

Submission 2
TT 9 May 2007

A SUBMISSION TO THE
JOINT STANDING COMMITTEE ON TREATIES

**THE HONG KONG AMENDMENT
TO THE TRIPS AGREEMENT**

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EXECUTIVE SUMMARY

I am a senior lecturer and the director of Higher Degree Research at the Australian National University College of Law based in Canberra, Australia. I have a BA (Hons) and a University Medal in literature, and a LLB (Hons) from the Australian National University, and a PhD in law from the University of New South Wales. I am an associate director of the Australian Centre for Intellectual Property in Agriculture (ACIPA). I am the author of thirty-four refereed articles and a book chapter on copyright law, patent law, trademark law, and defamation law. In particular, I have written a couple of pieces on the issue of patent law and access to essential medicines:

Rimmer, M. 'The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid', *Expert Opinion on Therapeutic Patents*, July 2005, Vol. 15 (7), p. 889-909, SSRN: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=680222

Rimmer, M. 'The Race To Patent The SARS Virus: The TRIPS Agreement And Access To Essential Medicines', *Melbourne Journal of International Law*, October 2004, Vol. 5 (2), p 335-374, SSRN: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=603234

I have also edited a special collection on patent law for *Law in Context*, and I am writing two monographs, including the titles, *Digital Copyright and the Consumer Revolution* and *Intellectual Property and Biotechnology*. I have also been a chief investigator for an ARC Discovery project on gene patents, an ARC Linkage project on plant breeders' rights, and an ARC Linkage project on 'Unlocking Intellectual Property'. This is a submission made in my personal capacity.

I would like to address the Joint Standing Committee on Treaties on the Protocol Amending the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – the so-called Hong Kong Amendment.

The Joint Standing Committee has been poorly served by the National Interest Analysis [2007] ATNIA 8. Unfortunately, the National Interest Analysis provides an inadequate summary of the complex legal, political, and economic issues at stake.

The Australian Parliament faces a difficult quandary – Should it support the codification of the Hong Kong Amendment, given that the *WTO General Council Decision 2003* has failed to achieve its promise of facilitating the efficient and timely export of pharmaceutical drugs to address public health concerns?

This submission is divided into three parts. First, the submission considers the relevant international framework – looking at the *TRIPS Agreement 1994*, the *Doha Declaration on the TRIPS Agreement and Public Health 2001* and the *WTO General Council Decision 2003*, and the Hong Kong Amendment proposed in 2005. It 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. There is great political debate as to whether it is a wise course of action to entrench the Hong Kong Amendment into the *TRIPS Agreement 1994*, given this systematic failure.

Second, this submission evaluates the implementation of the *WTO General Council Decision 2003* in national jurisdictions. A case study of the *Jean Chretien Pledge to Africa Act 2004* (Canada) highlights some of the problems faced in designing a legislative regime, which allows for the export of pharmaceutical drugs to developing countries to address public health concerns.

Third, this submission laments the failure of the Australian Parliament thus far to initiate any legislative or administrative measures to facilitate access to essential patented medicines, both domestically and for export. Unfortunately, there has been little policy discussion in the Australian Parliament and the public service about patent law and access to essential medicines in the last six years. It is particularly unfortunate that the Department of Foreign Affairs and Trade has not undertaken any meaningful public consultations on the topic; or shown leadership on this important international issue. In the same time, a middle international power, such as Canada, has introduced legislative amendments; undertaken a review of its access to essential medicines regime; and played a very prominent role in international debates.

1. THE HONG KONG AMENDMENT

There has been much international debate over patent law and access to essential medicines under the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (the *TRIPS Agreement* 1994) of the World Trade Organization (WTO).¹ As Ruth Mayne observes:

The global campaign on access to medicines grew in response to the major health crisis in the developing world. While public health is being transformed by medical advances in rich countries, 14 million people die every year of treatable diseases in poor countries. HIV/ AIDS is compounding the problems of infectious tropical diseases, and ravaging not only the poorest countries in Africa, but also middle-income countries such as South Africa and Thailand. Yet those most in need are the least able to afford treatment. Around one third of the world's population do not have regular access to essential medicines, and tropical diseases account for less than 1 per cent of the global health-research budget.²

There have been a series of disputes which have highlighted the political tensions over the relationship between patent rights and access to vital medicines. Such events have included the legal action brought by pharmaceutical drug companies against the South African Government over the *Medicines Act* 1997 (RSA), the United States trade dispute with Brazil over its patent law, and the efforts by the Canadian and the United

¹ Faunce, T. and P. Drahos (1998), 'Trade Related Aspects of Intellectual Property Rights (TRIPS) and the Threat to Patients: A Plea to Doctors to Respond Internationally', *Medicine and Law*, 17, 299; Nielsen, J. and D. Nicol (2000), 'Pharmaceutical Patents And Developing Countries: The Conundrum of Access and Incentive', *Australian Intellectual Property Journal*, 13, 289; Drahos, Peter and Ruth Mayne (eds) (2002) *Global Intellectual Property Rights: Knowledge, Access and Development*. Hampshire, Palgrave Macmillan; Gervais, Daniel (2003) *The TRIPS Agreement: Drafting History and Analysis*: 2nd ed. London: Sweet and Maxwell; Sell, Susan (2003), *Private Power, Public Law: The Globalization of Intellectual Property Rights*. Cambridge: Cambridge University Press; and Abbott, Frederick (2005), 'Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines', in Maskus, Keith and Jerome Reichman, eds., *International Public Goods and the Transfer of Technology Under a Global Intellectual Property Regime*. Cambridge: Cambridge University Press.

² Mayne, Ruth (2002), 'The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective', in Drahos, Peter and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge, Access and Development*. Hampshire, Palgrave Macmillan, p 245.

States Governments to gain access to cheap supplies of anti-anthrax drugs in the wake of a concern about bio-terrorism after the September 11 attacks.

Most dramatically, in March 2001, thirty-nine pharmaceutical drug companies brought legal action against the South African government over the *Medicines Act 1997* (RSA), arguing that the parallel importation of medicines breached their patent rights.³ The companies also argued that the legislation violated South Africa's new constitutional protections of the right to property. In response, the South African government argued that it was entitled to engage in parallel importation and compulsory licensing under the *TRIPS Agreement 1994*.⁴ The state maintained that the patent rights violated constitutional protections of the right to health. In response to the protests over non-government organisations such as the Treatment Action Campaign, Oxfam and Médecins Sans Frontières, which obtained international media attention, the pharmaceutical drugs manufacturing companies withdrew the action from the South African Supreme Court. The case nonetheless provided a focal point for a discussion of the need for a declaration on access to essential medicines within the framework of the WTO.

In another development, the United States requested WTO consultations and the establishment of a panel against Brazil over the compulsory licensing provisions in Brazilian industrial property law.⁵ In the face of hostile public attention, the United

³ McGreal, C. (2001) 'South Africa's Sick Await Judgment Day', *The Guardian Weekly*, 8-14 March, p. 1; O'Loughlin, E. (2001) 'Politicians And Drug Firms Playing With Lives In Cynical Squabble Over AIDS', *The Sydney Morning Herald*, 10 March, p. 20-21; and EO'Loughlin, E. (2001), 'New Hope On AIDS Drugs For The Poor', *The Sydney Morning Herald*, 19 April, p. 1.

⁴ For an archive of the litigation between *The Pharmaceutical Manufacturers' Association of South Africa et al v the Government of South Africa*, see: <http://www.cptech.org/ip/health/sa/pharma-v-sa.html>. For academic commentary, see: Nash, D. (2000) 'South Africa's Medicines And Related Substances Control Amendment Act of 1997', *Berkeley Technology Law Journal*, 15, p. 485; Wooldridge, F. (2000), 'Analysis: affordable medicines - TRIPs and United States policies', *Intellectual Property Quarterly*, 103; and Bombach, K. (2001), 'Can South Africa Fight AIDS? Reconciling the South African Medicines and Related Substances Act with TRIPS agreement', *Boston University International Law Journal*, 19 (2), 273-306.

⁵ 'Brazil - Measures Affecting Patent Protection', WT/DS199/4, G/L/454, IP/D/23/Add.1, 19 July 2001, (01-3506). For an archive of documents on the WTO challenge by the United States against

States negotiated a settlement to its WTO dispute settlement claim against Brazil whereby that country agreed to consult with the United States before invoking any domestic compulsory licensing provisions

The debate over access to essential medicines arose again in relation to the drug ciprofloxacin - trade name Cipro - manufactured by the pharmaceutical drugs company Bayer in the wake of anthrax bio-terrorist attacks in October 2001.⁶ The United States and Canadian Governments considered whether to invoke compulsory licensing provisions to gain access to Bayer's patent on Cipro. In the end, the patent holder was amenable to granting voluntary licences to Cipro, at competitive rates.

At a meeting in Qatar in November 2001, the members of the WTO adopted the *Doha Declaration on the TRIPS Agreement and Public Health* 2001.⁷ This acknowledged 'the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.' Article 4 emphasized 'that the *TRIPS Agreement* does not and should not prevent Members from taking measures to protect public health.' It highlighted a number of measures to promote access to essential medicines - most notably, compulsory licensing, in which a patent holder can be compelled to provide

Brazil, see: <http://www.cptech.org/ip/health/c/brazil/>. Champ, P. and A. Attaran (2002), 'Patent rights and Local Working under the WTO TRIPS Agreement: An analysis of the U.S.-Brazil patent dispute', *The Yale Journal of International Law*, 27 (2), 365-393.

