THE AUSTRALIA INSTITUTE

A backdoor to higher medicine prices?
Intellectual property and the Australia-US Free Trade Agreement

Dr Buddhima Lokuge
MBBS MPH

Dr Thomas Alured Faunce
BA LLB (Hons) B Med. PhD.
Lecturer ANU Law Faculty
Senior Lecturer ANU Medical School

Richard Denniss
Senior Research Fellow
The Australia Institute

November 2003

Table of Contents

Summary

The Australia-US Free Trade Agreement (FTA) has the potential to significantly undermine the effectiveness of the Pharmaceutical Benefits Scheme (PBS) and reduce the affordability of medicines in Australia. Both Australian and US negotiators have repeatedly claimed that 'the FTA will in no way affect the basic framework of the PBS' (Ives 2003). However, recent comments by Australian negotiators indicate that the USA is seeking changes to Australia's intellectual property (IP) laws, particularly as they relate to pharmaceuticals (Hansard 2003, p. 104). This paper explains how changes to the IP regime have the capacity to undermine the effectiveness of the PBS and lead to higher pharmaceutical costs in Australia.

In the USA, IP regulations such as those being discussed in the FTA, have led to the effective extension of pharmaceutical monopolies by delaying and preventing the entry of low cost "generics"[1] to the market. According to FUSA 'these delays have cost consumers and other health care payers millions of dollars' in America (FUSA 2002 p. 1).

Analysis of PBS data indicates that the prices of brand name (patented) drugs fall by an average of more than 30 per cent after patent expiration and the entry of generic medicines.[2] Delays to the arrival of generic pharmaceuticals will therefore significantly increase pharmaceutical expenditures in Australia over time. Additionally, these delays will weaken the PBS reference pricing system, a critical component of the 'PBS framework'. Reference pricing depends on the availability of low cost generic medicines within a therapeutic group to achieve pricing discounts. Reference pricing has little impact in therapeutic classes where generic competition does not exist.[3] Studies estimate that PBS pricing controls, particularly reference pricing, save Australia between $1 and 2.4 billion annually (Lokuge and Denniss 2003). Thus IP provisions in the FTA have the capacity to create upward pressure on co-payments and threaten the sustainability of the scheme in the long run.

This paper examines five leading medicines nearing the end of their patent lives in Australia. Based on PBS expenditures for these drugs in 2003, we estimated the potential cost of likely changes to IP provisions under the FTA to the PBS and Australian taxpayers. The costs accrue over a four-year period from 2006 to 2009. These findings are summarised in Table S1. The 'central case' estimate is that the additional cost of these five drugs alone, as a result of IP provisions in the FTA, will be more than $1.12 billion with a lower estimate of $850 million and an upper estimate of $1.56 billion.[4]

[1] Biologically equivalent versions of the original pharmaceutical. These are compounds over which patents have expired and are thus subject to competition for bioequivalent versions.
[2] See Section 2b.
[3] For a discussion see *Evaluation of the Pharmaceutical Industry Investment Program 2003*, Productivity Commission, (PC 2003, p.3.8)
[4] See Section 2, Table 1 for explanation of delay assumptions.

Table S1: Likely cost of an Australia-US FTA on five selected PBS medicines

Drug	Use	PBS expenditure in 2003 ($)	Patent expiration	Cost of FTA to the PBS ($) (2006-2009)
Zocor (simvastatin)	Lipid (Cholesterol) lowering agent	335,856,135	Jul-05	387,613,446
Lipitor (atorvastatin)	As above	374,917,136	Reference priced to Simvastatin	347,229,671
Pravachol (pravastatin)	As above	118,531,753	Reference priced to Simvastatin	122,545,749
Zoloft (sertraline)	Antidepressant	92,157,744	Oct-05	95,278,602
Fluticasone (Flixotide)	Asthma/CAL	168,804,501	Feb-06	165,330,480
Total for five medicines				**1,117,997,948**

In addition to threatening the sustainability of the PBS, IP reforms in the FTA will also have an impact on the price of over-the-counter (OTC) medicines. This is in contrast to direct changes to the PBS which would only affect Government subsidised medicines. Importantly these expenditures are paid entirely by patients without Government subsidies, concessional discounts or safety-nets. Therefore the additional OTC costs as a result of pharmaceutical IP provisions in the FTA will be directly borne by patients.

Table S2: Likely impact of Australia-US FTA on the price of Claratyne, an over the counter medication for allergies

Dose	Price in Australia in 2003	Expected price when patent expires in 2006	Cost to patients of inclusion of pharmaceutical IP in the FTA (per packet)
Claratyne 10mg (10 tablets)	$ 12.95	$ 7.77	$ 5.18
Claratyne 10mg (30 tablets)	$ 27.95	$ 16.77	$ 11.18

Notes: Based on observed decline in price of Claratyne in the US following the entry of generic competition after patent expiration (Wellmark 2003).

Despite the significant impact that pharmaceutical IP changes could have on the cost of medicines in Australia, it is clear that Australian negotiators are under significant pressure to make concessions in this regard. In fact, during his recent visit President Bush is reported to have told Prime Minister Howard that higher pharmaceutical prices

were a key goal for United States negotiators in the FTA (Colebatch 2003). Making concessions via reforms to pharmaceutical patent laws in the IP chapter of the FTA may provide a less visible, and more politically acceptable, method to weaken the PBS and raise pharmaceutical prices in Australia. It allows US negotiators to make reassurances that the PBS is safe, while still seeking concessions that would lead to higher pharmaceutical prices.

Reforms that threaten the sustainability of the PBS and transfer costs directly to patients are a high price to pay for possible gains in other sectors of the economy. The current pharmaceutical regulatory system ensures that essential medicines are available to all those in need at a price both individuals and the community can afford. Changes to the PBS and IP regime will increase the financial uncertainty of illness and ageing and create economic barriers for access to essential medicines in Australia.

A final issue to note in relation to concerns regarding the FTA and the PBS is the possible inclusion of investor state complaints provisions similar to those included in Chapter 11 of the North American Free Trade Agreement (NAFTA) (CCJDP 2003). These permit corporations and private investors to litigate against future government legislation, regulations or administrative decisions that are claimed to have adversely affected the value of investor assets. As of March 2003, $11.5 billion in such claims had been made against Canada, $16 billion against the US and $500 million against Mexico (CCJDP 2003).

