



Australian Government

IP Australia

**Recent Developments in Protecting and
Commercialising Intellectual Property**

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*Examining the Impact of the Australia - United States Free Trade
Agreement (AUSFTA) on Intellectual Property*

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INTRODUCTION

In this paper I would like to outline the IP content of the Australia United States Free Trade Agreement and discuss the implications of the agreement for the Australian IP regime. While I will touch on all the IP areas of the Agreement including copyright and data protection, my main focus is on the areas of my direct responsibilities - the administration of the patents, trade marks and designs systems.

Negotiation of the Agreement

The Australia-United States Free Trade Agreement (AUSFTA) was signed by Australia's Minister for Trade — the Hon Mark Vaile MP, and the United States Trade Representative, Robert Zoellick in Washington on 18 May 2004.

The AUSFTA is a major bilateral trade agreement for Australia and the negotiated text of the Agreement is therefore quite rightly receiving a great deal of attention and scrutiny.

The text of the Agreement follows from an extensive consultation process. Australia's positions in the negotiations were developed through consultation with State and Territory Governments, business and professional groups, non-government organisations (NGOs) and the general public. In November 2002 the Department of Foreign Affairs and Trade (DFAT) invited public submissions on Australia's approach to the negotiations. The Government received some 200 submissions from a wide range of organisations and individuals which helped to inform the development of the Government's negotiation objectives. During the course of the negotiations, Ministers and the negotiating team met with over 400 industry groups, professional organisations, businesses, State Governments, consumer groups, unions and NGOs. State and Territory Governments were consulted before and after each negotiating round and sent representatives as observers to a number of the negotiating rounds.

With the signing of the Agreement, the key focus for public scrutiny and review shifted to the Parliament. Two separate parliamentary committees are reviewing the Agreement.

The first is the Joint Standing Committee on Treaties (or JSCOT). This committee reviews all proposed treaty actions by Australia and, where appropriate, makes recommendations to the Government regarding the proposed action. JSCOT tabled its report on the AUSFTA on 23 June 2004. In its report, this committee recommended that binding treaty action be taken with respect to the Agreement. The report also contains a number of recommendations relating specifically to IP which I will discuss later.

The second committee reviewing the Agreement is the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America. This committee tabled its interim report on 24 June 2004 with its final report due to be tabled in Parliament by 12 August 2004.

Both of these committees sought submissions from the public on the AUSFTA and have conducted public hearings.

Now that the Agreement has been signed and once both countries have completed the necessary Parliamentary (or Congressional) processes, including the passage of legislation necessary to give effect to the provisions of the Agreement, the two Governments can decide on a date for entry into force. This will occur 60 days after an exchange of diplomatic notes agreeing to enter the AUSFTA into force. The target date for the Agreement to enter into force is 1 January 2005.

Examining the basic thrust of the AUSFTA as it relates to intellectual property

Intellectual property is covered in chapter 17 of the AUSFTA. The IP chapter is the longest chapter in the agreement, reflecting the importance of a strong and effective IP protection regime to the United States.

The subject matter covered in the chapter includes:

- copyright and related rights including encrypted program-carrying satellite signals;
- trade marks — including geographical indications (or GIs);
- domain names;
- designs;
- patents;
- regulated products; and
- IP enforcement.

The length and complexity of this chapter also reflects the United States' 'template' approach to their bilateral free trade agreements. The results of this approach are particularly apparent in the text of the IP chapter which contains far more detail about the IP system than might otherwise be expected in an Agreement with a developed country like Australia — which the US acknowledges as generally having a strong and effective IP regime.

A number of the provisions simply restate existing obligations but there are a number of provisions that are "TRIPS plus", that is, they go beyond our obligations under the TRIPS agreement. From a patents perspective, these provisions do not require any change to Australia's current practice, but they do remove some of the flexibilities available under some of the international agreements like the TRIPS Agreement. For example, under the FTA, we will be required to continue to provide patent protection for plants and animals which, while this is a current practice, is not required under TRIPS. However, we have retained the capacity to exclude from patentability inventions on morality grounds or for methods of treatment.

In considering the effect of the Agreement and impact on Australia's IP system, it is important to read all the relevant text — there are a number of important qualifications to the provisions that are contained in side letters. The side letter text has the same level of

force as the text of the main Agreement. Whether text is contained in a side letter or forms part of the main agreement again is simply a reflection of the US's template approach to negotiating these bilateral trade agreements.

