ACA submission to Joint Standing Committee on Treaties on the Australia/US Free Trade Agreement

About the ACA

The Australian Consumers' Association (ACA) is a non-profit, non-party-political organisation. We are completely independent. We are not a government department or agency and we receive no funding from any government. Neither do we receive subsidies from industry, manufacturers, unions or any other groups, and we don't take advertisements in any of our printed magazines or on our website. We get our income from the sale of *Choice* magazine, *Choice* Online and our other publications and products and currently have over 145,000 subscribers to our products.

We represent and act in consumers' interests. We lobby and campaign on behalf of consumers to promote their rights, to influence government policy, and to ensure consumer issues have a high profile in the public arena.

We are committed to providing information on a whole range of consumer issues including health, financial services, information technology & communications, travel, food & nutrition, computer technology and consumer policy.

Introduction

The Australian Consumers' Association (ACA) has consistently and publicly supported open and competitive trading arrangements over many years. We have long recognised the benefits that more open trading arrangements can bring to consumers, and the detrimental impacts of tariffs and similar measures on the prices that consumers pay and the range of goods that they will be able to select. ACA has therefore, as an example, supported the dismantling or reduction of tariffs in many cases. ACA has also supported genuine progress towards free and fair trade through multilateral agreements and arrangements, usually in preference to so-called "preferential trade agreements".

However, ACA has also sought to analyse proposals for trade reform on the basis of whether they represent real gains for consumers. Too often proposals for "free" trade have involved damaging compromises that leave unacceptable barriers in place and/or involve provisions that clearly favour particular producer interests over those of consumers both in Australia and other nations. Too often there has been a tendency to overstate gains and understate costs when modelling the impact of such agreements. Such outcomes tend to be more common when the consultation with consumer and community organisations is limited or does not take place at all.

While ACA supports the objective of more open trade with the US, we are concerned by the implications for effective government regulation in Australia going forward. The FTA as currently structured contains several sections that would clearly shift the balance in markets decisively towards large producer interests and against the interests of consumers. This submission focuses in two areas in particular:

- those provisions relating to pharmaceuticals, in particular the PBS; and
- the provisions relating to intellectual property.

Background

Proposed changes to the Pharmaceutical Benefits Scheme and intellectual property outlined in the Free Trade Agreement offers no clear benefits for consumers. Rather, the vague language used in the Agreement and the stated commitment to commercial rather than public health considerations raise the possibility that implementation of the FTA may seriously undermine the PBS and increase the cost of essential medications. If it is to implement the Agreement in such a way as to have limited impact on the PBS the Australian government would have to ignore the Agreed Principles enunciated in the Agreement.

The Australian Consumers' Association therefore recommends that issues relating to pharmaceuticals be removed from the FTA.

In addition, the copyright aspects of the Agreement potentially upset the established balance of producer and consumer interests. We would have significant concerns about the implementation of this element of the FTA in its current form.

The FTA and the Pharmaceutical Benefits Scheme

Relationship between Agreed Principles of the Free Trade Agreement and the Pharmaceutical Benefits Scheme

1. Agreed Principles

The Parties are committed to facilitating high quality health care and continued improvements in public health for their nationals. In pursuing this objective, the Parties are committed to the following principles:

a) the important role played by innovative pharmaceutical products in delivering high quality health care;
b) the importance of research and development in the pharmaceutical industry and of appropriate government support including through intellectual property protection and other policies;
c) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures without impeding a Party's ability to apply appropriate standards of quality, safety and efficacy; and
d) the need to recognise the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining the procedures that appropriately value the objectively demonstrated therapeutic significance of pharmaceuticals.

Australia's Pharmaceutical Benefits Scheme (PBS) has provided consumers with timely and affordable access to medications for over 50 years. It is a unique system that Australians recognise as a key pillar of the Medicare system. As with other parts of Medicare, the underlying philosophy of the Pharmaceutical Benefits Scheme is based on equity; that is, access to medicines should be based on clinical need rather than ability to pay. It has also been consistently attacked by industry interests.

It is worth noting at the outset that there is a fundamental mismatch between the wording of the agreed principles of the Free Trade Agreement and the guiding philosophy of the Pharmaceutical Benefits Scheme. While the FTA (both in the principles outlined in Annexure 2C and the exchange of letters) emphasises the importance of 'recognising the value of innovative pharmaceuticals' and the 'importance of research and development', decisions to list drugs on the PBS are not based on these considerations. In fact drugs are listed on the PBS on the basis of their cost effectiveness, that is their proven health benefit. Listing of a medication on the Pharmaceutical Benefits Scheme occurs because it is deemed by the Pharmaceutical Benefits Advisory Committee to be both effective and 'cost effective'; there is no recognition of innovation and research and development costs incurred by the manufacturer. Manufacturers' desires to recoup their research and development costs are simply not relevant to PBS listing decisions where priority should be given to achieving the best value for tax payers and consumers. Issues relating to research and development costs can be pursued through other mechanisms (see below).