The inclusion of such a chapter in the US Australia FTA would mean that subsequent Governments could be blocked or sued by US corporations if they attempt to pass legislation to improve the PBS, or regulate the supply of medicines in Australia. The PBS has served the community for 50 years and has enjoyed bipartisan support during that time. It is a crucial component of Australia's universal health insurance system, which no Government has the right to trade off irrevocably.

.

1. Intellectual Property and the FTA

Due to the complex nature of the PBS insurance and purchasing system, reforms in areas external to the health system can impact on its operation and effectiveness. Early in negotiations between Australia and the US, direct changes to the PBS were raised by industry representatives, including measures to weaken PBS pricing controls (see Lokuge and Denniss 2003).

However, it now appears that US negotiators are seeking indirect changes to the PBS that would lead to higher pharmaceutical profits and prices in Australia. In particular it is now likely that US negotiators will seek changes to Australia's pharmaceutical patent system. Pharmaceutical patent regulations determine the length of time that low cost generic medicines are barred from competing against patented medicines. Measures such as those that are being discussed in the FTA have been used in the US to delay the entry of generic competition to the market for 30 months and longer (FUSA 2002). According to Families USA 'these delays have cost consumers and other health care payers millions of dollars' (FUSA 2002 p 1).

a. Intellectual Property and Pharmaceutical Patents

Intellectual Property laws impact on the prices paid for, and profitability of, pharmaceuticals and other innovative products. Patents were introduced to encourage investments in research and development by providing an assured period of monopoly profits. Equally important, however, was the limitation of this monopoly to a defined period to ensure that knowledge was, as soon as possible, made available for the public benefit.

Initial prices for pharmaceuticals covered by patents can therefore be set by the monopolist at the point of greatest profitability. During the term of the patent, products generate high profits for the manufacturer. The cost of creating this monopoly in order to encourage investment in research is that purchasers of pharmaceuticals pay higher prices during the term of the patent.

Once a pharmaceutical patent expires, generic products can enter the market and compete with the brand named medicine. Economic theory and empirical evidence suggests that the presence of several therapeutically similar drugs results in a lowering of prices, compared to the situation where only one product is available during the patent term. It is, therefore, critical that patent terms balance the interests of IP owners with the interests of the community by means of competition and lower prices. Longer patent terms, and regulations that delay the entry of generic products into the market, are likely to significantly increase the cost of pharmaceutical products in Australia.

b. Current Intellectual Property Laws and Pharmaceutical Patent Regulations in Australia

There is little justification to further extend anti-competitive IP regulations under an Australia-US FTA. Under the Patents Act 1990 (Commonwealth), Australia currently has high levels of IP protection, comparable with most developed economies (Drahos and Braithwaite 2002). The prescribed period was increased in 1994 to fully comply with the Agreement of Trade-Related Aspects of Intellectual Property (TRIPS) and currently allows 20 years of patent protection (section 67).

This period was further extended in 1998 as a result of US tariff pressure exerted under section 301 of the US Trade Act. The Commonwealth Government added, under section 70, the right of a patentee to apply for an extension of the term of a pharmaceutical patent (up to five years, depending on the time it took to get the patent approved) if the relevant drug substances are disclosed in the complete specification of the patent and are included on the Australian Register of Therapeutic Goods (ITR 2002). Currently, however, this extended period of up to five years beyond the original 20 years is not infringed by generic manufacturers who make an application for their product to be included on the Australian Register of Therapeutic Goods (Patents Act 1990, Commonwealth. s 78(2)). Pressure from US section 301 also led to 'supra-TRIPS data exclusivity protections for first registrants under a 1998 amendment to the Therapeutic Goods Act 1989 (Cth) (Drahos and Braithwaite 2002).

In fact the Productivity Commission concluded in a 2003 report that Australia's intellectual property regime for pharmaceuticals was 'one of the most stringent in the world' (PC 2003 p 8.10). It is seen by many in the international community already to have a heavy tilt towards protecting the interests of IP owners (Love 2001).

Australia and the US are members of the World Trade Organisation (WTO) and are party to TRIPS which establishes an international benchmark of patent protection that all WTO member states must provide under their national laws. TRIPS provides IP owners, including pharmaceutical manufacturers, with a minimum patent terms of 20 years (ALRC 2003).

However, under TRIPS, members are allowed to issue compulsory licences provided that they respect certain conditions. The Doha Declaration on TRIPS and Public Health affirmed the 'right of members to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted' (MSF 2003). It appears that the push by the USA to negotiate bilateral FTAs outside the TRIPS regime is partly designed to extend patent protection beyond that provided by the Doha Declaration (MSF 2003).

Given Australia's high standard of IP protection, it is hard to justify, on arguments of economic efficiency and free trade, the inclusion of further IP provisions in the FTA. US efforts should, therefore, be seen as a strategic option to navigate the political sensitivities involved with weakening the PBS and raising pharmaceutical prices.

c. How IP provisions in the FTA could delay the entry of low cost medicines to the Australian market

Currently, manufacturers of generic pharmaceuticals in Australia can anticipate the expiration of patents and complete the market approval process for their products so that low cost medicines become available to consumers soon after the expiration of patents. In order to get products to market quickly, generic manufacturers 'springboard' off information provided to regulators by the original product's manufacturers. The so called 'Bolar provisions' permit the use of technology of a patented pharmaceutical to perform work that would assist in the marketing or regulatory approval of a generic product while the patent is in force. Bolar provisions are an acknowledgement that 20 year patent terms provide sufficient monopoly protection for innovators to recover R&D costs. At the end of the 20 years, the Bolar provision aims to ensure that generic producers are able to market their goods and deliver lower priced products to consumers immediately after patents expire. For these reasons Bolar Provisions have been upheld as conforming to the TRIPS agreement by the WTO (WTO 2001).

Additionally, generic manufacturers need not complete costly and time-consuming safety studies for compounds that are bioequivalent to the brand name product. Instead, by demonstrating bioequivalence, they can then rely on the safety and efficacy data of the brand name compounds to complete the registration process. The modification of IP regulations as part of an Australia-US FTA could delay this process. The result would be that generic manufacturers could be blocked by legal means from developing a product or would not be able to springboard off data previously submitted to regulators by the brand name producers. Such changes are likely to mean delays in the launch of new generic products or even to make the marketing of a cheaper generic product financially non-viable.

