

Pharmaceuticals, Intellectual Property and Free Trade: The Case of the US–Australia Free Trade Agreement

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ABSTRACT *Australia did poorly in several key areas of the recently completed free trade agreement with the US. It failed to insulate the Pharmaceutical Benefits Scheme (PBS) from significant change, and conceded to increased intellectual property standards. The PBS, as a system of effective bargaining with multinational pharmaceutical firms, has been deeply compromised and higher drug prices can be expected over time. The intellectual property chapter strengthens the position of patent owners and undermines the evolution of a competitive generics industry. These developments are part of a broader and internationally coordinated strategy being pursued by pharmaceutical multinationals to globalize and strengthen patent rights and monopoly profits.*

Keywords: free trade agreements, intellectual property, pharmaceutical benefits scheme, bargaining.

Introduction

The negotiation between the US and Australia of a free trade agreement (FTA) was a negotiation between the first and 15th biggest economies in the world.¹ On the key issue of intellectual property rights one might have expected Australia to do better than Chile (47th), Jordan (90th) or Honduras (101st) did in their respective FTAs with the US. It did not. One might also have expected that Australia would have found ways to insulate its Pharmaceutical Benefits Scheme (PBS), regarded by many as representing the world's best practice, from significant change. It did not.

This paper explores just how badly Australia did in these two areas. Whether the agreement, which is around 1,000 pages long, leads to an overall gain or loss for Australia is a separate issue. The virtues of preferential trading agreements (PTAs) have for some time now been the subject of a complex debate amongst trade economists.² Moreover, as PTAs have shifted from being simple *tariff-reducing* instruments to *institution-regulating* instruments (for example, many recent PTAs

contain chapters that regulate, amongst other things, intellectual property, services, investment, government procurement, labour standards and movement of people) they become part of the shifting sands of dynamic effects in an economy. They become much harder to model. In the real world the effects of the agreement may be deeply affected by the interpretation that a trade dispute body places on, for example, intellectual property rules. Many of the obligations in a PTA are, in effect, unknown at the time of signing by the parties to it. The Australian government's claim that this FTA will bring six billion dollars a year in benefits to the Australian economy rests on an analysis provided to it by a consulting firm.³ Others are reaching different modelling conclusions. The National Institute of Economic and Industry Research found that the FTA would cost Australia \$50 billion and up to 200,000 jobs.⁴

In the final section of the paper we show how the intellectual property (IP) chapter in the US–Australia FTA is part of a broader and globally coordinated strategy being pursued by pharmaceutical multinationals. These organizations that grew to prominence after World War II have relentlessly pursued an agenda of globalizing and strengthening patent rights.⁵ The only thing that has changed over time is how much resistance governments have shown to this agenda. The signing of the US–Australia FTA suggests that in Australia resistance is at an all-time low.

The PBS—How it Works⁶

The PBS is a tool for achieving one of the central goals of the National Medicines Policy—‘timely access to the medicines that Australians need, at a cost individuals and the community can afford’.⁷ Following the recommendations of an expert committee the Minister declares selected medicines on the PBS. The full cost of a listed medicine is not directly passed on to a patient. Instead patients are required to make a co-payment. They, of course, get the benefit of the government's capacity to negotiate better deals with large companies.

The philosophy behind the PBS is driven by the principle of equity of access. All Australians have a right of access to needed medicines. Need, however, has a utilitarian dimension. The PBS is not designed to provide medicines for specific individuals with specific needs. Rather its purpose is to maximize the access of a community of individuals with limited resources to essential medicines. To paraphrase Jeremy Bentham, the PBS is all about the greatest health of the greatest number.

To understand fully how the various provisions of the FTA will lead to increased PBS costs, it is necessary to recognize the pressures that will be brought to bear on its key committee, the Pharmaceutical Benefits Advisory Committee (PBAC). And this requires an understanding of the way the PBS listing system operates.

In 1987, Section 101 of the *National Health Act 1953* was amended to require the PBAC to consider the cost effectiveness of a drug when deciding whether to recommend it for subsidy on the PBS. The new process based on that change was introduced in 1993. The PBAC judges whether a new drug is cost-effective at the price the company requests. It does this by comparing it (reference pricing) with an existing therapy (usually another drug). If the PBS is to pay a higher price for the new drug than for the old, Section 101 of the *National Health Act* requires that the committee be convinced that the new one is more effective, safer, or both. The selection of the comparator drug is important. Not all older, already-listed drugs

are of equal cost-effectiveness. Companies would usually prefer their drug to be compared with one against which their new product looks good—and which would allow them to claim a higher price.

