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Agony in the Antipodes: The Generic Drug Provisions of the Australia-U.S. Free Trade Agreement

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Abstract

The Australia-US free trade agreement which entered into force on 1 January 2005 contains many remarkable provisions of interest to generic drug companies. Independent Australian researchers expect that generic entry will be delayed by up to three years once the provisions are fully implemented.

Keywords

Australia – United States Free Trade Agreement (AUSFTA); Agreement on Trade-Related Intellectual Property Rights (TRIPS); TRIPS+; free trade agreement (FTA); pharmaceuticals; generic; Hatch-Waxman Act; pharmaceutical benefits scheme (PBS)

INTRODUCTION

On January 1, 2005, the Australia-US Free Trade Agreement (AUSFTA) entered into force.[1] (The timeline for the AUSFTA negotiations is found in Table 1.) Apparently for the first time,[2] a free trade agreement modifies domestic pharmaceutical pricing policy,[3] moving well beyond the intellectual property provisions of the WTO TRIPS Agreement.[4] The AUSFTA also exports some provisions of the US Hatch-Waxman Act, with some interesting domestic political implications in both the US and Australia. Generic drug makers would do well to pay careful attention to the process of international trade agreements.[5]

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[1] Australia-United States Free Trade Agreement (2004 (*available at* http://www.dfat.gov.au/trade/negotiations/us.html).
[2] Becker, E. & Pear, R. (2004) 'Trade Pact May Undercut Inexpensive Drug Imports', N.Y. Times (12 July 2004).
[3] In Australia's case, the modification is made to the government's decision to list a drug for reimbursement at an agreed price under the Pharmaceutical Benefits Scheme (PBS).
[4] World Trade Organization, Trade Related Intellectual Property Agreement (1994). The "TRIPS Plus" provisions of AUSFTA are listed in Table 3.
[5] While generic drug industry trade organizations submitted testimony in both Australia and the US, the brand name drug industry was much more active and effective, as demonstrated by the provisions of the AUSFTA.

Several excellent articles are available on the pharmaceutical provisions of the AUSFTA generally;[6] this article focuses on the aspects of particular interest to the generic drug industry.

ATTACKING FREE RIDERS THROUGH HIGHER DRUG PRICES

The most important pharmaceutical goal for the United States in the AUSFTA was to raise Australian drug prices.[7] Since most drugs in Australia are reimbursed under the Pharmaceutical Benefits Scheme (PBS), the AUSFTA had to modify PBS in order to meet US objectives. Brand-name drug companies have complained for years that PBS prices are too low; independent researchers have generally lauded the PBS as paying for value through an economics-driven Phase IV reimbursement process. The US took the former view in the negotiations, and sought to raise Australian drug prices so that Australia would stop 'free riding' and pay its 'fair share' of drug R&D costs. I am skeptical about many aspects of the free rider argument, but have written about it elsewhere and will not belabour the point here.[8]

What is the scope of Australia's alleged free riding? The US International Trade Administration recently calculated the amount as US$400 million per year.[9] Australian estimates of America's price-rise ambitions were similar, topping AU$500 million per

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[6] *See, e.g.*, Harvey, K. (2004) 'Patents, pills and politics: the Australia-United States Free Trade Agreement and the Pharmaceutical Benefits Scheme', Australian Health Review, Vol. 28(2), pp. 218-226 (Nov. 2004). Drahos, P. & Henry, D. (2004) 'The free trade agreement between Australia and the United States: Undermines Australian public health and protects US interests in pharmaceuticals,' British Medical Journal, Vol. 328, pp. 1271-1272 (29 May 2004). *See also* the submissions to the Australian Senate by the Generic Medicines Industry Association Pty Ltd., the Doctors Reform Society, the Public Health Association of Australia, Inc., the Australian Nursing Federation, Catholic Health Australia, the National Center for Epidemiology and Population Health, the Australian Consumers' Association, and Dr. Ken Harvey, all available at http://www.aph.gov.au/Senate/committee/freetrade_ctte/indes.htm.

