A SUBMISSION TO IP AUSTRALIA,
THE PRODUCTIVITY COMMISSION, AND
THE DEPARTMENT OF HEALTH AND AGEING,

INTELLECTUAL PROPERTY AND GLOBAL HEALTH

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BIOGRAPHY

I am an Australian Research Council Future Fellow, working on Intellectual Property and Climate Change. I am an associate professor at the ANU College of Law, and an associate director of the Australian Centre for Intellectual Property in Agriculture (ACIPA). I hold a BA (Hons) and a University Medal in literature, and a LLB (Hons) from the Australian National University. I received a PhD in law from the University of New South Wales for my dissertation on *The Pirate Bazaar: The Social Life of Copyright Law*. I am a member of the ANU Climate Change Institute. I have published widely on copyright law and information technology, patent law and biotechnology, access to medicines, clean technologies, and traditional knowledge. My work is archived at *SSRN Abstracts* and *Bepress Selected Works*.

I am the author of *Digital Copyright and the Consumer Revolution: Hands off my iPod* (Edward Elgar, 2007). With a focus on recent US copyright law, the book charts the consumer rebellion against the *Sonny Bono Copyright Term Extension Act* 1998 (US) and the *Digital Millennium Copyright Act* 1998 (US). I explore the significance of key judicial rulings and consider legal controversies over new technologies, such as the iPod, TiVo, Sony Playstation II, Google Book Search, and peer-to-peer networks. The book also highlights cultural developments, such as the emergence of digital sampling and mash-ups, the construction of the BBC Creative Archive, and the evolution of the Creative Commons. I have also also participated in a number of policy debates over Film Directors' copyright, the *Australia-United States Free Trade Agreement* 2004, the *Copyright Amendment Act* 2006 (Cth), the *Anti-Counterfeiting Trade Agreement* 2010, and the *Trans-Pacific Partnership*.

I am also the author of *Intellectual Property and Biotechnology: Biological Inventions* (Edward Elgar, 2008). This book documents and evaluates the dramatic expansion of intellectual property law to accommodate various forms of biotechnology from micro-organisms, plants, and animals to human genes and stem cells. It makes a unique theoretical contribution to the controversial public debate over the commercialisation of biological inventions. I edited the thematic issue of *Law in Context*, entitled *Patent Law and Biological Inventions* (Federation Press, 2006). I was also a chief investigator in an Australian Research Council Discovery Project, 'Gene Patents In

Australia: Options For Reform' (2003-2005), and an Australian Research Council Linkage Grant, 'The Protection of Botanical Inventions (2003). I am currently a chief investigator in an Australian Research Council Discovery Project, 'Promoting Plant Innovation in Australia' (2009-2011). I have participated in inquiries into plant breeders' rights, gene patents, and access to genetic resources.

I am a co-editor of a collection on access to medicines entitled *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, 2010) with Professor Kim Rubenstein and Professor Thomas Pogge. The work considers the intersection between international law, public law, and intellectual property law, and highlights a number of new policy alternatives – such as medical innovation prizes, the Health Impact Fund, patent pools, open source drug discovery, and the philanthropic work of the (RED) Campaign, the Gates Foundation, and the Clinton Foundation. I am also a co-editor of *Intellectual Property and Emerging Technologies: The New Biology* (Edward Elgar, 2012), with Alison McLennan.

I am the author of a monograph, *Intellectual Property and Climate Change: Inventing Clean Technologies* (Edward Elgar, September 2011). This book charts the patent landscapes and legal conflicts emerging in a range of fields of innovation – including renewable forms of energy, such as solar power, wind power, and geothermal energy; as well as biofuels, green chemistry, green vehicles, energy efficiency, and smart grids. As well as reviewing key international treaties, this book provides a detailed analysis of current trends in patent policy and administration in key nation states, and offers clear recommendations for law reform. It considers such options as technology transfer, compulsory licensing, public sector licensing, and patent pools; and analyses the development of Climate Innovation Centres, the Eco-Patent Commons, and environmental prizes, such as the L-Prize, the H-Prize, and the X-Prizes. I am currently working on a manuscript, looking at green branding, trade mark law, and environmental activism.

I also have a research interest in intellectual property and traditional knowledge. I have written about the misappropriation of Indigenous art, the right of resale, Indigenous performers' rights, authenticity marks, biopiracy, and population genetics.

EXECUTIVE SUMMARY

One of my key research, teaching, and policy interests is intellectual property and public health. In particular, I have co-edited a collection on the topic, and written several pieces on the issue of patent law and access to essential medicines:

Matthew Rimmer, 'Patents for Humanity', (2012) *The World Intellectual Property Organization Journal*, forthcoming.

Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (ed.) *Incentives for Global Public Health: Patent Law and Access to Medicines*. Cambridge: Cambridge University Press, 2010, http://www.cambridge.org/catalogue/catalogue.asp?isbn=9780521116565

Matthew Rimmer, 'The Lazarus Effect: The (RED) Campaign, and Creative Capitalism' in Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (ed.) *Incentives for Global Public Health: Patent Law and Access to Medicines*. Cambridge: Cambridge University Press, 2010, 313-340.

Thomas Pogge, Matthew Rimmer and Kim Rubenstein, 'Access to Essential Medicines: Public Health and International Law', in Thomas Pogge, Matthew Rimmer and Kim Rubenstein (ed.) *Incentives for Global Public Health: Patent Law and Access to Medicines*. Cambridge: Cambridge University Press, 2010, 1-32.

Matthew Rimmer, 'Race Against Time: The Export of Essential Medicines to Rwanda' (2008) 1 (2) *Public Health Ethics* 89-103, http://phe.oxfordjournals.org/cgi/content/abstract/1/2/89, SSRN: http://ssrn.com/abstract=1260188 and BePress Selected Works: http://works.bepress.com/matthew_rimmer/53/

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

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

I have also engaged in policy work in this field:

Matthew Rimmer, 'Implementing the TRIPS Protocol: A Submission to IP Australia', June 2010.

