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Protocol amending the TRIPS Agreement (Geneva, 6 December 2005)

Introduction

9.1 The proposed treaty action is that Australia accept the Protocol Amending the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (hereafter known as "the Protocol"). The Protocol amends the Agreement on Trade-Related Aspects of Intellectual Property ("the TRIPS Agreement"), one of the World Trade Organization (WTO) agreements constituting the integrated WTO system of trade rules. As a WTO member, Australia is a party to the TRIPS Agreement.[1]

Background

9.2 The TRIPS Agreement came into force for Australia and generally on 1 January 1995 as Annex 1C of the *Marrakesh Agreement Establishing the World Trade Organization*[2] ("the WTO Agreement"). At the WTO Ministerial Conference in Doha in November 2001, Ministers of WTO Member States made a declaration on the TRIPS Agreement and

1 National Interest Analysis (NIA), para. 1.

2 [1995] ATS 8.

public health.[3] 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[4] under the TRIPS Agreement, and instructed the Council for TRIPS to find a solution to the problem.

9.3 On 30 August 2003, the WTO General Council agreed to the terms of an interim waiver allowing Member countries with limited or no manufacturing capacity to access patented pharmaceuticals made under compulsory licence in another WTO Member country.[5]

9.4 In the lead-up to the WTO Ministerial Conference in Hong Kong in December 2005, the Member States endorsed the proposal to transform the 2003 Decision into a permanent amendment to the TRIPS Agreement. On 6 December 2005, the WTO General Council agreed to the text of an amendment to the TRIPS Agreement – the TRIPS Protocol.[6] The 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.

The Protocol

9.5 The key objective of the Protocol is to provide the world's poorest people with better access to medicines. Under the Protocol WTO Members with insufficient manufacturing capacity will be able to import patented pharmaceuticals made under a compulsory licence from other Member countries in certain circumstances.

9.6 The Protocol is intended to facilitate access for least-developed and developing countries to cheaper versions of patented medicines needed to address public health problems, including HIV/AIDS, malaria and other epidemics, by establishing an exception to Article 31(f) of the TRIPS Agreement. Article 31(f) currently provides that the production of pharmaceutical products under compulsory licence

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3 *Doha Declaration on the TRIPS Agreement and Public Health* 2001 ("the Doha Declaration").

4 Compulsory licensing is a process by which a patent holder can be compelled to provide access to a patented invention in return for a royalty. A compulsory licence is granted by a Government to allow the use of a patent without the patent owner's permission. The patent owner is paid adequate remuneration, taking into account the economic value of the licence: Article 31(h), TRIPS Agreement.

5 *WTO General Council Decision* 2003, known as "the 2003 Decision" or "the waiver".

6 Also known as "the Hong Kong Amendment".

must be predominantly for the supply of the domestic market of the Member country in which the licence was issued. Accordingly, Article 31(f) would hinder the importation of pharmaceuticals manufactured under compulsory licence by countries that are unable to produce them:

> The flexibilities afforded by compulsory licensing have always existed in the TRIPS agreement but with the stipulation that the use of the patent under the compulsory licence must be predominantly for the supply of a domestic market, thereby precluding export to countries without the ability to manufacture pharmaceuticals themselves.[7]

9.7 Article 31*bis* of the Protocol will allow a Member State to grant a compulsory licence over a pharmaceutical patent without complying with the condition in Article 31(f). This means the supply does not have to be predominantly for the domestic market, allowing for the exportation of generic drugs.

Obligations

9.8 Acceptance of the Protocol would not of itself establish any new obligations for Australia. Rather, the Protocol sets out the mechanisms that WTO Members must comply with if they are either:

- an eligible importing Member or
- an exporting Member

under the new system established by Article 31*bis* and the Annex to the TRIPS Agreement.