Tighter IP provisions, such as those described below, would create uncertainty for generic producers. It would provide multinational pharmaceutical corporations with additional opportunities to engage smaller generic producers in preemptive legal disputes over IP. In fact, the median time between filing and disposition of a patent suit in the US has been calculated at 36 months, with ten percent of cases taking over 77 months (more than six years) (FUSA 2002b).[5]

Additionally, unlike multinational pharmaceutical corporations, generic producers may not be able to afford costly litigation. They may be forced to delay application for marketing approval until after patent expiration and thus fail to take advantage of spring boarding provisions in Australian law. Over time such decisions would lead to significantly higher costs of medicines for Australian consumers.

d. IP provisions that are likely to be included in the FTA

There are a number of reasons to believe that US negotiators will seek to influence pharmaceutical prices via the IP chapter of the FTA. Firstly, Australian negotiators have made indicative comments (Hansard 2003 p. 104). Secondly, recent FTAs signed by the

[5] See Bulow 2003, for a detailed study of how IP litigation is used in the US to delay the entry of generic competition.

US with Chile and Singapore both include increased IP protection for pharmaceuticals. Finally, US domestic laws include IP provisions that have been used to delay the entry of generics into the market by linking patent expiration to the marketing approval process for generics.

During Senate Estimates Committee hearings in November this year, the Opposition Spokesman on Trade, Senator Conroy, asked Australia's Chief FTA negotiator, Mr Stephen Deady, about continued US interest in forcing changes to Australian pharmaceutical IP provisions under the FTA. In response to questions on whether US negotiators had flagged the possibility of introducing a 'paragraph 4' process (similar to the current US process linking intellectual property with the regulatory approval process), Mr Deady admitted that:

> There are a number of issues in the IP chapter that we are still negotiating hard with the Americans. This is another chapter where they do have some ambitions. They are the demanders in this chapter... There are some issues in relation to the arrangements as they apply to the marketing approvals for pharmaceuticals prior to the end of the patent terms' (Hansard 2003, p. 104).

Additionally Mr Deady was asked about the possibility of US demands to extend data exclusivity, another means by which IP regulation is used to hamper the market entry of low cost generics. Mr Deady was unable to deny this suggesting instead that, 'there is a raft of these issues which are linked to this question of prior approvals, but I am not familiar with that level of detail' (Hansard 2003, p. 104).

Similarly, the US has used recent FTAs in Chile and Singapore to achieve increased pharmaceutical IP protection beyond the international benchmark set by WTO countries in TRIPS. These agreements provide a useful template for measures likely to be included in the proposed US-Australia FTA. Both these FTAs include articles in the IP chapters that link pharmaceutical patent regulation to the marketing regulatory process. These clauses, detailed below, have the capacity to delay the entry of low cost generic medicines to the market.

The Chile and Singapore FTAs include clauses relating to;

- Data exclusivity (non disclosure to a third party) of information provided by the IP owner to obtain original market approval; and

- Making available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent and not granting marketing approval to any third party prior to the expiration of the patent term (USTR 2003).

i Linking Marketing Approval To Patent Status

In the US, marketing approval for generics is linked to patent expiration. This is the result of 'paragraph 4-certification processes' introduced in the Hatch-Waxman

amendments in 1984.[6] Paragraph 4 certification requirements link pharmaceutical patent expiration with the marketing approval process for generic pharmaceutical products. US pharmaceutical firms have exploited loopholes in these amendments to obtain automatic 30-month patent extensions and to block generic competitors entering the market (Bulow 2003).

Such IP provisions essentially have safety and regulatory authorities acting as patent enforcement authorities. Consequently consumers are denied the benefits of competition and lower prices for several years (FUSA 2002). As a result several bills such as 'the Prescription Drug and Medicare Modernization Improvement Act 2003' have been proposed in the US to eliminate IP provisions that lead to these delays (CBO 2003).

ii. Improper Extensions of Data Exclusivity

To gain marketing approval, generic companies typically need to show only that their product is bioequivalent to a brand name product, and then rely on the patented product's safety data to obtain approval. This avoids the duplication of information, and obviates the need to retrace old tests to reach a known result. The duplication of tests would be an inefficient use of resources. The benefits of this arrangement are twofold. By not having to duplicate already-generated registration data, generic companies can reduce the costs associated with bringing a compound on to the market. The price of generics can, therefore, be lower. Additionally, safety tests may take generic manufacturers several years to replicate, thus creating delays to the entry of generics once patents expire. Similarly, Australian ethical standards may prevent generic manufacturers who wished to repeat clinical safety trials from proceeding. That is, international medical ethics declarations may prevent clinical trials involving patients to occur in order to replicate already known test, simply for commercial purposes (WMA 1989).

Australian law currently provides the TRIPS standards for data protection of five years (Allens 2003). Despite this, when asked at Senate Estimates about US interest in extending data exclusivity, Australia's chief negotiator failed to rule this possibility out as described above (Hansard 2003). In the EU, data exclusivity laws range from six to ten years (Allens 2003). If further extensions of Australia's data exclusivity laws were to be sought under the Australia-US FTA, this would prolong the period during which generic manufacturers are unable to utilise the information necessary to springboard generic products on to the market. The result would be the delayed entry of generic medicines and higher costs being passed on to consumers in the form of higher prices. Additionally, if generic companies are unable to utilise this registration data, they may choose not to enter the market at all as the cost of reproducing this information may be too high.

[6] See Analysis of Changes to the Hatch-Waxman Act, by the Congressional Budget Office 2003 for a detailed discussion (CBO 2003).

2. The impact of IP changes on the cost of medicine in Australia

FTAs emphasise the equalisation and reciprocal treatment of polices and regulations between participatory countries. Therefore, if IP provisions, particularly changes to pharmaceutical patents, were included in the FTA, Australian laws are likely to be harmonised with those in the US. For this reason the US provides a useful template of the likely delays to the entry of generic competition that would occur in Australia as a result of the FTA.

Paragraph 4 certification provisions provide US brand name manufacturers with near automatic 30-month extensions after the expiration of the usual 20 year patent term (FUSA 2002, Bulow 2003). However, in many cases litigation leads to even longer delays and in some cases generic manufacturers decide not to risk the cost of protracted legal action. While some studies have estimated the delays as a result of such IP provisions to be 36 months, this study uses the conservative figure of a 24-month delay as its central case to calculate the cost to Australia of changes to the Australian IP regime as part of the Australia–US FTA.

