

Australia Passes US FTA with Amendments

On 13 August, the Australian Senate adopted implementing legislation for the free trade agreement it concluded with the US in February, but the treaty's entry into force depends on US acceptance of three amendments aimed at ensuring the availability of generic medicines in Australia.

The three amendments were pushed through by the opposition labour party whose support was necessary for the legislation to pass.

Brief Description of the Amendments

According to labour's description, the first amendment requires patent holding companies to issue a certificate when they seek to use the courts to block cheaper generic drugs coming to market. Patent companies must certify that the legal action has been commenced in "good faith, has reasonable prospects of success and will be conducted without unreasonable delay." If the certificate is false or misleading, or its undertakings are subsequently broken, the company can be fined up to AU\$10 million for each contravention. This provision seeks to balance the requirement that generic companies must certify the patent status of new drugs on the market.

The second amendment allows state authorities to recover costs incurred by the Pharmaceutical Benefits Scheme (PBS) and public hospitals due to a patent holder's legal action that "unreasonably delays" a generic drug coming onto the market. During the FTA negotiations, a large number of Australians were concerned about the FTA's impact on the PBS under which the government purchases about 90 percent of all prescription drugs in the country and sets subsidised prices for them. Australia eventually agreed to the establishment of a medical working group to address pricing issues, as well as the possibility for companies to appeal decisions against the inclusion of their products in the PBS list of drugs.

The third amendment reduces generic companies' burden of proof – from absolute to 'reasonable grounds' – when issuing a certificate regarding the patent status of a drug.

The labour party called these amendments "vital to safeguarding Australian consumers against evergreening practices and ensuring that affordable medicines are available in this country." Evergreening – or the extension of a patent on 'frivolous' grounds such as a negligible change – can delay the introduction of a generic version of the patented drug to the market.

TRIPs, FTA Incompatibility Raised

Some commentators have noted that the amendments may violate the WTO's Agreement on Trade-related Aspects of Intellectual Rights (TRIPs). For instance, the certification procedure only applies to pharmaceutical patents, whereas TRIPs Article 27.1 states that "patents shall be available and patent rights enjoyable *without discrimination as to the place of invention, the field of technology* and whether products are imported or locally produced" (editor's italics).

Others have pointed out possible inconsistency with the US-Australia FTA's provisions on the enforcement of intellectual property rights, which require the parties to ensure, *inter alia*, that right holders are not unreasonably deterred from legal recourse, as well as to "provide for a rebuttable presumption that the patent is valid."

US Stresses Right to Certify Australia's Legislation

The US-Australia FTA was easily passed by the US Congress in May, and President Bush signed implementing legislation on 3 August 2004. After the adoption of the three Australian amendments, the US Trade Representative released a statement emphasising that it was "Australia's obligation to implement the FTA in a manner consistent with both the terms of the FTA and international intellectual property agreements. We've made clear that the United States must certify that the implementation language fulfils the obligations under the FTA before the FTA can come into force. We reserve all our rights in this process. At no point have we expressed acceptance of the proposed legislation and/or amendments."

Asia Roundup

- **Australia – Thailand** On 5 July, Australia and Thailand signed a free trade agreement (TAFTA), which is to liberalise 95 percent of current bilateral trade by 2010. The agreement contains 19 chapters, including services, intellectual property, investment and competition policy. The two countries see the TAFTA as a stepping stone for a regional pact between Australia and the Association of South East Asian Nations (ASEAN). ASEAN has proposed starting negotiations with both Australia and New Zealand before the end of the year. Besides Thailand, ASEAN groups Indonesia, Vietnam, the Philippines, Brunei, Laos, Myanmar, Malaysia and Cambodia.

On 26 July 2004, Australia and Malaysia agreed to conduct parallel scoping studies on a bilateral FTA, to be completed in the first quarter of 2005. Australia and China also aim to conclude a joint FTA feasibility study by March 2005. An FTA with Singapore – Australia's first ever – entered into force last year.

- **Thailand – GMOs** On 24 August, Thailand revoked its three-year moratorium on the commercial planting and trading of genetically modified (GM) crops. Thai Prime Minister Thaksin Shinawatra said the decision was motivated by concern about "missing this scientific train and losing out in the world." GM crops will be allowed to grow in open field trials with non-GMO plants. Over the next three months, the National Biosafety Committee is to finalise new regulations on the growing, labelling and trade of GM products. The Ministry of Natural Resources and Environment will draft a comprehensive biosafety bill within the next year.

Agricultural industry representatives praised the move while environmental and organisations roundly condemned it. Monsanto said biotechnology could "bring enormous benefits to Thai farmers, environment and society", but Greenpeace Southeast Asia accused the government of "directly putting the Thai people and environment at risk."