Joint Standing Committee on Treaties, *Protocol Amending the TRIPS Agreement*, Canberra: Australian Parliament, August 2007, http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=jsct/9may2007/report.htm

Matthew Rimmer, 'Submission to the Joint Standing Committee on Treaties on the Protocol Amending the TRIPS Agreement - Consideration of Acceptance by Australia', June 2007, http://www.aph.gov.au/house/committee/jsct/9may2007/subs/sub2.pdf and http://works.bepress.com/matthew_rimmer/58/

Matthew Rimmer, 'Public Hearing on the Protocol Amending the TRIPS Agreement - Consideration of Acceptance by Australia', Joint Standing Committee on Treaties, 22 June 2007, http://www.aph.gov.au/hansard/joint/commttee/J10376.pdf (appearance)

Matthew Rimmer, 'Submission to the Department of Foreign Affairs and Trade on the Protocol Amending the TRIPS Agreement', May 2007

As well as teaching in the area, I have supervised research students in this field:

Hafiz Aziz ur Rehman, *The Pharmacy of the Developing World: India, Patent Law and Access to Essential Medicines*, PhD, 2007-2011. Awarded degree 2012.

Katherine Phillips, 'Converging Crises: Patent Law, Public Health, and Climate Change', Law Honours, First Semester, 2010.

Carla George, 'Treatment Action Campaign: HIV/AIDS and the Right to Health in South Africa', First Semester, 2009.

Cecilia Suatan, 'Novartis v Union of India: Patent Evergreening, the Right to Health, and Implications for Developing Countries', Second Semester 2007.

Shawanah Tasneem, 'The Canadian Solution to Paragraph 6 of the Doha Declaration', Law Honours, 2003-2004.

OUTLINE

It has taken nearly 10 years for the Australian Government to prepare legislation - *IP Laws Amendment Bill* 2012 (Cth) - to implement the *WTO General Council Decision* 2003. It is disappointing that such a narrow and limited approach has been taken to the topic of access to essential medicines – after the long period of time available to prepare a response.

It would be fair to say that, over the course of the last decade, the Australian Government has been unaccountably slow to respond to the urgent and pressing public policy issues in respect of patent law and access to essential medicines. It is hard to fathom the reasons for this procrastination. There has been bipartisan support for both the *Doha Declaration on the TRIPS Agreement and Public Health* 2001, and the *WTO General Council Decision* 2003, during the terms of office of the Howard Government and the Rudd and Gillard Governments. The public health epidemics in relation to HIV/AIDS, tuberculosis, malaria, and tropical diseases have caused great hardship particularly in developed countries and least developed countries. Moreover, there has been a spate of troublesome new infectious diseases, such as the SARS virus, avian influenza, and porcine influenza. Nonetheless, the Australian Government has been, inexplicably, tardy in reforming its patent regime to address the pressing public health concerns associated with access to essential medicines.

Rather than seeking to implement the *WTO General Council Decision* 2003 in a bare bones fashion, the Australian Government should design a regime that has a positive health impact. My argument is that the Australian Government needs to take an integrated approach to access to essential medicines – taking into account intellectual property, trade, public health, and human rights. An effective compulsory licensing regime should be a part of a larger strategy in respect of intellectual property and global health research and development.

This submission is relevant to the current inquiries of IP Australia, the Productivity Commission, and the Department of Health and Ageing.

THE WORLD TRADE ORGANIZATION

The Doha Declaration on the TRIPS Agreement and Public Health 2001

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.[1] 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 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.'

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

[1] WTO Doc WT/MIN (01)/DEC/2 (2001).

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.[2]

The WTO General Council Decision 2003

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.[3] The decision has been known as the *WTO General Council Decision* 2003[4] 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 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.

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

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[2] 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

[3] 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.

[4] 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.

amendment of the *TRIPS Agreement* 1994.[5] In an accompanying statement to the decision, the WTO General Chairman, Pascal Lamy made a number of comments.[6] 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.[7]

There has been an extension for acceptances of this regime as at 2011. At 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.

A small number of developed countries, members of the BASIC group, and regional groups have established domestic regimes to implement the *WTO General Council Decision* 2003. According to the World Trade Organization, here are the countries

- **Norway**: Amendments to Sections 49 and 50 of the Patent Act of 15 December 1967 No.9 and to Patent Regulations of 20 December 1996 No.1162 provide the legal basis to act as an exporting Member — document IP/C/W/427
- **Canada**: Amendments to the Patent Act and Food and Drugs Act, as well as the Use of Patented Products for International Humanitarian Purposes Regulations provide the legal basis to act as an exporting Member — notifications IP/N/1/CAN/P/5, IP/N/1/CAN/P/6 andIP/N/1/CAN/P/7, and document IP/C/W/464
- **India**: Section 92-A of the Patents (Amendment) Act 2005 provides the legal basis to act as an exporting Member — notificationIP/N/1/IND/P/2

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5 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).

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

7 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).

- **European Union/European Communities**: Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems provides the legal basis for EU Member States to grant compulsory licences for export of patented medicines — notificationIP/N/1/EEC/P/5

- **Hong Kong, China**: the Patent (Amendment) Ordinance No.21 of 2007 provides the legal basis to act as an exporting Member, as well as importing Member in situations of extreme urgency — notifications IP/N/1/HKG/P/1/Add.6 and IP/N/1/HKG/17

- **Switzerland**: Articles 40d and 40e of the consolidated version of the Federal Law on Patents for Inventions of 1 July 2008 and the Ordinance on Patents for Invention provide the legal basis to act as an exporting Member. Further terms and conditions are addressed by Article 111 of the Patent Ordinance — notifications IP/N/1/CHE/P/9and IP/N/1/CHE/4

- **Philippines**: Section 93-A of the Republic Act No. 9502 (also known as the "Universally Accessible Cheaper and Quality Medicines Act 2008") and Rule 13 of the Implementing Rules and Regulations of Republic Act No. 9502 provide the legal basis for the grant of a special compulsory licence for the import of patented drugs and medicines, as well as for their manufacture and export — notificationIP/N/1/PHL/I/10

- **Singapore**: Sections 2, 56, 60, 62 and 66 of the Patents Act 2005 Revised Edition provide the legal basis to act as an importing Member in situations of national emergency or other circumstances of extreme urgency — notification IP/N/1/SGP/P/Rev.1