Australia pays for its medicines on the basis of the proven health benefit each drug can achieve relative to the available alternatives. The present system of cost-effectiveness pricing, introduced almost a decade ago, has been widely praised and emulated around the world. The PBS attempts to price drugs not according to what they cost to develop, or by what the world market may be able to stand, but their proven health benefit.

Cost-effectiveness pricing allows drugs with radically different applications and levels of clinical efficacy to be priced in a consistent way. It ensures that the way the PBS treats one patient group is fair and consistent with the way it treats another.

Governments may choose to provide support for industry, however, this sort of support should be seen within the context of industry policy, not within the context of the Pharmaceutical Benefits Scheme. Since 1987, the Commonwealth has given more than $1.3 billion to pharmaceutical companies' research and development programs through the Factor (f) Scheme and its successor, the Pharmaceutical Industry Investment Program. This is in addition to the money spent by Commonwealth, state and territory governments on medical research, much of which is directed toward the development and evaluation of pharmaceuticals, ranging from basic research aimed at identifying potential therapeutic targets through to the clinical studies needed for the registration of products. In addition, maintenance of a responsible and viable medicines industry is recognised as one of the four goals of the National Medicines Policy.

If the government wishes to provide support to the industry it should do it through the industry portfolio, not attempt to subvert the principles of the Pharmaceutical Benefits Scheme to allow drug manufacturers to extract a higher price for their drugs.

Unfortunately, it appears that producer interests are driving the agenda on this area of the FTA. The goal of building in recognition of R&D to drug pricing was in fact highlighted by Bob Zoellick, the Chief US negotiator, in very clear terms:

"I think the challenge that we have is, you know, how do we emphasize the principles we can all agree on to move forward? High quality health care. Making sure that if they're going to set prices in some ways it's a transparent system; people know the basis of the rules. To make sure that those rules, as we do in the Australia agreement, include recognition of the role of innovation and the role of R&D, have review processes for those rules" [1]

Clearly, the Chief US negotiator believes that either PBAC will change the basis for its decision-making or that there will be some other mechanism to force the 'recognition of research and development' into the decision-making process, perhaps in relation to the proposed review body (See comments below).

The ACA would strongly oppose any attempt to change any of the guidelines or processes of the PBS so that they more closely reflect the principles outlined in Annex 2C of the Free Trade Agreement.

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[1] Hearing of the Senate Finance Committee. Subject:The Administration's International Trade Agenda. Washington DC Wednesday March 9 2004.

The Impact of a Review Mechanism on the Pharmaceutical Benefits Advisory Committee and the Pharmaceutical Benefits Scheme

2. Transparency

To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing of new pharmaceuticals or indications, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs. It shall:

a) ensure that consideration of all formal proposals for listing are completed within a specified time;
b) disclose procedural rules, methodologies, principles and guidelines used to assess a proposal;
c) afford applicants timely opportunities to provide comments at relevant points in the process;
d) provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;
e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and
f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

The Australian Consumers' Association has no comment on criteria a) – e) as our understanding is that these processes already exist within PBAC and the PBS and no changes will be required.

With regard to f) the ACA is of the view that a review process is unnecessary. A review body would have the potential to undermine PBAC decision-making processes and bring unnecessary pressure to bear on PBAC. Pharmaceutical manufacturers who are dissatisfied with outcomes of PBAC decision-making processes already have the option of resubmitting their applications to PBAC. If, as Government negotiators have claimed, the Review body will have no power to overturn decisions of the PBAC, it is not clear what powers, if any the Review body will have, beyond serving to exert pressure on the PBAC.

In addition the ACA has the following concerns regarding the implementation of this part of the Agreement:

- What criteria will the Review body use to make decisions? Will it be the same 'cost effectiveness' criteria used by the PBAC or will the focus be more sympathetic to industry and recouping research and development costs, as suggested by Mr Zoellick?
- How many times will 'the applicant' be able to request a review?
- Will every pharmaceutical manufacturer dissatisfied with a PBAC decision be able to automatically request a review, thus possibly lengthening the whole process for getting drugs listed?
- Who will be on the Review body? Will it comprise the same balance of health and consumer interests as the PBAC or a different mix of interests?

Medicines Working Group

3. Medicines Working Group

a) The Parties hereby establish a Medicines Working Group.

b) The objective of the Working Group shall be to promote discussion and mutual understanding of issues relating to this Annex (except those issues covered in paragraph 4) including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes.

c) The Working Group shall comprise officials from federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.