Table 1: Likely delays in the entry of low cost generics as a result of the FTA: based on estimates in the US

IP provisions	Data exclusivity (Loss of springboarding) (a) **Base case estimate**	**Central case estimate**	Automatic Patent extensions as a result of Paragraph 4 (Hatch Waxman) (b) **Upper case estimate**	Median time taken for generic producers to settle patent disputes(c)
Delays in Generic entry	18 months	24 months	30 months	36 months

Sources:
(a) Internal pharmaceutical industry sources in Australia. This reflects the time that generic manufacturers would take to do necessary studies such as bioequivalence, develop a market application, and receive TGA approval if changes to patent laws prevent this work from progressing until after patents expire.
(b) FUSA 2002.
(c) FUSA 2002b.

a. Price reductions that result from the entry of generic competition

International studies confirm the impact of the entry of generic competition on the price of medicines. The Productivity Commission (2003) studied the difference between brand named (originator) medicine and the cheapest generic (off-patent) drugs in the US for a variety of common medicines (Ranitidine, Salbutamol, Diazepam, Metoprolol, Diltiazem, Proxicam, Atenolol, Temazepam, Oxazepam and Betamethasone). For these seven drugs, the lowest generic prices were between *two and six percent* of the original brand named product (PC 2003, p. 3.4).

The US Congressional Budget Office (CBO) estimates that generic versions of pharmaceuticals cost an average 25 percent less than the brand name (patented) drug (CBO 1998). Additionally, the CBO found that as the number of generic manufacturers producing the same drug increases, the price falls even further. The CBO found that when one to ten firms are manufacturing and distributing a particular drug, average

prices are 40 percent lower than the brand-name price. When more than ten manufacturers have entered the market, the average generic prescription price is less than 50 percent of the brand named price (CBO 1998).

In Australia, more than ten generic manufacturers produce versions of 'blockbuster' [7] drugs once patents expire. For example in 2003, there were ten or more versions of Australia's highest selling patent drugs, including Amoxil (antibiotic), Zantac (peptic ulcer disease and indigestion), Renitec (High blood pressure), and Lasix (diuretic) (DoHA 2003a). This competition ensures that once patents expire, products are priced efficiently. Additionally, reference pricing ensures that in order to maintain market share, brand name manufacturers cannot set prices for their products that are significantly above the lowest cost generic competitor. This is discussed in more detail in section 3.d.

b. PBS price trends for high expenditure brand name medicines following the entry of generic competition

The impact of generic competition on the prices of four 'blockbuster' medicines listed on the PBS is shown in the tables below. The examples shown in Tables 2.1, 2.2 and 2.3 provide a useful insight into the effects of generic competition on price. The products examined below were leading compounds in relation to PBS prescription volumes and cost and therefore attracted significant competition from generic competitors. Table 2.1 to 2.3 examines price trends for Prozac, Losec and Zantac during the period of transition from monopoly to that of competition from the entry of generics.

Table 2.1: Impact of generic competition on the price of Prozac (antidepressant)

	Apr-94	Apr-95	Feb-96	Feb-97	Feb-98	Feb-99
Prozac 20mg (28pack)	$ 55.09	$ 55.32	$ 59.19	$ 35.50	$ 35.55	$ 35.55
Number of generic competitors	**0**	**0**	**1**	**3**	**3**	**5**

Source: DoHA 2003b

Table 2.2: Impact of generic competition on the price of Losec (proton pump inhibitor- peptic ulcer)

	Feb-97	Feb-98	Feb-99	Feb-00	Feb-01	Feb-02
Losec 20mg (30 pack)	$82.93	$82.98	$82.98	$58.86	$57.63	$46.9
Number of generic competitors	0	0	1	1	1	1

Source: DoHA 2003b

[7] High selling pharmaceutical products with several billion dollars in worldwide sales.

Table 2.3: Impact of generic competition on the price of Zantac (H2 antagonist-peptic ulcer disease)

	Feb-96	Feb-97	Feb-98	Feb-99	Feb-00	Feb-01
Zantac 150mg (60 pack)	$33.02	$33.04	$26.41	$24.18	$23.73	$ 23.83
Number of generic competitors	**0**	**1**	**2**	**2**	**6**	**10**

Source: DoHA 2003b

Table 3 considers the unweighted average price of four leading compounds on the PBS following the entry of generic competition. Prices reductions are expressed in real terms.

Table 3: Average affect on price of four high expenditure brand name medicines, of the entry of generic competition in the PBS

Years after entry of Generic Competition	Year 1	Year 2	Year 3	Year 4	Year 5
Average adjusted price paid by PBS	-2%	-27%	-31%	-35%	-37%

Source: DoHA 2003b.

Notes: Analysis of dispensed prices. Estimates examined price trends for Prozac, Losec, Zantac and Renitec for four years after the entry of generic competition. Average prices are tabulated. CPI used to adjust prices to year of generic entry.

Table 4 provides a list of drugs, which are approaching the end of their 20-year patent life in Australia. As discussed in detail below, changes to the effective patent life of top selling drugs in Australia have the potential to cost Australian consumers and taxpayers billions of dollars per year.

Table 4: Medicines nearing patent expiration that would be affected by changes to IP provisions under the FTA

Brand name	Drug name (generic)	Use	Patent expiry (Australia)
Zocor	simvastatin	serum lipid reducing agent	Jul-2005
Lipitor	atorvastatin	serum lipid reducing agents	May-2012
Norvasc	amlodipine	Hyper-tension	Feb-2008
Prevacid/ Zoton	lansoprazole	Proton pump Inhibitor (Peptic ulcer disease)	Sept-2009
Claritin/ Claratyne	Loratadine	Anti-histamine	Jun-2006
Zyprexa	olanzapine	Anti-psychotic	Mar-2012
Zoloft	Sertraline	Anti-depressant	Oct-2005
Pravachol	pravastatin	serum lipid reducing agents	Jun-2006
Flovent/ Flixotide	fluticasone	Asthma/ CAL	Feb-2006
Zyrtec	Cetirizine	Anti-histamine	Feb-2007
Prinivil	Lisinopril	ACE Inhibitor (Hypertension)	Dec-2004
Aredia	disodium pamidronate	Tumor induced hypercalcaemia	Aug-2010
Accupril	Quinapril	ACE Inhibitor (Hypertension)	Sept-2006
Mevacor	Lovastatin	serum lipid reducing agents	Jun-2005
Monopril	Fosinopril	ACE Inhibitor (Hypertension)	Nov-2006
Serzone	nefazodone	Anti-depressant	Mar-2007

Source: ITR (2002)

c. Cost to Australia of IP provisions in the FTA that delay generic competition

In order to highlight the cost of potential changes to IP provisions in the FTA on the PBS and Australian taxpayers, this study examined five medicines nearing the end of their 20-year patent terms. These five products account for a significant proportion of expenditures in the PBS. The study estimates the impact on the PBS of a range of delays[8] that would be likely to result from the changes to Australia's IP regime and examines the cumulative cost to Australia over the four years from 2006 -2009.