Submissions received from a sponsor company go for detailed technical evaluation by an economist, epidemiologist and statistician, working within the Pharmaceutical Evaluation Section of the Department of Health and Aged Care, and/or to a contracted external evaluator. The evaluator's report is sent simultaneously to the sponsor and to the PBAC's Economic Sub-Committee (ESC), which consists of independent expert pharmacoeconomists, clinical epidemiologists, statisticians, clinical pharmacologists and a representative of Medicines Australia (the industry peak body). The principal technical measures of value-for-money are the cost per life year gained or quality adjusted life year gained with use of the new drug compared with the old one. This puts a dollar value onto how much the new drug is worth compared to the comparator, taking into account a wide range of factors including clinical effectiveness, side-effects, quality of life, and the cost savings if the drug helps avoid hospitalization, doctor visits, tests and so on.

Sponsors are given the right to respond to the evaluation; this response is considered by the PBAC when making its recommendation regarding listing of a new drug to the Minister. The ESC advises the main PBAC committee on whether the technical evaluation is valid but is not involved in the decisions themselves.

The PBAC: Composition and Role

The PBAC consists mainly of medical practitioners from a wide range of specialities, including general practice, as well as a consumer member and (more recently) an industry representative. The committee is independent of both the Department and the Minister and, legally, is the only body that can recommend whether a new drug should be listed on the PBS. The Minister may decline the PBAC's recommendation to list a new drug, but cannot list a drug in the absence of a positive recommendation from the PBAC.

The PBAC judges whether the drug, taking into account the technical evaluation as well as the clinical and social need, is worth the money the company asks, and what the specific clinical indication should be. If the PBAC decides the drug is not worth the money, the company will usually make another submission, either with a lower price, newer (and better) safety and efficacy data, or an indication more narrowly targeted at particular patient groups.

The PBAC recommendation formally goes to the Minister for Health; in practice it goes first to the Pharmaceutical Benefits Pricing Authority (PBPA) and the Health Department officials who work with both committees. The PBPA is a five-person committee, one of whom is a representative of Medicines Australia. During this process, the precise conditions of pricing are hammered out, including any price-volume agreement (under which price discounts are given by the company after certain thresholds of usage are reached).

The PBPA was established as an independent non-statutory authority in 1988 for the purpose of reviewing prices of listed PBS products and recommending the prices of products that the PBAC decides should be listed. The PBPA has the advantage of information about the drug's clinical and cost effectiveness from the PBAC. It may also have price information about other brands of the drug in Australia or overseas, as well as price information about drugs in the same therapeutic category. The PBPA does not have perfect information, but it has

much more information than say a hospital or an average consumer would have in making a drug pricing decision. The actual price negotiation is done by the Department of Health and Ageing. In order for a drug to be listed the company and the Department must agree on a price.

From Bargaining to Coercion

The PBS does not attempt to gain the lowest price possible; it attempts to pay what it believes, based on the evidence, is a fair price. In order to obtain that price the PBS through its committees of experts aggregates information about a drug and then develops a sophisticated evaluation of a drug's clinical worth. This system meets the real costs of obtaining this information, information that pharmaceutical companies have little incentive to gather or reveal. This information feeds into a negotiating process in which the Department of Health becomes the sole negotiator. The PBS creates a system in which it becomes possible for a government to bargain with multinational suppliers of a medicine.

The problem with the FTA is that it will allow multinational companies acting through US trade officials to make more threats. This in turn will see the process of offer and counter-offer that characterizes bargaining slide into threat and coercion. It is a fundamental assumption of economics that bargaining rather than coercion brings economic benefits.⁸ Once the power of the PBAC to reject unsatisfactory prices and conditions is weakened, increases in prices are likely to follow. This will inevitably threaten the long-term financial viability of the PBS.

One also has to remember that the incentives for the pharmaceutical industry to find ways to erode the bargaining power of the PBS are very large. US companies want to maximize their profits in all countries. They do not want information about price disparities to leak back into high paying markets or worse still to have other countries use Australian prices as a benchmark for their own purchasing policies, as they have been shown to be cheaper than in other OECD countries, particularly in North America.⁹ Most important of all, they do not want the PBS to become a regulatory model for other countries.