This group is entirely focussed on research and development, not on equity and affordable access to drugs. It may be an avenue for some within the US Government to pursue an agenda of "getting other countries in the world to bear the burden of R&D". This agenda was outlined by Senator John Kyl as follows. Senator Kyl congratulated US negotiators on "the breakthrough with respect to pharmaceuticals" in the Australian-US Agreement. He went on to say "I hope that's not only the first breakthrough with Australia specifically, because there's more work to be done there as you know....But one of the ways of addressing the causes is to get the other countries of the world to help bear part of the burden of R&D that is so critical to this[2]" **Senator Kyl also mentioned the need for "further discussion" with the Australians. It seems likely that the proposed officials working group is the avenue to these further discussions and simply provides another forum for some within the US government as well as various industry groups to continue to apply pressure to the PBS.**

While some within the US Government clearly have an agenda of forcing greater priority to be given to recognising R&D in the pricing of drugs through the PBAC, this agenda is not in the interests of Australian taxpayers or Australian consumers. Neither is it in their interests to set up a forum for these interests to be pursued more aggressively.

Intellectual property, generic drugs and the Pharmaceutical Benefits Scheme

Summary

Chapter 17 covers intellectual property rights. The Agreed Principles of the FTA recognise 'the importance of research and development in the pharmaceutical industry and of appropriate government support including through intellectual property protection and other policies;'

Provisions outlined in Chapter 17 of the Agreement appear to offer greater patent protection for brand name medicines and have the potential to delay the entry of generic pharmaceuticals to market. Delayed market entry of generics could increase the listed price of the brand name drug on the Pharmaceutical Benefits Scheme – or at least delay the point at which the price drops. This would mean lost savings to the taxpayer and increased costs for the PBS.

The relevant provisions are found in Article 17.10.5

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[2] Hearing of the Senate Finance Committee. Subject:The Administration's International Trade Agenda. Washington DC Wednesday March 9 2004.

Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory:

(a) that Party shall provide measures in its marketing approval process to prevent such persons from

(i) marketing a product, where that product is claimed in a patent; or
(ii) marketing a product for an approved use, where that use is claimed in a patent,
during the term of that patent, unless by consent or acquiescence of the patent owner; and

(b) if the Party permits a third person to request marketing approval to enter the market with;

(i) a product during the term of a patent identified as claiming the product; or
(ii) a product for an approved use, during the term of a patent identified as claiming that approved use,

it shall provide that the patent owner be notified of such request and the identity of any such other person.

Background

In Australia patents are granted for 20 years, which gives the patent holder the exclusive rights to produce and sell a patented product. The Intellectual Property Laws Amendment Act 1998 amended the Patents Act 1990 to provide for an extension of pharmaceutical patents of up to 5 years, allowing a maximum effective patent life of 15 years from the date of first regulatory approval. Limited 'springboarding' activities can be undertaken by generics manufacturers to enable them to prepare for regulatory approval so that the generic version of a drug is ready for market upon the expiry of the patent. 'Springboarding' is only available during the period of patent extension and is only available for the main product patent or 'molecule' patent.[3]

The existence of a generic version of a drug also means that the PBS listed price is reduced. Once a generic alternative becomes available, the 'benchmark' price paid by the Government for the brand falls, offering considerable savings to the taxpayer. Industry estimates savings to the PBS at about $1 billion annually. The drug Omeprazole (or Losec) provides a good case in point. When the generic was first listed the benchmark price was reduced by 25%. Once other generic competitors entered the market the price fell a further 22 %[4].

One of the important factors in reducing costs to the PBS is competition between generics manufacturers. Competition between a number of generics companies is a major factor in driving the benchmark price down. Fewer generics companies would mean less competition and less cost savings to the PBS.

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[3] Commonwealth Department of Industry, Tourism and Resources. Discussion paper on patent extensions and springboarding, and the effect on generic pharmaceuticals manufacturers in Australia. September 2002.

[4] Lofgren,H "Generic drugs:international trends and policy developments in Australia". In Australian Health Review Vol27 No1 2004 pp39-48.

It is worth noting that Australia's generics usage is quite low in comparison to other countries. In the US, for example, around 47% of prescriptions are filled with generic medications[5]. The comparable figure in Australia is 20%[6]. There are only 5-6 generics manufacturers in Australia. The Department of Industry has noted that the regulatory arrangements, and in particular 'springboarding' arrangements for generics manufacturers are already more restrictive than those in other countries. We also note that in around 70% of cases, pharmaceutical patents expire later in Australia than they do in comparable countries.[7]

Australia's patent protection is already generous. In a context where the generics industry is not particularly large, any measures designed to increase the patent protection for originator companies will impact upon generics manufacturers. If more generous patent protection leads to fewer generics manufacturers there will be less competition, higher prices for consumers, and less savings for the taxpayer on the PBS.