Table 5 examines the 'central case' analysis where IP provisions in the FTA are assumed to delay the arrival of generics by 24 months. The central case estimate, which is likely to be conservative given the impact of IP changes in the US, is that the additional cost of delaying the entry of generic competition for these five drugs alone would be more than $1.12 billion over four years. A more conservative estimate of an 18 month delay would lead to an additional cost to the PBS of $850 million and the

[8] These delays were summarized in Table 1.

upper estimate of a 30 month delay would result in additional costs to the PBS of $1.56 billion over four years.

Table 5: Cost to the PBS of price rises of five selected medicines as a result of a 24 month delay in the introduction of generic pharmaceutical competition

			Cost to Australia (c)			
Drug	Pre FTA Patent Expiration (a)	Total PBS expenditure Sept 2003 (b) ($)	2006 (d) ($)	2007 ($)	2008 ($)	2009 ($)
Zocor (simvastatin)	Jul-05	335,856,135	7,715,911	148,793,717	177,309,724	53,794,094
Lipitor (atorvastatin)	Reference priced to Simvastatin(e)	374,917,136	6,912,023	133,291,541	158,836,588	48,189,519
Pravachol (pravastatin)	Reference priced to Simvastatin(e)	118,531,753	2,439,420	47,041,808	56,057,274	17,007,247
Zoloft (sertraline)	Oct-05	92,157,744	1,896,635	36,574,731	43,584,202	13,223,035
Fluticasone (Flixotide)	Feb-06	168,804,501	-	3,821,454	73,692,961	87,816,065
Cost to Australia			18,963,989	369,523,250	509,480,750	220,029,960
Cumulative cost to Australia			**18,963,989**	**388,487,239**	**897,967,989**	**1,117,997,949**

Notes:
(a) ITR (2002)
(b) Projected total PBS expenditure for the period 2006-2009 are based on actual PBS expenditure on these items in 2003 (DoHA 2003c). PBS expenditure on these items for the period 2006-09 are inflated at an annual rate of increase of 10 per cent. This is a conservative estimate as total PBS expenditure over the previous decade increased by 11.9% (source: DoHA 1999 which considered the period 1984-5 to 1996-7). Additionally, serum lipid lowering drugs which feature prominently in this table have been one of the highest growing components of the PBS in the last few years with annual increases of 13 per cent for the year ending June 2002 and 11.4 per cent for the 12 month period ending September 2003 (source DoHA 2003c.
(c) Calculations assume average price reductions estimated in Table 3. Assumes FTA IP provisions lead to an average 24 months delay in the entry of generic competitors to the market.
(d) As the first patent expiration occurs in July 2005, the first year when costs are incurred under the PBS as a result of likely IP changes under the FTA are in 2006.
(e) Therapeutic group reference pricing links patent expiration discounts for the first statin ending patent terms (Simvastatin) to other statins in the therapeutic reference group. Therefore similar price reductions can be expected for atorvastatin and pravastatin at the same time as Simvastatin comes off patent.

d. Impact of IP reforms on reference pricing and the viability of the PBS

Delays to the entry of generic pharmaceuticals will have a significant impact on reference pricing and therefore lead to higher costs in the entire PBS scheme. Reference pricing, a critical component of the 'PBS framework', depends on the availability of low cost generic medicines within a therapeutic group to achieve pricing discounts.

Reference pricing has little impact in therapeutic classes where generic competition does not exist[9]. Reference pricing mechanisms set the PBS subsidies that patients are entitled to at the price of the lowest cost generic medicine in a therapeutic class. This means that after patents expire, in order to maintain market share brand name manufacturers cannot set prices for their products substantially above the lowest cost generic competitor. Generic entry, combined with reference pricing, therefore leads to a significant drop in the price that the PBS, and therefore Australian taxpayers, pay for essential medicines.

A report by the Productivity Commission in 2003 highlighted the crucial role that generic competition played in the success of the PBS reference pricing system. The Commission reported, for example, that reference pricing in Australia was likely to lead to greater savings than in other OECD countries due to the role of generics in price setting processes (PC 2003). In relation to the above, the Commission went on to clarify that:

- 'Off-patent' pharmaceuticals – which are subject to much greater competition in supply are typically much lower priced than pharmaceuticals still under patent and are likely, in the Australian reference pricing system, to constrain patent drug prices' (PC 2003, p. 3.8); and

- 'Whereas Australia uses the minimum price as the benchmark, some other countries use the average group price' (PC 2003, p. 3.8). Therefore prices across a therapeutic group will be lower in the presence of generic competition in Australia.

Studies estimate that PBS pricing controls particularly the reference pricing system, save Australia between $1 and 2.4 billion dollars annually (Lokuge and Denniss 2003). Therefore IP measures that delay generics and weaken reference pricing will have a significant impact on the cost and sustainability of the PBS.

e. Impact on Over the Counter (OTC) pharmaceutical prices

Strengthening pharmaceutical patent laws under the FTA could have a much greater impact on patients than direct changes to the PBS because changes to IP laws will also increase the cost of medicines in Australia outside the PBS system. The price of all pharmaceutical products, including the prices paid for PBS and over the counter (OTC) medicines will be affected by increased patent protection and the resulting delayed generic competition.

Approximately 43 per cent of all expenditure on pharmaceuticals in Australia is financed directly by patients and occurs outside the PBS system (DoHA 1999). This includes OTC medicines sold at pharmacies and retail outlets and prescription medicines not qualifying for PBS subsidies. OTC medicines include anti-inflammatory medicines used commonly by seniors and anti-histamines for hay fever.

[9] For a discussion see Evaluation of the Pharmaceutical Industry Investment Program 2003, Productivity Commission, Canberra (PC 2003, p.3.8)

It is important to note that there are no safety nets or concessional arrangements for OTC expenditures. Individuals must purchase these products without the protection of the PBS insurance scheme. OTC prescriptions are responsible for a significant percentage of the out-of-pocket expenses faced by Australian each year and accounted for 17 per cent of total health expenditures in 1998; that is, one in six dollars was paid directly by patients at the time of illness (EOHCS 2001, p. 36).

Therefore, if the FTA extends monopoly protection over pharmaceuticals by delaying the entry of generic medicines, the prices of OTC medicines will also be affected. For example, Australia could expect significant reductions in the price of the top selling non-sedating antihistamine Claratyne (and as a flow on, all other comparable antihistamines) when it comes off-patent in Australia in June 2006. This common OTC medication currently faces no generic competition in Australia. However, if IP changes as part of the Australia-US FTA come into effect then such price reductions will be delayed.

