

Patents, pills and politics: the Australia–United States Free Trade Agreement and the Pharmaceutical Benefits Scheme

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Abstract

There is tension between the need of the pharmaceutical innovator for intellectual property protection and the need of society for equitable and affordable access to innovative drugs. The recent Australia–United States Free Trade Agreement provides a nice illustration of this interplay between patents, pills and politics. This article provides a brief history of patent law as applied to pharmaceuticals, describes how the Pharmaceutical Benefits Scheme got caught up in AUS-FTA negotiations, analyses the clauses that are likely to impact upon the PBS and describes the political process that reviewed and ultimately amended the AUSFTA.

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WITHOUT PATENT PROTECTION it would not be in the interests of the pharmaceutical industry to invest the large amount of money needed for the research and development of new drugs. While there is controversy about the precise amount of money required to bring a new drug to market, the process has undoubtedly become more expensive, more complex and more time consuming (Goozner 2004). However, if patents were held in perpetuity there would be no price competition from generic manufacturers, and essential medicines might be affordable only by the rich. Thus, there is a tension between the need of the pharmaceuti-

What is known about the topic?

Negotiations between Australia and the United States in 2003–04 about a Free Trade Agreement were accompanied by an intense public debate, much of which focused on the implications of an agreement for pharmaceutical prices and the operation of the PBS.

What does this paper add?

This article provides a succinct overview and analysis of the background to these negotiations, including the role of patent law in the pharmaceutical sector, and the likely impact of the Agreement reached regarding the PBS. It also describes the political process through which the Agreement was reviewed and ultimately amended.

What are the implications for researchers and policymakers?

The challenge for health policymakers is to ensure that health and social policy commitments made in respect of the Free Trade Agreement be met. It is imperative that researchers now monitor closely the implementation of the Agreement.

cal innovator for intellectual property protection and the need of society for equitable and affordable access to innovative drugs. In a democratic society, legal and political processes provide the means for resolving this tension. The recent Australia–United States Free Trade Agreement (AUSFTA) provides a nice illustration of this interplay between patents, pills and politics. This article first provides a brief history of patent law as applied to pharmaceuticals; second, it reviews why the Pharmaceutical Benefits Scheme (PBS) got caught up in AUS-FTA negotiations; third, it analyses the clauses that are likely to impact upon the PBS; and, finally, it describes the political process that reviewed and ultimately amended the AUSFTA.

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A brief history of patent law relevant to pharmaceuticals

Conventional patent laws have a history of over 500 years, beginning with the Venetian Patent Law in 1474. The first international agreement, the Paris Convention, was agreed upon in 1883. The Paris Convention gave Member States considerable flexibility in enacting their national legislation on intellectual property rights. Both developed and developing countries used the provisions in the Paris Convention to enact their national legislation on patents to serve as policy instruments for developing and strengthening their pharmaceutical industry. One important provision was that countries could exclude pharmaceutical products from patent protection. France, Germany, Italy, Japan, Switzerland and Sweden used these provisions to refuse patent protection for pharmaceutical products until their industries had reached a certain degree of development and international competitiveness (Balasubramaniam 2002).

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was negotiated in the Uruguay Round of GATT (General Agreement on Tariffs and Trade) talks from 1986 to 1994 and came into effect in January 1995 (World Trade Organization 1995). Before TRIPS, many developing countries provided no patent protection on pharmaceutical products, or they recognised patents on products but not process. Some developing countries had patent coverage as short as three years (Thailand) or as long as sixteen years (South Africa). This flexibility on patent laws facilitated the local production of cheap generic medicines long before patents had expired in developed countries.

Although the TRIPS Agreement was likely to have a substantial impact on the price and access to medicines there was no participation by the World Health Organization (WHO), public health experts or officials of health ministries during the negotiating process. In addition, negotiators from developing and the least developed countries were placed under political and economic pressure to accept terms that did not adequately take into consideration their specific interests, particularly in relation to pharmaceuti-

als. The end result was that developed countries with a research-based pharmaceutical industry, particularly the United States of America (US), used the TRIPS Agreement to remove the flexibility given to Member States in the Paris Convention. The TRIPS Agreement required all countries, both developed and developing, to grant patent protection for pharmaceutical products and processes for 20 years (although developing countries were given longer periods in which to implement these changes).