[7] Pharmaceutical Research and Manufacturers of America (2003) 'PhRMA "Special 301" Submission to the Office of the United States Trade Representative: Australia' (available at www.ustr.gov). Colebacht, T. (2003) 'Bush Wants End to Medicine Subsidies', The Age (Melbourne), (24 Oct. 2003, at 5). Hearing of the US Senate Finance Committee (2004), 'The Administration's International Trade Agenda' (Witness: Ambassador Robert Zoellick, US Trade Representative). McClellan, M. B. (2003) 'Speech before the First International Colloquium on Generic Medicine' (25 Sept. 2003, available at www.fda.gov/oc/speeches/2003/genericdrug0925.html. Serafini, M.W. (2004) 'Drug Prices: A New Tack' National Journal, Vol. 36, p. 16 (17 April 2004) ("So [House Speaker] Hastert and [Senator] Kyl championed the novel idea that the key to lowering U.S. prescription drug prices is to persuade foreign governments to raise their prices…The idea of trying to level the international playing field on prescription drug pricing originated with the U.S. pharmaceutical industry. But Hastert and Kyl played significant roles last fall in persuading the Bush administration to embrace this strategy…The result was the United States' first free-trade agreement that included modest concessions on pharmaceutical price controls.") Of course, increased prices for brand-name drugs would be good news for generic makers, permitting them to increase their own prices whilst still undercutting the competition.

[8] *See* Outterson, K. (2004a), 'Free Trade Against Free Riders?', Pharma Pricing & Reimbursement, Vol. 9, pp. 254-55.

[9] [US] International Trade Administration (2004) 'Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation.

year.[10] Table 2 illustrates how much the US International Trade Administration thinks drug prices should rise in several OECD countries. The process will require further trade agreements.[11]

The primary AUSFTA mechanism for increasing PBS prices was the addition of an appeal in the Australian government's pharmaceutical reimbursement process.[12] Under the AUSFTA, if the Pharmaceutical Benefits Advisory Committee (PBAC) declines to list a drug for reimbursement at a particular price, the drug company may request an independent review. The appeal will apparently rest in a single Department of Health and Aging (DoHA) reviewer, who will look at the PBAC file, as well as other data which may be submitted by the companies or the government.[13] Commentators with direct experience with the PBAC believe this process will pressure to the PBAC to list drugs they would not have otherwise listed, or to list drugs at higher reimbursement prices than otherwise would have been the case.[14] Indeed, higher prices were the explicit purpose of the provision, at least for the US negotiators.

The question of free riding places Australian and US politicians in the position of quietly undermining each other's announcements. In the US, USTR Zoellick was congratulated on a job well done,[15] which means that the process will cause PBS drug prices to rise. In Australia, Trade Minister Vaile, in the midst of the recent Australian election campaign, insisted that prices would not rise at all.[16] Success cannot have come to both.

Independent observers expect the appeals process and other AUSFTA provisions to have a significant upward impact on PBS drug prices.[17] Whether it reaches the magnitude of

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[10] The estimate was AU$ 1.5 billion over 2006-2009. Productivity Commission (2001), 'International Pharmaceutical Price Differences: Research Report' (available at http://www.pc.gov.au/study/pbsprices/finalreport/pbsprices.pdf (assumes that the top 5 PBS expenditure drugs are delayed). For a higher estimate, *see* Burton, B. (2004) Brit. Med. J., Vol. 329, p. 7461 (Sept. 2004).

[11] Becker, E. & Pear, R. (2004) 'Trade Pact May Undercut Inexpensive Drug Imports', N.Y. Times (12 July 2004) (statements of Dr. Mark B. McLellan, former head of FDA and current administrator of Medicare and Medicaid) (statement of Joseph M. Damond, Associate Vice President of PhRMA). Maher, S. (2004), 'US Drug Makers Pressure Canberra', The Australian (29 Dec. 2004) (statements of US Senators Rick Santorum and Jon Kyl).

[12] AUSFTA (2004), Annex 2-C, ¶2(f).

[13] Burton, B. (2004) Brit. Med. J., Vol. 329, p. 7461 (Sept. 2004).

[14] *See, e.g.*, Harvey, K., et al. (2004), 'Will the Australia-United States Free Trade Agreement Undermine the Pharmaceutical Benefits Scheme?', Med. J. Austr., Vol. 181, pp. 256-259 (Sept. 6, 2004). Dr. Harvey is a former member of the PBAC. *See also* Drahos, P. et al. (2004) 'The FTA and the PBS: A submission to the [Australian] Senate Select Committee on the US-Australia Free Trade Agreement', p. 3.

[15] Hearing of the US Senate Finance Committee (2004), 'The Administration's International Trade Agenda' (Witness: Ambassador Robert Zoellick, US Trade Representative) (2004).

[16] Vaile, M. (2004), 'Free Trade Agreement with the United States', Media Release, 8 Feb. 2004 (MVT08/2004) (available at http://www.trademinister.gov.au/releases/2004/mvt008_04.html). *See also* Abbott, T. (2004) 'Australia-United States Free Trade Agreement (AUSFTA), Implementation of the Obligations to Improve Transparency of the Pharmaceutical Benefits Scheme (PBS) through An Independent Review Mechanism, Hearings before the Pharmaceutical Benefits Advisory Committee (PBAC) (25 July 2004) (statement of The Hon. Tony Abbott, MP, Minister for Health and Ageing).

