

Appendix 4

The PBS and the Australia-US Free Trade Agreement

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Much of the debate over the Australia–US Free Trade Agreement (AUSFTA) centres on whether and how it will affect the Pharmaceutical Benefits Scheme (PBS).

This Research Note examines the parts of AUSFTA that have caused the most concern and assesses their likely impact on the PBS.

Changes to the PBS

One of the concerns about AUSFTA is that proposed changes to the PBS could lead to higher drug prices in Australia—a cost that would be borne by the government, at least initially, but perhaps also by consumers.

PBS costs, already high, are still growing. Since the early 1990s, the PBS has been growing at an average annual rate of 12.7 per cent¹. According to the 2004–05 Budget, average annual growth will fall to about 4 per cent over the next few years, but even at this rate the PBS is the fastest-growing area of Commonwealth health expenditure.²

So what aspects of AUSFTA could lead to further pressure on PBS costs? Before answering this question it is helpful to consider how the PBS currently works.

Listing new drugs

The current arrangements for listing a drug in the PBS are as follows (see figure 1):

- registration with the Therapeutic Goods Administration (TGA), which assesses drugs for quality, safety and efficacy
- assessment by the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the PBS.³ The Committee evaluates whether a drug is more therapeutically effective and/or cost-effective

than existing treatments. The evaluations are based partly on submissions by the drug's manufacturers, which include the price they would like to be paid

- once approved for PBS listing, the Pharmaceutical Benefits Pricing Authority recommends to the Department of Health what price to offer the drug's manufacturer. In doing so it relies on the Committee's advice
- if the drug's sponsor agrees on the government's price, the drug is added to the PBS. If not, the sponsor can return to the Committee or the Authority with further information, or introduce/keep the drug on the market without PBS listing.⁴

PBS listing and AUSFTA

AUSFTA introduces procedural changes to this system that give drug manufacturers more opportunities to press for their drugs to be listed on the PBS (see figure 1). The most controversial of these changes has been the review mechanism for decisions not to list a drug.⁵

Some fear the review process will reduce or remove Australia's control over the PBS listing process by overturning decisions made by the Committee.⁶

However, the text of AUSFTA only dictates that Australia institutes a review process; it does not specify that the review process be binding. In addition, AUSFTA does not change the Committee's legislative requirement to make decisions on the basis of therapeutic effectiveness and cost-effectiveness. So whatever form the review process takes, the Committee remains bound to these criteria. *If* new drugs are listed on the PBS as a result, it could be argued that consumers will be better off

because they will pay less for these medicines and have access to more effective drugs.⁷

Another concern is that, in addition to the review process, the increased advocacy opportunities AUSFTA affords drug companies—for example, through 'more frequent revisions' of the PBS 'where possible'⁸—will result in pressure on the Committee to list drugs, sometimes inappropriately.

A decision not to list a drug already places the Committee under pressure from a range of interests, including drug companies, medical specialists, patient support groups and the media.⁹ In the case of Celebrex, an arthritis drug, even the Health Minister entered the debate.¹⁰ Peter Drahos and colleagues, two of whom are former Committee members, argue that AUSFTA will make it more difficult for the Committee to resist these pressures and to continue to make decisions in the public's interest:

The PBAC members, although unable to publicly defend themselves, have had the advantage that they are the only independent authority that has fully examined the data. Now it will have another authority (the review panel) that has power (officially appointed) but no responsibility (it cannot legally list a drug on the PBS), which presumably will be unfettered in terms of the secrecy of its considerations and advice ... when its advice differs from the committee, this will be seized on by all of the vested interests, who will use the media to undermine integrity of the committee. The confidentiality provisions of the *National Health Act* will effectively prevent the committee from defending itself ...¹¹

There are transparency provisions in AUSFTA, but these are unlikely to assist the Committee to defend its decisions.¹² These provisions indicate that commercial-in-confidence considerations will continue to limit what the public is entitled to know about a decision, while the Committee is expected to continue providing applicants with ‘detailed’ information regarding its decisions.

A radical change?

AUSFTA does not directly undermine the rationale of the PBS, which is to ensure access to drugs based on their clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Both countries agree to recognise the value of innovative pharmaceuticals *either* through competitive markets *or* through procedures that value their therapeutic significance.¹³

This second option affirms the current principles guiding PBS listing in Australia.