⁶ Resnik, D. and K. De Ville (2002), 'Bioterrorism And Patent Rights: 'Compulsory Licensure' And The Case Of Cipro', *The American Journal Of Bioethics*, 2 (3), 29-39; Goldberg, R. (2002) 'Terrorising Patents', *Expert Opinion on Therapeutic Patents*, 12 (3), p. 329-330; and Ferrone, J. (2003), 'Compulsory Licensing During Public Health Crises: Bioterrorism's Mark On Global Pharmaceutical Patent Protection', *Suffolk Transnational Law Review*, 26, 385.

⁷ WTO Doc WT/MIN (01)/DEC/2 (2001). For academic commentary, see: Abbott, F. (2002) 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', *Journal of International Economic Law*, 5, p 469-505; Gathii, J.T. (2002), 'The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties', *Harvard Journal of Law & Technology*, 5 (2), 291-317; Murthy, D. (2002), 'The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health', *American University International Law Review*, 17 (6), 1299-1346; and Rott, P. (2003), 'The Doha Declaration - Good News for Public Health', *Intellectual Property Quarterly*, 3, 284-311.

access to a patented invention in return for a royalty. The *Doha Declaration on the TRIPS Agreement and Public Health* 2001 also emphasized the need for member nations to resolve outstanding issues over patent law and access to essential medicines. Article 6 provides: ‘We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the *TRIPS Agreement*’. It furthermore urged: ‘We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.’

On 30 August 2003, the member governments of the WTO reached an agreement on implementing the paragraph of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001 that calls for a solution to compulsory licensing for member states without manufacturing capabilities.⁸ The decision has been known as the *WTO General Council Decision 2003*⁹ Article 2 emphasized that a member country could export pharmaceutical products made under compulsory licences within the terms set out in the decision. Article 3 emphasized the need for ‘adequate remuneration’ with respect to such compulsory licences. Article 4 stressed that eligible importing members should take reasonable measures to address the risk of trade diversion, and prevent re-exportation of the products. Article 5 observed that members should ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision. Article 6 enables a pharmaceutical product produced under a compulsory licence in one country to be exported to the markets of developing countries who share the health

⁸ General Council, ‘Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’, 1 September 2003, WT/L/540, http://www.wto.org/english/tratop_e/TRIPS_e/implem_para6_e.htm. For academic commentary, see Attaran, A. (2003), ‘Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: the Case for Greater Flexibility and a Non-justiciability Solution’ *Emory International Law Review*, 17, 743-780; and Matthews, D. (2004), ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?’, *Journal of International Economic Law*, 7, 73-107.

⁹ This decision has also been variously called ‘the August 30 decision’ because of its timing; ‘the Geneva decision’ because of the locale where it is reached; ‘the Cancun decision’ due to its proximity to the trade talks in Cancun; and ‘the Motta text’ in honour of the TRIPS Council Chair, Ambassador Perez Motta of Mexico.

problem in question. Article 7 stressed the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration.

The General Council chairperson, Carlos Pérez del Castillo, the ambassador of Uruguay, made a statement to reassure patent holders about the impact of the *WTO General Council Decision 2003* ‘I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the *Doha Declaration on the TRIPS Agreement and Public Health* [2001]’.¹⁰ First, he emphasized that the system that will be established by the Decision should be used ‘in good faith to protect public health’ and ‘not be an instrument to pursue industrial or commercial policy objectives.’¹¹ Indeed, Article 9 stressed that the decision only affected paragraphs (f) and (h) of Article 31 of the *TRIPS Agreement* 1994; it had no wider impact. Second, the chairperson stressed that ‘the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended.’¹² Third, Carlos Pérez del Castillo emphasized that member countries would have to provide notification that they had insufficient or no manufacturing capacities in the pharmaceutical sector. Finally, the ambassador observed that all information gathered on the implementation of the Decision would be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

With the full implementation of the *TRIPS Agreement* 1994 from January 2005, India and other developing countries will have to provide full patent protection for pharmaceutical drugs. As a result, access to essential medicines is expected to become more difficult. At the Committee on International Trade in the European Parliament, Ellen 't Hoen, the director of policy of the Access to Essential Medicines Campaign of Médecins Sans Frontières, observed:

¹⁰ Statement of General Council Chairperson, November 13, 2003, WT/GC/M/82 http://www.wto.org/english/tratop_e/TRIPS_e/gc_stat_30aug03_e.htm

¹¹ Ibid.

¹² Ibid.

In the post 2005 era where all drugs may be patented in most countries in the world, a lot more action will need to be taken to ensure that drug prices are set at a level the people who need them and their communities can afford. Essential medicines are not a luxury whose availability can be left to private market forces only, but an essential component of the fulfilment of the right to health.

While it is easy to get lost in the legal details, it is crucial not to lose the human picture in this discussion. The fact is that effective medicines that dramatically increase the life expectancy of people living with AIDS became available in Europe and North America a decade ago. Today, 40 million people in the developing world are infected with HIV, and six million people need access to these medicines now. Only 400,000 do. The result is that, at the end of today, another 8,000 people will have died of AIDS.¹³

There has been some concern that countries have not taken advantage of the flexibilities present within the *TRIPS Agreement* 1994. Indeed the TRIPS Council of the WTO has yet to receive any notifications that the system developed to facilitate export of pharmaceutical drugs has been used.

In the lead-up to the World Trade Organization Ministerial in Hong Kong in December 2005, the Member States endorsed the proposal to transform the *WTO General Council Decision* 2003 – described as a ‘waiver’ - into a permanent amendment of the *TRIPS Agreement* 1994.¹⁴ In an accompanying statement to the decision, the WTO General Chairman, Pascal Lamy made a number of comments.¹⁵ He promoted the amendment in these terms:

The agreement to amend the TRIPS provisions confirms once again that members are determined to ensure the WTO’s trading system contributes to humanitarian and development goals as they prepare for the Hong Kong Ministerial Conference. This is of particular personal satisfaction to me, since I have been involved for years in working to ensure that the TRIPS Agreement is part of the solution to the question of ensuring the poor have access to medicines.¹⁶

¹³ Ellen 't Hoen, ‘Hearing on TRIPS and Access to Medicines’, Committee on International Trade, European Parliament, Brussels, 18 January 2005.

¹⁴ WTO General Council (2005), *Amendment of the TRIPS Agreement*, WT/L/641, http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (8 December).

¹⁵ http://www.wto.org/english/news_e/news05_e/trips_319_e.htm

¹⁶ WTO (2005), ‘Members OK Amendment to Make Health Flexibility Permanent’, Press/426, http://www.wto.org/english/news_e/pres05_e/pr426_e.htm, (6 December).

Two thirds of the members will need to ratify the change by 1 December 2007. present, there would appear to be little enthusiasm for codifying the WTO General Council Decision, given its failure to facilitate the export of pharmaceutical drugs.

James Love of CPTech was scathing about the proposed amendment to the *TRIPS Agreement* 1994:

Today the WTO created some space in its patent rules for exports of generic medicines, but at a high price. The new WTO rule is complicated and designed to increase political pressure on countries that export or import generic medicines. It is protectionist by design... The developing country negotiators were bullied and pressured by the big pharmaceutical companies and the EU to accept this deal, but they should have put up more resistance. Everyone will have to make the best of this, and try to make it work, but it is an awful decision. It is anti-consumer, anti-competition, and anti-free trade.¹⁷

He lamented that national implementation of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001 had been very patchy and poor, five years later.¹⁸

Médecins Sans Frontières argued that the proposed amendment to the *TRIPS Agreement* 1994 disregarded the fact that there is no proof of the Decision's efficacy: 'In fact proof to the contrary exists: nearly three years on from the August 30th Decision, not a single drug has reached a single patient under the WTO mechanism'.¹⁹ The group expressed alarm at the decision of the WTO to amend the *TRIPS Agreement* 1994, contending: 'The so-called 'August 30th decision,' which was designed in 2003 to allow production and export of generic medicines, has long been

¹⁷ Love, J. (2005) 'Statement of CPTech on TRIPS Amendment', <http://www.cptech.org/ip/wto/p6/cptech12062005.html> (6 December).

¹⁸ Love, J. (2006) 'Doha + Five: The Doha Declaration on the TRIPS Agreement and Public Health, after five years', CPTech, <http://www.cptech.org/ip/health/wto/dohaplus5.html>, (5 November).

¹⁹ MSF (2006), 'Neither Expeditious or Workable, the WTO General Council Decision is Unworkable', <http://www.accessmed-msf.org/documents/WTOaugustreport.pdf> (August).

viewed by MSF and public health groups as overly cumbersome and inefficient'.²⁰ Ellen t' Hoen commented:

Delaying the amendment would have been a far better option, as it would have ensured the possibility of testing and improving the mechanism in practice. This decision shows that the WTO is ignoring the day-to-day reality of drug production and procurement. The amendment has made permanent a burdensome drug-by-drug, country-by-country decision-making process, which does not take into account the fact that economies of scale are needed to attract interest from manufacturers of medicines. Without the pull of a viable market for generic pharmaceutical products, manufacturers are not likely to want to take part in the production-for-export system on a large scale. And without competition among several manufacturers, MSF fears it will be extremely difficult to ensure that prices of newer medicines will fall the way first-generation AIDS medicines did.²¹

The aid group stressed: 'Yet to date there is no experience using the mechanism – not one patient has benefited from its use – despite the fact that newer medicines, such as second-line AIDS drugs, are priced out of reach of poor patients.'²² Médecins Sans Frontières argued that the WTO must review the implementation of the *TRIPS Agreement* 1994 flexibilities, and in particular assess the efficacy of recent TRIPS amendments based on the August 30th Decision, with a view to proposing alternative mechanisms that meet health needs, are expeditious and take into account the economic reality of global drug procurement. In particular, the WTO should explore automatic solutions that do not necessitate complex time-consuming procedural steps.