In the US, the patent on Loratadine (the active ingredient of Claratyne) expired in 2002.[10] Soon after expiration cheaper generic versions appeared on the market – 40 per cent cheaper than the original brand Claratyne (Wellmark 2003).

Table 6: Likely impact of changes to Australia's IP regime on the cost of Claratyne

Dose	Price in 2003 (a)	Expected price in 2006 without FTA (b)	Cost to Australian consumers if FTA delays arrival of generic competition (per packet)
Claratyne 10mg (10 tablets)	$12.95	$7.77	$5.18
Claratyne 10mg (30 tablets)	$27.95	$16.77	$11.18

Notes:

(a) Based on prices quoted in a selection of pharmacies in Australia, 24 November 2003.

(b) Based on observed decline in price of Claratyne in the US following the entry of generic competition after patent expiration (Wellmark).

[10] It is not uncommon for manufacturers to apply for Australian patents several years after US application.

3. The politics of pharmaceutical reform

In order to understand the reasons behind ongoing efforts to use the FTA to increase pharmaceutical prices in Australia it is useful to consider the influence of the pharmaceutical industry in the US and Australia. The issues raised in this section appeared in a previous report published by the Australia Institute, *Trading in our Health System* (Lokuge and Denniss 2003).

a. Influence of the industry in the US

The pharmaceutical industry has considerable influence with the current US Administration. During the 1999-2000 election cycle in the US, and with billions at stake in a heated debate over prescription drug prices at home and a growing number of patent disputes abroad, the industry gave disproportionate support to George W. Bush. In that election nearly 70 per cent of the industry's unprecedented US$24.4 million campaign contributions was spent on George W. Bush and other Republicans (Borger 2001).

Since coming to office President Bush has appointed several advisers with close ties to the pharmaceutical industry. Defense Secretary Donald Rumsfeld has previously served as Chief Executive Officer, President, and then Chairman of G.D. Searle & Co., a worldwide pharmaceutical company (USDD 2003). Until being sworn in as the 21st Secretary of Defense, Mr. Rumsfeld served as Chairman of the Board of Gilead Sciences, Inc., another pharmaceutical company (Gilead 1997).

Mitch Daniels, the Director of the Office of Management and Budget, was previously the senior vice president of the Indianapolis-based pharmaceuticals firm Eli Lilly and Company (TIS 2001). The Office of Management and Budget is responsible for preparing the President's budget proposals to Congress.

The pharmaceutical industry has used this influence to maintain prices and profit margins in the US. When US legislators have sought to address the issue of unregulated pharmaceutical prices, the industry has been swift to respond. For example, the American pharmaceutical industry body, PhRMA, recently took the US state of Maine to court for attempting to introduce legislation similar to the PBS. Maine legislators realised the need for such a program when they found that:

> the citizens of Maine have been denied access to medically necessary drugs due to the excessively high prices being charged by pharmaceutical companies. The inability of Maine's citizens to pay for these drugs often results in costly – and otherwise avoidable – hospitalization or institutionalization. Second, Maine residents pay much higher prices for drugs than do citizens of other countries (Phelps 2001, p. 4).

According to the Governor of Maine, Angus King, under the new legislation 'ordinary people will be able to get the drugs they need without necessarily having to face the terrible choice between the rent, the food, and the medicine' (Barrington 2002, p. 3).

Similarly, PhRMA filed lawsuits to stop the state of Florida from introducing a law requiring drug manufacturers to provide discounts if they wanted their drugs to be included on a list of preferred drugs for recipients of Medicaid. Florida Governor Jeb Bush stated 'protecting the large profit margins for multibillion-dollar pharmaceutical companies is not a priority. We are more concerned about making sure our senior citizens have better access to affordable prescription drugs' (Tieman 2001, p. 31).

It appears that US politicians are becoming increasingly aware of the failures that have resulted from allowing unregulated markets to determine the price of essential goods such as medicines. US legislators are responding to calls to intervene and develop initiatives like the PBS that will provide affordable medicines to all Americans. It is, perhaps, ironic that while such measures are occurring in the domestic setting, in Australia, US negotiators are exerting pressure on the Australian government to weaken its pharmaceutical regulatory and pricing system.

b. Influence of the industry in Australia

Similarly in Australia the industry has moved to establish high-level representation and used a variety of strategies to lobby against pharmaceutical regulatory and pricing policies in Australia (Jackson 2001). Publicity over pharmaceutical industry influence in undermining the Pharmaceutical Benefits Advisory Committee (PBAC)[11] highlights the industry's influence in Australia's political process (Jackson 2001). The former Minister for Health, Michael Wooldridge, was criticised for removing several long standing members of the PBAC and appointing an industry representative to the board. One of those removed was Professor David Henry, who as chairman of the economic subcommittee of the PBAC, had built an international reputation as an expert in determining the cost-effectiveness of new drugs. His removal was, he believed, a result of intense lobbying by the pharmaceutical industry and an attempt by the Howard Government to appease industry frustration at what it claimed were Australia's overly restrictive drug listing and pricing policies (Davies 2001).

In addition to the direct lobbying of parliamentarians, the industry has hired numerous former Liberal party staffers to facilitate access to the Commonwealth Government. Most notable of these is the recent appointment of the former chief advisor to Finance Minister Nick Minchin, Kieran Schneemann, as CEO of the Australian drug industry lobby group, Medicines Australia (Metherell 2002).

Given the industry's influence within both the US and Australian governments and its widely expressed dissatisfaction with the price it receives for medicines in this country, it is not surprising that Australia's pharmaceutical regulatory and pricing processes remain on the FTA agenda. In fact on the first day of public hearings into the FTA in the US, drug industry lobbyist Joe Damond formally made the price of pharmaceuticals in Australia a target for US interests, arguing that companies should be allowed to charge higher prices for medicines in Australia (Allard 2003).

[11] The PBAC is a committee of experts whose role is to assess pharmaceutical industry applications for product listing for subsidies on the PBS against a number of criteria including the need for the product and the outcomes and costs of a particular pharmaceutical when weighed against other available therapies.

c. Should Australia pay higher prices for pharmaceuticals?

It is important to consider the arguments put forward by the US and international pharmaceutical industries and their representatives to argue for higher pharmaceutical prices in Australia. The first argument is that Australia under-prices pharmaceuticals and thereby 'free rides' on the research and development investments of international pharmaceutical firms (Colebatch 2003). While the argument that there is a need to fund R&D appears compelling, a recent report by Families USA examined R&D expenditures in the pharmaceutical industry in relation to other spending and total profits (FUSA 2002c). These findings are echoed in the work of Henry and Lexchin (2002).