[17] Drahos, P. et al. (2004) 'The FTA and the PBS: A submission to the [Australian] Senate Select Committee on the US-Australia Free Trade Agreement', p. 1.

US$400 million per year remains to be seen. More importantly, the AUSFTA will not affect 90% of the alleged OECD free riding described in the US ITA Report. US officials suggest that additional trade agreements are in the offing on this issue.

The trade agreement strategy is unlikely to be effective. To raise global prices significantly, the US must force Canada, Australia, Japan and all of Europe to change an important domestic policy. Is this likely to be effective? Would it be a prudent use of American diplomatic and trade leverage?

It is far more likely that the US will 'succeed' in raising drug prices in smaller and more vulnerable countries. In the face of genocidal access issues, do we really want to raise drug prices in Central America and the Dominican Republic through CAFTA-DR? In the Morocco or Jordan FTAs? In sub-Saharan Africa? Can anyone imagine a *worse* idea for global drug pricing?[18]

When it comes to the world's poorest countries, the free rider label is especially inapposite. Low income countries cannot contribute much global drug R&D cost recovery, and should be considered *fair followers* rather than free riders. The eminent economist F.M. Scherer described this policy in a recent article, echoing the cries of essential medicines advocates like Médecins Sans Frontières.[19]

EXPORTING HATCH-WAXMAN

The Hatch-Waxman Act[20] regulates the generic entry process, striking an often-controversial compromise between innovation and low-cost generic access. The current state of Hatch-Waxman leaves much to be desired, but it probably reflects the current political balance of power between PhRMA and those who pay for drugs, including governments and managed care companies.

Whatever its charms for the US population, it seems unlikely that Hatch-Waxman represents the ideal policy for countries as diverse as Israel, the Dominican Republic, Morocco or Australia. When the US inserts Hatch-Waxman provisions into trade agreements, the policy debate is not transparent.[21] Health experts are frequently not

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[18] Outterson, K. (2005) 'Pharmaceutical Arbitrage: Balancing access and Innovation in International Prescription Drug Markets' Yale Journal of Health Policy, Law & Ethics, Vol. 5(1), pp. 193-286.

[19] 't Hoen, E. (2002) 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' Chicago Journal of International Law, Vol. 3, p. 27.

[20] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28 and 35 U.S.C.) [hereinafter Hatch-Waxman Act]. Under the Hatch-Waxman Act, the FDA also influences the patent process, since Hatch-Waxman extends the patent for half of the period that a drug is undergoing clinical trials, plus the full amount of time spent in the FDA approval process. 35 U.S.C. §§ 155, 155A, 156 (2000).

[21] *See, e.g.,* Médecins sans Frontières (2004), MSF Briefing note, Access to Medicines at Risk Across the Globe: What To Watch Out For in Free Trade Agreements with the United States, pp. 4-6. (available at http://www.accessmed-msf.org/documents/ftabriefingenglish.pdf); Vivas-Eugui, D. (2003) Quaker U.N. Office, Regional and Bilateral Agreements and a TRIPS-Plus World: The Free Trade Area of the Americas (FTAA), pp. 16-18.

involved. Hatch-Waxman provisions may be quietly accepted in exchange for limited US concessions regarding market access for agricultural or manufactured products. These processes lack transparency and democratic legitimacy.

Several provisions of the AUSFTA are grafted from Hatch-Waxman. Article 17.10.4 of the AUSFTA introduces into Australian law the new "26B Certificate."[22] The 26B Certificate is similar to the Hatch-Waxman provision which ties marketing approval to patent status. Generic entry in the US has been greatly delayed by litigation under this provision, particularly the automatic 30-month stay. The Federal Trade Commission criticized many anticompetitive aspects of this situation,[23] which has now been modified.[24] Trading partners should carefully review the American experience with these provisions before importing them unawares. Generic companies with experience with the Hatch-Waxman system could be valuable sources of advice to governments negotiating free trade agreements with the US.

Another provision of the AUSFTA locks-in domestic law in both countries which provides patent term extensions for the regulatory approval process.[25] This portion of Hatch-Waxman is now carved in stone in both US and Australian law, and cannot be modified without approval from both governments. Since the US initiated this provision of the AUSFTA, in a sense the US has tied its own hands, preventing some future amendments to Hatch-Waxman in the US. Upon closer examination, it was the USTR, under the strong influence of PhRMA, and with the consent of Congress under fast track authority, which has tied the hands of future Congresses. While the chance of Congress repealing patent term extension for the regulatory approval process was admittedly remote, it is now remoter still. More fundamental reforms to the drug innovation system, such as the Hubbard-Love R&D proposal,[26] face additional barriers due to the AUSFTA. The political effects of the AUSFTA process is discussed in more detail below.