Eminent international scholar, Professor Frederick Abbott, has commented upon the critical reaction to the *WTO General Council Decision* 2003 from both developing countries and civil society organizations:

There may be a better international approach than the present one to the development and distribution of new medicines. The current system involves constant tension between patent

²⁰ Médecins Sans Frontières (2005) 'Amendment to TRIPS Agreement Makes Access to Affordable Medicines Even More Bleak', <http://www.accessmed-msf.org/prod/publications.asp?scntid=71220051425522&contenttype=PARA&> 7 December.

²¹ Ibid.

²² Ibid.

holder and consumer, mediated through a complex body of rules. The objective of this article is not to recommend a better approach, but to emphasize that the equitable functioning of the present system depends on checks and balances. The Decision may not be the first-best instrument from anybody's perspective, but it does give countries lacking adequate manufacturing capacity some flexibility to make use of compulsory licensing—one of the core balancing mechanisms. The adoption of the Decision shows that the WTO can address important issues of social concern. But adoption standing alone does not show that the WTO can do so effectively. Effective implementation of the Decision is threatened by newly negotiated bilateral and regional agreements. The WTO's effectiveness can be better assessed if, and when, developing countries actually use the Decision to address their public health needs.²³

Abbott argues that the multilateral system needs to be reinvigorated. He noted: 'The relationships between the FTAs, the TRIPS Agreement, the Doha Declaration, and the Decision might be clarified in the context of transforming the Decision into an amendment.'²⁴ Abbott suggests that a hierarchy of norms could be established: 'From a legal standpoint, such clarification might require WTO members to recognize the priority of TRIPS flexibilities with respect to pharmaceutical products.'²⁵ He argues: 'Rights' established under the TRIPS Agreement, the Doha Declaration, and the Decision would not be subject to derogation in another agreement.'²⁶

In 2007, there have been a new suite of conflicts arising over patent law and access to essential medicines in the South-East Asian region. Swiss drug manufacturer, Novartis, has sought a declaration in an Indian court as to whether the *Patent Amendment Act 2005* (India) is compliant with the *TRIPS Agreement 1994*. The Thai Government has made use compulsory licensing provisions in relation to a number of pharmaceutical drugs. Indonesia refused to provide access to samples related to avian influenza because of concerns about access to essential medicines.

²³ Abbott, F. (2005) 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health'. *American Journal of International Law*, 99, 317-58.

²⁴ Ibid, p. 356.

²⁵ Ibid, p. 356.

²⁶ Ibid, p. 356.

2. THE JEAN CHRETIEN PLEDGE TO AFRICA ACT

A number of developed countries and regional groups have established domestic regimes to implement the *WTO General Council* 2003 decision, including Canada, Norway, the European Union, and India, and China. However, the practical operation of such regimes has been sub-optimal.

In September 2003, Canadian diplomat Stephen Lewis, the United Nations Secretary General's special envoy on HIV/ AIDS in Africa, challenged Canada to amend its patent law to give poor countries devastated by AIDS a cheap source for drugs. He made a passionate plea:

It's time for one of the major industrial countries, in particular, one of the G7 countries, to announce the manufacture and export of generic drugs to Africa. I would wish it to be my country, Canada, but it doesn't really matter which. The proposition is simple: if the WHO is going to move from 50,000 now in treatment in Africa to over two million by 2005 (Africa's share of the 3 million target), then they will need a fast, reliable, scientifically sound, continuous flow of generic drugs in order to keep the prices low enough - roughly \$250 to \$300 per person per year - for the plan to succeed. There will obviously be some provision from Brazil, Thailand and India, but much more will be needed. A western country could fill that need and do it at the highest standards of quality.²⁷

Lewis argued the support of a major industrialised nation was essential: 'If a G7 country issues a compulsory license so that its generic industry can provide the drugs, then the G7 country can join the African importing country when it goes before the WTO Council or responds to some challenge.'²⁸ Lewis concluded: 'It would at least be a small act of redemption if the same wealthy countries now provided low cost generic anti-retrovirals to help to diminish the scourge of AIDS'.²⁹ The envoy concluded that such measures would not harm the pharmaceutical drugs industry

²⁷ Stephen Lewis, 'The Politics of Resource Allocation', Statement by United Nation Secretary General's Special Envoy on HIV/ AIDS, Nairobi, Kenya, 25 September 2003, <http://www.awcfs.org/Icasa/DayFive/StephenLewis4.html>

²⁸ Ibid.

²⁹ Ibid.

because they would be limited to exports only.’³⁰ Lewis reiterated such comments to the *Globe and Mail*: ‘If a major Western government would undertake the simple legislative amendment allowing for the production and export of generic antiretrovirals, it would make a tremendous difference for Africa’.³¹

Taking up the challenge, Richard Elliott of the Canadian HIV/AIDS Legal Network and the Global Treatment Action Group wrote an editorial for the *Globe and Mail*, calling upon the Government of Canada to reform patent law to allow for access to essential medicines.³² He submitted:

Canada could do much, much more to respond to the desperate need for affordable medicines in many developing countries. Most of these people died prematurely because they could not afford to buy their lives — because medicines accepted as standard in wealthy countries are simply too expensive. Had the drugs been more affordable, many of these deaths could have been prevented. Families and communities could have been spared terrible suffering, and nations could have avoided the dreadful economic toll of losing teachers, farmers, nurses, labourers, miners, community leaders, students.³³

Elliott emphasized that the Government of Canada could easily remove the barrier to the export of pharmaceutical drugs: ‘A simple amendment to our patent legislation could authorize the manufacture of generic drugs by Canadian companies for export to those developing countries that cannot make their own.’³⁴

In November 2003, the Canadian Prime Minister, Paul Martin, announced the introduction of a new Bill to provide low cost drugs to fight AIDS in developing

³⁰ Ibid.

³¹ Nolen, S. (2003), ‘Spearhead AIDS fight, UN envoy tells Canada; Lewis seeks looser generic drug law: ‘It would save millions of lives, it would cost nothing, and it's such an easy thing to do’’, *The Globe and Mail*, 25 September, A1.

³² Elliott, R. (2003), ‘Canada can carry much more; Canadian firms stand ready to manufacture affordable AIDS drugs. The WTO has even relaxed its patent rules. So why won't the PM give the green light?’, *The Globe and Mail*, 23 September, A23.

³³ Ibid.

³⁴ Ibid.

countries. He dubbed the proposed legislation, the ‘Jean Chrétien Pledge to Africa Act’,³⁵ to honour his predecessor’s initiatives in that area. Martin observed:

The world needs our values. The world needs us now. That is why we will be the first country in the world with legislation to open the door to increased export and production of patented medicines to help people suffering from HIV/AIDS, malaria and TB, among other diseases, in the developing world.³⁶

This statute amends the *Patent Act*³⁷ and the *Food and Drugs Act*³⁸ ‘to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics’.³⁹ These amendments were introduced to implement paragraph 6 of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001. The legislation was passed by the Canadian Parliament and received Royal Assent in May 2004.⁴⁰

Apotex

In November 2003, the Canadian private generic pharmaceutical company, Apotex, expressed a willingness to produce a key HIV/AIDS drug, Apo-Zidovidine, a generic equivalent of Retrovir-AZTÒ, under the new legislation, which allowed

³⁵ *An Act to Amend the Patent Act and the Food and Drugs Act*, SC 2004, c 23.

³⁶ Martin, P. (2003) ‘Confederation Dinner’ <http://www.paulmartin.ca/home/stories_e.asp?id=886> at 9 December 2003. This page is no longer available, copy on file with author.

³⁷ *Patent Act*, RSC 1985, c F-27.

³⁸ *Food and Drugs Act*, RSC 1985, c P-4.

³⁹ Canada, *Government Orders*, Edited Hansard No 044, 37th Canadian Parliament, 3rd Session, April 29 2004 (Charles Caccia, Davenport, Lib) <http://www.parl.gc.ca/37/3/parlbus/chambus/house/debates/044_2004-04-29/han044_1345-E.htm> at 1 October 2004.

⁴⁰ For an extended account of the legislative history of the bill, see this, in hindsight, overly optimistic account: Rimmer, M. (2005), ‘The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid’, *Expert Opinion on Therapeutic Patents*, 15 (7), 889-909.

pharmaceutical drugs to be exported to developing countries.⁴¹ President and Chief executive officer, Jack Kay, observed:

With our expertise and experience in producing the generic equivalent of AZT, we can gear up fairly quickly. We are ready to assist in the fight against the HIV/AIDS disaster in Africa and other parts of the developing world.⁴²

Nonetheless, the company noted: ‘Our ability to supply AZT is dependent on our receiving a compulsory licence under the newly introduced legislation.’⁴³

In May 2004, Médecins Sans Frontières (MSF) made a public commitment to test the efficacy of the *Jean Chrétien Pledge to Africa Act 2004* (Canada) by placing an order for medicines needed for its field projects. In August 2004, MSF identified to Health Canada and representatives of the Canadian generic pharmaceutical industry five drugs that were urgently needed to treat its patients.