The FUSA study shows that R&D expenditures are less significant than marketing costs, for example, and that the pharmaceutical industry has been the most profitable industry in the US for over a decade. It is therefore difficult to justify the high cost of pharmaceuticals based on R&D arguments alone. A comparison of profits, expenditure on marketing and administration and expenditure on R&D for major US drug companies is provided in Table 7.

Table 7 Outlays of major US drug companies, 2001

Company	R & D (% of revenue)	**Marketing/ advertising/ administration (% of revenue)**	Profit (net income as % of revenue)	Revenue (net sales US$ million)
Merck & Co., Inc.	5%	**13%**	15%	$47,716
Pfizer, Inc.	15%	**35%**	24%	$32,259
Bristol-Myers Squibb Co.	12%	**27%**	27%	$19,423
Abbott Laboratories	10%	**23%**	10%	$16,285
Wyeth	13%	**37%**	16%	$14,129
Pharmacia Corporation	16%	**44%**	11%	$13,837
Eli Lilly & Co.	19%	**30%**	24%	$11,543
Schering -Plough Corp.	13%	**36%**	20%	$9,802
Allergan, Inc.	15%	**42%**	13%	$1,685
Average	11%	**27%**	18%	
Total (million)	$19,076	**$45,413**	$30,599	$166,678

Source: FUSA, 2002

Table 7 shows that all but one company spent more than twice as much on marketing, advertising and administration as they did on research and development. On average, the nine companies reported profits of 18 per cent of total revenue, but only 11 percent of total revenue was allocated to R&D. Furthermore, the net profit of six out of the nine companies exceeded expenditure on research and development in 2001.

FUSA also considered the relative profitability of the pharmaceutical industry in the US compared to other US industries (FUSA 2002). They concluded that it had been the

most profitable industry in America for each of the past ten years and, in 2001, was more than five times more profitable than the median Fortune 500 companies. A list of the most profitable industries in the Fortune 500 between 1991 and 2001 is provided in Table 8.

Table 8 Pharmaceutical industry Fortune 500 ranking (return on revenues)[1]

	Drug Industry rank	% Return	Industry ranked number 2	% return	Fortune 500 median return %[2]
1991	1	12.8	beverages	5.5	3.2
1992	1	11.5	toys, sports goods	6.5	2.4
1993	1	12.5	publishing, printing	6.4	2.9
1994	1	16.1	commercial banks	13.5	4.6
1995	1	14.4	commercial banks	13.3	4.8
1996	1	17.1	commercial banks	13.9	5.0
1997	1	16.1	commercial banks	13.6	4.9
1998	1	18.5	commercial banks	13.2	4.4
1999	1	18.6	commercial banks	15.8	5
2000	1	18.6	commercial banks	14.1	4.5
2001	1	18.5	commercial banks	13.5	3.3

1. Prior to 1993, return on sales.
2. Median return on revenues for all Fortune 500 companies.
Source: Fortune Magazine's annual rating of the industries, 1992-2002 (cited in FUSA 2002).

It is clear that research and development is not constrained by a shortage of money, with outlays on administrative and marketing expenditure and returns to shareholders far exceeding current levels of R&D expenditure.

The second argument for deregulation of the PBS is that price controls delay or prevent patient access to new therapies. The evidence does not support this assertion. A report by the Productivity Commission (2001) found that for most countries there was no significant difference in the delay between the global and the local launch dates. For example, the delay between the global and Australian launch dates for new drugs is 2.2 years. This is similar to the results for Canada and NZ and not substantially longer than the figure for the US or Spain. These data are summarised in Table 9.

Table 9 Time from international launch to availability of medicine in domestic market (median value in years)

	US	Australia	France	Spain	Canada	NZ	UK
All drugs	3.5	3.4	3.3	3.3	3	2.8	0.9
New drugs	1.9	2.2	3.3	1.8	2.2	2.2	0.4

Source: Derived from PC (2001, p. E24)

Moreover, if pharmaceutical companies are concerned with patient access to new medicines, then they should also be concerned with the impact of high prices on the affordability of new drugs.

This particularly applies to reforms to patent regulation which would increase the cost of OTC medicines paid directly by patients. As shown in Table 10, the proportion of the population in Australia who could not afford to have a prescription filled in 2001 is nearly one in five. Raising pharmaceutical costs will only make this situation worse.

Table 10 Survey on the affordability of medicines, five countries, 2001

Access	US	Australia	New Zealand	Canada	UK
Percentage of people who did not fill a prescription due to cost	26%	19%[a]	15%[a]	13%[a]	7%[a]

Source: (Blendon 2002).

4. Conclusion

In an analysis by Blendon (2002), the US was found to be the only country where costs faced by consumers created greater barriers to the access of pharmaceuticals than Australia. If the Australia-US FTA includes changes to the PBS and IP regime designed to make the Australian system closer to that of the US, then the affordability of medicines in Australia can only deteriorate.

The Australian Government began 2003 by denying that the US trade negotiators were interested in the Australian PBS. It has ended the year by claiming that it will protect that same system in any Australia-US FTA. However, it appears that the US negotiators have discovered an alternate path to higher profits from the sale of pharmaceuticals in Australia. Rather than seeking direct changes to the PBS, negotiations now appear to be revolving around Australia's intellectual property regime.

Changes to Australia's IP regime have the potential to weaken the PBS reference pricing system and to impose substantial costs on both the PBS and consumers directly in the form of higher prices for over the counter medicines. The current IP regime in Australia allows patent holders to enjoy a monopoly over their product for 20 years. The changes being sought by US drug companies would see this effective monopoly extended for two to three years by creating legal obstacles to the rapid approval of generic competitors to patented medicines at the end of the 20 year patent life. In the short term this report estimates that the likely delays in the arrival of generic competition will cost Australians more than $1 billion dollars over four years. This is a very conservative estimate as it is based on the likely increase in cost of only five top selling medicines. In the long run, however, the reforms sought by the US to Australian IP laws under the FTA would undermine the PBS reference pricing system and thereby threaten the affordability and sustainability of the entire scheme.