Appealing Decisions of the PBAC

Under the current system, if the PBAC rejects a submission on the grounds of inadequate cost-effectiveness it is usual for the company to re-submit, either with improved data or, more usually with a lower price. There is also scope for an appeal to the Federal Court under the *Administrative Decision (Judicial Review) Act* to ensure that decisions of the PBAC are procedurally fair.

Major pharmaceutical companies have for a number of years proposed that they should be able to have additional means of appealing a decision by the PBAC. Successive Commonwealth governments have rejected these proposals whenever they have been put forward. The most recent rejection of a PBAC appeals process came from a review of the committee's procedures conducted in 2000 by Senator Grant Tambling, then the Parliamentary Secretary for Health.¹⁰

The FTA begins the process of creating an alternative forum that will allow pharmaceutical companies to go 'shopping' for another decision if they do not like the decision of the PBAC. The text obliges Australia to:

Make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.¹¹

The exchange of letters between Mr Vaile and the US Trade Representative, Mr Zoellick, state the following:

Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC decision to list.¹²

In public statements, the industry lobby group, Medicines Australia, immediately welcomed this measure.¹³ The US government saw things similarly. US trade law requires specialist advisory committees to advise the President and the Congress on all aspects of trade and trade agreements. The Industry Sector Advisory Committee for Chemicals and Allied Products, which includes representatives of Pharmaceutical Research Manufacturers Association (PhRMA), Eli Lilly and Schering-Plough, welcomed this aspect of the agreement.¹⁴

Senior trade negotiators on both sides of a negotiation know that the agreement has to pass domestic political hurdles and constituencies. For that reason trade agreements sometimes do not go beyond the level of general principle.¹⁵ Technologies of spin are mobilized to disseminate interpretations of the principle that reassure the public that their interests have been safeguarded.¹⁶ Over time, as the public is distracted by new spectacles, the interest groups that were responsible for establishing the principle in the first place begin the process of shaping its evolution. In the case of the PBS, the FTA simply establishes independent review as a beachhead principle. Anything more would have been politically unsaleable. The large pharmaceutical industry will be interested in seeing an independent review mechanism that in some way makes inroads into the PBAC's bargaining power. One way in which the industry may seek to mediate its influence during the design stages of the independent review mechanism is to work through the Medicines Working Group (MWG). This MWG is established by the FTA and is comprised of government officials from the healthcare sectors of both countries. It may well take the view that it is chartered by the statement of principles to be found in Annex 2-C on pharmaceuticals. Those principles weigh heavily in favour of the need to recognize the full value of innovative pharmaceutical products.

Other measures to be found in the exchange of letters on the PBS and Annex 2-C on pharmaceuticals are also aimed at restricting or eroding the system of bargaining that the PBS has established. Australia's ban on direct-to-consumer advertising of prescription medicines will become easier for companies to circumvent. This will add to the pressure on the PBAC to make new drugs available whatever the cost. It will also increase the total cost as patients are induced to switch to new, expensive drugs from older, cheaper ones or from no drug at all.

Company representatives will become involved in the actual meetings of the PBAC and its technical sub-committees, and will be able to make personal sales pitches to the meetings deciding on the value of their products. The FTA will reinforce companies' abilities to seek higher prices for already-listed drugs, but there will be no capacity for the PBS to review prices downwards if (as often happens) drugs perform less well in the 'real world' of actual clinical use than they did in the original clinical trials.

Trade Threats and the PBAC

A potentially much greater threat to the PBS system of bargaining comes from the fact that the PBS is now a potential target of trade litigation. The US has a highly sophisticated public–private partnership system for trade litigation that depends on, amongst other things, the resources of more than 80,000 US trade associations.¹⁷ Under this system trade associations such as PhRMA may petition the United States Trade Representative (USTR) to bring an action against a country that it believes is acting inconsistently with its trade obligations. Over the last 20 years US pharmaceutical companies have used this public–private system of trade threats and litigation to persuade countries to raise their standards of patent protection to those of the US.¹⁸ Table 1 below shows the number of trade actions with respect to intellectual property that were brought under US trade law during 1980–98. It does not show the number of countries that are listed by the USTR each year for possible trade enforcement action. For example, in 2003, 50 countries were listed for enforcement activity because they did not meet US standards of intellectual property protection.¹⁹ Many, but not all, of these countries were listed because of weak patent or data protection.