Currently, originator companies use patent laws aggressively to protect their patent rights through the Courts. The court can grant injunctions either halting the marketing approval process, the market launch of a generic or removing a generic from the market where it is contended that a patent has been breached. In granting injunctions, courts have historically tended to favour the status quo so if a product has been launched the court will most likely let the generic stay on the market. If the originator can keep the generic from launching then the status quo will work in favour of the originator.[8] It is in the interests of originator companies to pursue cases through courts because of the likelihood that the court will issue an injunction, thus delaying market entry for the generic and preserving monopoly rights for the originator. This is the case even when the originator company ultimately loses the case in court. In the US, the Federal Trade Commission found that generic applicants have prevailed in 73 percent of the cases in which a court has resolved a patent dispute[9].

There may be up to four types of pharmaceutical patent covering a drug. These include the main patent or 'molecule' patent, the formulation of the product, the manufacture of the product and the use of the product[10]. While it may be simple for a generic company to recognise when the main product 'molecule' patent expires, determining the validity or expiry of other patents is far less clear cut. This is exacerbated by the process of 'evergreening' where brand-name companies make slight modifications to their drugs and continue to file new 'later listed' patents on top of existing ones, thus attempting to extend their intellectual property rights[11].

17.10.5 of the FTA appears to offer greater patent protection to originator companies:

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[5] US Federal Trade Commission Generic Drug Entry Prior to Patent Expiration: An FTC Study. July 2002.

[6] Lofgren,H "Generic drugs:international trends and policy developments in Australia". In Australian Health Review Vol27 No1 2004 pp39-48.

[7] Commonwealth Department of Industry, Tourism and Resources. Discussion paper on patent extensions and springboarding, and the effect on generic pharmaceuticals manufacturers in Australia. September 2002.

[8] Private communication from generics industry.

[9] US Federal Trade Commission Generic Drug Entry Prior to Patent Expiration: An FTC Study. July 2002.

[10] Commonwealth Department of Industry, Tourism and Resources. Discussion paper on patent extensions and springboarding, and the effect on generic pharmaceuticals manufacturers in Australia. September 2002.

[11] For a good example of 'evergreening' and patent protection see Kevin Libin "Patently absurd:Canada's copyright law" In Toronto Star March 15 2004.

17.10.5a) requires that market approval be denied where the product "is *claimed*" in a patent. This is problematic for a number of reasons. Firstly, the type of patent is not specified, a single product could be covered by perhaps a hundred different patents, which may have varying expiry dates and in fact differing validity. **Where a patent claim is not valid it should not be protected.** The wording in this part of the Agreement refers only to 'claims' of a patent, not the validity of a patent or who would be involved in determining the validity of a patent.

As the Therapeutic Goods Administration is the regulator charged with giving market approval this would seem to require the TGA to make the decision as to the validity of a 'claimed' patent- a task that the TGA does not necessarily have the expertise to make. It appears as though the originator company need only claim a patent to prevent marketing of a generic, not prove the validity of that patent.

Secondly, it seems curious to include this provision in the Agreement when originator companies already have the option of pursuing their patent rights through the courts. Where the court determines that a valid patent has been breached it will deny market approval, or in the case where market approval has been granted remove the product from market and order that the generics manufacturer pay damages.

The second part of 17.10.5a) specifically mentions that marketing approval be denied where a product is claimed in a 'use' patent. Again the originator company has the option of pursuing patent rights through the courts. Specifically mentioning any 'use' patent as sufficient reason to delay market approval regardless of the validity of that patent, appears to support evergreening activities by originator companies.

The early notification clauses outlined in 17.10.5 b) are also curious. These clauses would require that originator companies be informed where a generics company intends to market a product prior to the expiry of a patent, or market a product for an approved use where that use is claimed in a patent. Marketing a product prior to the expiry of a valid patent is a breach of the Patents Act – a fact that is recognised by the generics industry. The issue here again is what sort of patent and who determines whether a patent is valid? Also, how early must the notification be given? If it is very early the originator company has more power in obtaining an injunction to halt any development work in preparing a generic product for market, thus delaying market entry for the generic.

In short, this part of the Agreement has the potential to delay market entry of generic medications and thus increase PBS costs.

Changes to Intellectual Property

Overview

The ACA finds the proposed changes to the Australian Copyright regime mooted in the draft text of Chapter 17 of the FTA raise significant issues for Australian consumers, few of them positive. The current copyright regime in Australia has been arrived at as a result of extensive debate over an extended period, most recently in the passage of the Digital Agenda amendments to the Copyright Act. There was a sense among most stakeholders that these achieved a balance between protection and access in the digital environment similar to that obtaining in the world of physically printed material. The impact of these changes to the Act was the subject of a searching

review last year (2003) by the law firm Phillips Fox, commissioned by the Commonwealth Attorney General's Department. Phillips Fox identified key aspects of the reforms that required inquiry and review, summed up in the titles of the discussion papers issued:

- Libraries, archives and educational copying;
- Carriers and carriage service providers;
- Technology and rights; and
- Circumvention devices and services, technological protection measures and rights management information.