Notably missing from the AUSFTA was the Bolar Amendment, which permits generic companies to perform the research necessary to have a generic drug ready to market upon

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[22] US Free Trade Agreement Implementation Bill 2004, The Senate, The Parliament of the Commonwealth of Australia.

[23] Federal Trade Commission (2002) GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION, pp. 13-23.

[24] Pub. L. No. 108-173, 117 Stat. 2066 (2003), tit. IX (partially codified at 21 U.S.C. § 355(j)). The Congressional Research Service prepared a summary of the Act which provides some guidance on Congress's intent in amending Hatch-Waxman. *See* Cong. Research Service (2003) 'Prescription Drug and Medicare Improvement Act of 2003, Bill Summary and Status, S.1, 108th Cong.' (June 13, 2003).

[25] AUSFTA (2004), art. 17.9.8.

[26] Hubbard, T. 'Alternatives to the Price System, Presentation at Columbia University' (Dec. 4, 2003) (available at http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html). Love, J. (2003) 'A New Trade Framework for Global Healthcare R&D, Presentation at Columbia University' (Dec. 4, 2003) (available at http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html).

patent expiration.[27] The AUSFTA also granted 5 years of market exclusivity for new uses, beyond the US standard of 3 years.[28]

Beyond the AUSFTA, recent US free trade agreements have tinkered with various Hatch-Waxman and related provisions, including data exclusivity delaying generic entry, the Bolar Amendment, exhaustion rules on parallel trade, and freedom to utilize the Doha Paragraph 6 process for compulsory licensure.[29]

The Labour Amendments

Australian critics charged that the AUSFTA could permit 'evergreening,' the Australian term for artificially extending the effective length of patents and exclusive marketing periods.[30] Independent researchers determined that the AUSFTA would likely delay generic entry by an average of three years.[31] The Australian Labour party, then in the control of the Senate, offered amendments to the AUSFTA implementing legislation to address this concern. The amendments caused quite a stir in Washington, which threatened to undo the AUSFTA on that basis alone.[32] In the end, the US reluctantly allowed the amendments to stand, but reserved its rights to challenge the practice at a later date.

The Labour amendments can best be described as a toothless tiger. The most important amendment permits an AU$ 10 million penalty for drug patent litigation in bad faith. This penalty will never be imposed. The amendment provides broad exceptions for 'reasonable grounds' for suing for infringement.[33] Any decent legal opinion will immunize the company against the AU$ 10 million penalty. Proving bad faith will be difficult, absent a smoking gun document from the drug company. The final provision of the penalty requires a promise to conduct the patent litigation "without unreasonable delay."

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[27] Jaeger, K. (2004) 'Statement of Kathleen Jaeger, Generic Pharmaceutical Association' US House Ways & Means Committee Hearings on the US - Australia Free Trade Agreement.

[28] AUSFTA (2004), art. 17.10(1)(c); Jaeger, K. (2004) 'Statement of Kathleen Jaeger, Generic Pharmaceutical Association' US House Ways & Means Committee Hearings on the US - Australia Free Trade Agreement.

[29] Letter to Robert B. Zoellick from Charles B. Rangel, Jim McDermott, Sander M. Levin & Henry A. Waxman (15 July 2004) (US-Morocco FTA); Médecins sans Frontières (2004), MSF Briefing note, Access to Medicines at Risk Across the Globe: What To Watch Out For in Free Trade Agreements with the United States, pp. 4-6. (available at http://www.accessmed-msf.org/documents/ftabriefingenglish.pdf); Vivas-Eugui, D. (2003) Quaker U.N. Office, Regional and Bilateral Agreements and a TRIPS-Plus World: The Free Trade Area of the Americas (FTAA), pp. 16-18.

[30] For Australian concerns about evergreening, *see* Lokuge, B., Faunce, T. & Denniss, R. (2003) 'A Backdoor to Higher Medicine Prices? Intellectual Property and the Australia-US Free Trade Agreement' (Nov. 2003). *See also* Bulow, J. 'The Gaming of Pharmaceutical Patents', in Innovation Policy and the Economy, Vol. 4.

[31] Drahos, P. et al. (2004) 'The FTA and the PBS: A submission to the [Australian] Senate Select Committee on the US-Australia Free Trade Agreement', p. 2.

