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National Interest Analysis [2007] ATNIA 8

with attachments on consultation

Protocol Amending the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
(Geneva, 6 December 2005)
[2005] ATNIF 36

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SUMMARY PAGE

Protocol Amending the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
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Nature and timing of proposed treaty action

1. It is proposed that Australia accept the *Protocol Amending the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights* (the Protocol). Australia is a member of the World Trade Organization (WTO) pursuant to the *Marrakesh Agreement Establishing the World Trade Organization* 1995 (the WTO Agreement) ([1995] ATS No. 8), and the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (the TRIPS Agreement) forms Annex 1C of the WTO Agreement.

2. The proposed Protocol is open for acceptance by WTO Members until 1 December 2007, or any later date that the WTO Ministerial Conference may decide, pursuant to paragraph 2 of the General Council Decision of 6 December 2005 (WT/L/641) and paragraph 1 of Article X of the WTO Agreement. The Protocol will enter into force generally upon acceptance by two thirds of WTO Members and thereafter for each Member upon acceptance of the Protocol, pursuant to paragraph 3 of Article X of the WTO Agreement.

3. The proposed Protocol amends Article 31 of the TRIPS Agreement, by inserting Article 31*bis* after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

Overview and national interest summary

4. The key objective of the proposed Protocol is to facilitate access for least-developed and developing countries to cheaper versions of patented medicines needed to address public health problems (such as HIV/AIDS, malaria and other epidemics). The Protocol establishes a mechanism for pharmaceutical products manufactured under compulsory licence to be exported to eligible importing Members under certain circumstances (see background information for definitions of pharmaceutical products, compulsory licensing and eligible importing Member).

5. Acceptance of the Protocol would impose no significant new obligations or costs for Australia, and would be consistent with Australia's general approach to global health issues and support Australia's approach to regional health security issues. By accepting the Protocol, Australia would be supporting a mechanism to provide the world's poorest people with better access to medicines.

Reasons for Australia to take the proposed treaty action

6. Accepting the proposed Protocol would be consistent with Australia's general approach to global health and intellectual property rights issues, and would not undermine Australia's policy on intellectual property rights regimes. While Australia would not be a beneficiary of the proposed system, acceptance would support WTO Members' right to protect public health and promote broader access to medicines.

7. The flexibilities afforded by compulsory licensing, allowing for the production of medicines to protect public health, have always existed in the TRIPS Agreement. This Protocol will ensure that the benefits of these flexibilities extend to developing and least developed countries with limited or no pharmaceutical manufacturing capacity.

Obligations

8. The proposed Protocol creates no significant new obligations for Australia. Article 31 of the TRIPS Agreement currently permits compulsory licences—a licence granted by a Government allowing the use of a patent without the patent owner's permission—under certain conditions. One of these conditions is that use of the patent must be predominantly for the supply of the domestic market (Article 31(f)). Article 31*bis*, introduced by the Protocol, will allow a Member to grant a compulsory licence over a pharmaceutical patent without complying with the condition in Article 31(f), thereby allowing export of the 'generic' drugs produced. Where a Member chooses to take advantage of this new provision, it must also comply with additional obligations introduced in Article 31*bis* and the new Annex.

9. Where a WTO Member produces generic drugs pursuant to Article 31*bis* for export to a specified second WTO Member, paragraph 4 of the Annex obliges each other WTO Member to 'ensure the availability of effective legal means' to prevent both the importation into and sale in its territory of those drugs. That is, this provision aims at preventing the generic drugs being sold in unauthorised markets. This obligation to prevent importation and sale will apply to Australia irrespective of whether it chooses to export drugs itself under Article 31*bis*. However, the obligation is similar to other obligations in the TRIPS Agreement generally, and is therefore already adequately implemented in Australian legislation.

10. The remaining new obligations under Article 31*bis* and the Annex of the TRIPS Agreement will only apply if Australia allows the export of pharmaceutical products made under compulsory licence (as Australia has indicated that it will not use the system to import drugs produced in another Member under compulsory licence). Under current Australian legislation (*Patents Act 1990*), pharmaceutical products made under compulsory licence must be primarily for supply of the domestic market, i.e., not for export. However, if the Australian Government decides to allow the export of such products in the future, Australian legislation will need to be amended to implement the following conditions from Article 31*bis* and the Annex:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence, and the entirety of this production shall be exported to the Members(s) which has (have) notified its needs to the WTO Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system, through specific labelling or marking;

(iii) prior to shipment, the licensee shall post on a website information detailing the quantities being supplied to each destination referred to in indent (i) above and the distinguishing features of the product(s) referred to in indent (ii) above; and

(iv) the exporting Member shall notify the Council for TRIPS of the grant of the licence (including any conditions attached to it), and this notification shall include the name and address of the licensee, the name(s) and quantity(ies) of the product(s) for which the licence has been granted, the country(ies) to which the product(s) is (are) to be supplied, the duration of the licence and the address of the website referred to in indent (iii) above.