When reading this table it is useful to know that in 1992 a study prepared for the United Nations Industrial Development Organization pointed out that only five developing countries had innovative capabilities in the pharmaceutical sector (defined as the capability of producing new drugs by a process of reverse engineering).²⁰ These were Argentina, China, India, Korea and Mexico. Since then a few other developing countries have developed strong pharmaceutical capabilities, most notably Brazil and Thailand.

Trade litigation of the kind that the US undertakes requires sophisticated evidence gathering capabilities and high levels of legal and economic expertise.

Table 1. Cases brought between 1980 and 1998 by the USTR, US pharmaceutical companies or the Pharmaceutical Manufacturers Association (PMA) under Section 301 of the US Trade Act concerning protection of intellectual property

Year	Target country	Petitioner
1985	Korea	USTR
1987	Korea	Bristol Myers
1987	Brazil	PMA
1988	Chile	PMA
1988	Chile	Squibb Corporation
1988	Argentina	PMA
1988	Korea	Bristol Myers
1991	Thailand	PMA
1991	India	USTR
1991	China	USTR
1992	Taiwan	USTR
1993	Brazil	USTR
1994	China	USTR
1996	Portugal	USTR
1996	Pakistan	USTR
1996	India	USTR
1997	Honduras	USTR
1998	Paraguay	USTR

The commercial networks that large pharmaceutical multinationals have in countries means that they are able to gather and analyse the kind of information that is needed for a successful trade action against a target country. They are able to offer the USTR a great deal of support in trade litigation strategies. Shaffer summarizes the process in this way:

Building a strong legal case requires an intensive exchange of information between the relevant public authority (USTR) and private firms. ... The USTR has limited resources, particularly to compile and organize the factual basis for a successful WTO claim. It thus relies on industry assistance. ... Firms are, in many ways, the USTR's eyes.²¹

Intellectual Property

The IP provisions of this FTA that relate to patents and pharmaceuticals either lock Australia into its current position (meaning that any future changes to its position could become a trade issue) or they increase the strength of patent rights. The rights of patent owners are strengthened in several ways. For example, over the years compulsory licensing has been an important means by which governments have been able to bring competitive or bargaining pressures to bear on large pharmaceutical industries.²² In Canada for example, the government used compulsory licensing to foster the development of a generic industry.²³ As a result of the FTA, compulsory licenses will be prohibited unless their issue relates to an anti-competitive matter, a public non-commercial use or an emergency of some kind.²⁴ This provision represents a fundamental shift from the standard on compulsory licensing that is to be found in the WTO Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS). Under TRIPS there are no restrictions on the circumstances in which a compulsory license may be issued provided that certain conditions are met. One consequence of this more restrictive standard in the FTA is that it will be harder for the government or third parties to gain access to the databases that large pharmaceutical companies are generating with respect to the effects of their products on different classes of the population.

The FTA also introduces a set of provisions that deal with the protection of data that is submitted by companies as part of the drug registration process. This data relates to the chemical characteristics of the drug as well as its safety and efficacy.²⁵ Protection for this type of data has been globally pushed by the large pharmaceutical industry because it offers a means of creating a regulatory barrier to entry for generic companies that is independent of the patent system. It is useful for drugs where no patent protection can be obtained. The development of data protection has followed a familiar pattern. The TRIPS agreement sets a benchmark principle that requires members to protect such data against unfair commercial use. Of itself this principle does not prevent drug registration authorities or even generic companies from making use of the data. Subsequent bilateral agreements, however, have taken this principle and turned the protection of this data into an exclusive form of protection, creating in effect a type of property right. The FTA prevents third parties (generic companies) from making use of the data submitted by the originator company or even the fact of approval having been given to the originator company for a period of five years. As a result of trade pressure from the US, Australia had in 1998 introduced a provision on data exclusivity for

pharmaceutical products.²⁶ However, by including this provision in the FTA, the US continues the process of setting a new international standard on data protection. Developing countries that do not yet have a standard on data protection will find it difficult to argue for an alternative.

A new regulatory barrier that the FTA creates for generic entry into the pharmaceutical market is the obligation it imposes on Australia's drug registration authority to prevent the marketing of products or uses of products that are the subject of a patent claim.²⁷ This obligation applies for the term of the patent (in Australia the 20 year term for patents can be extended for pharmaceutical patents).