It can be seen that there is a considerable congruity between matters that agreed in the FTA and matters that the Review (the Report of which has yet to be made public) regarded as key uncertainties. Many parties, the ACA included, put considerable effort into the Review, addressing the issues in good faith.[12] We did so under the direction from Phillips Fox not to stray beyond the specific terms of reference to broader issues of copyright policy, since these were deemed to have been 'settled' by the Digital Agenda amendments. It is disappointing to see that in the FTA many of these points have been resolved by fiat, and that the balance determined by the Digital Agenda amendments has been profoundly unsettled. In our view if the changes envisaged by the FTA agreement are enacted this will upset the copyright "balance" between producer and consumer interests (and it is worth noting that the word balance does not appear once in Chapter 17). We view the changes struck in the FTA as a significant reversal for the consumer interest in intellectual property, copyright in particular. The changed regime will lack consensus support and risks compounding the alienation from the intellectual property system that many consumers feel.

Some observations on economic issues

A piece of wisdom that should be drawn from the Phillips Fox review last year (2003) is the great difficulty in undertaking an economic analysis of changes to the copyright rules - causal linkage are complex and uncertain. Multi-variate analysis is essential - it is difficult to sustain simple assertions about the cause of any particular trend in consumer markets – there are long-standing trends and then sudden discontinuities in a market that is often fickle and fashion driven.

Despite their importance for our community, entertainment and cultural goods are not purchased in some simple sense because they a "necessity"; they are discretionary and discretion is not always exercised according to the dictates of economic rationality. Consumers' behaviour with regard to intellectual property cannot be examined in isolation from the general consumer entertainment, recreational, and cultural markets. Trends in disposable income are important, but so demographic trends and the alternatives different demographic segments might adopt to dispose of that income. If these difficulties were apparent in examining changes that had been in effect for 3 years, we are unpersuaded that any meaningful economic analysis can be made with regard to the proposed changes. However, whatever the economic impact, we feel the proposals embody consumer detriment because of the way they shift the balance in favour of the producer interest. This is illustrated by the extremely scant reference to users of IP in Chapter 17 – users are mentioned chiefly in terms of obligations and limitations, and never in term of rights, exceptions or expectations. Consumers are not mentioned at all.

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[12] ACA is aware of and supports the comments and recommendations of the Australian Digital Alliance submission on the copyright aspects of the FTA

Application of Agreement to Existing Subject Matter

We note and approve the recognition of the current public domain status of existing material in Section 17.1.10 as indicated in the online DFAT Guide to the FTA " The obligations do not apply to subject matter that has fallen into the public domain at the time the Agreement comes into force."[13]

Article 17.4: Obligations Pertaining To Copyright

Article 17.4.1: With reference to "the right to authorise or prohibit all reproductions, in any manner or form, permanent or temporary (including temporary storage in material form)", the ACA submits that the question of the status of temporary copies in the Australian copyright regime is far from settled. Digital technology functions by constant copying of information within machines, onto display devices, between machines and media, and between machines linked by networks, probably via a number of nodes that reproduce the information to forward it. In our view it is nonsense to suggest every copy should be subject to the will of IP originators, or indeed is a remunerable right.

Cached pages or pipelined instructions are essentially invisible to the consumer, hence of no direct value and should not be part of the value equation. Arguments that there is some efficiency dividend in temporary copying, such as caching, that should be shared with rights owners are unjustified. The rights holder does not do anything to create the efficiency and it would be a complete windfall to gift them with a remunerable right with regard to such temporary copies. This is an important issue to settle before micro-payment and monitoring systems become technologically feasible and such a right can be asserted de facto. Caching is one example, but it is important to realise that many other forms of copying are found under the covers of computers – there is buffering, pipelining, virtual memory paging, context swapping, RAID arrays, all of which create temporary copies. Any time an image or document is viewed on a screen copies are made – as a document is resized or moved on a computer display copying takes place in screen memory. We think there is a clear imperative to take transient non-persistent copies out of the copyright domain, not write them in as this obligation does.

Article 17.4.4: Term of Copyright Protection

ACA does not consider that the case to extend copyright term in Australia has in any way been won in domestic debate. Our chief concern is that there appears to be a global agenda for a rolling extension of copyright that will work like permanent copyright, blocking information from free or public domain access forever. This has never been the operating principle of copyright. Ideas and intellectual productions spring from the culture that nurtures their creator, and the goal is that eventually these creations will join the cultural heritage available to all comers to freely graft and grow from. In this sense the extension of copyright robs future IP producers of the advantage that current producers enjoy, access to a rich public domain heritage. It is clear example of inter-generational inequity. Australia should not contribute to the perpetuation of this unfair situation.

If it is deemed essential to extend the commercial window of exploitation for certain copyright material, then a less blanket way of achieving this would be to create a system of registration

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[13] http://www.dfat.gov.au/trade/negotiations/us_fta/guide/17.html

for aging copyright material. Hence material deemed valuable could be registered for ongoing protection (at an escalating fee to recompense society for the deprivation of public access) while less valuable material would fall automatically into the public domain where it would benefit the culturally enriching processes of recycling and reuse.