Health activists and non-government organisations (NGOs) were concerned that the TRIPS agreement would deny developing countries access to cheaper generic medicines, especially those needed to treat diseases such as HIV/AIDS, tuberculosis and malaria. They began a sustained campaign to reassert the supremacy of public health needs over trade interests. This culminated in the 4th World Trade Organization (WTO) ministerial conference in Doha in November, 2001. Led by the Africa Group, Brazil and India, a coalition of more than 80 developing countries convinced the major industrialised countries to affirm the Doha “Declaration on the Agreement and Public Health” which stated that the 1995 TRIPS agreement “can and should be interpreted and implemented to protect public health and promote universal access to medicines” (World Trade Organization 2001).

However, the response of the US has been to put impediments in the way of implementing the Doha declaration and negotiate bilateral trade agreements containing intellectual property standards much stronger than those to be found in TRIPS (’t Hoen 2003). The AUSFTA is one such example.

US pressure to include the PBS in AUSFTA negotiations

In January 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA) lobbied US trade negotiators to seek Australian government commitment to “refrain from trade distorting, abusive, or discriminatory price controls such as current PBS reference pricing” (PhRMA 2003). In October, President George Bush allegedly told Prime Minister John Howard that raising

drug prices was a key goal for United States negotiators in any FTA deal. Mr. Bush was reported to have said that his pharmaceutical industry believed some countries did not pay their share of the cost of research and development to create new medicines, making US consumers pay the bill (Colebatch 2003).

In December 2003, Senator Ian Campbell, representing the Australian Minister for Health, told the Senate that “The Prime Minister and the Minister for Trade have both made it very clear that the PBS is not on the table . . . the government is committed to maintaining a viable generic medicines industry and the negotiation of a free trade agreement will not, I repeat, not compromise this commitment. I should also add that the United States has made no proposals to Australia regarding the PBS”. Subsequently, it became clear that the PBS was in fact ‘on the table’ from the very first round of negotiations (Senate Committee Report 2004, p. 103).

PhRMA had made no secret of its dislike of the Australian PBS which it believed eroded intellectual property protection, devalued innovation and discouraged investments in new medical discoveries. Australian drug prices are 2–3 times lower than prices in the US. This has been achieved by the use of pharmacoeconomic analysis and reference pricing to determine what the benefits of a new drug are genuinely worth and employing the monopsony power of the PBS to counter the monopoly power of patents. However, the Productivity Commission (2001) has noted that the largest price differences in Australia (compared with other countries) were for new drugs that offered little benefit over existing other products (so-called me-to drugs). Genuinely innovative pharmaceuticals had prices closer to those in most comparator countries. In addition, over the last few years the Australian Department of Industry, Tourism & Resources (2004) has administered a \$300 million Pharmaceutical Industry Investment Program (PIIP) that provides additional rewards for pharmaceutical manufacturers for undertaking research and development in Australia. From July 1, 2004 a Pharmaceuticals Partnerships Program will take over from the PIIP and provide an additional

\$150 million over the next 5 years. In short, PhRMA’s opinion that Australia “does not pay its way” with respect to pharmaceutical innovation is not substantiated by the evidence.

Furthermore, over the last 10 years, the pharmaceutical industry has been by far the most profitable in the US. The pharmaceutical giants spend 2–3 times more on marketing and administration than on research and development (R&D); their profits are about twice R&D costs. Regardless, PhRMA has a reputation for vigorously opposing public policy that may impact on the profitability of its members. In the fiscal year July 2003–June 2004, PhRMA was reported to be spending US \$150 million to influence public policy (a 23% increase over the previous year). Their spending priorities are detailed in the Box (Pear 2003).

Given that background, it’s not surprising that the FTA became a PBS negotiating battleground. The key question is, “Who won?” Australian Trade Minister Mark Vaile said, “The PBS, in particular the price and listing arrangements that ensure Australians access to quality, affordable medicines, remains intact” (Vaile 2004). However, members of the US Congress congratulated US Trade Representative Bob Zoellick on securing a deal that made Australians pay a greater proportion of R&D costs for US drugs (US Senate 2004).