AUSFTA does give drug companies more opportunities to exert influence at different points in the PBS listing process. It is not clear whether this will result in more drugs being listed on the PBS, or drugs being listed at a higher price, than would otherwise be the case.¹⁴

In Addition, it is not the case that either of these would result in a *direct* flow-on to prices for consumers—though increasing PBS costs are often used to justify increased co-payments.¹⁵

It could be argued that the danger in AUSFTA is the Committee’s independence and integrity could be undermined through the increased pressure to which it is likely to be subjected. The result might be poor policy decisions that further undermine the body and leave the government, taxpayers and, ultimately, consumers worse off.

Intellectual property changes and the PBS

Some commentators have been concerned that aspects of the intellectual property (IP) chapter of AUSFTA would lead to increased PBS costs.¹⁶ The concern is that provisions relating to patent law, principally Articles 17.9 and 17.10,

would delay the entry of generic drugs: those drugs made without the approval of the patent holder once the patent has reached its expiry date.

In a paper, produced before the text of AUSFTA had been agreed, the Australia Institute claimed that even a small delay in the entry of generic

drugs to market would create significant cost increases to the PBS.¹⁷ This is because the entry of a generic version of a drug significantly lowers the price the patent holder can demand for their version of the drug.

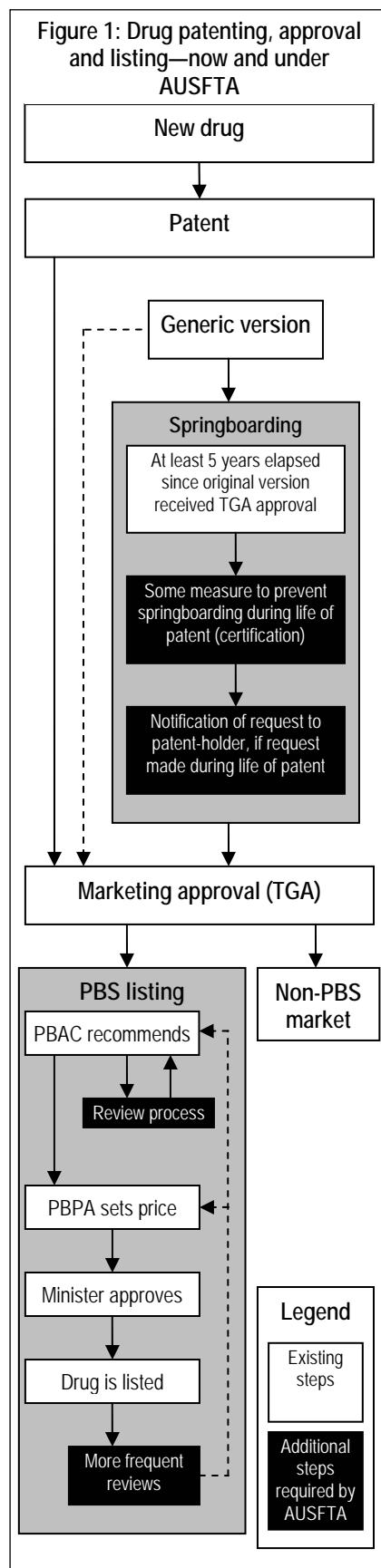
‘Springboarding’

AUSFTA requires Australia to make two subtle changes that will affect the practice of ‘springboarding’ generics.

Springboarding is a process that allows a generic drug to obtain approval from the TGA on the basis of test data proving the drug’s safety and efficacy already submitted by the patent holder. This allows the generic drug manufacturer to avoid duplicating much of the costly and time-consuming process of drug testing, resulting in a faster entry to market and cheaper drug prices. Under current rules, generics may not springboard during the first five years that the original drug has had marketing approval. This is known as the ‘data exclusivity’ period.

Currently, as long as the data exclusivity period has elapsed, the TGA is not concerned about intellectual property issues. This means that manufacturers of generic drugs may seek TGA approval even where a patent is still active. Once the TGA has approved the drug, it is up to the generic manufacturer to decide whether or not to enter the market while a patent is still alive. In most circumstances, generic manufacturers will have obtained TGA approval, organised production and distribution and be ready to enter the market as soon as the patent expires. In other circumstances, though, they might intend to dispute the validity of the patent or argue that theirs is a non-infringing use, in which case they might release the product and wait until the patent holder takes action. The ball is then in the patent holder’s court—it is up to them to sue the generic manufacturer for infringement.