- **Albania**: Article 50 of the Law No.9947 of 7 July 2008 on Industrial Property provides the legal basis to act as an exporting Member — notification IP/N/1/ALB/I/2

- **Croatia**: Articles 69a to 69h of the amended Patent Act of 2009 provide the legal basis to act as an exporting Member — notificationIP/N/1/HRV/P/2

- **China**: Articles 50, 53 and 57 of the amendment to the Patent Law of the People's Republic of China, which was adopted on 27 December 2008 and entered into force on 1 October 2009, provide the legal basis to act as an exporting Member. In addition, Article 49 provides the legal basis to act as an importing Member in situations of national emergency or other circumstances of extreme urgency, or if public interest so requires — notification IP/N/1/CHN/P/2. Further details, such as the definition of a pharmaceutical product, are addressed in chapter V of the Revised Rules for the Implementation of the Patent Law — notification IP/N/1/CHN/P/3.

- **Rep. of Korea**: Article 107 of the Patent Act and Presidential Decree No. 23306 of 26 July 2010 on "Provisions Regarding the Expropriation and Implementation of the Patent Right" provide the legal basis to act as an exporting Member, as well as an importing Member in

> situations of national emergency or other circumstances of extreme urgency — notification IP/N/1/KOR/P/4.

However, a significant number of key developed countries have egregiously not implemented domestic regimes under the *WTO General Council Decision* 2003. Most notably, the United States, and Japan have shown little enthusiasm in establishing regimes to facilitate the export of pharmaceutical drugs to developing countries. The partial, uneven implementation of the *WTO General Council Decision* 2003 by developed countries has raised questions about both its efficacy and its legitimacy.

Export of Pharmaceutical Drugs

In July 2007, Rwanda became the first country to notify the World Trade Organization of its intention to import essential medicines under the *WTO General Council Decision* 2003. The Delegation of Rwanda informed the TRIPS Council thus:

> Based on Rwanda's present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine (hereinafter referred to as the 'Product') manufactured in Canada by Apotex, Inc. However, because it is not possible to predict with certainty the extent of the country's public health needs, we reserve the right to modify the foregoing estimate as necessary or appropriate. Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of 27 June 2002), we have decided that we will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within Rwanda's territory with respect to the Product.

There have been no other successful instances of imports of essential medicines under the *WTO General Council Decision* 2003. It is problematic in terms of health impact that the compulsory licensing export regime has been so little used – especially given the serious public health issues, particularly in relation to infectious diseases.

There has been some discussion about this issue. The World Trade Organization reported upon the diplomatic views of Pascal Lamy on the matter:

> The "Paragraph 6" debate. He noted the current debate about whether the system is working. One side argues that it is working, because it has been used once (for generics exported from Canada to Rwanda) and that the existence of the system helps countries bargain more effectively to lower medicines' prices. The other side argues that the fact it has only been used once shows it is too complicated, and that prices are lower for other reasons such as the increased scale of purchases. "It's not for me to take sides," Mr Lamy said. "We can only hope that we can have, as much as possible, an informed debate."[8]

The failure of the export regimes has led to much discussion as to whether the international framework should be modernised and revised.

Joint Standing Committee on Treaties

In 2007, the Joint Standing Committee on Treaties in the Australian Parliament recognised: 'Providing better access to medicines to the world's poorest people is a worthy subject for an international treaty'.[9] The Committee agreed 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.' The Committee observed:

> 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.

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[8] World Trade Organization, '10-year-old WTO declaration has reinforced health policy choices, Lamy tells symposium', 23 November 2011, http://www.wto.org/english/news_e/news11_e/trip_23nov11_e.htm

[9] Joint Standing Committee on Treaties. *Protocol Amending the TRIPS Agreement*, Canberra: Australian Parliament August 2007, http://www.aph.gov.au/house/committee/jsct/9may2007/report/chapter9.pdf

However, the Committee also noted that it shared my concerns 'that the TRIPS Protocol requires intricate, time-consuming and burdensome procedures for the exportation of medicine, when what is needed is a simple, fast and automatic mechanism'.

Nearly three years after the Joint Standing Committee on Treaties report, in April 2010, IP Australia released its consultation paper, *Implementing the TRIPS Protocol*. In 2011, the Minister for Innovation, Senator Kim Carr, and the Minister for Trade, Dr Craig Emerson, put out a press release, observing 'the Government would introduce legislation to allow Australian courts to grant compulsory licences to manufacture and export patented pharmaceuticals to countries trying to deal with epidemics and other types of health crises.'[10] The press release noted:

> The United Nations estimates that nearly two billion people do not have access to essential medicines. In 2008, an estimated 285 million people were infected with malaria, HIV/AIDS or tuberculosis, causing 4.2 million deaths. Many of the countries that are suffering such epidemics are developing or least-developed countries with limited resources and manufacturing capabilities.

Senator Kim Carr observed: "The new system will enable a country that is experiencing a serious epidemic to ensure that its own population is supplied with vital treatments," He added: 'The Government continues to support and encourage innovation, investment and international competitiveness by ensuring that patent owners will receive adequate compensation for any licences issued.' Carr noted: 'Measures will also be taken to help ensure that pharmaceuticals exported under the system reach the people that need them and are not diverted to other markets.' Dr Emerson added: "Pandemics and other serious health issues remain a terrible problem in many of the world's poorest countries.' He commented: 'Anything Australia reasonably can do to alleviate the suffering in these countries should be done and we

[10] Department of Innovation, Industry, Science and Research, 'Better Access to Medicines For Countries in Need', Press Release, 22 March 2011, http://archive.innovation.gov.au/ministersarchive2011/carr/MediaReleases/Pages/BETTERACCESSTOMEDICINESFORCOUNTRIESINNEED.html

are delighted to be able to help through this initiative.' In 2012, IP Australia published a draft version of the bill.