9.9 An 'eligible importing Member' is any least-developed country Member, and any other Member that has made a notification to the TRIPS Council of its intention to use the system. Under paragraph 2(a) of the Annex to the TRIPS Agreement, an eligible importing Member must:

- Notify the TRIPS Council that it intends to use the system as an importer;

7 Ms Jane Madden, *Transcript of Evidence*, 22 June 2007, p. 6.

- Specify the names and expected quantities of the product(s) needed; and
- Establish that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question.

9.10 Australia has indicated that it will not use the system to import drugs produced in another Member country under a compulsory licence.[8]

9.11 An 'exporting Member' is a Member using the system to manufacture pharmaceutical products under compulsory licence for export to an eligible importing Member. Under paragraph 2(b) of the Annex, exporting Members issuing a compulsory licence under the new system must comply with the following conditions:

- Only the amount of the product(s) 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 those Member(s);
- Products produced under the licence shall be clearly identified as produced under the system, through specific labelling or marketing;
- Prior to shipment, the licensee shall post on a website information detailing the quantities being supplied to each destination and the distinguishing features of the product(s); and
- The exporting Member shall notify the TRIPS Council of the grant of the licence and certain details (such as name of licensee, quantity of product, duration of licence, etc).

9.12 The Committee notes that, under paragraph 4 of the Annex, all Members to the Protocol are obliged to prevent the importation and sale of generic drugs in unauthorised markets. The obligation to prevent importation and sale will apply to Australia irrespective of whether it chooses to export drugs itself under Article 31*bis*. However, this obligation is similar to other obligations in the TRIPS Agreement generally and is already adequately covered in Australian legislation.

8 NIA, para. 10.

Issues

9.13 While the goal of the Protocol, to provide cheaper versions of patented medicines to least-developed and developing countries to address public health problems, seems to be universally supported, one submission to this inquiry was particularly critical of the TRIPS Protocol and its ability to achieve this goal. According to Dr Matthew Rimmer, a Senior Lecturer at the Australian National University College of Law:

> The Hong Kong amendment to the TRIPS agreement is a very controversial amendment. The WTO General Council decision is highly problematic. It is highly problematic because only a few countries have actually implemented the decision. [9]

9.14 Dr Rimmer notes that there has been "much disappointment that the *WTO General Council Decision* 2003 has failed to realise its promise of enabling the export of pharmaceutical drugs to developing countries".[10] He suggests that it may not be wise, given this systematic failure to facilitate the export of pharmaceutical drugs, to entrench this decision into the TRIPS Agreement via the TRIPS Protocol:[11]

> The key point that you really need to pick up is that there have been no notifications whatsoever in the last four years that any of those export schemes have actually been used. There have been no drugs whatsoever exported under the WTO General Council decision, despite the best of intentions. That is a critical thing to understand. I think the talk that we heard earlier was a little bit naive in suggesting that merely adopting this protocol will of itself lead to the greater export of pharmaceutical drugs. The experience thus far has been that those mechanisms have not been working.[12]

9.15 The view that the waiver has proven too complex and ineffective has been echoed by Members of the European Parliament, who recently voted to delay approval of the Protocol pending European Union

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9 Dr Matthew Rimmer, *Transcript of Evidence*, 22 June 2007, p. 10.

10 Dr Matthew Rimmer, *Submission 2*, p. 3.

11 Dr Matthew Rimmer, *Submission 2*, p. 3.

12 Dr Matthew Rimmer, *Transcript of Evidence*, 22 June 2007, p. 10.

governments giving greater political and financial support to poor countries seeking to boost the supply of affordable drugs.[13]

9.16 The Department of Foreign Affairs and Trade (DFAT) responded to Dr Rimmer's claims that the lack of export schemes established under the 2003 Decision indicates that the Protocol is unworkable:

> An issue raised during the hearing was that there have been no compulsory licence notifications under the TRIPS waiver since it was adopted in 2003. This does not, however, mean that the TRIPS waiver or Protocol are flawed. There are several good reasons for the absence of notifications. One of these is that least-developed countries have a transition period (until 2016) where they are not bound by TRIPS. As they don't have to protect patents, they have no need to use the waiver. Need for recourse to the TRIPS waiver may also have been substantially reduced by the option of parallel importation, particularly from India where many drugs are not covered by patent. Governance and capacity issues within developing and least-developed countries also impact on the use of the waiver.[14]

9.17 Dr Rimmer points to numerous authorities, including Médecins Sans Frontières (MSF), who believe the amendments contained in the TRIPS Protocol are complicated, overly cumbersome and inefficient. The main argument is that the proposal to codify the 2003 Decision in the TRIPS Protocol disregards the fact that there is no proof of the efficacy of the 2003 Decision.[15] MSF asserts that the WTO has decided to amend the TRIPS Agreement based on a mechanism that has failed to prove it can increase access to medicines. To date only one importing country has notified the TRIPS Council that it intends to use the 2003 Decision mechanism to import cheaper life-saving medicines.[16] According to Dr Rimmer, this lack of uptake illustrates the hurdles which make it difficult for countries with little or no manufacturing capacity to import a generic under a compulsory licence, and difficult for generic manufacturers to export a drug under compulsory licence:

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13 Exhibit No 3.

14 Department of Foreign Affairs and Trade, *Submission 5,* p. 1.

15 Dr Matthew Rimmer, *Submission 2*, pp 10-11.

16 On 19 July 2007, Rwanda became the first country to inform the WTO that it is using the 30 August 2003 decision: http://www.wto.org/english/news_e/news07_e/public_health_july07_e.htm

> Doctors Without Borders, MSF, who have been very active on this issue, have been very upset that several years on from the 30 August decision 'not a single drug has reached a single patient under the WTO mechanism'. They have been very critical of the fact that the mechanism that has been put in place is 'overly cumbersome and inefficient' and fails to take into account the realities and the economics of drug production. Essentially, their criticism is that there is no incentive for generic drug manufacturers to participate in such a process, especially because they have to do a country-by-country, drug-by-drug application to obtain compulsory licences to obtain exports.[17]

9.18 Some of the problems MSF perceives there to be with the mechanism are discussed on their Campaign for Access to Essential Medicines website:[18]

- Before a generic drug company can apply to a government to issue a compulsory licence allowing the firm to begin exporting a drug under the 2003 Decision, it has to engage in negotiations with the patent holder for a voluntary licence. Negotiations for a voluntary licence are protracted and complex, and a source of considerable delays. Prolonged prior negotiations are a disincentive to manufacturers to make use of the system.
- The 2003 Decision imposes conditions that the drugs must be clearly identified through specific labelling and marketing to ensure that they will only be exported to the destination stated in the compulsory licence. These anti-diversion measures are onerous and are further disincentives to the participation of generic companies in the process.
- A potential importing country must send a notification in writing to the WTO TRIPS Council declaring its intention to import pharmaceutical products according to the provisions set out in the 2003 Decision. The notification must include the specific names and expected quantities of the product needed. Such precise requirements may deter importing countries from making use of the system.

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17 Dr Matthew Rimmer, *Transcript of Evidence*, 22 June 2007, p. 12.

18 The Médecins Sans Frontières Campaign for Access to Essential Medicines website: www.accessmed-msf.org/documents/WTOaugustreport.pdf

- The compulsory licence must stipulate the destination and quantity of drugs that are to be purchased and exported under the licence. Drug needs must therefore be determined with extreme precision beforehand, and are binding. If medical needs increase, the only way to purchase more drugs is to begin the process again, starting with the voluntary licence negotiations between brand-name and generic manufacturers. This is not practical; flexibility and rapidity of response to ever-changing circumstances are vital in managing a health programme.