The first change that AUSFTA requires is the introduction of some measure in the marketing approval process to prevent springboarding generics from entering the market during the life of a patent.¹⁸ The second change is that, if generic drug makers are allowed to request



approval to enter the market during the life of the patent, the patent holder must be notified of this and told the identity of the putative generic manufacturer (see figure 1).¹⁹

This requires the TGA to adopt a policing role, vetting applications on patent grounds rather than purely on safety and efficacy grounds. The US Free Trade Agreement Implementation Bill 2004 proposes that this be done through a certification scheme. Under this scheme, generic manufacturers would be required to certify to the TGA that they do not propose to market the drug in infringement of a patent or that they have notified the patent holder of their TGA application.²⁰

One difficulty is that 'infringement' is not always clear. For example, a patent may have expired on one use of the drug but not another, as new patents are filed for newly discovered uses. Similarly an active patent may not be valid because it does not fulfil one of the requirements for patentability, such as novelty or inventiveness. These are complex legal issues that only the courts can resolve.

Under the certification scheme, generic manufacturers would have three options before applying to springboard. They could:

- certify that they will not infringe, if they believe that to be the case
- apply for a court declaration to settle the uncertainty before certifying, or
- notify the patent holder of the application and certify to that effect.

Taking first option would risk a fine if the certification is later found to be false or misleading. However, it might be a safe option where the patent clearly has expired, or where other generics are on the market already.

Where the issue is particularly complex, the last two may be the only options. The second option involves the commencement of litigation. The third option allows the patent holder to consider litigation. In either case, litigation of these matters would happen

before rather than after the generic has entered the market. Currently, generic manufacturers have much more control over when any litigation takes place, with the option to enter the market first.

It is not clear that this shift, on its own, would make a significant difference in practice. A reduction in control over timing may have adverse consequences for generic manufacturers' litigation and business tactics. It may also increase the likelihood of early injunctions being ordered against generic manufacturers that delay their initial entry to market. The complexity of the scheme, costs of litigation and risk of penalties for false and misleading certification might theoretically deter generic manufacturers from entering a generic drug on the market. On the other hand, the regulatory and IP environment for generics is already complex, so the new scheme might be accepted as a relatively small technical change in an uncertain business. Overall, the effect of these subtle technical changes on the time it takes for generics to enter the market are difficult to predict.

'Evergreening'

A related concern is that these processes might encourage 'evergreening' as a tactic to delay generic entry.²¹ Evergreening involves filing 'new use' patents toward the end of the patent. When this happens, the patent on the old use expires as usual, but the patent for the new use arises and continues until its own expiry. This creates a complex situation in which generics may be sold for some uses of a drug but not for others.

Evergreening is already available under Australian law. But, given that new use patents can make determining infringement more difficult, thereby reducing the options available to generic manufacturers under the certification scheme, evergreening might become a more common practice used to deter generics from entering even the 'old use' market. Whether this occurs, and whether it is successful, will depend on whether the certification scheme significantly affects or constrains generic manufacturers in practice.

'Locking in' current law

A feature of the IP chapter that has not been much discussed in the debate on AUSFTA is the extent to which it confirms current law. As far as pharmaceutical patents are concerned, the IP chapter would, among other things, require Australia to keep its current laws regarding the data exclusivity period of five years, patent extensions to compensate for delays in TGA approval and the right to restrict parallel importing. In effect, AUSFTA 'locks in' these laws.

Thus, even where the chapter requires no changes to current law, it does constrain the ability of parliament to make changes in the future. Given the increasing operating costs of the PBS, these areas might have been reform options for future legislators.

The requirement to provide a right to restrict parallel importing is probably the most significant of these constraints.²² These rights allow patent holders to prevent products they have sold in one country being exported to another. For example, if parallel importing is allowed and drugs are sold wholesale cheaper in, say, China than in Australia, importers are able to import (legitimately purchased) drugs to Australia from China, resulting in a lower price of the drug for the PBS. Restrictions on parallel importing, on the other hand, allow drug companies and other IP holders to divide the world into several markets and sell their product at the most favourable price in each. As David Richardson of the Parliamentary Library has noted, effectively this is privatised protectionism.²³

Globally, parallel importing has developed into a significant issue. Least-developed countries have argued that restrictions on parallel importing make life-saving drugs too expensive for public health authorities to afford.²⁴ In the US itself, where drugs are sold at higher prices than in Canada, consumers in northern states are reported to be crossing the border in significant numbers to purchase drugs, performing their own small scale and illegal parallel importing.²⁵ There have been increasing calls in the US to reduce the exclusive rights of patent holders so that this

can be done legally and in commercial quantities.²⁶

AUSFTA requires that Australia maintain either:

- a system of 'national exhaustion', in which exclusive importation rights of the patent holder continue even after the product has been sold abroad, or
- (at least) the current system in which the patent holder may impose restrictions on the exportation of the product to Australia when it is sold in foreign countries.