THE WORLD INTELLECTUAL PROPERTY ORGANIZATION

In October 2007, the WIPO General Assembly adopted a series of 45 recommendations to enhance the organisation's development activities.[11] The recommendations are organised into six clusters. The first cluster relates to technical assistance and capacity building. The second cluster looks at norm-setting, flexibilities, public policy and public domain. The third cluster concerns technology transfer, information and communication technologies (ICT) and access to knowledge. The fourth cluster concerns assessment, evaluation and impact studies. The fifth cluster concerns institutional matters including mandate and governance. The final cluster focuses upon enforcement, emphasizing the need 'to approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns… in accordance with Article 7 of the *TRIPS Agreement*'.[12]

As part of its Global Issues programme of activities, the World Intellectual Property Organization is considering the matter of intellectual property and public health.

THE WORLD HEALTH ORGANIZATION

The World Health Organization (WHO) aspires to realise 'the attainment by all peoples of the highest possible level of health'.[13] The organisation has a mandate 'to stimulate and advance work to eradicate epidemic, endemic and other diseases', and

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[11] World Intellectual Property Organization Development Agenda, <http://www.wipo.int/ip-development/en/agenda/>.

[12] Ibid.

[13] The World Health Organization, http://www.who.int/en/; and Article 1 of the *World Health Organization Constitution* 1946.

to 'furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of Governments'.[14]

Responding to concerns of the World Health Assembly in 2003,[15] the Director-General of the WHO established the Commission on Intellectual Property Rights, Innovation, and Public Health in 2004.

After a number of meetings, workshops, and classifications, the Commission released its report on *Public Health, Innovation, and Intellectual Property Rights* in 2006.[16] The report sought to classify infectious diseases into three distinct categories. Type I diseases are 'incident in both rich and poor countries, with large numbers of vulnerable populations in each'.[17] Examples of Type I diseases are measles, hepatitis B, diabetes, cardiovascular diseases, and tobacco-related illnesses.[18] Type II diseases — sometimes called 'neglected diseases' — are 'incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries'.[19] The report noted: 'HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 percent of cases are in the poor countries'.[20] Type III diseases — often described as 'very neglected diseases' are those that are 'overwhelmingly or exclusively incident in developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis)'.[21] The Commission offered a number of recommendations to improve access to essential medicines (particularly focusing upon Type II and Type III diseases).

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14 Article 2 of the *World Health Organization Constitution* 1946.

15 The World Health Organization, <http://www.who.int/intellectualproperty/en/>.

16 The Commission on Intellectual Property Rights, Innovation, and Public Health. *Public Health, Innovation, and Intellectual Property Rights* (2006). For further analysis, see Kevin Outterson, 'Should Access to Medicines and TRIPS Flexibilities Be Limited To Particular Diseases?', (2008) 34 *American Journal of Law and Medicine* 279.

17 The Commission on Intellectual Property Rights, Innovation, and Public Health. *Public Health, Innovation, and Intellectual Property Rights* (2006), 13.

18 Ibid.

19 Ibid.

20 Ibid.

21 Ibid.

In May 2008 the WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) agreed upon a global strategy and plan of action to promote incentives for the promotion of research and development of neglected diseases.[22] Director-General of the WHO, Dr Margaret Chan, observed of the initiative:

> I am fully committed to this process and have noted your desire to move forward faster. We must make a tremendous effort. We know our incentive: the prevention of large numbers of needless deaths and suffering.[23]

The resolution summarizes the aims of the strategy thus: 'The global strategy on public health, innovation and intellectual property aims to promote new thinking on innovation and access to medicines, as well as, based on the recommendations of the CIPIH report, provide a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area'.[24]

The *WHO Global Strategy* is animated by a number of guiding principles. First, the 'WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandates (including those contained in relevant WHA resolutions), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations'.[25] Second, the *WHO Global Strategy* noted the importance of human rights: 'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social

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22 *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, World Health Assembly 61st mtg, Res WHA61.21 (2008) ('*WHO Global Strategy*').

23 World Health Organization, 'World Health Assembly Closes: Agreement reached on influenza virus sharing, intellectual property', Geneva: World Health Organization, 23 May 2007.

24 Article 13 of the *WHO Global Strategy*.

25 Article 15 of the *WHO Global Strategy*.

condition.'[26] Third, 'The promotion of technological innovation and the transfer of technology should be pursued by all states and supported by intellectual property rights.'[27] Fourth, 'Intellectual property rights do not and should not prevent Member States from taking measures to protect public health'.[28] Fifth, 'International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health'.[29] Sixth, 'The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health'.[30] Seventh, 'Research and development of developed countries should better reflect the health needs of developing countries'.[31] Eighth, 'Intellectual property rights are an important incentive in the development of new health care products'.[32] However, it was recognised that 'this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain'.[33] Ninth, 'Countries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices'.[34]

The *WHO Global Strategy* has eight key elements. First, WHO seeks to 'provide an assessment of the public health needs of developing countries with respect to diseases that disproportionately affect developing countries and identify their R&D priorities at the national, regional and international levels'.[35] Second, WHO aims to 'promote R&D focusing on Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases.'[36] Third, WHO seeks to 'build and

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26 Article 16 of the *WHO Global Strategy*.

27 Article 19 of the *WHO Global Strategy*.

28 Article 20 of the *WHO Global Strategy*.

29 Article 21 of the *WHO Global Strategy*.

30 Article 22 of the *WHO Global Strategy*.

31 Article 23 of the *WHO Global Strategy*.

32 Article 25 of the *WHO Global Strategy*.

33 Article 25 of the *WHO Global Strategy*.

34 Article 26 of the *WHO Global Strategy*.

35 Articles 27-28 of the *WHO Global Strategy*.

36 Articles 29-30 of the *WHO Global Strategy*.

improve innovative capacity for research and development, particularly in developing countries'.[37] Fourth, WHO will strive to 'improve, promote and accelerate transfer of technology between developed and developing countries as well as among developing countries'.[38] Fifth, WHO will 'encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, possible incentive schemes for R&D'.[39] Sixth, WHO will seek to 'improve delivery of and access to all health products and medical devices by effectively overcoming barriers to access'.[40] Seventh, WHO will aim to 'secure and enhance sustainable financing mechanisms for R&D and to develop and deliver health products and medical devices to address the health needs of developing countries.'[41] Finally, WHO will strive to 'develop mechanisms to monitor and evaluate the implementation of the strategy and plan of action, including reporting systems.'[42]

The *WHO Global Strategy* recognises that 'the price of medicines is one of the factors that can impede access to treatment'.[43] This suggests that the aim of reducing the price of pharmaceutical drugs should be included in the global strategy. But the United States Government expressed reservations on this point.[44] The question of differential

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37 Articles 31-32 of the *WHO Global Strategy*.