The danger from a public welfare point of view is that such a provision creates the incentive for companies to register junk patents. Generic companies plan their entry into a given drug market on the basis of the expiry of the key patent that protects the compound. A provision that prevents the marketing of a product that is the subject of a patent claim provides an incentive for the owner of the key patent that is about to expire to generate as many patent claims as possible. In the case of the US–Australia FTA the incentive to register junk patents is very high because the relevant provision obliges Australia's drug registration authority to prevent the marketing of a product *for the duration of the patent*. The number of patents applied for is a matter for the patent applicant. Moreover, it is important to understand that pharmaceutical patenting allows many opportunities to generate patents and patent claims. For example, the fact that active ingredients may have a number of distinct crystal forms allows a company the possibility of extending the patent on the basic active ingredient by claiming its polymorphs.²⁸ Such patents may, of course, be challenged. But the cost of that challenge falls on the generic company. And as experienced patent attorneys often remark, it is better to have a weak patent in strong hands than a strong one in weak hands.

In the US, the Food and Drug Administration has had experience with provisions (commonly referred to as the Hatch-Waxman provisions) that require it to delay the registration of a generic product because of patent claims. A study of these provisions by the Federal Trade Commission in 2002 showed that they had been abused.²⁹ The FTC pointed out that these abuses had required it to take anti-trust actions against large pharmaceutical companies as well as generic companies (for collusion). An example of the kind of problem that has occurred is illustrated by the class action that was brought against AstraZeneca companies for their drug Prilosec (the generic name being omeprazole), a drug used in the treatment of stomach ulcers and heartburn.³⁰ The main patent on the compound had expired on 5 October 2001. The allegations were that the defendants had stockpiled a number of patents. They filed patent infringement actions thereby preventing the FDA from granting approval to generic companies. The strategy was aimed at invoking a provision in US law that would bring an automatic delay of 30 months with each alleged patent infringement.

Other provisions in the FTA also impact on competition in pharmaceutical markets. One way in which governments attempt to build pro-competitive effects into intellectual property law is to limit the duration of the relevant right. Under the FTA, however, Australia will be required to compensate the patent owner for unreasonable delays by offering an extension of term.³¹ Importantly this obligation is in *addition* to the five year extension of term that Australia already grants to pharmaceutical patent holders. Another source of competitive pricing pressure on

patent owners is the capacity of individuals to import pharmaceutical products from the cheapest market once they have been placed on that market by or with the consent of the owner. The capacity of individuals to set up ‘parallel’ streams of importation leads into the economics of price discrimination. For present purposes it is worth noting that smaller wealthier economies like Australia are better off allowing for parallel importation.³² The FTA, however, allows the patent owner to control parallel importation by means of contract.

Price Effects

The FTA and its effects on the market in pharmaceuticals in Australia is a matter of complex causality. By this we mean that the effects have to be understood by reading the intellectual property chapter, the annex on pharmaceuticals and the dispute resolution chapter together and seeing how these offer large pharmaceutical companies strategic opportunities to undermine public sector bargaining power and how they change the entry costs facing generic firms. Generic firms will have to respond to these costs. They may do so by seeking strategic alliances with larger manufacturers and this in turn will have consequences for competition in the Australian market as well as the PBS. Even though the PBS pricing system does not take maximum benefit of generic competition—and needs reform for that reason—a study in 2003 by the Australia Institute of high-cost drugs that had recently become subject to competition found the PBS made savings of around 35% by the fourth year after the entry of generic competition. This study was undertaken prior to the text of the US–Australia FTA being released. However, its analysis of the costs of delayed generic entry provide a guide to the likely costs of the FTA because, as we saw earlier, the FTA does contain provisions that will prevent the marketing of generic drugs that are the subject of patent claims by others.

On the basis of the estimate that measures contained in the FTA would delay generic competitors entering the marketplace by an average of 24 months, the study calculated that the cost of delays, for five drugs that are soon to be subject to competition, would be more than \$1.1 billion in lost savings to the PBS for the period 2006–09.³³ Clearly, this amount would be multiplied many times as these delays applied to more and more drugs. Importantly, delayed generic competition will also have an impact on the price of non-PBS medicines, particularly over-the-counter (OTC) drugs sold in Australia. These cost increases will be directly borne by patients without the protection of Government subsidies or safety-nets.