Article 17.4.7: Effective Technological Measures

The Guide to the FTA on the AG website notes that "Implementation of this Article will require legislative change. The nature and extent of those changes need to be carefully explored." The question of circumvention devices is a highly vexed one in Australia, settled in the Digital Agenda amendments and subject of ongoing contention in the Phillips-Fox review. We regard as undesirable, and oppose the extension of the prohibition of circumvention devices to individual possession or use. We feel the prohibitions in the Act currently go too far and extending such measures would intrude into consumers' lives excessively, particularly given the unresolved and potentially very broad definition of Technological Protection Measures (TPM). We are concerned that TPM devices deliver rights and enforcement by assertion, with little room for consumer negotiation or appeal.

We note with great concern that the Article refers to a "technological measure that controls ***access***[14]", not one that specifically purports to inhibit copying. As technology moves the point of control from copying to access, consumers may need to utilise various techniques to obtain access to material they have legitimately obtained, or feel they have rights to access for various reasons (public domain, fair dealing exceptions etc). In our view it would be unreasonable to prohibit the means by which consumers might access material they have purchased but may have become unavailable for various reasons, or that they wish to back up for reasons of security or fragility. To apply individual penalties for assertion of consumer control of access to their legitimate information environment is unfair.

We feel this point cannot be separated from the essential need for consumers in Australia to have a fair use right, something enjoyed to some degree at least by consumers in the US. We feel this would balance the existence and potential excesses to TPMs, but of course such a right would have to be protected from contractual and technological derogation. Therefore we would consider a prohibition on owners contractually preventing consumers exercising any copyright exception or rights they might enjoy, or use of circumvention devices in appropriate circumstances to enforce those rights, is an essential corollary of such a fair use right. TPM should not be used to override exceptions or uses granted by contract or consumers legitimate expectations. The provisions of the FTA as currently expressed would unreasonably support the ambitions of some technologists to effectively abolish the existing copyright exceptions, not to mention any fair use right the Australian consumers might ultimately achieve.

[14] emphasis added

DVD as an example

In our view the TPM issue is exemplified in the case of DVD zoning in Australia. The zoning system is not designed to counter consumer-level *copying* but is intended to structure the global market to the advantage of the content producers. The system is an imposition on consumers and does control their *access* to material. It places an artificial barrier in the market place where a software product *legally* acquired by a consumer may not work with a hardware product expressly designed and advertised for the purpose of playing the software. This occurs because of a commercial arrangement made by the supplier of the software with the maker of the hardware and is enforced by technological means. This arrangement has been made before the contract with the consumer comes into existence. Consumers have no means or right to negotiate the nature of the arrangement or its enforcement, irrespective of the impact on them. The zoning system means that the release of catalogue to Australia can be tightly managed, and a situation of artificial scarcity could be maintained. In common with old-fashioned parallel importing, the DVD zoning system may well act as a price support mechanism. The chief rationale for reforming parallel import rules (which ACA has supported) has been to deliver better price and choice outcomes for consumers, since the limitation of supply to pre-designated providers means that competition is hindered, prices are higher than otherwise and the incentive to service the market in a variety of non-price ways is impaired.

Consumers who have their players modified to be multi-zone players are currently caught in a grey area. Modifying machines may technically place the consumer in jeopardy for their warranty support from the manufacturer. It is reasonably certain that the consumer has not committed any offence by so adapting their machine and using it. However there are those that maintain a commercial undertaking to provide multi-zoning may be caught as supplying a circumvention device defined by the Digital Agenda amendments to the Copyright Act, a risk that has been appreciably increased by the recent Sony decision.

However, we would contend that this Article of the FTA would unequivocally confirm zoning systems as a form of TPM, which would place the consumer who owns a multi-zone DVD player in contravention of the law – and there are hundreds of thousands of them_ Ironically so far as the sales of DVD equipment and discs is concerned, in our view one of the growth drivers is the availability of multi-zone players in the marketplace. So to the degree that multi-zone setting of players circumvents a copyright protection measure (something we dispute, see above), then the growth of the sector is being helped rather than retarded by the circumvention of that measure. Industry sources at the time of the DA amendments estimated that "... as many as 50 percent of all DVD units sold in Australia have been modified"[15], and that a "hard clampdown on modification might just 'halve hardware sales'". The proportion of modified or user modifiable players have climbed. More robust enforcement would be to the detriment of the marketplace and indeed in our view to the interests of most copyright holders as well as consumers.