38 Articles 33-34 of the *WHO Global Strategy*.

39 Articles 35-36 of the *WHO Global Strategy*.

40 Articles 37-39 of the *WHO Global Strategy*.

41 Articles 40-42 of the *WHO Global Strategy*.

42 Articles 43-44 of the *WHO Global Strategy*.

43 Article 11 of the *WHO Global Strategy*.

44 The World Health Organization, *Draft Global Strategy and Plan Of Action on Public Health, Innovation and Intellectual Property*, Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property, 3 May 2008, <http://www.who.int/phi/documents/IGWG_Outcome_document03Maypm.pdf>.

pricing for pharmaceutical drugs remains a sensitive and fraught subject for commercial companies.[45]

The *WHO Global Strategy* encouraged all parties to 'explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries'.[46] As part of the process of developing a global strategy, the WHO held public hearings and consultations 'to contribute to developing a solution to a major public health challenge — how to enhance innovation, research and development to address diseases predominantly affecting poor populations.'[47] There was extensive discussion about such possibilities as medical innovation prizes, a Health Impact Fund, patent pools, open source drug discovery, and priority review mechanisms.[48] Some have explored the option of university licensing and technology transfer.[49] There have also been an array of comments and submissions from member states, including Bolivia, Brazil, Chile, Columbia, Costa Rica, Nicaragua, Paraguay

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45 Patricia Danzon and Adrian Towse, 'Theory and Implementation of Differential Pricing for Pharmaceuticals' in Keith Maskus and Jerome Reichman (ed). *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime*. (2005), 425-456.

46 Article 36 (5.3) of the *WHO Global Strategy*.

47 World Health Organization, 'Report on developments since the first session of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property', Summary of the Second Hearing, A/PHI/IGWG/2/INF.DOC./4, (Geneva: World Health Organization, 2 November 2007), <http://www.who.int/gb/phi/pdf/igwg2/PHI_IGWG2_ID4-en.pdf>.

48 David Ridley, Henry Gabowski and Jeffrey Moe, 'Developing Drugs for Developing Countries' (2006) 25 (2) *Health Affairs* 313-324; Duke University, 'Duke Faculty Propose Incentives For Developing Drugs For Neglected Diseases', Duke University, 7 March 2006; and Elimination of Neglected Diseases Amendment to the *Food and Drug Administration Revitalization Act* 2007 (US).

49 Gail Evans, 'Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries' (2008) 34 (2-3) *American Journal of Law and Medicine*175-223.

and Cuba; as well as China, India, Malaysia, the Philippines, Uzbekistan, and Japan; Morocco, and Qatar; the United States and Canada.[50]

In 2012, in response to the World Health Assembly's Resolution, the Australian Department of Health and Ageing has called for written submissions on the CEWG Final Report. Submissions should address the following questions:

> 1. Which options in the CEWG Final Report have the most merit and provide practical, implementable ways forward to better support health R&D addressing the needs of developing countries?
>
> 2. Are there any other options that are not supported in the CEWG Final Report that should be considered?
>
> 3. What are the opportunities and risks for Australia, its national interests and global public health in responding to the CEWG Final Report recommendations?

The process is intended to implement the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, and *WHO Strategy on Research for Health*.

[50] World Health Organization, 'Member States' Comments and inputs to the IGWG 2 Conference Paper' (A/PHI/IGWG/2/Conf.Paper1/Rev.1) (Geneva, World Health Organization, January 2008), <http://www.who.int/phi/submissions/submissions_confpaper/en/index.html>.

Recommendations

1. International Law

Recommendation 1.1

The Australian Government should seek to implement the *Doha Declaration on Public Health and the TRIPS Agreement* 2001.

Recommendation 1.2

The legislative model proposed by the Australian Government fails to acknowledge the frailties of the *WTO General Council Decision* 2003.

Quite clearly, the *WTO General Council Decision* 2003 has been a failure because it has only resulted in one shipment of pharmaceutical drugs from Canada to Rwanda in the last decade. This is clearly unsatisfactory, and raises questions about whether the *WTO General Council Decision* 2003 should be codified in the *TRIPS Agreement* 1994.

The reasons for the failure of the *WTO General Council Decision* 2003 are multidimensional. First, the international regime has proved to be cumbersome and unwieldy. Second, many governments, including the United States and Japan, have failed to honour their obligations to implement effective export regimes. Third, the export regimes implemented thus far by countries, such as Canada and India, have proven to be ineffective and flawed. 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). Fourth, brand name pharmaceutical companies have frustrated the use of compulsory licensing mechanisms through relying upon procedural complaints. Fifth, the export schemes have not provided sufficient incentives to encourage the participation of generic manufacturers or non-government organizations.

In light of the failure of the *WTO General Council Decision* 2003 to achieve its set aims, the Australian Government should establish an export domestic scheme, which facilitates the efficient and timely export of

patented inventions to address public health concerns. Rather than blindly following the flawed *WTO General Council Decision* 2003, the Australian Government should also rely upon the flexibilities in Articles 7, 8, 30 and 31 of the TRIPS Agreement and the *Doha Declaration on the TRIPS Agreement and Public Health* 2001 to construct an internationally best-practice, effective export regime.

Recommendation 1.3

The Australian Government should seek to implement the *World Health Organization Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*.

Recommendation 1.4

The Australian Government should support the development of a *World Health Organization Framework Convention on Research and Development*.

