceutical reimbursement and pricing schemes (Box 1). It is an annex because it is not designed to apply to the US, as it would if it was in the body of the treaty.

Clause (d) of paragraph X.3 of the draft annex would require countries to reimburse pharmaceutical companies based on "competitive market-derived prices in the Party's territory", or other benchmarks that "appropriately recognize the value" of the patented product. This wording represents a shift away from the more science-based standard in Annex 2-C of the Australia–United States Free Trade Agreement (AUSFTA), which refers to the "objectively demonstrated therapeutic significance" of the new patented pharmaceutical (http://www.dfat.gov.au/fta/ausfta/final-text). This provision includes no mechanism for proving that prices are derived from "competitive" markets. It undermines the world-class science-based mechanisms used by the Pharmaceutical Benefits Advisory Committee (PBAC) to determine whether a new patented medicine has sufficient health innovation to be listed on the PBS (based on a determination of cost-effectiveness, as well as efficacy, quality and safety).

Paragraph X.3 of the draft annex seeks to impose a new independent appeals process on determinations by government bodies such as the PBAC (Box 1). This is contrary to what was decided (after prolonged and acrimonious negotiations) under Annex 2-C of the AUSFTA, which only provides for independent expert review as a quality improvement exercise for the PBAC. The threat and the use of an independent appeals process would increase the capacity of the pharmaceutical industry to lobby against PBAC decisions and undercut their expert-informed determinations.

Paragraph X.4 of the draft annex requires parties to permit pharmaceutical companies to disseminate information to health professionals and consumers via the internet — a practice that is not permitted for prescription drugs in Australia due to concerns about overprescribing. This is also contrary to Annex 2-C of the AUSFTA, which makes the direct advertising of pharmaceuticals subject to Australia's domestic laws, regulations and procedures. There is a consensus against such advertising in the Australian national policy space, chiefly because of its capacity to increase lobbying of the medical profession for purposes of corporate gain rather than public health benefit.

While the effect of US TPPA proposals on Australia's PBS would be economically damaging and reduce the affordability of medicines in Australia, the effects on access to medicines in other TPPA countries could be far more severe, particularly for developing countries and those required to make greater changes to their domestic laws.[12]

Extending intellectual property rights

US TPPA proposals on intellectual property applying to patents[13,14] (Box 2) would also add to the cost of medicines overall, affecting the sustainability of the PBS. Non-government organisations have undertaken extensive analyses of these proposed provisions,[12,15] and have shown areas where TPPA provisions extend patent protection

2 Some United States proposals for extensions to intellectual property rights applying to patents

- Patent protection for new forms of existing drugs
- Patenting of diagnostic, therapeutic and surgical methods
- Elimination of pre-grant opposition
- Extensions to data-exclusivity periods for some drugs ◆

beyond comparable AUSFTA patent provisions and existing Australian law.[15]

For example, proposed article 8.1 of the intellectual property (IP) chapter of the TPPA provides patent protection for new forms, uses or methods of using a known product, whereas article 17.9.1 of the AUSFTA does not require patent protection to be provided for new forms of existing drugs.[15] Although, in practice, new forms are sometimes patented, the TPPA proposals would restrict efforts to tighten patenting standards in future.

Proposed IP article 8.2 requires patenting of diagnostic, therapeutic and surgical methods, whereas article 17.9.2 of the AUSFTA allows for its exclusion.[15] This change could restrict expeditious patient access to new clinical developments and substantially add to health care costs. Proposed IP article 8.7 would also eliminate pre-grant opposition to patent applications by third parties, a safeguard provided for in the Australian *Patents Act 1990*, which is designed to prevent unwarranted patents from being granted.[15]

Most concerning are the provisions for data exclusivity periods — where generic manufacturers cannot use clinical trial data to prepare and register their products for springboarding after patent expiry. Proposed IP article 9.2[14] provides an additional 3 years of data exclusivity for new uses of existing pharmaceutical products, on top of the 5 years of data exclusivity already permitted under article 17.10.1 of the AUSFTA. There is also a placeholder for specific provisions for biologics (medicines produced from biological products, which are not currently dealt with separately in Australia). US pharmaceutical companies are reportedly lobbying for 12 years of data exclusivity for biologics. If adopted, these proposals would lead to higher costs to the PBS (as drugs stay under patent for longer periods) and delayed entry of cheaper generic medicines into the market.

The US TPPA proposals for extended intellectual property rights and data exclusivity for pharmaceutical companies would require changes to Australian laws and administrative processes. They would also conflict with the spirit of the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011, which is currently before the Senate and seeks to raise patent standards and facilitate faster regulatory approval for generic medicines.

Conclusion

Recent Australian trade policy commitments to exclude ISDS and provisions that would affect the PBS from the TPPA are a positive step towards preserving sovereign, democratic and science-based control over our national health policy space. It is important that Australia continues to insist that future trade agreements, including the TPPA, do not extend the intellectual property privileges of patent holders, interfere with the operation of the PBS or provide foreign corporations with ISDS rights to challenge domestic public health policies.

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