In December 2004, Apotex Inc., a privately-held Canadian generic pharmaceutical company agreed to produce a three-in-one antiretroviral combination of zidovudine, lamivudine and nevirapine (AZT+3TC+NVP), drugs which represent one of the first-line treatment regimens for HIV recommended by the World Health Organization (WHO). At the time, those drugs were not available in the form of fixed-dose combination (FDC), a product that would simplify treatment significantly and help with the global effort to scale up treatment.

Apotex developed an active prototype of the Fixed Dose Combination by April 2005. However, this FDC was not on the list of products eligible for compulsory licensing for export in Schedule 1 of the *Patent Act*. The addition of a new product to the schedule requires a decision of the federal Cabinet, following the recommendation of both the Minister of Industry and the Minister of Health.

⁴¹ Apotex (2003), ‘Canadian-Owned Generic Company Prepared To Provide HIV/AIDS Drug to Developing Nations’, <http://www.apotex.com/PressReleases/20031107-01.asp> (7 November).

⁴² Ibid.

⁴³ Ibid.

In September 2005, after further pressure, the Cabinet made the requisite order amending Schedule 1. In late 2005, Apotex submitted to Health Canada an application for approval, as required under the legislation (a step not required under the WTO 2003 decision), at which time MSF began discussions with potential importing country authorities. The Health Canada review process took seven months; the product received approval in July 2006.

Apotex has had to approach a few brand-name drug companies to receive permission to sell the three-in-one antiretroviral to the aid group for distribution in the developing world. Jack Kay, president of Apotex, has said that such entreaties have met with hostility: 'How do they feel about us? They hate our guts.'⁴⁴

Apotex has been frustrated by negotiations with GlaxoSmithKline to include the drug Zivudine in a new three-in-one antiretroviral. In May 11, Apotex formally requested a voluntary licence to make a generic version of three patented drugs that would be included in the pill. GlaxoSmithKline has asked questions regarding packaging, dosage form and other technical considerations, and expressed concern that the name of the drug was close to the name of a patented GSK drug.⁴⁵ It also wanted assurances that the drugs would not be diverted to other markets. In a 9 June 2006 letter to Apotex, Joy Morrow, a lawyer for Glaxo, replied that Apotex had failed to indicate the specific country to which the drug was to be exported. He wrote that the request for a 'royalty-free licence was unreasonable: Our clients understand that ... Apotex is selling the product at its own cost and requests a royalty-free licence'.⁴⁶ He noted: 'Our clients reserve their right to have such a statement verified by independent auditors to verify the claim of non-profit supply.'⁴⁷ Kay of Apotex observed that Glaxo was resistant because, 'it's the thin edge of the wedge. They don't want to open

⁴⁴ Ibid.

⁴⁵ Silversides, A. (2006), 'Not a single pill', *Ottawa Citizen*, (13 August).

⁴⁶ Westhead, R. and T. Talaga (2006). 'Health Minister Tony Clement says he's launching an immediate review of why Canada has failed to deliver on a pledge to get low-cost AIDS drugs to countries in need', *Toronto Star*, 16 August, A01.

⁴⁷ Ibid.

any doors down the road to having exceptions granted on their patents.’⁴⁸ GlaxoSmithKline defended its requirement that Apotex produce unique colours and markings for any drugs destined for Africa: ‘Otherwise, the humanitarian spirit of this voluntary licence will be undermined if the medicines produced for export do not reach their destination.’⁴⁹

Apotex has also been involved in licensing negotiations with Boehringer-Ingelheim Canada and Shire BioChem.

Bruce Clark of Apotex has expressed his frustration with the process of engaging in voluntary licence negotiations with brand name pharmaceutical companies. He has observed that the brand name pharmaceutical companies have been unwilling to grant licences because ‘there’s no downside for the brand to not come to an agreement.’⁵⁰ There has been legal uncertainty as to what constitutes ‘thirty days’ of negotiations. Clarke also notes that developing countries have been reluctant to utilise the system. He noted: ‘Developing nations are interpreting it as having to ask for a hand-out’.⁵¹ President Kay has said that the company has given up trying to obtain voluntary licences from the brand-name companies involved. He says the process has been so frustrating that his company wouldn’t do it again unless there were significant changes to the law, such as scrapping the requirement to first seek a voluntary licence.

In August 2006, shortly before the XVI International AIDS Conference, the WHO Prequalification Project, having reviewed the dossier submitted to Canadian drug regulators, also gave its stamp of approval, a precondition upon which many developing countries insist when making procurement decisions.

During the 16th International AIDS Conference, a representative of the Clinton Foundation HIV/AIDS Initiative indicated the Foundation would be willing to place an order for the Apotex FDC product as the basis for a compulsory licence

⁴⁸ Ibid.

⁴⁹ Ibid.

⁵⁰ Kiladze, T. (2006) ‘Canada isn’t living up to its promise’, *McGill Daily*, 96 (24), (30 November).

⁵¹ Ibid.

application. Anil Soni of the Clinton Foundation said he would be 'thrilled' to see Canada issue a compulsory licence to export copies of life-saving drugs.⁵² The Clinton Foundation contracts with companies to supply needed drugs in over 60 developing-world countries

University of Toronto professor, Ariel Katz, was cynical about the prospects of generic drug makers:

It's all money. It may be good for generic companies to get involved in this if they can win some points on the PR front, but if it's not going to make any money, then why bother?⁵³

Apotex has expressed concern that, because of delays in the approval process, it could be undercut by a competitor, India-based Hetero Drugs.⁵⁴ Apotex wants to charge more than \$2 million more - \$18.4 million - for the identical drug, whereas Hetero Drugs has offered to sell the same amount of the newly created AIDS medicine for about \$15.8 million. Rachel Kiddell-Monroe of Doctors Without Borders commented: 'Of course, there's an irony to this. What happened was it took too bloody long here (Canada) to get the drug approved.'⁵⁵ The Apotex president, Jack Kay, observed that the price that it plans to charge would not cover its \$2 million-plus worth of research and legal expenses so far. He has observed that the Health Minister Tony Clement, said Canada needs to decide whether it wants to scrap the legislation: 'Either Canada wants to be a player here or it doesn't.'⁵⁶

Richard Elliot comments that the Canadian legislation failed to provide sufficient incentive for the manufacturers of generic drugs:

⁵² Silversides, A. (2006), 'Canada Falts on Promise of AIDS Drugs for Africa', *Ottawa Citizen*.

⁵³ Westhead, R. and T. Talaga (2006). 'Health Minister Tony Clement says he's launching an immediate review of why Canada has failed to deliver on a pledge to get low-cost AIDS drugs to countries in need', *Toronto Star*, 16 August, A01.

⁵⁴ Ibid.

⁵⁵ Ibid.

⁵⁶ Ibid.

The scheme depends on generics using it - essentially there has to be some economic incentive. Generics may have humanitarian reasons as well, but this can't just depend on goodwill. They are commercial enterprises. For it to be economically worth their time and effort, they need economies of scale.⁵⁷

He says that market failure is the root of the problem that sees people in the developing world dying for lack of essential medicines. The WTO's solution risks perpetuating that problem: 'The market does not respond to the needs of poor people ... they are not a big draw for pharmaceutical producers because they don't have money.'⁵⁸

Review of the Access to Medicines Scheme

In the 2006 Canadian election, there were great recriminations about the failure of the *Jean Chretien Pledge to Africa Act 2004* (Can) to achieve its stated aims. The Liberal Government stressed: 'Canada has undertaken to provide a number of countries (eg South Africa, Ghana) with information on Canada's legislation and will continue to do so over the coming months.' The Bloc Quebecois affirmed the need for the next federal government to implement a realistic plan for Canada to increase its foreign aid to the UN target of 0.7 percent of gross national income by 2015. The NDP complained that 'not a single drug approved for export is in production and 'not a single pill has reached Africa'. The party pledged: 'In this Parliament, Jack Layton and the NDP took tangible steps towards keeping this crucial promise to the world and its people.' The eventual winners of the election, the Conservatives, did not have a platform on the topic.

At the 16th International AIDS Conference in Toronto in 2006, Stephen Lewis expressed disappointment that the Canada's Access to Medicines regime had failed to meet his high expectations. He lamented: 'It's almost unbelievable that two governments - one Liberal and one Conservative - can't get a single pill to Africa.'⁵⁹

⁵⁷ Silversides, A. (2006), 'Not a single pill', *Ottawa Citizen*, (13 August).

⁵⁸ Ibid.

⁵⁹ Teotonio, I. (2006), 'Clement vows to get cheap drugs flowing; Health minister decries lack of aid But current law prevents action', *Toronto Star*, 14 August, A01.