Recommendation 1.5

The Australian Government has provided certain financial support to the World Intellectual Property Organization in 2012. This funding was designed to: 'Promote the development of IP systems in the Asia Pacific region as well as LDCs more broadly'; Contribute to Australia's obligations for technical assistance and technology transfer under Articles 66.2 and 67 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)'; 'assist WIPO and Australia to respond to country driven demands for technical assistance in the region in an expeditious manner'; and 'Support implementation of the WIPO Development Agenda as well as initiatives addressing specific global IP challenges such as neglected tropical diseases.' Arguably, the Australian Government could play a much more active role in supporting and promoting the Development Agenda – particularly in respect of access to essential medicines.

Recommendation 1.6

The World Intellectual Property Organization has established a special section on intellectual property and global challenges to address cross-cutting, horizontal issues – such as climate change, food security, public health and technology transfer. The European Patent Office has also re-organised itself to better deal with such global challenges. It is recommended that IP Australia establish a dedicated policy unit, so that it can address intellectual property and global challenges in a timely and effective fashion.

Recommendation 1.7

The Joint Standing Committee on Treaties has recommended that Australia defer the adoption of the *Anti-Counterfeiting Trade Agreement* 2011. There has been concern both locally and internationally that the agreement will have an adverse impact upon development, public health, access to essential medicines, and the generic pharmaceutical industry.

The *Anti-Counterfeiting Trade Agreement* 2011 should not be adopted in Australia given its limitations.

Recommendation 1.8

There has been widespread concern that the *Trans-Pacific Partnership* will have an adverse impact upon access to essential medicines.

The Australian Government has provided this response on this issue:

We are not able to comment on other countries' positions but, from Australia's perspective, the Government has made abundantly clear that Australia will not support provisions in trade agreements that constrain our ability to regulate legitimately on social, environmental or other important public policy matters, including healthcare. Retaining the ability to ensure access to quality, affordable medicines for Australian consumers is a priority, and the Government would not accept an outcome in the TPP that would negatively impact upon the integrity of Australia's public health system.

There is a need for the full and frank disclosure of the full negotiating texts of this agreement to parliament, civil society, and the wider public.

It is critical that the plurilateral free trade agreement does not directly or indirectly undermine the *Doha Declaration* 2001, the *WTO General Council Decision* 2003, or other measures designed to promote public health and access to essential medicines.

2. *IP Laws Amendment Bill* 2012 (Cth) and the Productivity Commission Inquiry into Compulsory Licensing

Recommendation 2.1

The legislation and the explanatory memorandum should be revised to properly explain the intended purposes of the new regime, and relevant international law. The current outline in the explanatory memorandum is inadequate:

'The objective of the intellectual property (IP) rights system is to support innovation by encouraging investment in research and technology in Australia and by helping Australian businesses benefit from their good ideas [*sic*]. The public benefits through having access to the latest technology, products and services. However, many least- developed and developing countries have difficulty manufacturing or accessing patented pharmaceuticals, and so are unable to respond effectively to public health problems. The first purpose of this Bill is to amend the patents legislation to allow Australian pharmaceutical manufacturers to supply these countries with the patented medicines they need.'

This overview just gives a misleading impression that the purpose of this particular regime is to assist Australian pharmaceutical manufacturers and businesses. Intellectual property law does not protect 'ideas' – be they 'good ideas' or not. 'Abstract ideas' remain in the public domain under patent law; 'ideas' are not protected under copyright law; distinctive signs are protected under trade mark law, not merely ideas.

The legislation and the explanatory memorandum should instead refer to articles 7 and 8 of the *TRIPS Agreement* 1994. Article 8 (1) is particularly pertinent – 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such

measures are consistent with the provisions of this Agreement'. The legislation and the explanatory memorandum should refer to the *Doha Declaration on the TRIPS Agreement and Public Health* 2001. The legislation and the explanatory memorandum should also refer to the right to health, as recognised under article 12 (1) of the *International Covenant on Economic Social and Cultural Rights* 1976. The legislation and the explanatory memorandum should refer to the World Intellectual Property Organization *Development Agenda*. The legislation and the explanatory memorandum should also refer to the *World Health Organization Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* 2011.

Recommendation 2.2

The legislative regime appears to be limited to patented pharmaceutical inventions

The legislation defines the products covered by the system as being limited to 'any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems afflicting many developing and least-developed countries'. This includes 'active ingredients necessary for its manufacture and diagnostic kits needed for its use. This is far too narrow and limited.

My concern would be that tying the definition to the pharmaceutical sector is too limited – especially in light of the significant research and development in the fields of biotechnology, medicine, environmental bioprospecting, biosecurity, nanotechnology, and synthetic biology on public health issues. This would certainly be the case in respect of the race to patent the genetic sequences associated with the SARS virus. Accordingly, it is recommended that the specific reference to 'the pharmaceutical sector' be deleted.

Moreover, I am conscious of the intersection between development issues such as public health, food security and nutrition, and environmental protection and climate change. My preference would be

that the legislation should instead focus upon inventions with humanitarian applications or humanitarian research.

Recommendation 2.3.

The legislation raises the question of who should be eligible to import patented inventions under the export mechanism.

All governments – whether members of the WTO or not – should be eligible to use the Australian scheme. Moreover, additional obligations should not be placed on non-WTO members, such as East Timor, through the terms of the compulsory licence in terms of anti-diversionary measures – which would be discriminatory and unfair, particularly in light of the capacities of least developed countries.

It is essential that non-governmental entities and civil society groups – such as MSF, the Treatment Action Campaign, the Medicines Patent Pool, and the Gates Foundation - be able to procure patented inventions under the regime. A major problem with existing export regimes is that they have been dependent upon governments seeking permission for compulsory licensing. Many developed nations and least developed countries have been reluctant to do so, under pressure from other countries, such as the United States and the European Union, and brand name pharmaceutical companies.

It is also advisable that there is flexibility for other parties to be parties to proceedings on an application – particularly representatives of public health groups, and civil society organisations.

Recommendation 2.4

The legislation deals with questions of negotiation and notification in the compulsory licensing process. The experience of the Canadian access to medicines regime has been sobering in that patent owners have exploited procedural requirements to frustrate and delay the issuance of compulsory licensing. The Australian regime needs to carefully define and limit any period of negotiation. There is also a need not to impose onerous

notification requirements, which could frustrate and delay the delivery of essential medicines, especially when dealing with public health epidemics.