9.19 Dr Rimmer highlights Canadian attempts to implement the 2003 Decision as evidence of the unworkable nature of the TRIPS Protocol. According to Dr Rimmer, all the conditions for successfully implementing the 2003 Decision were present in Canada – Canadian authorities stated their commitment to making it work, a generic drug company was interested in producing, and an NGO ready to place and pay for the order of the medicines was involved. Despite these conditions, no drug ever left the country. The main problem was the restrictive and time-consuming steps in the licensing process. There were endless negotiations between the brand-name and generic companies over voluntary licences, and the government refused to step in.

> The key thing we can learn from the experience of the other regimes that have put their system into practice is that you need a regime that is much more flexible, that allows applications to be made for batches of drugs and perhaps more than one particular country. I guess there is a necessity for intermediaries to play a role.[19]

9.20 Both Dr Rimmer and MSF believe that delaying the TRIPS Protocol would have been a better option, as it would allow for the possibility of testing and improving the mechanism in practice. Dr Rimmer believes Australia should lobby for the inclusion of a more effective mechanism than the cumbersome TRIPS Protocol. He wants the WTO to review the implementation of the TRIPS amendments, and particularly assess the efficacy of the amendments. He also wants the WTO to explore automatic solutions that do not necessitate complex, time-consuming procedural steps.

9.21 DFAT claims that the steps required by the Protocol are necessary.

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19 Dr Matthew Rimmer, *Transcript of Evidence*, 22 June 2007, p. 15.

> In the department's view, the requirements stipulated within the Protocol are not overly burdensome, but rather comprise important steps to prevent leakage of pharmaceutical products made under the Protocol into developed country markets. We regard the case-by-case basis upon which the amendment will operate to be an important measure to ensure that the system operates appropriate to the needs of each country. In this way, the Protocol maintains an appropriate balance of rights in the TRIPS Agreement between the innovators and the users of technology.[20]

Implementation

9.22 Mere acceptance of the Protocol would not require Australia to amend any law. The obligation to avoid trade diversion of generic drugs is similar to other obligations in the TRIPS Agreement generally and is already adequately covered in Australian legislation.

9.23 Under the *Patents Act 1990* (Cth), pharmaceutical products made under compulsory licence must be primarily for supply of the domestic market, i.e. not for export. A decision to accept the Protocol would in no way prejudge any decision as to whether or not Australia should amend the patents legislation in order to be able to export pharmaceuticals made under the new system. If Australia wishes to export drugs made under compulsory licence, amendments to the patents legislation would be required, consistent with the provisions of Article 31*bis* and the Annex. A decision to make such changes is separate from a decision to accept the Protocol.

> Amendments to Australia's patent legislation are not required upon acceptance. Should Australia wish to export pharmaceuticals made under compulsory licence, amendments to the patent legislation would then be required. In that event, the process would be coordinated by IP Australia, which is the government agency responsible for the administration of Australia's patent legislation.[21]

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20 Department of Foreign Affairs and Trade, *Submission 5*, p. 1.

21 Ms Jane Madden, *Transcript of Evidence*, 22 June 2007, p. 6.

9.24 Consultation on this aspect would be coordinated by IP Australia, and it is expected that such a consultation process will begin later in 2007.[22]

> IP Australia will be starting consultations later this year with regard to whether the Patents Act should be amended to allow for compulsory licensing under these circumstances.[23]

9.25 When asked whether the Australian Government intends to make use of the TRIPS Protocol to export patented pharmaceuticals and make them available for developing countries, DFAT responded:

> At this stage Australia has taken the decision to undertake consultation in relation to acceptance of the protocol, and that it is why we are here today before you, having undertaken the comprehensive treaty-making processes. The decision to arrange for exportation, as flagged, will require some legislative change. We had determined that it would be more appropriate for the protocol to be accepted as a first step and then, if and when that is agreed, we could embark—and it would be IP Australia—on some further consultation in terms of amending legislation with regard to exportation … we did note the future possibility of changes in DFAT's consultation proposals and called for submissions on the IP website. So we have certainly not precluded that option but, as I mentioned, we are embarking on this as a two-step process: first to consider acceptance with your permission and then, as a second phase, coordinated by IP Australia, the possible legislative amendments towards export.[24]

9.26 The Committee agrees that acceptance of the Protocol by Australia would demonstrate our support for the ability of developing countries and least developed countries to respond effectively to public health emergencies. However, the Committee is concerned about the efficacy of the Protocol in achieving its stated objectives.