Another contemporary example is the portable digital music players onto which consumers can load large amounts of compressed music to enjoy on the move – when travelling or while exercising for example. Consumers are not necessarily purloining music from the Internet when they load these players – often they are simply reformatting and editing music collections they have legitimately acquired on CD. Even if they were to be downloading,

[15] Sue Lowe "The backstreet market in DVDs grows", The Sydney Morning Herald, 30-Aug-99, P39

contrary to industry protestations, this seems as likely to lead to an enhanced interest in music as a life of crime:
"After several years warning of dire consequences for record companies because of rampant music downloading and copying, the Australian Record Industry Association yesterday released sales figures for 2003 showing an increase of nearly 8 per cent. Album sales topped 50 million units, up from nearly 47 million in 2002."[16]

And this is not confined to just the last year, as another observer wrote:
"Let's go back to 1998. The year before an 18-year-old college dropout named Shawn Fanning wrote a file-sharing program called Napster, the software that kick-started the downloading boom. In that year Australian record companies sold 39.6 million CD albums. Five years later the figure had gone up to 50.5 million. That makes it hard to argue that downloading and CD copying has been killing sales."[17]

An additional consumer imposition by DVD providers is found in the way that certain material (often advertisements) cannot be skipped or fast-forwarded – sometime the player cannot even be stopped until the segment is complete. Here the phrase "controls access" comes to bite hard. It would probably be an offence to overcome this technological prohibition on the consumer using the normal operations of the player on designated material. This would confirm the extension of copyright from the control of copying to the control of reading/viewing. These DVD player restrictions are a mild curtain raiser in comparison with the restrictions that have been contemplated for DVD recorders, personal video recorders (PVR) and high-capacity hard drive devices. A heavy-handed, intrusive TPM agenda as ushered in by the FTA risks limiting consumers' options, and interfering with the development of markets in content, services and equipment.

Article 17.11: Enforcement

We note with concern the DFAT commentary that "Australia will need to make some legislative change to implement aspects of this Article, including in relation to Internet Service Provider liability and providing that a broader range of activities will be subject to criminal sanctions."[18] In relation to the question of IP enforcement, the Government quite recently made a number of changes when it liberalised parallel importation of computer software, which advanced the domestic agenda in a balanced way. The FTA once again intrudes on that balance.

We note the liberal use of the phrase "pirated copyright goods". ACA considers that it is important to distinguish between personal or consumer copying and systematic commercial fraud or counterfeiting. In general in our view the word "pirated" has no utility in the copyright debate - it is a colloquial expression. If an umbrella term were required we would refer to "infringing copyright goods". Commercial misappropriation occurs when one business takes the intellectual property of another and masquerades or misrepresents it's right to obtain benefit from it. This is a business-to-business problem, and also a serious problem to consumers when counterfeit items are passed off at the premium price of the genuine article. Consumer copying is separate issue that relates more to marketplace behaviour and

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[16] http://www.smh.com.au/articles/2004/03/18/1079199330947.html Sound of cash registers is music to the ears By Bernard Zuel March 18, 2004
[17] http://www.smh.com.au/articles/2004/03/28/1080412234274.html
[18] http://www.dfat.gov.au/trade/negotiations/us_fta/guide/17.html

customer service. We strongly recommend the Australian Parliament not succumb to any temptation to insert the term "software piracy" in legislation.

We have a particular concern about the introduction or extension of criminal penalties. We do not favour criminalisation of end-user copying by consumers. We feel there would be significant problems in targeting any provisions, given the huge variability in the situations, scale and commercial impact of end-user copying, and consequent problems of discretionary prosecution. In a practical sense, it is unlikely that the crimes would attract significant police or prosecutorial attention. Even the rights holders recognise that very few (if any) prosecutions would occur, and in the more flagrant cases, civil action would be well placed to succeed in any event. We suggest that the public interest test of any monopoly must be substantially revisited before the sovereign power of the state is deployed to enforce it.[19] Criminalisation of consumer behaviour as a response to monopoly market failure is in our view poor public policy.

Article 17.11.4: Presumption of ownership

Implementation of the presumption provisions[20] must not slip over into ownership by assertion. Our chief concern would be the protection of public domain material from spurious assertions of ownership.

Article 17.11.7(a): Statutory damages

ACA does not favour statutory damages - in our view, copyright infringements subject to court action are typically complex and situational, and require consideration on a case-by-case basis. The best compromise would probably be a range of damages, which would restore judicial discretion in any event.

Article 17.11.26: Non-commercial infringement

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[19]The ACA takes an economic view of Intellectual Property (IP) in general and copyright in particular. Just as copyright holders are fond of asserting their exclusive rights and emphasize that what rights users have are by exception only, it is worth noting that copyright (and other IP instruments) can be characterised as an exception, an exception from competition law. Copyright is essentially an approved monopoly. It is our view that claims of copyright holders must be treated with the justifiable scepticism any prudent observer brings to monopoly. Monopoly tends to produce market failure. This means that any problems lamented by the monopoly holder must be tested to see if they do not stem in whole or in part from market failure or abuse of monopoly power.
Consumer behaviour is usually a response to market conditions – if the market fails to make a persuasive offering, consumers will seek other ways to meet their needs. Thus if copyright goods are priced in ways that consumer perceive as unfair, then they may well resort to methods that deliver them a better value proposition. We would argue this market failure is behind most of the individual consumer behaviour copyright holders complain of (such as CD copying, music computer game downloads, equipment modification). The cause of these is laid variously at the doors of technological change or human nature. Both of these factors remain constant in the lives of consumers – what is driving behaviour is the failure of commercial players to adapt to changed market circumstances, both in terms of opportunities and threats.