Recommendation 2.5

The legislative proposal on licensing is still very much focused on the export of a single order of pharmaceutical drugs to a single country. Such an approach has been unworkable and unviable in Canada. There needs to be scope for multiple orders of patented inventions for regions.

IP Australia's proposal on licensing needs to be much more specific about the nature of adequate remuneration paid to the patent owner. The Canadian regime provided quite specific information on royalty rates. It is essential that the Australian regime provide a sufficient incentive for generic manufacturers to participate in the scheme.

Recommendation 2.6

Section 136D (c) of the proposed legislation provides that compulsory licensing for the purposes of export should be limited to only cases of public non-commercial use, national emergency, or circumstances of extreme urgency. As was pointed out in consultations, this position is not required by the *TRIPS Agreement* 1994 or the *Doha Declaration* 2001 or *WTO General Council Decision* 2003.

During the debate over the *Australia-United States Free Trade Agreement* 2004, the chief negotiator, Stephen Deady, and the Australian Government unequivocally emphasized in the Australian Parliament that the treaty did not limit the grounds for compulsory licensing.

Furthermore, United States Trade Representatives and the United States Congress have stressed that United States bilateral agreements should not detract from, or limit the operation of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001 or the *WTO General Council Decision* 2003.

Consequently, the limitation proposed by IP Australia is unnecessary, and, indeed, contradictory to the stances of both the Australian and the United States Governments.

It is disturbing that the legislative drafters have misread the *Australia-United States Free Trade Agreement* 2004 for the ends of limiting the operation of compulsory licensing in this context, and more generally.

Recommendation 2.7

Section 133 (2)(b) provides that compulsory licensing can be deployed to deal with breaches of Part IV of the *Competition and Consumer Act* 2010.

Internationally, there have been a number of instances of anti-competitive conduct in respect of the supply of essential medicines – particularly in respect of unilateral refusals to licence, and pricing problems.

The Australian Competition and Consumer Commission needs to play a great role in respect of monitoring and responding to anti-competitive conduct by patent owners in the health sector.

Recommendation 2.8

The current provisions in sections 133 to 136 dealing with compulsory licensing of patents for domestic purposes are defective. There is a need to add new ground for compulsory licensing of patents for domestic purposes – namely, addressing public health concerns, including concerns about infectious diseases, such as HIV/AIDS, tuberculosis, malaria, tropical diseases, the SARS virus, and influenza; and non-communicable diseases, such as cardiovascular diseases, diabetes, cancers and chronic respiratory diseases. The Productivity Commission should also look at this issue.

Recommendation 2.9

As commentators such as Frederick Abbott have observed, there are many commonalities and resonances between the debate over intellectual property and access to medicines, and the discussion over intellectual property and climate change. Indeed, there is a convergence between the two global issues to the extent that climate change has a range of significant health-related impacts.

Similar access mechanisms have been mooted in respect of intellectual property and climate change – including the options of technology transfer, compulsory licensing, patent pools, public sector licensing, and co-operative management of intellectual property.

Ideally, the Australian Government needs to recalibrate its access mechanisms in respect of the *Patents Act* 1990 (Cth), so that they can be flexibly deployed to deal with a wide range of global challenges – not only recognising situations of public health, but also matters such as environmental protection, biodiversity, and climate change; food security and nutrition; and access to knowledge and education.

Recommendation 2.10

The Crown use and Crown acquisition provisions in Chapter 17 of the Patents Act 1990 (Cth) need to be amended to make it clear that the Government can use and acquire patented inventions to address public health concerns, including concerns about infectious diseases, such as HIV/AIDS, tuberculosis, malaria, tropical diseases, the SARS virus, and influenza; and non-communicable diseases, such as cardiovascular diseases, diabetes, cancers and chronic respiratory diseases.

Recommendation 2.11

The Australian Government is to be congratulated on its introduction of a general defence of experimental use under s119C of the *Patents Act* 1990 (Cth).

The Australian Government should reform s 119A of the *Patents Act* 1990 (Cth), so that it provides a broad safe harbour for research in respect of pharmaceutical drugs, in line with the Supreme Court of the United States decision in *Merck KGAA* v. *Integra Lifesciences I, Inc.,* 545 US 193 (2005) .

Recommendation 2.12

The Australian Government should reform the remedies sections of the *Patents Act* 1990 (Cth), so that courts have to closely consider the wider public interest, before granting injunctions. The Supreme Court of the United States decision in *eBay* v. *MercExchange* 126 S.Ct. 1837 (2006) should be codified in the *Patents Act* 1990 (Cth).

Recommendation 2.13

'Evergreening' is a particularly egregious, multi-dimensional problem in the context of access to essential medicines. As Graham Dutfield has observed: ''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.'

As Kirby J has observed, patent law 'should avoid creating fail-safe opportunities for unwarranted extensions of monopoly protection that are not clearly sustained by law.' Accordingly, there is a need to apply the patent standards of novelty, inventive step, and utility carefully in respect of essential medicines. Patent term extensions need to be closely monitored and evaluated. There should be greater penalties under the *Patents Act* 1990 (Cth) for unjustified threats of infringement proceedings, and false patent marking.

Moreover, there is need to ensure that related regimes – such as drug marketing laws, test data protection, and trade marks – are not abused for the purposes of 'evergreening'.

Recommendation 2.14

There is also a need for stronger penalties in respect of health care fraud. Professor Kevin Outterson has written about brand-name pharmaceutical companies such as GlaxoSmithKline (GSK) engaging in illegal conduct:

On July 2, 2012, the Department of Justice announced the largest settlement ever in a case of health care fraud in the United States. GlaxoSmithKline (GSK) agreed to plead guilty to three criminal counts and settle civil charges brought under various federal statutes; the company will pay a total of $3 billion to the federal government and participating states. Since 2009, the federal government has collected more than $11 billion in such settlements under the False Claims Act.