> Australia's support for the Hong Kong Amendment to encode the *WTO General Council Decision* 2003 in the *TRIPS Agreement* 1994 will be nothing more than an empty, symbolic

22 NIA, para. 12.

23 Ms Caroline McCarthy, *Transcript of Evidence*, 22 June 2007, p. 8.

24 Ms Jane Madden, *Transcript of Evidence*, 22 June 2007, p. 8.

> gesture, unless it establishes an effective domestic mechanism for the export of pharmaceutical drugs.[25]

9.27 Dr Rimmer also expressed concern that "the Australian Government has not yet implemented the *Doha Declaration on Public Health and the TRIPS Agreement* 2001 or the *WTO General Council Decision* 2003, nor even established a policy process to consider such issues." [26]

9.28 The Committee notes the parallel debate taking place in the European Union regarding the TRIPS Protocol. On 12 July 2007, the 785-strong European Parliament voted to delay acceptance of the Protocol,[27] and adopted a resolution setting out its position.[28] The European Parliament is not seeking a renegotiation of the Protocol, but rather is asking the Member States to "provide financial support for pharmaceutical-related transfer of technology and capacity building and local production of pharmaceuticals in developing countries, especially in least developed countries".[29]

9.29 For Australia, acceptance of the Protocol should be followed with legislative and administrative measures to facilitate access to essential patented medicines for export. The Committee supports IP Australia's consultation process due to begin later this year and encourages amendment of the *Patents Act 1990* (Cth) to allow for the export of pharmaceutical drugs to developing countries in an efficient and timely fashion.

Entry into force and withdrawal

9.30 The Protocol is open for acceptance by WTO members until 1 December 2007. Upon acceptance by two-thirds of WTO Members, the Protocol will enter into force for the Members that have accepted it and "thereafter for each Member upon acceptance by it".[30] This

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25 Dr Matthew Rimmer, *Submission 2*, p. 40.

26 Dr Matthew Rimmer, *Submission 2*, p. 28.

27 Exhibit No 3, p. 1.

28 http://www.europarl.europa.eu/sides/getDoc.do?type=MOTION&reference=B6-2007-0288&language=EN

29 From the European Parliament website: http://www.europarl.europa.eu/news/expert/infopress_page/026-9059-190-07-28-903-20070710IPR09047-09-07-2007-2007-false/default_en.htm

30 Paragraph 3, Article X, *Marrakesh Agreement establishing the World Trade Organization* [1995] ATS 8.

means Australia will not be bound by the Protocol if it does not accept it.

9.31 However, Australia is already a party to the 2003 Decision, and that Decision will only terminate for each Member "on the date on which an amendment to the TRIPS Agreement takes effect for that Member".[31] This means that, unless Australia accepts the Protocol, the 2003 Decision would not terminate for Australia:

> Australia is already a party to the TRIPS Waiver, just as it might become a party to the Protocol, and the existing TRIPS waiver operates in essentially the same way as the Protocol that may replace it.[32]

9.32 The proposed Protocol contains no withdrawal or denunciation clause. Accession to the TRIPS Agreement is a mandatory element of WTO membership, so withdrawal from the TRIPS Agreement or the Protocol would require the withdrawal from or denunciation of the entire WTO system.[33]

Consultation

9.33 The NIA states that DFAT consulted with numerous interested Government agencies about acceptance of the Protocol.[34]

> 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.[35]
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> Over many months the department has consulted with key stakeholders, including Commonwealth agencies … state and territory governments, pharmaceutical industry groups and