The measures in the FTA that strengthen the hand of large pharmaceutical companies (the compulsory licensing provision, the obligation to extend patent terms for unreasonable delays, the obligation to prevent the marketing of products that are the subject of patent claims) as well as the measures that entrench provisions favourable to those companies (the provisions on parallel importation, data exclusivity), create incentives and costs that are not especially conducive to the growth of an indigenous generic industry. Predicting the path that the generic industry will take is difficult, but the basic economic issue is clear. A strong generic industry is needed if large companies are to face price competition in the off-patent phase of a drug’s life.

The overall impact to the PBS of the FTA provisions we have discussed will be a progressive increase in drug prices as legislation, regulations and procedures are amended, and as new drugs are introduced and manufacturers are able to secure

prices closer to those in their US market. Because the bulk of PBS spending is always on relatively new drugs, the full effects can be expected within five to ten years.

A clue as to the size of the price increases can be found in the difference in drug prices between the United States and Australia. A comprehensive study of international comparative drug prices was conducted by the Productivity Commission in 2001, involving 150 drugs accounting for 83% of PBS expenditure. The study contained comparisons with, amongst others, prices in the US Federal Supply Schedule (FSS). The FSS lists the prices paid for pharmaceuticals purchased by the US Department of Veterans Affairs and other Federal agencies—large institutional buyers with bulk purchasing powers comparable to the PBS. Unlike the PBS, however, FSS price negotiations do not utilize PBAC cost-effectiveness evaluations or reference pricing mechanisms.³⁴ Therefore, while differences in health systems and demand conditions may make comparisons difficult, FSS prices nevertheless represent a useful indicator of what Australian prices would trend towards if PBAC pricing mechanisms were weakened and patent laws were harmonized with the US. According to the study's weighted average, prices for prescription drugs obtained by large institutional buyers in the US are more than twice (range 1.84 and 2.49 times) as high as in Australia.³⁵ These figures were accepted by the industry as accurate and mirrored in studies by Balasubramaniam in 1995, the PBPA in 1996 and last year in a more narrowly focused study by the Australia Institute.³⁶

Based on the Productivity Commissions analysis, complete regulatory harmonization with the US would lead to price increases in Australia of the order of 1.84–2.49. It is likely that FTA provisions, which weaken rather than remove PBS pricing processes and shift Australia towards US standards of IP laws, will lead to a narrowing of the differential to 1.5 within five to ten years. We use the conservative figure of 1.3 in our analysis to account for exchange rate fluctuations since 2001, and health system differentials. Applying this increase to current PBS expenditure levels we estimate that if the full effects of the FTA had been in place in 2003, the PBS cost-to-government would have been 30% higher or \$6.76 billion.³⁷ In other words, the Australian government would have had to pay around \$1.56 billion more for the same drugs at the same levels of use and with no additional benefit to the nation's health.

There would be strong budgetary pressure on the government to transfer some of these costs to the individual consumer, either through higher PBS co-payments, deleting drugs from the list, or both. Because the PBS provides a powerful price benchmark in the Australian market, other purchasers—such as public and private hospitals, some clinics, and the private buyer—would experience similar percentage increases.

The Global Intellectual Property Ratchet

In this section of the paper we want to show that the FTA is part of a broader global strategy for the strengthening of intellectual property rights. During the period that TRIPS was being negotiated (1986–93) there were suggestions that if developing countries agreed to TRIPS, the US would ease off negotiating intellectual property standards bilaterally.³⁸ During the 1980s the US had set the scene for TRIPS through a series of key bilateral negotiations on intellectual property with countries like South Korea and Brazil.

After TRIPS was concluded the US actually intensified the level of its bilateral activity. It used its trade enforcement tools under its Trade Act of 1974 to review the intellectual property standards of more and more countries and it concluded many more bilateral agreements related to intellectual property than it had in the 1980s.³⁹ In effect it had created, without anybody really noticing, a global regulatory ratchet for intellectual property. Moreover, the ratchet only travelled in the direction of stronger standards.