Lewis reflected upon his naivety that he believed that the Government of Canada would enable exports of pharmaceutical drugs, once the legislation had been passed:

Somehow it got sabotaged by a combination of bureaucracy on the one hand and big pharma on the other... I was thrilled when MSF [Medecins Sans Frontieres] decided to enter into a contract with Apotex asking for a particular fixed-dose combination generic drug, but then it just went on and on and on, and suddenly I understood where the problem lay. The problem lay in the endless negotiations by the brand-name companies with the generic companies over a voluntary licence. Quite rightly, the generic companies didn't want to go the compulsory-licence route because they didn't want to be thrown into a pitched battle with the brand names in the future over pricing and everything else, so they wanted the brand names to give them the voluntary licences as the brand names had been doing with companies in Africa. They had been willing to give voluntary licences to make generic equivalents, bio-equivalents, of the brand names. But that didn't happen with Apotex. So what we had was this unbelievably protracted bullshit negotiation between the generics and the brand names. The brand names stalling, stalling, stalling, elongating, and the government refuses to step in.⁶⁰

Lewis accused Health Canada and Industry Canada of a lack of initiative: 'And they could have at any point along the way and just say, 'We want someone to ask for compulsory licence', or to amend the regulation to say, you know, 'the purchaser can ask for the compulsory licence'.'⁶¹ He asked the rhetorical question: 'What's wrong with these governments? In truth, the minister of health and minister of industry have all the power in the world to issue a compulsory licence and get the generic drugs that Canada promised to Africa at prices that Africans can afford and will save, ultimately, millions of lives.'⁶²

He also reflected that he had under-estimated the balance-sheet considerations of both the brand name and generic pharmaceutical industries. Lewis also expressed concern about the proliferation of TRIPs-Plus bilateral free trade agreements, which undermined the WTO General Council decision.

⁶⁰ Straight, G. (2006), 'Lewis Battles to Elevate the Politics of AIDS', The Stephen Lewis Foundation, http://www.stephenlewisfoundation.org/news_item.cfm?news=1346, 24 August.

⁶¹ Ibid.

⁶² Teotonio, I. (2006), 'Clement vows to get cheap drugs flowing; Health minister decries lack of aid But current law prevents action', *Toronto Star*, 14 August, A01.

At the 16th International AIDS Conference, the Minister of Health, Tony Clement, confessed that Canada's access to medicines scheme had not been a success:

Exhibit A is not a single pill has flowed through the system and got to the people who need it. We need legislation that works.⁶³

He vowed that the Canadian Parliament would investigate the operation of the legislation, and seek to fix the problem: 'If we can put a man on the moon, we can solve this issue.'⁶⁴ Clement expressed surprised that developing countries had not made applications under the scheme: 'There hasn't been much take-up on it, you know? That's the big surprise, so far. That's the kind of thing that, after a while, you have to start asking yourself: Is it meeting its goal? Is there something we should do to improve?'⁶⁵ Clement said the government review intends 'to do this comprehensively, do it rationally to get some good information and advice because really this is our first opportunity as a new government to consider this legislation.'⁶⁶

In November 2006, the Government of Canada released a consultation paper to review Canada's Access to Medicines Regime. Tony Clement, Minister of Health, observed: 'CAMR is one part of Canada's broader response to fighting public health problems such as HIV/AIDS, tuberculosis, malaria and other epidemics afflicting the developing world.'⁶⁷ Maxime Bernier, Minister of Industry, commented: 'By undertaking an early review of the relevant *Patent Act* provisions of CAMR, the

⁶³ Westhead, R. and T. Talaga (2006). 'Health Minister Tony Clement says he's launching an immediate review of why Canada has failed to deliver on a pledge to get low-cost AIDS drugs to countries in need', *Toronto Star*, 16 August, A01.

⁶⁴ Teotonio, I. (2006), 'Clement vows to get cheap drugs flowing; Health minister decries lack of aid But current law prevents action', *Toronto Star*, 14 August, A01.

⁶⁵ Smith, G. and G. Galloway (2006), 'Chrétien's drug program ineffective, Clement says; Poor countries haven't taken advantage of cheap medicine, Health Minister notes', *The Globe and Mail*, 28 April, A12.

⁶⁶ Westhead, R. and T. Talaga (2006). 'Health Minister Tony Clement says he's launching an immediate review of why Canada has failed to deliver on a pledge to get low-cost AIDS drugs to countries in need', *Toronto Star*, 16 August, A01.

⁶⁷ Industry Canada (2006), 'Government of Canada Launches Review of Canada's Access to Medicines Regime', 24 November.

government is demonstrating its continued commitment to being a global leader in improving access to medicines in developing and least-developed countries.’⁶⁸

The Consultation Paper acknowledges that Canada’s access to medicines regime [CAMR] has not met its laudable objectives:

Despite being in force since May of 2005, CAMR has not yet resulted in the export of any eligible pharmaceutical products to eligible importing countries. Similarly, there have been no exports under comparable regimes in other countries that have implemented the WTO waiver. Critics have cited a number of reasons for this but a definitive diagnosis will prove difficult until such time as a compulsory licence is granted. Nevertheless, given the pressing humanitarian concerns which gave rise to the waiver and which underlie CAMR, a decision has been made to initiate the statutorily mandated review in advance of what is required in order to meet the May 2007 deadline for its completion.⁶⁹

The Consultation Paper was designed to ‘focus dialogue between stakeholders and government on how CAMR might better meet its humanitarian objectives, without derogating from international trade obligations or undermining the intellectual property rights necessary for continued innovation in Canada.’⁷⁰ The review of the regime is due to be completed by May 2007.

In its 2007 submission, the Global Treatment Access Group and Canadian HIV/AIDS Legal Network called upon the Government of Canada to fulfil its pledge.⁷¹ The coalition of organisations had a number of recommendations on how to improve Canada’s Access to Medicines Regime. The Global Treatment Access Group and Canadian HIV/AIDS Legal Network called on the Government of Canada to provide authorisations to export pharmaceutical drugs, which were not limited to a single drug order to a single country. The groups submitted that this could be done in a variety of

⁶⁸ Ibid.

⁶⁹ Canadian Government (2006), Canada’s Access to Medicines Regime – Consultation Paper’, http://camr-rcam.hc-sc.gc.ca/camr_rcam_consult_e.html, (24 November)

⁷⁰ Ibid.

⁷¹ Elliott, R. (2007), ‘Review of Canada’s Access to Medicines Regime — Legal Network submission to the Government of Canada’, <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=674>, 24 January.

ways. The Government of Canada could create a standing statutory authorization permitting export of generic medicines to eligible countries. On any given drug, grant a single, open-ended license to a given manufacturer. Licences additional to a first licence could be fast-tracked. The Global Treatment Access Group and Canadian HIV/AIDS Legal Network requested that the Government of Canada remove unnecessarily restrictive and time-consuming steps in the licensing process, especially those steps not required by the WTO General Council decision or Canadian law. In particular, the organisations asked for the removal on the time limit on licences granted; the limitation of the requirement of negotiating with a patent-holder before seeking a compulsory license; the elimination of the list of eligible drugs, the absolute requirement of Health Canada approval, and patent-holders' extra litigation rights; and enable non government organisations to seek exports of pharmaceutical drugs. The organisations also called upon the Government of Canada to remove the double-standards that apply to some importing countries.

In a recent submission to the Canadian Parliament, the Global Treatment Access Group and Canadian HIV/AIDS Legal Network contended:

Canada has implemented the mechanism embodied in the WTO Decision. So far, Canada's model has not worked — and the WTO Decision has not yet worked in any other country where it has been implemented. Canada was one of the first countries to implement the WTO Decision with a complete legislative framework, and it is the jurisdiction in which the most concerted efforts have been made to date to use the mechanism. As such, Canada is in a position to set a positive global precedent by acknowledging that the WTO Decision does not address the needs of developing countries, and to implement a better model, within the bounds of WTO rules, that stands a greater likelihood of actually engaging generic producers and developing-country purchasers in increasing access to more affordable treatment for millions of people.⁷²

The organisations recommended: 'Canada has the clear legal right and ethical duty to use the flexibility that it retains under TRIPS Article 30 to legislate, as a set of 'limited exceptions' to exclusive patent rights, the simpler, streamlined mechanism

⁷² Elliot, R. (2007), 'Getting the Regime Right: Compulsory Licensing of Pharmaceuticals for Export', Brief to the House of Commons Standing Committee on Industry, Science and Technology regarding Canada's Access to Medicines Regime, 18 April.

for compulsory licensing for export described above.’ It advised that the Canadian Government to provide authorizations to export that are not limited to a single drug-order for a single country. This could be done by creating a standing statutory authorization in the *Patent Act* authorizing the manufacture of generic versions of any drug patented in Canada for export to any eligible country specified in the legislation. Alternatively, a manufacturer could be granted a single, open-ended licence on a given drug that authorizes the exportation of that drug to any eligible country specified in the legislation.

Under such mechanisms, the authorization would not be limited to exporting a pre-determined quantity of the product to a single country, and would not require a new application process for every single contract negotiated between a generic manufacturer and a potential purchaser. Moreover, the organisations submitted that the authorization should extend to permit the use of *any* patented invention necessary for the manufacture and export of the medicine in question. Furthermore, the generic manufacturer would be required to remit periodically to the patentee(s) the royalties payable, which can be determined according to the existing formula in the Regime.