Implementation

11. Acceptance of the Protocol would not require Australia to amend any law, as the general obligation to avoid trade diversion of generic drugs is already covered by existing legislation and the remaining new obligations in Article 31*bis* and the Annex only apply if Australia chooses to take advantage of the amendments and export drugs produced under compulsory licence.

12. Should Australia wish to be able to export pharmaceuticals made under compulsory licence, amendments to the patents legislation would be required, and these would need to be consistent with the provisions of Article 31*bis* and the associated Annex. A decision by the Australian Government to make such changes is separate from a decision to accept the Protocol. As the Government agency with responsibility for administration of the patents legislation, consultation on this second aspect would be coordinated by IP Australia. IP Australia expects to begin such a consultation process later in 2007.

Costs

13. Acceptance of the Protocol would result in no costs to the Australian Commonwealth or State Governments.

14. Acceptance of the Protocol would also have little, if any, costs to Australian business or industry. Business and industry may incur some costs if Australia were to decide to amend its patents legislation to allow for export of pharmaceuticals made under compulsory licence. The nature and extent of these costs would be investigated as part of the consultation process to be coordinated by IP Australia (see paragraph 12).

Regulation Impact Statement

15. The Office of Best Practice Regulation (Productivity Commission) has been consulted and confirms that a Regulation Impact Statement (RIS) is not required.

Future treaty action

16. Any amendment of the Protocol or the TRIPS Agreement must be done in accordance with Article X of the WTO Agreement.

17. Any amendment to the Protocol or the TRIPS Agreement would be a treaty action and would be subject to Australia's domestic treaty process, including tabling in Parliament and consideration by the Joint Standing Committee on Treaties.

Withdrawal or denunciation

18. The proposed Protocol contains no withdrawal or denunciation clause. As accession to the TRIPS Agreement is a mandatory element of WTO membership, withdrawal from the TRIPS Agreement or the Protocol would require the withdrawal from or denunciation of the entire WTO system.

Contact details

International Intellectual Property Section
Office of Trade Negotiation
Department of Foreign Affairs and Trade (DFAT).

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CONSULTATION

1. The Department of Foreign Affairs and Trade (DFAT) consulted interested Government agencies about acceptance of the Protocol, including: IP Australia; Department of Industry, Tourism and Resources (DITR); Department of Health and Ageing (DoHA); and the Department of the Prime Minister and Cabinet (PM&C).

2. DFAT put on its website a paper seeking submissions regarding the Protocol. Copies of this paper were provided to interested agencies to forward to stakeholders and to put links on their websites. DoHA provided the paper to peak industry bodies, Medicines Australia and the Generic Medicines Association, and directly to companies which may be exporting pharmaceuticals from Australia under existing arrangements.

3. State and Territory Governments were advised of the Protocol through the Commonwealth-State/Territory Standing Committee on Treaties in 2006. Information on the Protocol has been released on the schedule of treaties to State and Territory representatives twice a year. No objections or concerns have been received from State or Territory Governments as a result of this notification.

BACKGROUND INFORMATION

History of the Protocol

1. The TRIPS Agreement, as Annex 1C of the WTO Agreement, is part of the integrated WTO system of trade rules. As a WTO Member, Australia is a party to the TRIPS Agreement.

2. At the WTO Ministerial Conference in Doha in November 2001, Ministers of WTO member states made a declaration on the TRIPS Agreement and Public Health. Paragraph 6 of that declaration recognised that Members with insufficient or no manufacturing capacity in the pharmaceutical sector could not make effective use of compulsory licensing under the TRIPS Agreement, and instructed the Council for TRIPS to find a solution to the problem. On 30 August 2003, the WTO General Council agreed the terms of an interim waiver which allows Member countries with limited or no manufacturing capacity to access patented pharmaceuticals made under compulsory license in another WTO Member.

3. On 6 December 2005, the WTO General Council agreed text of an amendment to the TRIPS Agreement – *The Protocol Amending the TRIPS Agreement.* This amendment will give permanent effect to the 30 August 2003 waiver. The amendment introduces a new Article 31*bis* and inserts an Annex to the TRIPS Agreement after Article 73.