Australia has a uniquely successful scheme for ensuring that all Australians have affordable access to essential medicines. Changes to the Australian IP regime as part of an Australia-US FTA have the potential to significantly reduce the effectiveness of the PBS and, in turn, increase the financial uncertainty of illness and ageing and create economic barriers for access to essential medicines in Australia. The PBS has served the community well for more than 50 years and has enjoyed bipartisan support during that time. It is a crucial component of Australia's universal health insurance system. Changes which reduce the effectives of the PBS as part of an Australia-US FTA will have long run impacts on Australians for decades to come.

5. References

Allens (2003), Data exclusivity: further protection for pharmaceuticals, Biotech news, 24 June 2002, Allens Arthur Robinson, [online access] http://www.aar.com.au/pubs/bt/24jun03/bio02.htm, last accessed 26 November 2003.

Allard, T. (2003), 'US drug companies cry poor over PBS', *Sydney Morning Herald*, 17/1/2003.

ALRC (2003), *Intellectual Property Rights over Genetic Materials and Genetic and Related Technologies*, Paper 27, Australian Law Reform Commission, Commonwealth of Australia.

Barrington, C. J. (2002), 'Concannon and Maine's prescription drug rebate statute: A twenty-first century solution to the Medicaid crisis*', Whittier Law Review,* 23.

Blendon, R. e. a. (2002). "Inequities in Health Care: A Five-Country Survey." *Health Affairs* **21**(3): 182-191.

Borger, J. (2001), 'The Pharmaceutical Industry Stalks the Corridors of Power', *The Guardian Unlimited*, February 13, 2001, http://www.corpwatch.org/news/PND.jsp?articleid=178.

Bulow, J. (2003), *The Gaming of Pharmaceutical Patents* by Jeremy Bulow, Innovation Policy and the Economy, Volume 4, MIT

Colebatch, T. (2003), *Bush wants to end medicine subsidies*, Age, 24 October 2003.

CCJDP (2003), *The Big Chill, Concerns about the Investor/State provisions in the proposed Australia US Free Trade Agreement*, November 2003.

CBO (2003), *Analysis of Changes to the Hatch- Waxman Act*, Congressional Budget Office.

CBO (1998), *How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry*, Congressional Budget Office.

Davies, J.A. (2001), 'Too many bitter pills', *The Ag*e, Friday 2 February 2001.

DoHA 1999, *Health Expenditure: Its Management and Sources, Occasional Papers: Health Financing Series*, Volume 3, Department of Health and Ageing.

DoHA (2003a), *The Pharmaceutical Benefits Schedule, November 2003*, Department of Health and Ageing, Canberra.

DoHA (2003b), *The Pharmaceutical Benefits Schedule, April 1991 to November 2003,* Department of Health and Ageing, Canberra.

DoHA (2003), *Summary of PBS processing 12 months ending September 2003*, Department of Health and Ageing, http://www.health.gov.au/pbs/pubs/pbbexp/index.htm

EOHCS (2001), *Health Care Systems in Transition*: Australia, The European Observatory on Health Care Systems, Vol 3, number 13.

ITR (2002), *Discussion paper on patent extensions and springboarding, and the effect on generic pharmaceuticals manufacturers in Australia*, Department of Industry, Tourism and Resources, Canberra. June 2002.

Ives, R. (2003), Transcript of Media briefing on the second round of Free Trade Agreement negotiations between Australia and the United States. Briefing conducted by Australia's chief negotiator Stephen Deady and the United States' chief negotiator Ralph Ives, Department of Foreign Affairs and Trade, 23 May 2003. http://www.dfat.gov.au/media/transcripts/2003/030523_ausfta.html

FUSA (2002), *Getting Access to Generic Drugs*: A Timeline, Families USA.

FUSA (2002b), *Overview of the Hatch- Waxman Amendments*, Families USA, 1 April 2002.

FUSA (2002c), *Profiting from Pain: Where Prescription Drug Dollars G*o, Families USA, July 2002.

Gilead (1997), Donald H. Rumsfeld, Named Chairman of Gilead Sciences, Press Release, January 3, 1997, http://www.gilead.com/wt/sec/pr_933190157/

Hansard (2003), Senate, Foreign Affairs, Defence and Trade Legislation, Committee Estimates (Budget Estimates Supplementary Hearings), Commonwealth of Australia, Thursday, 6 November 2003, Canberra. http://www.aph.gov.au/hansard/senate/commttee/S7062.pdf

Henry, D. and Lexchin, J. (2002), 'The pharmaceutical industry as a medicines provider', *The Lance*t, Vol. 360 (16), pp. 1590-1595.

Jackson, L. (2001), 'Paying the Price', Four Corners, Australian Broadcasting Corporation, 19/02/2001.

Lokuge, K. and Denniss, R. (2003) *Trading in our Health System: The impact of the US- Australia Free Trade Agreement on the Australia's Pharmaceutical Benefits Scheme*, DP 55, May 2003, The Australia Institute, Canberra.

Love, R.(2001), *Letter to Office of the USTR*, Consumer Project on Technology, January 29, 2001. www.cptech.org/ip/health/trade/gblue01292001.html

MSF (2003), *Trading Away Health. Intellectual Property and Access to Medicines in the Free Trade Area of the Americas (*FTA) Agreement, Medecins Sans Frontiers.

Metherell, M. (2002), 'Minchin's chief aide chosen as drug industry's cheerleader', *Sydney Morning Herald*, Sydney, 17/02/2002.

Productivity Commission (2001), *International Pharmaceutical Price Differences*, Research Report, Productivity Commission, Canberra.

Productivity Commission (2003), *Evaluation of the Pharmaceutical Industry Investment Program 2003*, Productivity Commission, Canberra.

Phelps, W. (2001), 'Maine's prescription drug plan: A look into the controversy', *Albany Law Review,* 64.

Tieman, J. (2001), 'A Formulary in Progress, Florida Panel Will Make Regular Changes to Medicaid List of Preferred Drugs', *Modern Healthcare,* 20.

TIS (2001), 'Library Fact Files: Mitch Daniels', *The Indianapolis Star*, 23/1/2001.

USDD (2003), *Defence link, Biography Secretary of Defence*, US Department of Defence., http://www.defenselink.mil/bios/secdef_bio.html.

USTR (2003), Office of the United States Trade Representative Website, last accessed 24 November 2003. http://www.ustr.gov/new/fta/chile.htm and http://www.ustr.gov/new/fta/singapore.htm

Wellmark 2003, *The Wellmark Report, 3rd edition*, Blue Cross Blue Shield Association.

WMA (1989), *Declaration of Helsinki* World Medical Association (1964 updated 1989, Appendix 6).

WTO (2001), TRIPS and pharmaceutical patents, fact sheet, April 2001.