AUSFTA provisions that impact upon the PBS

The 1100 page AUSFTA contains 57 references to pharmaceuticals that can be grouped under seven provisions that have the potential to impact on the PBS (Australian Government, Department of Foreign Affairs and Trade 2004). Four provisions are detailed in Annex 2-C (Pharmaceuticals), the fifth is contained in a side-letter between Trade Minister Vaile and US Ambassador Zoellick, the sixth resides in Chapter 17 (IP Rights) and the seventh is in Chapter 21 (Dispute Resolution Procedures).

The interpretative principles

The first concern is the interpretative principles set out at the beginning of Annex 2-C (dealing with pharmaceuticals). The principles are unbalanced

Pharmaceutical Research and Manufacturers of America (PhRMA) expenditure to influence public policy (July 2003–2004)

PhRMA Initiative	Budget (US\$ million)
Pharmaceutical lobbying at the federal level (there are 625 pharmaceutical lobbyists on Capitol Hill, more than the number of Congressmen)	72.7
Lobbying at state level	48.7
Fighting price controls and protecting patent rights in foreign countries and in trade negotiations	17.5
Fighting “a union-driven initiative in Ohio” which would lower drug prices for people who have no insurance to cover such costs	15.8
Lobbying the US Food and Drug Administration	4.9
Payments to research and policy organisations “to build intellectual capital and generate a higher volume of messages from credible sources” sympathetic to the industry	2.0
Funding a standing network of economists to speak against US drug price controls	1.0
Changing the Canadian health care system	1.0

Source: Pear 2003

in that they focus primarily on the rights of manufacturers of innovative pharmaceutical products and neglect the rights of consumers to equitable access to affordable drugs. In particular, the agreement leaves out the key principle of the Doha Declaration on the TRIPS Agreement and Public Health; namely that trade agreements should be interpreted and implemented so as to protect public health and promote access to medicines for all. In addition, the crucial role of generic manufacturers in moderating prices when patents have expired or in public health emergencies is not mentioned in the AUSFTA.

“Transparency” provisions

Second, Annex 2-C 2(f) under the heading “transparency,” allows US pharmaceutical applicants (but not consumer or public health organisations) to ask for an independent review of a decision by the PBAC not to list a drug. This is despite the fact that such appeals were previously rejected by the Tambling (2000) review of the PBS. The Department of Health and Ageing (DoHA) has argued that the proposed review process will not be able to overturn a PBAC decision. However, the review process will certainly increase the cost of administering the PBS, and it seems inevitable that such reviews will increase pressure on the PBAC to list

drugs at higher prices (or for broader indications) than were otherwise justified by evidence of cost-effectiveness. Ironically, the ‘transparency’ provisions of this section continue to enshrine the ‘commercial-in-confidence’ right of pharmaceutical applicants to deny the public access to their PBS submission despite increasing evidence that some drug companies withhold vital information needed to make informed decisions about treatment (Editorial 2004).

The Medicines Working Group

Third, the agreement sets up a Medicines Working Group between health officials from each country. The DoHA argues that this working group is similar to others set up for other industries affected by the AUSFTA; that the group is not a policy-making body and will only serve as a discussion forum. Once again, US officials appear to have a different view of the likely impact of the working group than do Australian officials. Senator Kyl (Chair, Republican Policy Committee) told the US Senate that, “During our meetings in Australia we suggested such a working group as a way to guarantee that, if our pricing concerns could not be resolved in the FTA, we could continue to discuss the issue. The subject matters that the group might consider are not limited by

the agreement, and therefore can be expected to include the importance of market-based pricing” (Senate Committee Report 2004, p. 117).