The Canadian Labour Congress called for ‘Canadian generic drug makers to export affordable and accessible medicines to countries that need them’.⁷³ It noted that ‘the hopes raised by the adoption, for these purposes, in 2004, of amendments to our patent laws have been totally dashed.’⁷⁴ The Congress observed: ‘Though the law came into effect in May 2005, not a single generic pill has left Canada because of disincentives in the legislation itself.’⁷⁵

The President of Apotex, Jack Kay, was critical of the design of the *Jean Chretien Pledge to Africa Act 2004* (Can) by the former Liberal Government: ‘They were trying so hard to protect the brand companies that they've almost killed the possibility

⁷³ The Canadian Labour Congress (2006), ‘Unions Join GTAG Demands for Government Commitment to Fight Pandemic’, *The Canadian Press*, (27 November).

⁷⁴ Ibid.

⁷⁵ Ibid.

of any Canadian company to take advantage of the bill the way it is structured.’⁷⁶ Kay welcomed Clement's initiative, but describes himself as ‘guardedly optimistic.’⁷⁷ He wondered, though, whether the Minister would be able to deliver a positive outcome:

Politically it was the right thing to say. Will he have the courage of his convictions? Or will the bureaucracy not allow it to happen?⁷⁸

Kay alleged that the bureaucracy, primarily Industry Canada officials, is pro brand-name drug: ‘They're there forever and the politicians come and go.’⁷⁹

For his part, Stephen Lewis, the United Nations special envoy for HIV/AIDS in Africa, was sceptical of value of the review:

This gives new meaning to the word immediate. They were elected eight months ago. If this is the nature of their particular dictionary, I wouldn't trust any word. We've lost another six months, in other words, and now we'll lose even more time.⁸⁰

Furthermore, a number of key developed countries have egregiously not implemented domestic regimes under the *WTO General Council Decision 2003*. Most notably, the United States has shown little inclination to establish a mechanism to facilitate the export of pharmaceutical drugs to developing countries. Indeed, the United States has instead pursued a course of bilateral and regional free trade agreements, which have imposed TRIPs-Plus Standards in respect of pharmaceutical drugs upon its trading partners.

⁷⁶ Martin, R. (2006), ‘Canada's empty pledge to Africa’, *Politics Watch*, (16 August).

⁷⁷ Ibid.

⁷⁸ Ibid.

⁷⁹ Ibid.

⁸⁰ Westhead, R. and T. Talaga (2006). ‘Health Minister Tony Clement says he's launching an immediate review of why Canada has failed to deliver on a pledge to get low-cost AIDS drugs to countries in need’, *Toronto Star*, 16 August, A01.

3. THE AUSTRALIAN POLICY DEBATE

In August 2002, the Trade Minister Mark Vaile endorsed the *Doha Declaration on the TRIPS Agreement and Public Health* 2001, saying:

As the WTO Director General Supachai Panitchpakdi has noted, this is an historic agreement. It is a further demonstration that the WTO is able to respond to the public-health problems faced by developing countries, and to make its contribution to broader domestic and global action to address this crucial social issue. I have consistently said, particularly since the Sydney WTO informal ministerial meeting in November last year, that all WTO member countries had a moral obligation to resolve this issue. The problems poorer countries face in dealing with ravaging diseases such as HIV/AIDS, malaria and tuberculosis are immense. After many months of work, all WTO members have agreed an outcome that will allow these countries better access to affordable medicines. This decision is one endorsed by all WTO members. Now we must move past old battle lines and all work to ensure the solution makes its contribution to dealing with the public health problems poorer countries face.⁸¹

Unfortunately, such rhetoric has been unaccompanied by any legislative action to fulfil this moral obligation. Six years later, the Federal Government has shown no inclination to implement domestic legislation to implement the *WTO General Council Decision*. Such a matter has not been considered to be a legislative priority.

In 2004, the Australian Government launched Australia's International HIV/AIDS Strategy.⁸² Strangely, the Strategy makes only a cursory mention of the impact of intellectual property upon access to essential medicines:

Anti-retroviral drugs are prohibitively expensive in many countries where the socio-economic impact of HIV/AIDS is greatest. It was argued that the [*TRIPS Agreement*] denied human rights to the poor by preventing access to effective and affordable HIV/AIDS treatment. In response, modifications to the original agreement grant countries the flexibility to protect public health through two mechanisms. First, through parallel importing of patented drugs from cheaper sources. Second, by issuing compulsory licences, under certain circumstances, to allow a patented product to be produced domestically without the consent of the patent owner.

⁸¹ Mark Vaile, 'Vaile Welcomes Breakthrough on Essential Medicines', Department of Foreign Affairs and Trade, 31 August 2002, http://www.trademinister.gov.au/releases/2003/mvt067_03.html

⁸² 'Meeting the Challenge: Australia's AIDS Policy', July 2004, http://www.ausaid.gov.au/publications/pdf/aids_strategy.pdf

Pharmaceuticals manufactured under compulsory licences may be used to supply either the domestic market or for export to countries without the capacity to manufacture their own.⁸³

The strategy notes that Australia offered in October 2001 to provide support upon request to Asia-Pacific governments to draft legislation to facilitate access to antiretroviral drugs, consistent with international trade agreements. However, there is no discussion of Australia implementing its own legislation to give effect to the *WTO General Council Decision* on the export of pharmaceutical drugs. Intellectual property is not mentioned as a key priority for the Government.

I am concerned 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. This has been particularly disappointing, given the alacrity with which the Intellectual Property Chapter of the *Australia-United States Free Trade Agreement 2004* was implemented.

Patent Term Extensions and Evergreening

There have been concerns that pharmaceutical drug companies have been extending the term of patent protection through both direct and indirect means. Graham Dutfield details a number of strategies and tactics, which he calls 'evergreening':

Pharmaceutical companies use patents (and also trade marks) strategically in order to restrict competition, in some cases for several years beyond the 20-year patent duration. 'Evergreening' or 'line extensions' are terms used to refer to the use of IP rights in order to extend the monopoly or at least the market dominance of a drug beyond the life of the original patent protecting it.⁸⁴

There have also been concerns that heightened protection afforded to pharmaceutical drugs will have a deleterious impact upon the generics industry in Australia.

⁸³ Ibid.

⁸⁴ Dutfield, Graham (2003), *Intellectual Property Rights And The Life Science Industries* Aldershot: Ashgate, p. 109.

In 1994, the Australian Government raised the term of patent protection from sixteen years to twenty years under the *Patents (World Trade Organization Amendments) Act 1994 (Cth)*. Such a move was justified by the need to comply with the *TRIPS Agreement 1994* of the WTO.

The Productivity Commission sought to conduct economic modelling upon the impact of the patent term extension.⁸⁵ The study found:

There is no economic justification for extending patents already in force. Doing so imposes costs on IP users, and only provides 'windfall' gains to producers on IP *already produced*.⁸⁶

The Commission found that the direct cost to the Australian economy of extending patent terms ranged from a probable underestimate of \$376 million in net present value terms, to a probable overestimate of \$3.8 billion. The direct cost to Australian consumers of intellectual property will be between \$1.5 billion and \$7.4 billion in net present value terms, although these costs to Australian consumers will be offset somewhat by gains of between \$1.1 billion and \$3.6 billion to Australian producers. Two thirds or more of the direct cost to Australia will come from the extension of Australian patents which were already in force on 1 July 1995. The study concluded: 'Because Australia is a strong net importer of IP, it will rarely be in Australia's interest to protect IP more than international agreements require.'⁸⁷

Nonetheless, such economic research did not dull legislative enthusiasm for additional patent protection for pharmaceutical drugs. In 1998, the Australian Government passed the *Intellectual Property Laws Amendment Act 1998 (Cth)* to provide for an extension of term for pharmaceutical patents. The scheme allows patentees to apply for an extension of term of up to five years for a standard patent that claims a pharmaceutical substance. The scheme also provides for 'spring boarding', which allows manufacturers of generic drugs to undertake certain activities at any time after

⁸⁵ Gruen, N., Bruce, I. and G. Prior (1996), *Extending Patent Life: Is It In Australia's Economic Interests?* Commonwealth Government: Productivity Commission.

⁸⁶ Ibid.

⁸⁷ Ibid.

the extension is granted. These activities are limited to the purpose of meeting pre-marketing regulatory approval requirements.

The Australian scheme appears to be modelled upon the *Drug Price Competition and Patent Term Restoration Act 1984* (US) (the ‘Hatch-Waxman Act’). The United States legislation sought to provide for patent term extensions in certain circumstances to brand-name pharmaceutical companies, and expedite the Food and Drug Administration approval process for the manufacturers of generic drugs.

In response, there was concern that extended protection for pharmaceutical patents would harm the significant generics manufacturing sector in Australia, conducted by such firms as Sigma, Alphapharm and GlaxoSmithKline.⁸⁸ The generic industry has argued that it should have a greater capacity to export pharmaceutical drugs:

A major challenge is to devise a means of overcoming barriers to exports of generic drugs without reducing the value of a patent in the Australian market. It has been argued that if manufacturing for export were allowed during the patent extension period, generics manufacturers could be ready sooner to market their medicines in Australia once the patent has expired. However, it would simply place Australian generics manufacturers on an equal footing with foreign generics manufacturers supplying the Australian market.⁸⁹

The generics industry is concerned that extended patents expire later in Australia than they do in the US and Europe: ‘Analysis in 1999 of some 208 medicines indicated that in around 70% of cases, patents expire in Australia after the equivalent patent in the US or the UK.’⁹⁰ As a result, generic manufacturers in Australia are at a competitive disadvantage, because they have to wait longer until they can enter into market.