The US was the principal architect of the global regulatory ratchet for intellectual property, with the EU to a lesser extent also making use of it.⁴⁰

In short form, this ratcheting process is dependent upon:

- (a) a process of forum shifting—a strategy in which the US and EU shift the standard-setting agenda from fora in which they are encountering difficulties to those fora where they are likely to succeed;
- (b) co-ordinated bilateral and multilateral strategies for intellectual property; and
- (c) the entrenchment in agreements on intellectual property of a principle of a minimum-but-not-maximum standard of protection.

Forum-shifting in international regulation is made up of three basic strategies—moving an agenda from one organization to another, leaving an organization and pursuing agendas simultaneously in more than one organization.⁴¹ The basic reason for forum-shifting is that it increases the forum-shifter's chances of victory. The rules and modes of operation of each international organization constitute the pay-offs that a state might expect to receive if it plays in that particular forum. Forum-shifting is a way of constituting a new game. Facing defeat or a sub-optimal result in one forum, a state may gain a better result by shifting its agenda to a new forum.⁴²

The principle of minimum-but-not-maximum protection plays a vital role in the regulatory ratchet. Each bilateral or multilateral agreement dealing with intellectual property contains a provision to the effect that a party to such an agreement may implement more extensive protection than is required under the agreement or that the agreement does not derogate from other agreements providing even more favourable treatment.⁴³ This means that each subsequent bilateral or multilateral agreement can establish a higher standard.

The global ratchet for intellectual property consists of waves of bilaterals (beginning in the 1980s) followed by occasional multilateral standard-setting exercises (see Figure 1 below). Each wave of bilateral or multilateral treaties never derogates from existing standards and very often sets new ones.

The dashed arrows in Figure 1 indicate that the US has the capacity and resources to pursue negotiations in different fora at the same time. Where the US or the EU are at any given moment in the cycle of ratcheting is determined essentially by how much effective resistance they are meeting in terms of their negotiating objectives. The bilateralism that preceded TRIPS and that laid the foundation for TRIPS was triggered by the resistance that the US encountered on its intellectual property agenda at the GATT.⁴⁴ Presently, it is clear that the US is in a bilateral phase. The Ministerial Declaration that launched the Doha round of multilateral trade negotiations in 2001 contained only a modest work programme in relation to TRIPS with geographical indications being the principal item listed for negotiation.⁴⁵ Bilaterally, however, the US has been busily negotiating FTAs with countries that it sees as being important regional models.

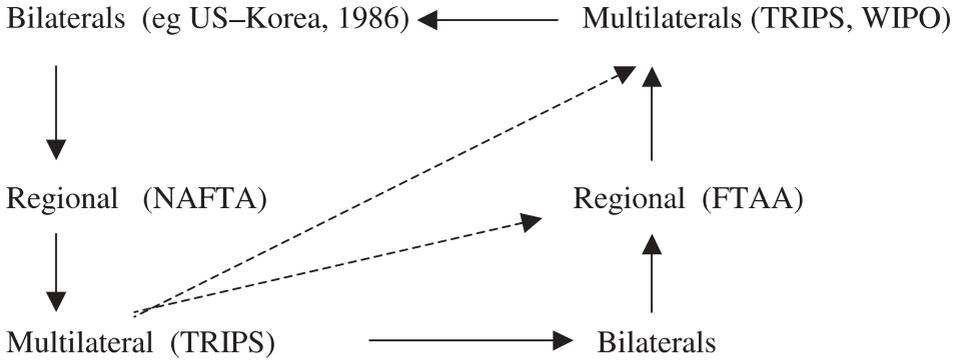


Figure 1. The global intellectual property ratchet.

Table 2 below provides an indication of recent activity by the US in the negotiation of FTAs.

In many ways this FTA with Australia is for the US the jewel in the crown. Australia is the leader of the Cairns group of agricultural exporters. To some extent at least this agreement must have an impact on Australia’s multilateral ambitions for agriculture. Historically, Australia’s strategy on international standards of intellectual property has been based on the fact that it has to participate in the international IP regime, but its interests in that regime are those of a net intellectual property importer. Summarizing a history of indigenous policy development that goes back to the 1980s and the reports of the Industrial Property Advisory Committee of that time, the position that Australia developed was to abide by but not argue for an extension of multilaterally agreed standards of IPRs, or, if necessary, agree to an extension of such standards if there were gains to it in other sectors (for example, agriculture).