Disseminating information via the Internet

Fourth, provision 2.5 in Annex 2-C permits a pharmaceutical manufacturer to disseminate pharmaceutical information via the Internet (for example via links on sites frequently used by Australian patients). This appears to be a ‘toehold’ strategy to eventually facilitate Direct to Consumer Advertising (DTCA) in Australia. DTCA is legal in the USA but not in Australia. It has been associated with a substantial increase in usage of the products which are often not in accord with best-practice (Mintzes et al. 2002). The DoHA argues that this clause contains nothing new and merely reiterates the current legal situation in both countries. The question as to why this and several other matters are specifically mentioned in the AUSFTA if they contain nothing new has not been satisfactorily answered.

Adjustment to PBS prices

Fifth, an exchange of letters between Trade Minister Vaile and US Ambassador Zoellick notes that Australia shall provide opportunities for pharmaceutical manufacturers to apply for an adjustment to PBS prices. The DoHA argues that provision for price adjustments by the Pharmaceutical Benefits Pricing Tribunal has been available for some time and this clause also adds nothing new. There is concern, however, that if this clause is interpreted in the light of the principles outlined above it will provide greater opportunities for US companies to seek price rises for ‘innovation’ as distinct from cost-effectiveness.

Intellectual property provisions

Sixth, the IP provisions of the FTA are likely to delay the introduction of cost-effective generic drugs and prevent our generic industry from alleviating public health crises in neighbouring countries (Article 17.9.6). Article 17.9.8 of the FTA locks in the preferential patent term extensions accorded pharmaceuticals. Article 17.10.4 takes the radical step of indefinitely ‘preventing’

market approval by the Therapeutic Goods Administration depending on whether any relevant patent has been ‘claimed’. This could facilitate litigation replacing innovation, here as it has in the US and Canada, as original patent owners seek to ‘evergreen’ their exclusive rights over ‘blockbuster’ pharmaceuticals with ultimately spurious ‘claims’ over the process or capsule rather than the active ingredient.

The Australia Institute has estimated that if such changes succeed in delaying market entry by generics over just the top five PBS expenditure drugs due to come off patent, this could increase the cost of the PBS by \$1.5 billion over 2006–2009 (Lokuge, Faunce & Denniss 2003). Delayed entry of generic drugs will not only affect the prices of PBS listed medicines and hospital medicines supplies, but also non-PBS products sold in Australia. These include pharmaceuticals purchased by private and public hospitals and over-the-counter medicines which are not covered by Government subsidies or safety nets. The end result will be higher pharmaceutical costs for the Commonwealth and state governments as well as consumers.

Dispute Resolution

Finally, under the dispute resolution chapter 21, an unelected panel of three nominated trade lawyers (Article 21.7) will have the power to interpret compliance with obligations in the AUS-FTA, including the required alterations to shift the focus of our PBS toward greater rewards for drug ‘innovation’. Faced, for example, with determining whether the PBS ‘review mechanism’ actually fulfils AUSFTA obligations, the panel will rely upon the interpretive ‘principles’ set out at the beginning of Annex 2-C. As previously mentioned, these principles are heavily weighted towards the agenda of the US pharmaceutical industry, emphasising ‘innovation’, ‘research and development’ and ‘transparent, expeditious and accountable procedures’ as well as ‘competitive markets’. The principles contain no unqualified reference to universal access to affordable and essential medicines. In addition, article 21.2 (c) allows a damages claim where a ‘benefit’ the US

could reasonably have expected to accrue under the AUSFTA is not realised even though no specific provision has been breached. The upshot of this is that PBAC decisions not to 'list' 'innovative' new US drugs (because they were not cost-effective) will be made in the shadow of possible US trade retaliation in important areas such as manufacturing and agriculture.

The political process that reviewed and ultimately amended the AUSFTA

Two parliamentary inquiries examined the AUSFTA; the Joint Standing Committee on Treaties (JSCOT) and a Senate Select Committee.

The JSCOT was a government committee and the Liberal party provided the Chair and a majority of the 16 members. Its brief was to determine if the AUSFTA was in the national interest. The JSCOT received 215 public submissions, conducted many public hearings and delivered its final report on June 23 (Joint Standing Committee on Treaties 2004).