[32] Letter from US Trade Representative Robert Zoellick to Australian Trade Minister Mark Vaile (Nov. 17, 2004).

[33] US Free Trade Agreement Implementation Bill 2004, Amendment (2), The Senate, The Parliament of the Commonwealth of Australia (codified as new section 26C of the Therapeutic Goods Act 1989).

If by some chance the penalty is ever proposed against a company, it may be challenged under WTO rules. The US has already warned of a challenge under WTO nondiscrimination rules.[34]

The other two amendments lower the standard for the Australian generic certification of noninfringement to "reasonable grounds," and regulate the process for interlocutory (declaratory) injunctions.[35] The Labour amendments failed to include many suggestions from Australian academics, including requests for a transparent 'Orange Book' register in Australia; a process for obtaining Orange Book data for other countries to facilitate generic exports from Australia; and more rigorous review of pharmaceutical patents by both IP Australia and the PBAC.[36] It also failed to take full advantage of the negative US experience with declaratory judgment actions involving generic drugs.

POLITICAL EFFECTS OF THE AUSFTA PROCESS

Free trade agreements permit companies to achieve indirect legal change that was blocked through direct routes, and does so with less transparency. The AUSFTA was no exception.

Changing domestic law

For example, in the US copyright terms were extended by an additional 20 years in 1998 to protect the nearly-expired copyrights on Mickey Mouse and other early 20th-Century copyrighted works. This law was upheld by the US Supreme Court in 2003.[37] The law protects Mickey in Southern California, but what about Australia? Attempts to get a similar law passed in the Australian Parliament were apparently unsuccessful, so the proponents of longer copyrights resorted to the AUSFTA process. Carefully placed in the 1000 page document, and receiving precious little public attention, was Australia's concession to extend copyright terms from 50 years to 70 years following the death of the creator, even if the creator was already dead. Walt Disney died on Dec. 15, 1966, and the original period would have expired in Australia on Dec. 15, 2006.

Lock-in current law

The AUSFTA also includes many provisions which allegedly don't reflect a change in law, such as the 'side letter' provision permitting company applications to the PBAC for

[34] TRIPS requires patent laws to not discriminate on the basis of technological field. The US argument would be that Australia's amendment discriminates against the field of drug patents, since the provision does not apply to non-drug patents. This raises the interesting question as to whether the entire US Hatch-Waxman apparatus violates TRIPS nondiscrimination rules.
[35] US Free Trade Agreement Implementation Bill 2004, Amendments (1) and (3), The Senate, The Parliament of the Commonwealth of Australia (codified as new section 26B(1)(a) and 26D of the TGA).
[36] Drahos, P. (2004) 'Dealing With Evergreening'.
[37] Eldred v. Ashcroft, 538 U.S. 916 (2003).

subsequent price adjustments.[38] Another Australian example is direct to consumer advertising (DTC). With the exception of New Zealand, PhRMA has been unable to persuade other major markets to embrace US-style DTC. The AUSFTA includes a provision on web-based advertising provision in paragraph 5 of Annex 2C. A domestic example is the provision blocking US importation of cheaper drugs from Australia while the issue was being hotly debated in Congress.[39]

Australian officials insist that these provisions (and many others, found on Table 3) merely reflect current law,[40] but their protestations ring hollow, for at least three reasons. We will take paragraph 5 of Annex 2-C as the example, but similar arguments apply to most of these provisions.

First, if paragraph 5 merely reflects current law, why give it a prominent place in the AUSFTA?[41] At the very least, enshrining a rule in the AUSFTA prevents the Australian Parliament from adopting a different rule later, absent the consent of the United States. This 'lock in' effect is significant, preventing later reconsideration of the issue in the Australian Parliament. The democratic legitimacy of using free trade agreements to lock-in domestic political gains is weak, for it effectively gives a veto to the other country for certain domestic legal changes.

A second major change is procedural. If a drug company mounts an overly aggressive web-based DTC campaign, the AUSFTA now provides a process and a remedy outside of Australian law. (Look at Pfizer Australia's Viagra site[42] for a possible example). The matter won't be decided solely under Australian law; the USTR may get involved; it can be discussed at the Medicines Working Group;[43] the US may apply 'Special 301' pressure, or request consultations under Chapter 21 of the AUSFTA. Ultimately, if compromise proves impossible, it will be decided by a panel of trade experts.

Finally, while the Australian government seems confident today that they would win such a case, trade lawyers may disagree. Paragraph 5 includes apparent standards for web-

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[38] AUSFTA side letter.