⁸⁸ Hill, J., Kirchner, A. and A. Holmes (2001) ‘Pharmaceuticals Industry Action Agenda: Discussion Paper’, September,

<http://www.industry.gov.au/assets/documents/itrinternet/PharmPapersep01.pdf>

⁸⁹ Department of Industry, Tourism and Resources (2002), ‘Discussion Paper on Patent Extensions and Springboards’, September,

<http://www.ipta.com.au/notices/Patent%20IDC%20Background%20Paper-%20Publicfinal1.doc>

⁹⁰ Ibid.

In this environment, there has been litigation over the practice of evergreening. In *Aktiebolaget Hassle v Alphapharm Pty Limited*, the High Court of Australia upheld by a majority of five to two an appeal by the patentee, Astra, against a finding that its patented invention was obvious.⁹¹ The patent in suit was a formulation patent relating to a method for manufacturing a stable preparation containing the active ingredient omeprazole for the treatment of stomach and duodenal ulcers. Astra had earlier patented the compound omeprazole, but difficulties had been encountered in formulating a pharmaceutical composition. After several years of research, Astra solved those difficulties by developing the invention claimed in the patent in suit.

The case raised wider public policy concerns. In his dissent, Justice Michael Kirby observed:

The entry of generic drugs as cheaper substitutes for branded ones at the expiration of patent protection is a feature of the market for pharmaceuticals in many countries. The strategies that large pharmaceutical manufacturers have employed to avoid such generic competition, which include the use of intellectual property law, have been detailed elsewhere. They have attracted the attention and response of the Federal Trade Commission in the United States. Such battles have had their counterparts in many other countries. They present serious issues for the developing world. In its interpretation of the legislation, and in identifying the proper approach to the ultimately factual determination of obviousness called for by that statute, this Court should avoid creating fail-safe opportunities for unwarranted extensions of monopoly protection that are not clearly sustained by law.⁹²

His judgment reveals deep concerns that the principle that patent law provides a limited period of protection has been eroded by the practice of evergreening.

There have also been concerns that the *Australia-United States Free Trade Agreement* 2004 will further encourage the evergreening of pharmaceutical drug patents.

Article 17.8 (a) provides: 'If there are unreasonable delays in a Party's issuance of patents, that Party shall provide the means to, and at the request of a patent owner, shall, adjust the term of the patent to compensate for such delays.' Furthermore,

⁹¹ *Aktiebolaget Hässle v Alphapharm Pty Limited* (2002) 212 CLR 411.

⁹² *Ibid* at 449-450.

Article 17.8 (b) stipulates: ‘With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.’

Article 17.10.4 deals with the marketing of pharmaceutical drugs. Subsection (a) stipulates that a Party shall ‘provide measures in its marketing approval process to prevent those other 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 approved use is claimed in a patent, during the term of that patent, unless by consent or acquiescence of the patent owner.’ Subsection (b) notes that ‘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, the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.’

To give force to such articles, the Australian Government has passed amendments to the *Therapeutic Goods Act 1989* (Cth) as part of the *US Free Trade Agreement Implementation Act 2004* (Cth). Again, such amendments seem to emulate features of the *Drug Price Competition and Patent Term Restoration Act 1984* (US) (the ‘Hatch-Waxman Act’). However, the Australian scheme only requires the generic company to provide notification; there is no scope in the drug marketing provisions for the brand name drugs company to seek an injunction.

In its final report, the Senate Select Committee observed that such additional measures in the *Australia-United States Free Trade Agreement 2004* could have unforeseen consequences for the sustainability of Australia's generic drug industry. It observed: ‘A viable generic medicines industry is essential to creating the competition needed to contain drug prices.’⁹³ The additional step in the marketing approval could well prove to be a burden to the generics industry. Given the United States experience

⁹³ Senate Select Committee on the Free Trade Agreement between Australia and the United States of America (2004), *Final Report*. Canberra: Australian Parliament, August, p. 137.

with marketing approval,⁹⁴ there needs to be proper incentives in place in Australia to encourage generic companies to export pharmaceutical drugs to countries in the grip of public health problems. Perhaps such compulsory licenses should be granted for a minimum of 5 years, and automatically qualify for procurement under all Australian foreign aid programs.

Export of Pharmaceutical Drugs and Compulsory Licensing

There have been concerns expressed that bilateral agreements such as the *Australia-United States Free Trade Agreement 2004* will undermine the *Doha Declaration on the TRIPS Agreement and Public Health 2001* and the *WTO General Council Decision 2003*.⁹⁵

Article 17.9.6 of the *Australia-United States Free Trade Agreement 2004* provides that the export of patented drugs can only be permitted for the purposes of gaining marketing approval in another country. Article 17.9.7 (b) provides that a party shall not permit the use of the subject matter of a patent without the authorisation of the right holder except ‘in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency’ subject to some stringent conditions to safeguard the commercial interests of the patent owner. Such measures will circumscribe how the Australian Government could implement an export scheme for pharmaceutical drugs.

In the course of a parliamentary inquiry, Dr Thomas Faunce suggested that the provisions on compulsory licences in Article 17.9.7 of the *Australia-United States Free Trade Agreement 2004* will have a detrimental effect on drug prices. He said:

By effectively restricting the situations in which governments can issue compulsory licenses to particular manufacturers to produce cheap drugs, we are really giving a hostage to fortune in

⁹⁴ The Federal Trade Commission has been critical of the operation of the ‘Hatch-Waxman Act’ in the United States, and has proposed a number of legislative reforms. Federal Trade Commission (2002), *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July, <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>

⁹⁵ Fraser, A. (2004), ‘Fears FTA Will Stop Vital Drugs’, *The Canberra Times*, 30 June, p. 13.

terms of public health. In an era where we are at risk of bioterrorist attack and unusual viral diseases such as SARS, this agreement essentially locks us out of compulsory licenses in all except very restricted circumstances. This restriction is a breach of United States law - which requires any bilateral treaties such as this to respect the capacity of countries to use the flexibility to the full to implement the public health exceptions in the *Doha Declaration*.⁹⁶

The underlying fear is that the conditions contained in the *Australia-United States Free Trade Agreement 2004* are TRIPS-Plus measures, because they go beyond the minimum obligations under the *TRIPS Agreement 1994*.⁹⁷ Thus the bilateral agreement between Australia and the United States serves to undermine the intent of the multilateral negotiations over patent law and access to essential medicines.

In response to this concern, the chief trade negotiator for the Australian Government, Stephen Deady, denied that the conditions in respect of compulsory licences were any more onerous:

My understanding is that this reflects current *TRIPS* commitments of Australia. In any event, just looking at the language makes it very clear that, despite what Dr Faunce has said, there are exceptions in the case of public non-commercial use, legitimate government use, national emergency or other circumstances or circumstances of extreme emergency. There are exceptions that would allow future Australian governments to deal with these sorts of issues in an appropriate way.⁹⁸

He also said that: 'There is nothing in [Article 17.9.7] that affects our existing WTO rights and obligations - these articles reflect the status quo in Australia. We have not taken on additional commitments with the United States as part of the FTA in this area.'⁹⁹

⁹⁶ Faunce, T. (2004), 'Hearing', Senate Select Committee on the Free Trade Agreement Between Australia and the United States of America. 21 June, p.7

⁹⁷ Lawson, C. and C. Pickering (2004), 'TRIPS-Plus' Patent Privileges – An Intellectual Property 'Cargo Cult' in Australia', *Prometheus*, 22 (4), p. 355.

⁹⁸ Deady, S. (2004), 'Hearing', Senate Select Committee on the Free Trade Agreement Between Australia and the United States of America, 21 June, p.18.

⁹⁹ Ibid at 53.

Similarly, Martin Quinn, a public official from the Department of Foreign Affairs and Trade, argued:

Australia can and does provide life-saving pharmaceuticals to developing countries under its aid program. Our capacity to provide assistance is unaffected by the FTA. We are also a strong supporter of the WTO declaration on *TRIPS* in public health. There is nothing in the FTA which affects our ability to implement the declaration on public health under *TRIPS*.¹⁰⁰

However, Quinn did concede that at present the export of patented pharmaceutical drugs to a developing country remains a breach of Australian patent law, without the authorisation of the patent holder: ‘This does not allow manufacture for export on a commercial basis while there is an existing patent in Australia, nor do our current arrangements. In the view of the Department of Foreign Affairs and Trade, the current WTO obligations limit us from doing that.’¹⁰¹

In its final report, the Senate Select Committee was unconvinced by the hollow assurances of the trade negotiators. It expressed reservations about the language used in the *Australia-United States Free Trade Agreement 2004*:

Although there is nothing in the FTA implementation bill that changes the status quo in Australia, the wording in the FTA is significantly different to *TRIPS*. *TRIPS* neither lists nor restricts the circumstances in which compulsory licences can be issued provided that a number of conditions aimed at protecting the patent holder are met. Some of these conditions are waived in ‘national emergencies’, ‘other circumstances of extreme urgency’, ‘public non-commercial use’ or anti-competitive practices. In contrast, the FTA appears to limit compulsory licensing only to cases where it is needed to remedy anti-competitive practices or to public non-commercial use, national emergency or other circumstances of extreme urgency. This is a significant departure from *TRIPS*, and one which the government has not adequately explained.¹⁰²

¹⁰⁰ Quinn, M. (2004), ‘Public Hearing: Intellectual Property, Senate Select Committee on the United States-Australia Free Trade Agreement’, 6 July.