[20] Presumption that, in the absence of evidence to the contrary, the person or legal entity whose name is indicated in the usual manner is the right holder in the work...

We note the tortured logic of this Article that strains to define "copyright piracy on a commercial scale" to include "significant wilful infringements of copyright, that have no direct or indirect motivation of financial gain;" In our view stretching copyright enforcement beyond commercial realms (financial gain being the motivation for commercial activity) places copyright law in unfortunate juxtaposition with free speech rights. This is something perhaps less apparent in the USA where citizens have a constitutional guarantee of such rights.

Article 17.11.29 Limitations on liability for service providers

In our opinion this article would be better described as Imposing liability on ISPs. ACA has considerable concerns about the implications of arrangements that would make an ISP or similar carrier a proxy or statutory agent for copyright holders. We fear this could create significant economic burdens on such carriers as they strive for compliance, costs that would be passed on to the users of their services. We do not endorse the FTA move to the US style 'safe harbour', since this is prescriptive and technologically specific. There have been suggestions that there is need for clarification in the Australian legislation that providing a carriage service does not authorise copyright infringement. We would support this.

A key question is: what is required to authenticate a claim of copyright ownership?[21] We are concerned that a general system such as the 'safe harbour' approach increases the likelihood of copyright ownership by assertion. The burden lies on the ISP to react to an assertion of ownership – there is little incentive for the ISP to resist that claim. The only countervailing pressure is the potential liability of the ISP to a subscriber for wrongful takedown of material. Here Article 29 (b)(x) is relevant. Any statutory indemnity from liability takes away any incentive for the ISP to question the ownership assertions of any and everybody that approaches them. It is also important to note the general imperfection of the software tools used by the owner interests in their attempts to police the Internet – they are often crude and broad brush, making assertions that when challenged may fail to cohere. In addition, the exact status of rights in any given object are often complex and shared between multiple parties – do all have equal claim and do any have a veto on the rights of others? Is the ISP best placed to decide – often in an automated environment?

Article 29 (b)(vi)(A): We note the provision that the ISP must provide "for termination in appropriate circumstances of the accounts of repeat infringers". This makes the ISP an inappropriate extension of the judicial system and raises significant questions of procedural fairness, rights of appeal and natural justice that any proposed legislation must accommodate.

Article 29 (b)(xi): Access to subscriber details

We would not support any implementations of "administrative or judicial procedure" that encourage as a matter of routine infringement of the privacy of consumer subscribers to ISP services. We think it is important for any claim for access to be tested and to pass a hurdle of due cause with a relevant, independent judicial authority. Search warrants and court orders may be cumbersome, but they have the virtue of requiring a case to be sustained before access is granted, and a relatively transparent way of reviewing the reasons access is sought.

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[21] Article 29 (a) and (b)(v)(B)

Setting up an access regime where copyright holders can assert a right of access with ease compromises the legitimate expectation of privacy of an individual consumer. It would probably require amendment to the Telecommunications Act, which defines a taken-for-granted level of privacy in communications. This should not be derogated simply to assuage the commercial concerns of a specific producer interest.

We do not think there should be such a wholesale reorientation of consumers' rights simply to facilitate an entertainment industry to pursue individuals for what are typically minor transgressions. What it certainly risks is creating a dampening effect on the participation of consumers in the online economy, which has ramifications much further than the thwarted commercial ambitions of one industry sector. We are also concerned that allowing access to personal details of consumers in pursuit of commercial defaults would set a dangerous precedent to justify access by other claimants who assert consumer liability – debt collectors, credit referees and other commercial agents would all dearly like to be able to pursue consumers by these means.

Since the status of certain aspects of the Internet are uncertain in copyright law (temporary copies and caching for instance) and because Australia lacks reasonable fair use or private copying provisions, it would mean that virtually any consumer logged on to the Net could be liable to some form of monitoring or reporting and possibly demand for payment or other action. While it may be denied that the agenda is pursuit of individual consumers into their infringement, it must be confronted that this would be a possible result from broad access arrangements. It is also unlikely that access to static subscriber details would content the owner interests for long. Once access to these has been assured, the next demand will be for real-time monitoring, reporting and blocking, followed perhaps by demands for decryption keys. There is no substitute for scrutiny by the courts for demands of access to personal details and the contents of physical or virtual possessions of consumers.