[39] Becker, E. & Pear, R. (2004) 'Trade Pact May Undercut Inexpensive Drug Imports', N.Y. Times (12 July 2004). Shaffer, E. and Brenner, J. (2004) 'The US-Australia Free Trade Agreement Can Preempt Drug Reimportation Bills' (12 July 2004) (available at www.cpath.org). The debate was primarily about imports from Canada, yet one has to ask why the USTR insisted in blocking cheap imports from Australia when Congress was considering permitting imports. By placing the provision in a free trade agreement, USTR locked in the law for Australia, safe from Congressional legislation. One commentator suggest that the AUSFTA provision actually commits the US to forego re-importation from any country. Weissman, R. (2004) 'Patent provisions in Australia FTA' IP-Health list serve (7 July 2004).

[40] *See, e.g.,* Senate Select Committee on the AUSFTA Roundtable on the PBS (June 21, 2004); personal communications with Ruth Lopert, DoHA.

[41] A remarkable number of the AUSFTA pharmaceutical provisions are apparently already provided in Australian law. The Australian FTA Implementation Bill covered only a limited range of issues raised in the AUSFTA, namely the issues of patent scope and the new "26B Certificate" a generic company must provide when applying for marketing approval. The scope of lock-in appears to have been great.

[42] *See* http://www.welcomebacktiger.com.au/.

[43] Indeed, the US plans to call the first meeting of the Medicines Working Group in early 2005 to complain about Australian attempts to reduce drug prices. Maher, S. (2004), 'US Drug Makers Pressure Canberra', The Australian (29 Dec. 2004).

based DTC, and the panel may well decide that the paragraph was intended to have some meaning, rather than none at all. The panel hearings and deliberations need not be public, and are not required to welcome submissions from nongovernmental organizations and trade associations.[44]

Creating new law-making processes

We can also expect the AUSFTA to continue to provide new law making processes, far from the public eye. The AUSFTA created a "Medicines Working Group" to facilitate further discussions on pharmaceutical issues under the Agreement. The creation of the MWG is significant, and is likely to represent the cutting edge of the US-PhRMA agenda. The terms of reference are unbalanced, including "the importance of pharmaceutical research and development" but excluding universal access to medicines.[45] Much as the generic industry was shut out of USTR's IFAC-3 and ISAC-3 Committees,[46] it may also lack representation or clout on the MWG. The MWG will be a political process which is not transparent, with direct input into Australian drug policy, dominated by pro-PhRMA constituencies.

Affecting multilateral trade negotiations

A final example of the political effects of the AUSFTA is its use to subtly undermine multilateral agreements promoting generic production of medicines. The Doha Declaration to the TRIPS Agreement states that "trade agreements should be interpreted and implemented to protect public health and promote universal access to medicines."[47] The interpretative principles found in Annex 2-C of the AUSFTA focus primarily upon the IP rights of drug companies, omitting the proper balance of affordable access to therapy. Most notably, the interpretive principles omit the Doha language and other TRIPS provisions protective of public health. This is the language which has been used by advocates of essential access to speed the delivery of generic anti-retroviral drugs to sub-Saharan Africa and other impoverished areas stricken with the AIDS crisis. The absence of this language in the AUSFTA is a missed opportunity by the Australian generic industry to participate in compulsory licensing for export under TRIPS. It also bodes ill for any future Australian attempt to claim the benefit of the TRIPS public health language to address the needs of the Australian public. Global advocates of essential medicines access (and the generic companies which supply such medicines) should have had a larger role in the negotiation of the AUSFTA.

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[44] AUSFTA (2004), Article 21.5 – 21.11.
[45] AUSFTA (2004), Annex 2C.
[46] This Committee advised USTR on pharmaceutical IP issues in the AUSFTA. The Committee includes several representatives from PhRMA or PhRMA member companies, but no representative from generic manufacturers or healthcare consumer interests. [USTR website] The GPhA did not testify before the Committee on Ways and Means Hearing on AUSFTA, but submitted a written statement only. List of Witnesses To Appear Before Committee on Ways and Means, Full Committee, On Hearing on Implementation of the United States-Australia Free Trade Agreement, June 16, 2004.
[47] WTO (2001) 'Declaration on the TRIPS Agreement and Public Health', Doha WTO Ministerial, WT/MIN(01)/DEC/2, ¶ [ ] (Nov. 20, 2001).

CONCLUSION

Generic companies and their customers have much to lose in free trade agreements negotiated around the world. Policy arguments are available to counter PhRMA's one-sided lobbying, but the industry and its customers must be more fully engaged in the process of agenda-setting and negotiations in future free trade agreements.