The JSCOT report concluded that ratification of the AUSFTA was in Australia's national interest. The committee noted a number of concerns expressed by the public submissions and made a number of recommendations. These included, that any independent review of PBAC processes should be pragmatic, transparent and report back to PBAC, and that any changes made to the Therapeutic Goods Act 1989 with respect to Chapter 17 of the AUSFTA should ensure no undue delay of generic drugs. The committee was confident that the ongoing involvement and vigilance of health professionals, organisations and individuals would ensure that any changes which may be seen to threaten or undermine the Australian health system would be the subject of spirited debate and public involvement in the future. There was a dissenting report by opposition members of JSCOT who recommended that the AUSFTA not be approved until adequate opportunity has been given to consider the necessary legislative, regulatory and administrative action that underpins the implementation of the Treaty.

A Senate Select Committee had the broader task of examining the impact of the AUSFTA on Australia's economic, trade, investment and social and environment policies, including, but not limited to, agriculture, health, education and the media. The Opposition parties had a majority of the 8 committee members including the Chair. This committee received 543 public submissions and also conducted many public hearings, including a PBS 'round table'. It delivered an interim report on June 24, 2004 and a final report on August 5 (Senate Committee Report 2004).

The interim report acknowledged that the AUSFTA could open the PBS listing process to increased lobbying from pharmaceutical companies, impact on pharmaceutical policies through the operation of the Medicines Working Group and provide scope for US pharmaceutical companies to extend the life of pharmaceutical patents by the IP and the dispute resolution processes. The report noted government assurances that the fundamental architecture of the PBS, including the pricing and listing policies, remained unchanged by the Agreement. However, it observed that, at the time of writing, the government had not been able to back up these assurances with detail on implementation, thus the actual effect of the changes could not be conclusively determined. The committee planned to scrutinise the AUSFTA enabling legislation and other implementation details to assess whether the issues and concerns that had persisted throughout the inquiries would be satisfactorily resolved. The interim report contained a dissenting report from Government members who believed these concerns were without foundation and that the AUSFTA should be approved forthwith.

The US Free Trade Agreement Implementation Bill (2004) was introduced into the House of Representatives on June 23, 2004. Schedule 7 of the Bill contains provisions to amend the *Therapeutic Goods Act 1989* (Cwlth) which relate to the interaction between patents and the listing of goods by the Therapeutic Goods Association. Schedule 7 appeared to cover only the least controversial patent provisions — a new certificate that generic companies must provide when

applying for marketing approval of a generic drug. This legislation does not appear to be consistent with the words of Article 17.10.4, and it is unlikely to prevent patent owners from using the AUSFTA to 'evergreen' their exclusive rights over 'blockbuster' (high sales volume) pharmaceuticals by making speculative and ultimately spurious 'claims' over the process or capsule rather than the active ingredient.

The government also outlined the proposed operation of the AUSFTA PBAC review process (Abbott 2004). A working group recommended that PBAC reviews be conducted in secret by an individual expert chosen by a government appointed convenor who would oversee and manage the review process. The lone expert reviewer would come from a list of identified experts drawn up by the convenor but would also be allowed to consult other experts on the basis of prior consultation with the convenor. The review should be completed in a time frame that allows the reporting back to the PBAC meeting in the same time frame as a resubmission. The outcomes of completed reviews would be made public but "any consultations relating to the conduct of the independent review will be conducted in closed session". Confidential information would be afforded the same level of protection as information put to the PBAC. A pharmaceutical company could either have a review of a negative PBAC decision (without submitting new data) or they could resubmit an application (with new data): they cannot do both.

The working party also proposed (in principle) that all PBAC recommendations should be made public in a timely manner following each PBAC meeting, including the relevant clinical, economic and utilisation data justifying the PBAC's recommendations. Currently only the reasons for positive decisions are made public; the data supporting the decision is not, being regarded as commercial-in-confidence by pharmaceutical manufacturers. However, the working group (and the AUSFTA) have also agreed that confidential material (to be defined) should be protected. The working group have requested additional time to resolve these issues and also to be informed by the public response to the position paper.

The issue of genuine rather than selective 'transparency' is a matter of considerable importance, as there is increasing evidence that some drug companies withhold information needed to make informed decisions about their products (Editorial 2004). As a consequence, there is increasing support for the view that 'commercial confidentiality' should be confined to details of product manufacture and formulation, not to clinical trial methods, data, or results (Herxheimer 2004).