4. The proposed amendment will make it easier for poorer countries to obtain cheaper versions of patented medicines needed to address public health problems by establishing an exception to Article 31(f) of the TRIPS Agreement, which provides that production under compulsory licence must be predominantly for the domestic market. Accordingly, Article 31(f) would hinder the importation of pharmaceuticals manufactured under compulsory licence by countries that are unable to produce them. The purpose of the amendment is to allow WTO Members with insufficient manufacturing capacity to import patented pharmaceuticals made under compulsory licence in certain circumstances.

5. "Pharmaceutical product" is defined in the Annex to Article 31*bis* as any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included. The definition does not exclude vaccines.

6. "Compulsory licensing" is where a government allows someone to use a patent without the consent of the patent owner. If compulsory licensing is permitted under a WTO Member's law, the terms of the compulsory licence must be consistent with the relevant provisions of Article 31 of the TRIPS Agreement (*Other Use Without Authorization of the Right Holder*).

7. An "eligible importing Member" means any least-developed country Member or any other Member that: a) has notified the TRIPS Council that it intends to use the system as an importer; b) specifies the names and expected quantities of the product(s) needed; c) has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question; and d) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Articles 31 and 31*bis* (including Annex) of the TRIPS Agreement.

8. Article 31 of the TRIPS Agreement requires that, prior to such use, the proposed user must make efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency, in other circumstances of extreme urgency or in cases of public non-commercial use. The scope and duration of such use shall be limited to the purpose for which it was authorised. The patent right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation.

BACKGROUND INFORMATION

WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[10] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

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[10] "Other use" refers to use other than that allowed under Article 30.

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

BACKGROUND INFORMATION: Current status list of parties to the Protocol

As of April 2007, seven WTO Members had notified acceptance of the Protocol:
El Salvador, India, Norway, the Philippines, the Republic of Korea, Switzerland and the United States of America.

The following states are party to the WTO and thus also party to the TRIPS Agreement:

Albania	Dominican Republic	Lesotho	Saint Kitts & Nevis
Angola	Ecuador	Liechtenstein	Saint Lucia
Antigua and Barbuda	Egypt	Lithuania	Saint Vincent & the Grenadines
Argentina	El Salvador	Luxembourg	
Armenia	Estonia	Macao, China	Saudi Arabia
Australia	European Communities	Madagascar	Senegal
Austria	Fiji	Malawi	Sierra Leone
Bahrain, Kingdom of	Finland	Malaysia	Singapore
Bangladesh	Former Yugoslav Republic of Macedonia (FYROM)	Maldives	Slovak Republic
Barbados		Mali	Slovenia
Belgium		Malta	Solomon Islands
Belize	France	Mauritania	South Africa
Benin	Gabon	Mauritius	Spain
Bolivia	The Gambia	Mexico	Sri Lanka
Botswana	Georgia	Moldova	Suriname
Brazil	Germany	Mongolia	Swaziland
Brunei Darussalam	Ghana	Morocco	Sweden
Bulgaria	Greece	Mozambique	Switzerland
Burkina Faso	Grenada	Myanmar	Chinese Taipei
Burundi	Guatemala	Namibia	Tanzania
Cambodia	Guinea	Nepal	Thailand
Cameroon	Guinea Bissau	Netherlands — for the Kingdom in Europe and for the Netherlands Antilles	Thailand
Canada	Guyana		Togo
Central African Republic	Haiti		Trinidad and Tobago
	Honduras	New Zealand	
Chad	Hong Kong, China	Nicaragua	Tunisia
Chile	Hungary	Niger	Turkey
China	Iceland	Nigeria	Uganda
Colombia	India	Norway	United Arab Emirates
Congo	Indonesia	Oman	
Costa Rica	Ireland	Pakistan	United Kingdom
Côte d'Ivoire	Israel	Panama	United States of America
Croatia	Italy	Papua New Guinea	
Cuba	Jamaica	Paraguay	Uruguay
Cyprus	Japan	Peru	Venezuela (Bolivarian Republic of)
Czech Republic	Jordan	Philippines	
Democratic Republic of the Congo	Kenya	Poland	
	Korea, Republic of	Portugal	Viet Nam
Denmark	Kuwait	Qatar	Viet Nam
Djibouti	Kyrgyz Republic	Romania	Viet Nam
Dominica	Latvia	Rwanda	