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Table 1. AUSFTA pharmaceutical provisions time line

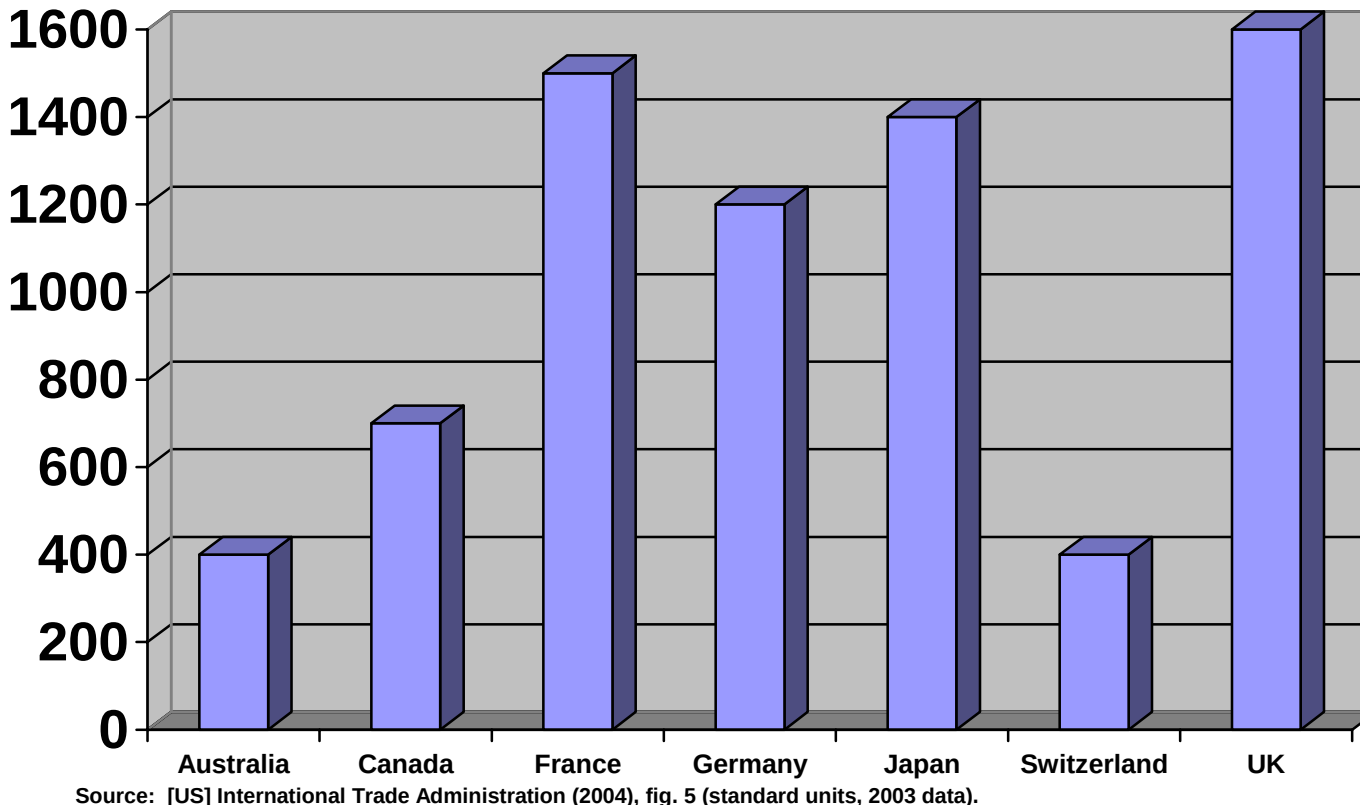
January 2003	PhRMA lobbied the USTR, demanding that Australia "refrain from trade distorting, abusive, or discriminatory price controls such as the current PBS reference pricing."[48]
March 2003	First round of AUSFTA negotiations begin, including discussions about the PBS drug pricing system.
October 2003	President Bush and Prime Minister Howard meet. President Bush is reported to have pushed for higher PBS prices as a key goal for the AUSFTA, suggesting that Australia was free riding on American innovation.[49]
Dec 2003	Sen. Ian Campbell, representing the Australian Health Minister, stated in Parliament: "The Prime Minister and the Minister for Trade have both made it very clear that the PBS is not on the table…The US has made no proposals to Australia concerning the PBS." Stephen Deady, Australia's chief negotiator later told the Senate inquiry that PBS was discussed at the first round of negotiations, in March 2003.[50]
Feb 2004	Treaty negotiations completed in record time (11 months). Trade Minister Vaile claims "The PBS, in particular the price and listing arrangements that ensure Australians access to quality, affordable medicines, remains intact."[51] But USTR Zoellick was congratulated by members of the US Senate Finance Committee