¹⁰¹ Ibid.

¹⁰² Senate Select Committee on the Free Trade Agreement between Australia and the United States of America (2004), *Final Report*. Canberra: Australian Parliament, p. 135.

Despite such misgivings, the Federal Parliament ultimately approved the bilateral free trade agreement between Australia and the United States.

Australian Law Reform Commission

The Australian Law Reform Commission (the Commission) has recently undertaken a wide-ranging inquiry into gene patenting and human health.¹⁰³ As part of its investigation, the Commission considered whether the *Patents Act* 1990 (Cth) should be amended to provide that a compulsory licence may be granted over a patented product or process in circumstances of ‘a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use’. Furthermore it inquired into whether a compulsory licence should be available whether or not the applicant had tried for a reasonable period to obtain a licence from the patent holder.

In its discussion paper, the Commission canvassed some of the circumstances in which a compulsory licence might be sought to gain access to a patented invention. The law reform body noted that there could be the need for the use of compulsory licensing to deal with domestic crises:

In future it is possible that Australia could face a public health crisis or bio-terror attack, requiring a rapid and efficient response... The SARS outbreak showed that developed countries also may be threatened by public health epidemics. The bio-terror attacks using the anthrax organism in the United States could be characterised as a circumstance of extreme emergency.¹⁰⁴

¹⁰³ Australian Law Reform Commission (2003), *Gene Patenting and Human Health: Issues Paper* 27. Sydney: Australian Commonwealth, July, <http://www.austlii.edu.au/au/other/alrc/publications/issues/27/>; Australian Law Reform Commission (2004), *Gene Patenting and Human Health: Discussion Paper 68*. Sydney: Australian Commonwealth, February, <http://www.austlii.edu.au/au/other/alrc/publications/dp/68/>; and Australian Law Reform Commission (2004), *Genes and Ingenuity: Gene Patenting and Human Health. Report 99*. Sydney: Australian Commonwealth, June, <http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>

¹⁰⁴ Australian Law Reform Commission, *Gene Patenting and Human Health: Discussion Paper 68*, 731.

However, the Commission did not fully or properly explore whether a compulsory licence could be invoked to deal with public health issues or national emergencies overseas.

In its inquiry, the Commission received a range of submissions. Several submissions supported extending the compulsory licensing provisions to enable the supply of drugs manufactured under a compulsory licence to countries that lack manufacturing capabilities. The Department of Health from the State Government of Western Australia suggested that the *Patents Act* 1990 (Cth) be amended in accordance with the waiver of negotiation provisions of Article 31 (b) of the *TRIPS Agreement* 1994.¹⁰⁵ The Caroline Chisholm Centre for Health Ethics submitted that WTO Member states ‘should be able to protect and optimise public health and overly burdensome or uncooperative patent holders may be forced to accept a compulsory licence for their invention.’¹⁰⁶ The Centre for Law and Genetics suggested that such reforms would fully reflect the provisions of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001 and would reflect well on Australia’s role as a good international citizen.¹⁰⁷

However, the industry departments of the Federal Government argued that the Crown use provisions would be a more appropriate mechanism for addressing a national emergency or similar circumstances of extreme urgency, or cases of public non-commercial use. The Department of Industry, Tourism and Resources considered that removing the requirement of prior negotiation in these circumstances would be ‘draconian, especially in view of the lack of empirical data to support the existence of a significant problem’.¹⁰⁸ IP Australia noted that that compulsory licences are an exception to the exclusive rights granted to a patent holder, and the circumstances of their use should be limited and carefully considered.¹⁰⁹ It believed that any changes to

¹⁰⁵ Ibid at 730.

¹⁰⁶ Ibid at 730.

¹⁰⁷ Australian Law Reform Commission (2004) *Genes and Ingenuity: Gene Patenting and Human Health. Report 99*, 629.

¹⁰⁸ Ibid.

¹⁰⁹ Ibid.

the provisions need to be balanced against the potential to devalue patent rights, and considered in the light of other provisions already available, especially Crown use. Such resistance reveals a deep hostility towards the use of compulsory licenses in any circumstances. It also shows a valorisation of industry concerns, and a denial of the existence of humanitarian problems, particularly in respect of infectious diseases.

In its final report on *Gene Patenting and Human Health*, the Commission failed to make any recommendations to reform the *Patents Act* 1990 (Cth) to deal with circumstances of national emergency or public health crisis. The Commission observed that the existing Crown use provisions could be invoked:

The ALRC does not consider it necessary to recommend any reforms to the compulsory licensing provisions to address circumstances of emergency, or public non-commercial use of patented inventions. Most submissions did not consider it necessary to make specific provision for the grant of a compulsory licence, without prior negotiation, in these circumstances. In their view, the Crown use provisions are a more appropriate mechanism.¹¹⁰

The Commission noted that ‘several submissions suggested that the existing compulsory licensing provisions should be amended to enable the supply of drugs manufactured under a compulsory licence to countries that lack manufacturing capabilities’.¹¹¹ However, it observed ‘that, although such an amendment may have merit, it falls outside the Inquiry’s Terms of Reference.’¹¹²

The position taken by the Australian Law Reform Commission can be criticised on a number of grounds. First of all, the Commission takes an unnecessarily narrow view of its Terms of Reference. The Attorney-General, Daryl Williams, specifically instructed the Commission to take heed of ‘international practices and developments, including any existing or proposed international obligations’. The *Doha Declaration on the TRIPS Agreement and Public Health* 2001 and the *WTO General Council Decision* 2003 comprise existing international obligations, which have to be acted under on by the Australian Government. Such matters cannot be ignored.

¹¹⁰ Ibid.

¹¹¹ Ibid at 630.

¹¹² Ibid.

Second, the Commission places too much reliance upon the mechanism of Crown use. It ignores an obvious drawback - the Australian Government, and its state counterparts, have never invoked Crown use to address any circumstances of serious emergency. The current provisions provide little guidance as to how Crown use might operate. It is unclear whether such powers would extend to the authorizing of exports of pharmaceutical drugs to other nations.

Third, the Commission fails to fully come to grips with the issues surrounding patent law and access to essential medicines. The cursory treatment of the topic is somewhat disappointing, given the urgency and the gravity of the issues.

CONCLUSION

In the wake of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001 and the *WTO General Council Decision* 2003, there is a need for industrialised nations to implement legislation to enable the export of pharmaceutical drugs to address public health concerns.

I would argue that the *Patents Act* 1990 (Cth) should make provision for the grant of a compulsory licence over a patented invention in circumstances of ‘a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use’. Such a measure is necessary to deal with the possibility of public health epidemics that may take place in Australia – for instance, to deal with a future outbreak of the SARS virus or avian influenza.

The Australian *Patents Act* 1990 (Cth) should also be amended to allow for the export of pharmaceutical drugs to developing countries, as allowed under Paragraph 6 of the *Doha Declaration on Public Health and the TRIPS Agreement* 2001. There is a need for a regime for access to medicines, which overcomes the limitations of existing models, such as the *Jean Chrétien Pledge To Africa Act* 2004 (Can). There should be a flexible mechanism to allow for the export of pharmaceutical drugs in an efficient and timely fashion. There is no need, though, for drugs manufacturers to have a first right of refusal. The definition of pharmaceutical drugs, vaccines and diagnostics should be broad. The definition of a national emergency and public health epidemic should be left to individual nations to determine. Furthermore, the legislation should include WTO members, as well as non-WTO members, such as East Timor.

I would urge the Australian Government to play a leadership role in respect of the international debate in respect of patent law and access to essential medicines. Being a passive bystander in this important policy debate does our international reputation no credit. 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 gesture, unless it establishes an effective domestic mechanism for the export of pharmaceutical drugs. The Federal Government should

lobby for the inclusion of a more effective mechanism than the cumbersome *WTO General Council Decision 2003* in the *TRIPS Agreement 1994*.

I would note that the Australian Government is currently seeking to negotiate a number of bilateral and regional free trade agreements with our trading partners. Such agreements will, of course, feature Intellectual Property Chapters. Already, scholars, such as Dr Charles Lawson, have suggested that the Australian trade negotiators have a ‘cargo-cult’ mentality to bilateral agreements over intellectual property.¹¹³ The Australian Government will gain much credibility and legitimacy in such negotiations, if it can demonstrate a willingness to implement its multilateral obligations under the *TRIPS Agreement 1994*, with respect to access to essential medicines. Otherwise, the Australian Government will be left vulnerable to the accusation that it has little commitment to a development agenda in respect of international intellectual property.

Furthermore, I would argue that the development of a mechanism for the export of patented pharmaceutical drugs would complement Australia’s humanitarian aid policy in respect of combating infectious diseases, particularly in the region of South-East Asia. There is a need for the Australian Federal Government to reform its intellectual property laws in order to deal with public health epidemics, such as HIV/AIDS, malaria, tuberculosis, the SARS virus, and avian influenza. The provision for a mechanism within the *Patents Act 1990* (Cth) to allow for the export of pharmaceutical drugs to tackle such public health epidemics would be a further sign of this serious commitment.

¹¹³ Lawson, C. and C. Pickering (2004), ‘TRIPs-Plus’ Patent Privileges – An Intellectual Property ‘Cargo Cult’ in Australia’, *Prometheus*, 22 (4), p. 355.