There are three side letters associated with the IP chapter — one on ISP liability, one on a variety of aspects of IP that apply to Australia and our IP provisions and a third on national treatment in respect of phonograms. The second side letter is important to IP Australia's activities as it contains a number of paragraphs relevant to the work we do. For example, this letter includes a paragraph on the remedies available to right holders in infringement actions. This paragraph preserves the provisions in our patents, trade marks and designs legislation that allow the right holder to choose either damages or an account of profits (not both) or in some circumstances provide that only one or neither remedy is available.

Evaluating the effect on the Australian IP landscape resulting from the Agreement

I will shortly outline a number of legislative changes that Australia will need to make to meet our obligations under the AUSFTA.

It is too early to be definitive on what might be the broader longer term effects on the Australian IP landscape that may result from the Agreement — assuming that it comes into force. I would however like to use this opportunity to consider some of the concerns that have been expressed — both in the media and to the JSCOT and Senate Select Committee in submissions and at hearings — regarding the likely impacts of the AUSFTA on the Australian IP system and make some comments about those concerns. Again the focus of my comments will mainly relate to the IP rights that IP Australia administers, that is, patents, trade marks and designs.

Harmonisation — the provisions relating to harmonisation (Articles 17.2.11, 17.8.2 and 17.9.14) will require Australia to further harmonise with the US IP system.

These Articles simply reflect the current Australian commitment to greater harmonization in the global IP system and our practice of pursuing this agenda in international discussions, particularly those in the World Intellectual Property Organization (or WIPO). They are 'best endeavours' clauses that encourage harmonisation of laws and practices — they do not require harmonisation and certainly do not require Australia to adopt US practices against our wishes. These provisions can equally be used to encourage the US to harmonise with Australian systems in areas where their practices differ from ours and those of other countries, for example the patent issue of first to file versus first to invent. From IP Australia's point of view, we will continue to work as we are — participating in international discussions, with a view to continuing to provide a system that works best in the Australian context.

The amendments required under the AUSFTA to the marketing approval process will delay the entry of generic medicines into the Australian market and encourage the evergreening of patents

The text of Article 17.10.4 led to a great deal of concern that the effect of implementing the obligations under this Article would introduce delays into the regulatory approval process and thereby delay the entry of generic products onto the Australian market. This concern was reflected in JSCOT's report to the Parliament, with the committee including the following statement in recommendation 20 of their report:

And, accordingly it is essential that in drafting the legislation, there should be no mechanism that will cause undue delay of the entry to the market of generic pharmaceuticals.

Many of the comments and concerns about this Article appear to arise from people looking at this provision in light of US practice rather than considering the actual text of the AUSFTA. The text of Article 17.10.4 is one of those where the language was specifically crafted in such a way that Australia has the flexibility to be able to implement this obligation in a way which best suits the Australian system, rather than being forced to adopt the US approach.

The proposed amendments to the Therapeutic Goods Administration Act represent a careful balance between the interests of the generic and innovator pharmaceuticals in Australia. It is important to emphasise a number of important elements about how this will be implemented in Australia. Specifically, the requirement to notify a pharmaceutical company of an application for marketing approval will only be required if the generic company intends to market the product during the term of the patent and is merely a notification requirement – that is, it does not give the pharmaceutical company any additional rights other than to be notified.

In relation to 'evergreening', we will not be making any changes to the type of inventions for which patent protection can be obtained. Under the terms of AUSFTA, Australia will not be required to make any changes to our existing patent extension regime – that allows for an extension of patent terms for certain pharmaceutical patents — patent owners will not be able to extend the term of their patents beyond what they can do under existing arrangements. We have also retained our current springboarding arrangements. Nor does the AUSFTA require us to make any change to our regime for the protection of pharmaceutical test data — companies will not get any more data protection than they currently get. Therefore it is hard to see how the Agreement will have the effect that is being suggested.

Australia will be required to provide patent protection for software

Australia will not be making any changes to our laws concerning what can be patented in Australia as a result of the AUSFTA. Nor will there be any change to Australian practice regarding the grant of patents in relation to business methods or software. Business

methods and computer software inventions are already patentable in Australia provided they meet the patentability requirements set out in the Australian Patents Act. This will not change.

Access to medicines and the Doha Declaration

Another area of concern has been the implications of the AUSFTA for Australia's ability to implement the WTO TRIPS declaration on public health and the interim waiver that was agreed to by the WTO General Council in August 2003 as the means by which the Doha Declaration on public health could be implemented. The waiver is designed to make it easier for poorer countries to import cheaper generic medicines made under compulsory licence if they are unable to manufacture the medicine themselves. Nothing in the AUSFTA affects our ability to exercise compulsory licensing in the case of national emergencies, including for public health emergencies and nothing in the FTA affects our ability to implement the current interim waiver to assist in providing developing countries with medicines in a health crisis. Specifically, we have retained the ability to manufacture under a compulsory licence patented pharmaceuticals for any eligible country in the event of a request from such a country.