[48] Pharmaceutical Research and Manufacturers of America (2003) 'PhRMA "Special 301" Submission to the Office of the United States Trade Representative: Australia' (available at www.ustr.gov).
[49] Colebacht, T. (2003) 'Bush Wants End to Medicine Subsidies', The Age (Melbourne), (24 Oct. 2003, at 5).
[50] [Australia] Senate Committee Report (2004), 'Final Report on the Free Trade Agreement between Australia and the United States of America', The Parliament of the Commonwealth of Australia, p. 103.
[51] Vaile, M. (2004), 'Free Trade Agreement with the United States', Media Release, 8 Feb. 2004 (MVT08/2004) (available at http://www.trademinister.gov.au/releases/2004/mvt008_04.html).

	that the AUSFTA achieved its goal to raise Australian drug prices.[52]
18 May 2004	AUSFTA signed by US and Australia.
14-15 July 2004	Approval by US House and Senate, respectively.
3 Aug 2004	US implementing legislation signed by President Bush.
13 Aug 2004	Australian Senate approval of the Implementation Bill, with 3 Labour Amendments.
1 Jan 2005	AUSFTA enters into force.

[52] Hearing of the US Senate Finance Committee (2004), 'The Administration's International Trade Agenda' (Witness: Ambassador Robert Zoellick, US Trade Representative).

Table 2. ITA estimated annual pharmaceutical free riding (in millions of US$)



Source: [US] International Trade Administration (2004), fig. 5 (standard units, 2003 data).

Table 3. Comparison of AUSFTA Pharmaceutical Provisions with TRIPS and the (Australian) AUSFTA Implementation Bill 2004.

AUS FTA		**TRIPS+?**	**FTA Bill**[53]
Annex 2-C.1	Principles (priority of R&D, 'access' an issue only in the context of gaining marketing approval, market distribution of pharmaceuticals unless appropriate value paid by government)	Yes Arts.7, 8, 30	
Annex 2-C.2	Transparency	Yes Art. 63	
Annex	Medicines Working Group	Yes	

[53] This column lists the provisions of the FTA Bill which implement the AUSFTA. As can be seen, most of the provisions of the AUSFTA are not covered by the FTA Bill. In a few instances, citations to existing law are given (ie., [Australian] Therapeutic Goods Act of 1989, §25A(2)), but references to existing Australian law have not been made systematically.

2-C.3			
Annex 2-C.5	Internet marketing permitted	Yes	
17.1.9	Grandfathers all existing IPRs under the AUSFTA	No Art.70	
17.9.2	Patent scope: *ordre public* and morality, etc.	No Art.27	Sch.8
17.9.2	Patent scope: plant and animal patents	Yes Art.27.3(b)	Sch.8
17.9.3	Limits the exceptions to patents	No Art.30	Sch.8
17.9.4	Adopts the domestic exhaustion rule, preventing parallel imports of patented goods. This provision allows companies to price discriminate on a State basis.	Yes Art. 6	
17.9.5	Revocations only on basis which would have justified refusal to grant, or fraud, misrepresentation or inequitable conduct	Yes Art.32	Sch.8
17.9.6	Allows a Party to permit generic drug companies to use patented products solely to prepare for marketing approval	Yes	
17.9.7	Addresses compulsory licensure and bypassing patents for anti-competitive reasons	Yes Art.31	
17.9.8(a)	Party must lengthen patent term if patent approval was delayed more than 4 years after application, or 2 years after a request for examination, or was otherwise delayed unreasonably. Unclear whether the 'compensation' must be a day-for-day extension.	Yes Art.33	
17.9.8(b)	Party must lengthen pharmaceutical patent term to compensate for unreasonable curtailment of the effective patent term for the marketing approval process	Yes	
17.9.11	Disclosure: eliminates the TRIPS requirement that the 'best mode' be disclosed	Yes Art.29.1	
17.10.1(a)	Use of safety and efficacy data by generic applicants: 5 year exclusivity	Yes Art.39.3	Existing TGA §25A(2)
17.10.1(c)	Use of third State's marketing approval: 5 year exclusivity	Yes Art. 39.3	
17.10.2	Data on 'similar' products: 3 year exclusivity	Yes Art.39.3	
17.10.3	Exclusive marketing rights can extend beyond the expiration of the 20-year patent	Yes Art. 33	

17.10.4	Measures to block generic marketing if a patent is claimed	Yes	Sch.7-New §26B of TGA