31 Paragraph 11, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health* (30 August 2003).

32 Department of Foreign Affairs and Trade, *Submission 5*, p. 1.

33 NIA, para. 18.

34 NIA, para. 1.

35 NIA, Consultation, para. 1.

> the general public. No objections to Australia accepting the protocol have been raised. Indeed, the responses that we have received indicate that the protocol enjoys widespread community support.[36]

9.34 However, Dr Rimmer claimed that there had been inadequate consultation in relation to the TRIPS Protocol.

> For a topic of such complexity and importance, it would have been helpful to have had many more submissions both from lawyers and economists and from health specialists and specialists in relation to infectious diseases. The topic also demands greater consideration than what has taken place thus far.
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> I have been very frustrated with the consultations that have been undertaken in relation to this particular issue. I put in a submission to the Department of Foreign Affairs and Trade. They did not alert me that they were sending off the protocol here, to the Joint Standing Committee on Treaties. I found that out by accident. Many of my colleagues who also heard very recently about this just said they did not really have enough time, in the very short time frame, to make a submission to you.[37]

9.35 Consultation and public involvement is an important part of the treaty-making process. Committee inquiries serve a key purpose in allowing the community to participate directly in the parliamentary process, a key feature of democracy. Inadequate facilitation of community involvement by Government departments and agencies undermines this democratic function. Consultation is most effective when it occurs at an appropriate time. The Committee is concerned that the consultation undertaken by the Department of Foreign Affairs and Trade in relation to the TRIPS Agreement may not have been as thorough as it could or should have been.

9.36 The Committee is able to perform its function best when it has a comprehensive understanding of a treaty action. To this end, it would be helpful if witnesses, particularly from Government departments, are prepared to address all questions relating to a treaty action, including any criticisms raised in other submissions received in the course of the inquiry. In this instance, the Committee is disappointed

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36 Ms Jane Madden, *Transcript of Evidence*, 22 June 2007, p. 6.

37 Dr Matthew Rimmer, *Transcript of Evidence*, 22 June 2007, p. 14.

that the Government representatives at the public hearing on Friday 22 June 2007 did not seem to have come prepared to directly address the issues raised in Dr Rimmer's submission.

Costs

9.37 There are no costs involved for Federal or State Governments in accepting the Protocol. Business and industry may incur some costs if Australia were to decide to amend its patents legislation to allow for export of pharmaceuticals under compulsory licence. The nature and extent of these costs would be determined as part of the IP Australia consultation process.[38]

Future Treaty Action

9.38 Any future amendment of the Protocol or the TRIPS Agreement must be done in accordance with Article X of the WTO Agreement. Such a treaty action would be subject to Australia's normal domestic treaty processes.[39]

Conclusion and Recommendation

9.39 Providing better access to medicines to the world's poorest people is a worthy subject for an international treaty. The Committee agrees with the Department of Foreign Affairs and Trade that

> Acceptance of the protocol by Australia would demonstrate our support for the ability of developing countries and least developed countries to respond effectively to public health emergencies.[40]

9.40 However, the Committee shares Dr Rimmer's concerns that the TRIPS Protocol requires intricate, time-consuming and burdensome procedures for the exportation of medicine, when what is needed is a

38 NIA, para. 14.

39 NIA, paras 16-17.

40 Ms Jane Madden, *Transcript of Evidence*, 22 June 2007, p. 6.

simple, fast and automatic mechanism. However, the Committee does not believe opposing the TRIPS Protocol will necessarily have the effect Dr Rimmer desires.

9.41 The Committee supports acceptance of the Protocol, followed by any necessary amendments to the *Patents Act 1990* (Cth) to allow for compulsory licensing to enable export of cheaper versions of patented medicines needed to address public health problems to least-developed and developing countries. The Committee encourages the consultations to be coordinated by IP Australia later this year and urges the Government to actively support the provision of patented medicines to least developed and developing countries.

Recommendation 8

The Committee supports the *Protocol Amending the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights* and recommends that binding treaty action be taken.