Clearly, as the government promised, the above review process does not have the power to overturn or set aside PBAC decisions. However, there is concern that this process will prove unacceptable to the Americans and become the subject of an AUSFTA Chapter 21 dispute action. US pharmaceutical companies have shown little hesitation in taking negative PBAC decisions to the High Court (Aroni, de Boer & Harvey 2003). Chapter 21 of the AUSFTA now provides them with another path to follow.

The final Senate Select Committee report became available on August 5, 2004. In it, Labor senators noted that, as a core social policy in Australia, the PBS should never have been on the negotiating table. They also observed that several members of the US Congress expressed similar views during their debate on the FTA. Nevertheless, Labor senators recommended that the Senate should pass legislation that would give effect to the AUSFTA, subject to adding an amendment to the implementing legislation that would create an offence (with substantial fines) for the lodgement of a spurious patent claim that delays the entry of a generic drug onto the market (Latham & Conroy 2004). They also made a number of other recommendations concerning the PBS and the AUSFTA to be implemented if Labor came to office. The Senate report contained an additional section by Liberal members and dissenting reports from Democrat and One Nation members.

On August 13, 2004 the government reluctantly supported the Labor amendment, and the AUSFTA implementing legislation passed the Senate despite ongoing opposition from the Democrats and the Greens. The following day, US Trade Representative spokesman, Richard Mills said,

“We understand that the FTA implementing legislation and amendments pose important issues in Australia, just as they did in the United States. We have chosen not to intervene in the internal debate within Australia about the FTA implementing legislation and amendments at this point. We have stated that it is 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.” (Mills 2004)

If the US decides that the legislation is consistent with the agreement, the final confirmation of the agreement should occur in October, and the agreement will come into force from January 2005.

Conclusion

In the final report of the Senate Select Committee, Labor members noted that it was entirely inappropriate to go beyond TRIPS commitments in negotiating a bilateral trade deal with the US. The Greens, the Democrats and One Nation totally opposed the AUSFTA. Nevertheless, with an election imminent it seemed that both the Liberal and Labor hierarchy wanted the AUSFTA debate swept off the political agenda. A deal was done before most parliamentarians, let alone the public, even had time to read the Senate report.

The motive for both parties appeared politic rather than principled. The Prime Minister and the Liberal party wanted a signed and sealed AUSFTA as a demonstration of their economic credentials and the value of the American alliance, despite the intransigence of the Americans on agriculture and other matters. The ALP Left opposed the AUSFTA but the majority Right faction, especially key pro-US front benchers, supported signing the agreement, apparently because they thought further debate was politically unsustainable given the cries from the government that Labor was ‘anti-Ameri-

can’. After some equivocation, the Leader of the Opposition (Mark Latham) supported the AUSFTA but insisted on amendments to penalise patent abuse by drug companies (and protect current media content rules). This was acknowledged to be an astute political move and it exposed those issues to belated public debate. But neither the Labor amendments, nor the additional measures Labor proposed if they won office, are likely to protect the PBS from the varied pressure points that the AUSFTA has created. In particular, they provide no redress from a likely complaint under the agreement’s dispute resolution process that Australia has failed to meet an implicit obligation to increase drug prices in order to pay its share of R&D costs. If the US convinces a panel of international trade lawyers that its interpretation is correct, then stiff penalties could be imposed on Australia.

This outcome could have been prevented if, in the introduction of Annex 2-C (Pharmaceuticals) of the AUSFTA, it had also agreed that, “This agreement shall be interpreted and implemented to protect public health and promote universal and affordable access to necessary medicines”. One can only concur with Colebatch (2004); the problem was that negotiations were concluded prematurely. In February, the negotiators should have walked away, taken a long break for consultations and rethinking, and then resumed talks after both countries had got their elections out of the way. That could have been possible if Labor had the courage to defy the government and vested interests, vote the agreement down in the Senate, and restart negotiations in 2005.

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Statement of competing interests

The author is a Councillor of the Australian Consumers Association and a member of the Australian Labor Party.

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