Over the last two decades, parliament has been progressively allowing parallel importing of other forms of IP, such as copyright over music, books and computer software. Similarly, Australian patent law now provides that patent holders cannot place certain anti-competitive restrictions on the sale of products.²⁷

Given these trends, as well as escalating PBS costs and the competitive advantages that parallel importing may provide, it is reasonable to assume that future parliaments would consider changes to patent law that would void restrictions on parallel importing. AUSFTA would remove this as an option for pharmaceutical reform.

Endnotes

1. M. Rickard, '[How much will the PBS cost?](#)', *Research Note* no. 29, Parliamentary Library, Canberra, 2003–04. This figure takes into account only prescription drug costs.
2. *Budget Strategy and Outlook 2004–05*, 6–11. For the reasons behind this likely growth see M. Rickard, '[The Pharmaceutical Benefits Scheme: options for cost control](#)', *Current Issues Brief*, no. 2, Department of the Parliamentary Library, Canberra, 2001–02.
3. The Committee is appointed by the Minister for Health, its members are medical practitioners, pharmacists and health economists. Membership details can be found on the Department's web site.
4. It is in most sponsors' interests to successfully negotiate a price with the PBPA. That is because without government subsidy the drug will cost a lot more than its

listed counterparts. While this means higher profits to the manufacturer for each sale, it also probably means a lower volume of sales.

5. Department of Foreign Affairs and Trade, *Australia–United States FreeTrade agreement*, Final text of the Australia–United States free trade agreement signed in 2004, Department of Foreign Affairs and Trade, Canberra, 2004, Annex 2-C.2(f).
6. P. Drahos, T. Faunce, M. Goddard and D. Henry, '[The FTA and the PBS: a submission to the Senate Select Committee on the US–Australia Free Trade Agreement](#)', 2004.
7. Unless this results in such high PBS costs that it is unsustainable. See below for further qualification.
8. '[Exchange of letters on the PBS](#)' 3(b), *Australia–United States FreeTrade agreement*; see also Annex 2-C.2(c) for another provision aimed at securing more access.
9. See R. Moynihan et. al, 'Selling sickness', *British Medical Journal*, vol. 324, April 2002, pp. 886–891.
10. 'Drug's listing cost taxpayers millions', *The Age*, 2 February 2001.
11. Drahos et al., op. cit., p. 42.
12. See Annex 2-C.2 (d) and (e), *AUSFTA*.
13. Annex 2-C.1(d), *AUSFTA*.
14. As noted above, this is not necessarily a bad thing, at least for consumers.
15. A 28 per cent co-payment rise was proposed in the 2002–03 Federal Budget. On 25 June 2004 a rise of about 21 per cent was passed in the Senate.
16. For example, Drahos et al., op. cit.
17. B. Lokuge, T. Faunce, R. Dennis, *A backdoor to higher medicine prices: Intellectual property and the Australia–US Free Trade Agreement*, Australia Institute, Canberra, 2003.
18. Article 17.10.4(a), *AUSFTA*.
19. Article 17.10.4(b), *AUSFTA*.
20. US Free Trade Agreement Implementation Bill 2004, Schedule 7, Item 6.
21. See D. Ford, 'Submission to Joint Standing Committee on Treaties' Generic Medicines Industry Association Pty Ltd, 8 April 2004 <http://www.aph.gov.au/house/committee/jsct/usafra/subs/SUB83.pdf>.

22. Article 17.9.4, *AUSFTA* and s. 13 definition of 'exploit' in Schedule 1, *Patent Act 1990*.
23. D. Richardson, 'Intellectual Property and the Australia–US Free Trade Agreement', *Research Paper*, no. 14, Parliamentary Library, Canberra, 2003–2004, p. 12. <http://www.aph.gov.au/library/pubs/rp/2003-04/rp14.pdf>.
24. See Surya Subedi, 'The Road from Doha: the Issues for the Development Round of the WTO and the Future of International Trade', *International and Comparative Law Quarterly*, vol. 52, no. 2, 2003, p. 436.
25. 'Canada, Ho!', *The Economist*, 16 October 2003.
26. For example the Pharmaceutical Market Access Act of 2003, which was passed by the US House of Representatives and is now before the US Senate, would relax current restrictions on parallel importing of pharmaceuticals. In fact, according to newspaper reports from the United States, restrictions on parallel importing of drugs required by AUSFTA were cited as a key problem by members and senators who voted against the agreement in the US Congress: see E. Becker and R. Pear 'Trade Pact May Undercut Inexpensive Drug Imports' *New York Times*, 11 July 2004.
27. Section 144, *Patents Act*.

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