By signing the FTA with the US, Australia has signalled a fundamental change in the strategy that it has developed over the last few decades. The FTA gives the US standards on IPRs that it would not have been able to obtain in the

Table 2. The US and recent Free Trade Agreements and negotiations

Passed by Congress	Concluded, but not passed by Congress	Ongoing or to commence
Jordan (2001)	Costa Rica (2004)	Bahrain
Chile (2003)	El Salvador (2004)	Bolivia
Singapore (2003)	Guatemala (2004)	Botswana
Australia (2004)	Honduras (2004)	Colombia
	Nicaragua (2004)	Dominican Republic
	Morocco (2004)	Ecuador
		Lesotho
		Namibia
		Panama
		Peru
		South Africa
		Swaziland
		Thailand

WTO or would have had to make considerable concessions to obtain. The FTA also throws away IPRs as a bargaining tool in the WTO with respect to other countries, most notably Europe and Japan, *because the TRIPS MFN clause picks up the Australia–US FTA*.⁴⁶ In other words, Japanese and European IPR owners also benefit from the IPR chapter. This FTA also ties the development of Australian patent law to that of the US. There is a best-efforts provision that requires the parties to reduce the differences between their respective patent systems. Other provisions suggest that in practical terms this will mean Australia matching US domestic standards. The FTA obliges Australia to provide that an invention is useful if it has ‘specific, substantial and credible utility’ (see Article 17.9.13). This wording picks up the Utility Guidelines that were issued by the US Patent and Trademark Office in January 2001.⁴⁷ In effect, Australia has tied itself to a US standard of utility and its subsequent interpretation. The economic consequences for Australia of buying into the US harmonization agenda for patents and IP more generally are beyond the scope of this paper to evaluate, but it is worth noting that the significant differences amongst the economies of the world forms the basis of a line of analysis that suggests that societies should retain sovereignty over property rights and choose that regulatory arrangement that best suits their economic context.⁴⁸ In short, given the differences between the Australian and US economies there may be few economic gains to Australia in signing on to the US harmonization agenda and many significant economic costs.

Conclusion

The provisions of the intellectual property chapter, the dispute resolution chapter and the pharmaceuticals annex in the FTA have the effect of undermining the system of effective bargaining that the PBS represents. The intellectual property chapter strengthens the hand of patent owners and offers no incentives to encourage the local generic industry. As a result the probability of an evolution in Australia of a strong price competitive generic industry has declined. The provision that obliges Australian health authorities not to approve the registration of products that are the subject of patent claims is likely to lead to the kind of abuses by patent owners that have been seen in the US.

Predicting the price effects of all these changes is complex, but we estimate that had they all been in place in 2003 the Australian government would have had to pay around \$1.56 billion more for the same drugs at the same levels of use. Our main point, however, is the institutional one. The PBS as a system for meeting the costs of effective bargaining with multinational monopolies has been deeply compromised. The FTA sets up new rules that will produce a new dynamic of change. We can be sure that this will produce price increases, but the size of these increases remains a matter of estimation.

Finally, we have argued that the intellectual property chapter in the FTA has to be seen in the broader context of the globalization of intellectual property standards. The US state and US pharmaceutical multinationals remain committed partners in the institutional project of globalizing and harmonizing patent rights. The aim of these companies is to increase their market power through the ownership of knowledge assets that matter to the health of citizens. States, for the time being, are doing little to combat the global intellectual property ratchet that lies at the heart of this project.

Notes and References

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12. Exchange of letters on the PBS; 1 March 2004.
13. K. Schneeman, *Medicines Australia Welcomes FTA Announcement*, media release, Medicines Australia, Canberra, 9 February 2004.
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24. See Article 17.9.7 of Chapter 17 of the FTA.
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26. See Section 25A of the Therapeutic Goods Act 1989.
27. See Article 17.10 of Chapter 17 of the FTA.
28. Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre, 2000, p. 53.
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41. For a detailed explanation of this strategy and some examples see *Ibid.*, ch. 24.
42. *Ibid.*, pp. 564–5.
43. See, for example, Article 1702 of NAFTA, Article 1.1 of TRIPS, Article 4.1 of the US–Jordan FTA and Article 17.1.1 of the US–Australia FTA.
44. Drahos and Braithwaite, *op. cit.*, p. 134.
45. See Ministerial Declaration, WT/MIN(01)/DEC/1, paragraphs 17–8.
46. See Article 4 of TRIPS.
47. See 66 *Fed Reg* 1092, 5 January 2001.
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