What changes to IP law are anticipated?

We will need to make a number of legislative changes to implement the IP chapter of the Agreement and a number of these changes will bring Australian law into line with US practice. However at the same time the text of a number of key Articles in the Agreement provides Australia with considerable flexibility to implement the Agreement in a way that reflects Australia's interests and Australia's legal and regulatory environment.

Mr Vaile introduced the US Free Trade Agreement Implementation Bill 2004 into the Australian Parliament on 23 June 2004. Most of the provisions in the Bill are due to commence on the later of 1 January 2005 or the day on which the AUSFTA comes into force. Most of the provisions in the Bill will not commence if the Agreement does not come into force.

The US Free Trade Agreement Implementation Bill has nine schedules. Five of those — schedules 2, 3, 7, 8 and 9 — make amendments to legislation resulting from our obligations under chapter 17 – the IP Chapter of the Agreement.

We hope that a number of the concerns expressed about the effects of the Agreement, particularly about possible delays of generic drugs onto the market through implementation of the requirements under article 17.10.4, have been allayed by the introduction of the implementation Bill into the Parliament.

Schedule 2 — Agriculture and Veterinary Chemicals

There will be no change to the existing data protection regime for pharmaceutical products as a result of the AUSFTA, only to that for agricultural and veterinary chemicals. In the case of agricultural and veterinary chemicals, the terms of the AUSFTA are consistent with a suite of proposed reforms to the existing data protection regime that had already been agreed by all State and Territory Governments.

The reforms will introduce certain measures to increase the transparency of decision-making within the domestic regulatory regime for agricultural and veterinary chemicals and to stimulate access to protected information by potential competitors under reasonable market conditions.

10 years data protection will be provided to certain information submitted in support of a marketing approval by a combination of a base period of protection with a capacity to extend to 11 years should certain conditions that assist innovation in minor uses of chemicals in the agricultural section be satisfied.

Schedule 3 — Australian Geographic Indications for Wine

The amendments to the Australian Wine and Brandy Corporation Act will:

- (i) introduce procedures to allow for a GI to be cancelled; and
- (ii) allow the owner of a trade mark to object to the determination of an Australian GI on the basis of pre-existing trade mark rights and include the grounds for refusing an application for a GI on the basis of pre-existing trade mark rights.

These amendments simply codify the current practice of the Geographical Indications Committee of the Wine and Brandy Corporation.

Schedule 7 — Therapeutic Goods

The primary purpose of these amendments is to implement article 17.10.4 of the Agreement. The way in which Article 17.10.4 would be implemented was the cause of a lot of concern that we hope has been allayed now that the wording of the draft legislation is available. An applicant seeking to include therapeutic goods in the Australian Register of Therapeutic Goods will need to provide one of two certificates. Either, they will need to certify that they do not propose to market those therapeutic goods in a way or in circumstances that would infringe a patent. Alternatively, the applicant will need to certify that that they propose to market the therapeutic good while a relevant patent is in force and that they have notified the patent owner of their application to include goods in the Register. In all other ways, the TGA's marketing approval process will proceed as it does now. These proposed amendments will give the patent owner no additional rights to intervene in the process of a generic company seeking marketing approval.

Schedule 8 — Patents

Under Article 17.9.5 of the AUSFTA, the grounds on which a patent may be revoked are restricted to grounds on which the grant of the patent could have been refused. The current grounds for revocation set out in the Patents Act are broader than the grounds on which the grant of a patent can be refused. These amendments will extend the grounds upon which the grant of a patent can be opposed (or refused) to include the grounds that the invention is not useful, or was secretly used and thus retain these as grounds upon which a patent may be revoked.

Schedule 9 — Copyright

The major changes resulting from the Chapter 17 of the AUSFTA, from both a legislative and policy perspective, will need to be made to the Copyright legislation.

Schedule Nine introduces a range of amendments to the Copyright Act to give effect to Australia's obligations under Chapter 17 of the Agreement. Certain amendments are also to be made to allow Australia to accede to the World Intellectual Property Organization (WIPO) Copyright Treaty 1996 (WCT) and the WIPO Performances and Phonograms Treaty 1996 (WPPT) — which we are required to do by the date of entry into force of the Agreement. These treaties, also referred to as the WIPO Internet treaties, set world IP standards on the treatment of digital copyright material on the Internet.

