

Negotiating FTAs and Public Health: The Australian Experience

Professor Peter Drahos

The Australian National University
Canberra, Australia

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- US-Australia FTA part of long term strategy.

US IP Bilateralism in Africa



US IP Bilateralism in Europe



US IP Bilateralism in Asia



US IP Bilateralism in Central America



Global Intellectual property ratchet based on a principle of minimum protection that permits more extensive protection.



Australia's Strategic Thinking

- TRIPS for AGRICULTURE
- Australian Pharmaceutical Benefits Scheme used to regulate price of patented medicines.

What happened After TRIPS?

- US continued to watchlist Aust.
- In 1998 Australia introduced
 - Patent Term Extension
 - Data Exclusivity

The FTA – 1 January 2005

- CHANGES
 - PBS reform – principle of innovation
 - Patent link to Drug Registration
 - Dispute Resolution
 - Stop Export under Patent Rule

- PBS reform – principle of innovation
- the important role played by **innovative** pharmaceutical products in delivering high quality health care;

- Will the insertion of the principle of innovation in FTA lead to a dismantling of reference pricing?
- Aust Generic industry strong supporter of reference pricing as it currently exists.

Patent link to Drug Registration Australia's Implementation

- TGA has 250 days in which to evaluate generic application

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Generic company lodges
s26B certificate of
compliance on patent
issue

- Section 26B certificate has to say either
 - 1. Generic company believes it is not violating a patent claim
 - 2. There is a patent and the Generic company has given notice of its marketing to the patent owner.

- Article 17.10.4 obliges Australia to have measures in its marketing approval process to PREVENT a generic company from marketing a product where that product is claimed in a patent.

Dispute Resolution

- WTO v FTA – where are developing countries better off?
- Availability of non-violation complaints under FTAs

Lock-in Effects of FTA

- Data Exclusivity
- Patent Term Extension
- Harmonization Obligation

Evergreening

- 'Patent issue is becoming exponentially more complex
- 'patents around patents'
- 'second generation evergreening'

Australia's Anti-evergreening provisions

- Section 26C – If the brand company wishes to sue generic company
 - (a) are to be commenced in good faith; and
 - (b) have reasonable prospects of success; and
 - (c) will be conducted without unreasonable delay.

- FALSE CERTIFICATE under s26C = FINE \$10 Million
- Commonwealth AG can join proceeding to recover losses to PBS.

Reaction of US



- 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. [28

- Effect of US trade strategy on Australian generic industry
- Effect on Australia and its region

Professor Peter Drahos

Director
Centre for Governance of Knowledge
and Development
Regulatory Institutions Network (RegNet)
The Australian National University, Canberra

peter.drahos@anu.edu.au

www.cgkd.anu.edu.au