The amendments to the Copyright Act cover the following areas:

- new rights – both economic and moral – for performers in sound recordings;
- extension of the term of protection for most copyright material by 20 years;
- alignment of the term of protection of photographs with other artistic works;
- implementation of a scheme for limitation of remedies available against Carriage Service Providers for copyright infringement in relation to specified activities carried out on their systems and networks, providing certain conditions are satisfied;
- wider criminal provisions, including for copyright infringement that was undertaken for commercial advantage or financial gain, and significant infringement on a commercial scale;
- new provisions in relation to the unauthorised receipt and use or distribution of encoded program carrying signals;
- broader protection for electronic rights management information; and
- protection against a wider range of unauthorised reproductions.

In addition to the amendments to be made by the Bill, corresponding regulations will be made to implement some aspects of the limitation of remedies scheme for Carriage Service Providers and for the purposes of Australia's accession to the WCT and WPPT.

Implementation of the Article relating to technological protection measures will also require legislative change. The nature and extent of those changes will need to be

carefully explored. Australia has a two year period from the date of entry into force of the Agreement to implement its obligations under this provision.

Assessing the key impacts of the AUSFTA for IP owners — in relation to patents, trade marks and designs.

There have been a number of concerns raised both in the press and to the parliamentary committees about possible impacts of the AUSFTA on the industrial property system. However, as I have already explained, we expect the AUSFTA to have minimal, if any, impact on owners of patents, trade marks or designs.

The trade marks text reflects current Australian practice and in relation to the Trade Marks Act, current Australian law. The proposed amendments to the Wine and Brandy Corporation legislation, to codify existing policy and practice, should provide greater certainty for trade mark owners.

We are only making a minor change to the Patents Act to ensure that existing grounds of revocation are retained. We have preserved our existing extension of patent term and springboarding arrangements — that allow generic manufacturers to obtain marketing approval in overseas jurisdictions. We will not be making any changes to what can be patented, nor will we be providing patent owners with any additional rights than they currently have.

The requirement to introduce measures to prevent the marketing of pharmaceutical products that infringe patents and to notify the patent holder in certain circumstances of a request for marketing approval of a pharmaceutical product has no impact on the patents legislation and, as I have outlined above, the amendments to the TGA legislation have been drafted to provide minimal impact on the TGA's operations and therapeutic registration process.

Where to from here? — looking at the future of international IP developments.

The AUSFTA is consistent with Australia's international obligations under the WTO. The standards of IP protection required under the AUSFTA will in a number of areas go beyond those provided by multilateral agreements such as the WTO TRIPS Agreement and WIPO treaties. However, the Agreement does not represent an abandonment of the multilateral system — as evidenced by Australia's commitment under the AUSFTA to sign up to the WIPO Internet treaties.

In addition the Agreement includes provisions that encourage both Australia and the United States to accede to a number of other international IP agreements — including the Hague Agreement concerning the International Registration of Industrial Designs and the Patent Law Treaty.

There are a number of IP issues that are not addressed in the Agreement, where international discussions are currently underway. Perhaps most notable of these is the protection of indigenous traditional knowledge. This subject is currently being discussed in a wide range of international fora, including both the WTO and WIPO. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the WIPO IGC) was established in October 2000 specifically to provide a forum for the discussion of the issues associated with access to genetic resources and benefit sharing; the protection of traditional knowledge, whether or not associated with those resources; and the protection of expressions of folklore.

Australia is an active participant in these discussions, and the Australian delegation to the IGC meetings generally includes representatives from a wide range of Government departments. Discussions are still ongoing and are not yet at a stage where these issues should be codified in a bilateral agreement. At this point in time, it would not be wise to be making commitments in this area that may not be consistent with subsequent international developments and directions or reflect Australia's best interests.

CONCLUSION

While there are significant changes being implemented in copyright, the direct impact on industrial property (patents, trade marks and designs) is minimal.

Where changes have occurred - in the linkage in the Wine and Brandy Corporation Act with Trade Marks and GIs, and in grounds for revocation in patents - I would suggest these are incremental improvements to an already sound system.

While we have committed to maintain some of our existing practice - software and life form patents - and thereby lost some existing (but unused) flexibility, this outcome is not likely to be problematic in the market-place.

There is the issue of bilateral versus multi-lateral which needs to be properly managed. There is much in the agreement reinforcing our multi-lateral approaches and we need to recognize this. We have not seriously fettered ourselves in this bilateral agreement for future multi-lateral action. We should continue to try to progress some future issues - such as issues associated with Traditional Knowledge - in multi-lateral ways. While there may be sensitivities in multi-lateral forums around our bilateral agreement to continue to patent like forms, we should be able to continue to be a significant player in all IP multi-lateral processes.