In the Federal District Court in Boston a few days later, GSK pleaded guilty to two criminal counts for sales of misbranded Paxil (paroxetine) and Wellbutrin (bupropion). These drugs are considered misbranded when they are promoted for indications for which they have not been approved by the Food and Drug Administration — the practice commonly known as off-label promotion. Providers cannot be reimbursed for misbranded drugs under federal and state rules. GSK also pleaded guilty to a third crime, failing to report safety data related to

Avandia (rosiglitazone). Failing to report safety data violates the Food, Drug, and Cosmetic Act and leads to serious questions about whether clinicians are basing their decisions on the best evidence. GSK also settled related civil liabilities for these and other drugs.

Despite the size of the fine and civil settlements, it would be a mistake to assume that GSK was an outlier in the global pharmaceutical and medical-device industries. Indeed, many of the major companies have settled with the Department of Justice in recent years. When the GSK settlement was announced, 25 major companies and 8 of the top 10 global pharmaceutical companies were under "corporate integrity agreements".

Kevin Outterson's paper - 'Punishing Health Care Fraud: Is the GSK Settlement Sufficient?' (2012) 367 *New England Journal of Medicine* 1082-5 – recommends a number of legislative and regulatory measures to address such illegal conduct by pharmaceutical drug companies.

3. Research and Development

Recommendation 3.1

The Australian Government should support the development of a *World Health Organization Framework Convention on Research and Development.* Such a convention could support:

- **Implementing states' obligations and commitments arising under applicable international human rights instruments with provisions relevant to health.**
- **Promoting R&D for developing new health technologies addressing the global challenges constituted by the health needs of developing countries by means which secure access and affordability through delinking R&D costs and the prices of the products Securing sustainable funding to address identified R&D priorities in developing countries. Improving the coordination of public and private R&D.**
- **Enhancing the innovative capacity in developing countries and technology transfer to these countries.**
- **Generating R&D outcomes as public goods, freely available for further research and production.**
- **Improving priority-setting based on the public health needs of developing countries, and decision-making relying on governance structures which are transparent and giving developing countries a strong voice.**
- **Addressing intellectual property rights barriers to access to essential medicines; and**
- **Promoting countries taking flexible measures under international treaties to address public health concerns.**

Recommendation 3.2

Under a *World Health Organization Framework Convention on Research and Development*, the World Health Organization would exercise a co-ordination function in relation to research and development. This would include:

(1) A global health R&D observatory.

(2) A network of research institutions and funders; and

(3) an advisory committee

Recommendation 3.3

The *World Health Organization Framework Convention on Research and Development* should also establish a funding mechanism for research and development. The Australian Government should support a Tobacco Solidarity Contribution – a Tobacco Tax – and a Financial Transactions Tax as part of an international commitment to finance global public goods, including for health and health R & D relevant to developing countries. A Tobacco Tax would be particularly appropriate – given Australia's leadership in respect of plain packaging of tobacco products, and tobacco control, both domestically and internationally.

The World Health Organization has elaborated upon its proposal in respect of tobacco taxation thus:

A solidarity tobacco contribution (STC) for international health: A global initiative

An additional small amount levied as part of the regular tobacco excise on each pack of cigarettes consumed could generate substantial revenues and increase the effective total tax rate on cigarettes towards the WHO recommended level of 70% of the retail price. Given the low price elasticity of demand for cigarettes, higher excise taxes will generate sustainable revenues for governments worldwide for at least the short- to mid-term and ensure sustainable revenue stream for financing international health. WHO estimated that by introducing USD0.05/0.03$/0.01$ per pack of cigarette sold in 43 selected high-/middle-/low-income countries, respectively, a solidarity tobacco contribution (STC) would generate an additional $US 5.46 billion. This is a substantial amount providing much-needed funds for global health.

Recommendation 3.4

The *World Health Organization Framework Convention on Research and Development* should define which research entities in the public and private sectors, in public-private partnerships are eligible for funding.

Recommendation 3.5

The *World Health Organization Framework Convention on Research and Development* should also address matters about intellectual property and access to medicines. As Dr Margaret Chan has observed:

Public health needs innovation, and it needs access to good quality medical products. These are long-standing needs. But recent trends have forced governments everywhere to look at the efficiency and fairness of their health services. This includes a close look at pharmaceutical expenditures, and this close look inevitably turns to questions of affordability, including access to generic medical products.

The Convention should seek to implement the *World Health Organization Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*.

Recommendation 3.6

The Australian Government should collaborate with the Medicines Patent Pool in relation to essential medicines. However, the GSK Patent Pool for Neglected Diseases is too limited in its scope, and range.

Recommendation 3.7

The mechanism of Public-Private Partnerships has become a popular tool in respect of dealing with global development issues – such as public health. A good example would be the GAVI Alliance – which is a partnership focused upon vaccination between the governments, the private sector, not-for-profit entities, and philanthropists. Professor Margaret Chon from Seattle University has provided a useful framework to analyse the strengths and limitations of Public-Private Partnerships in a talk in September 2012 at the Australian National University.

Recommendation 3.8

There has been much discussion about the development of Technology Mechanisms of late – with a Technology Hub and a network of Technology Centres. For instance, the recent climate talks have established the UNFCCC Climate Technology Centre – a hub and a network of clean technology centres – to facilitate research, development, and deployment of clean technologies. A similar model of a Technology Mechanism could be developed under the *World Health Organization Framework Convention on Research and Development* to address research, development, and deployment of humanitarian inventions in the health sector.

Recommendation 3.9

The Australian Government should promote humanitarian licensing of publicly-funded research on essential medicines, in line with the best practice standards developed by the Universities Allied for Essential Medicines and the University of California.

Recommendation 3.10

The Australian Government should promote open innovation in respect of medical research and development.

Recommendation 3.11

The Australian Government should experiment with complementary means of encouraging research and development in respect of essential medicines – through the creation of medical prizes.

Recommendation 3.12

The Australian Government should establish a pilot scheme in relation to a Health Impact Fund – focusing upon neglected diseases.

Recommendation 3.13

The Australian Government should not adopt the use of Priority Review Vouchers. Such a mechanism has not proven to be an effective mechanism for encouraging research, development and deployment of medicines and health products in the United States. Indeed, there has been concern about brand-name pharmaceutical companies abusing the regime for Priority Review Vouchers in the United States.

Recommendation 3.14

The Patents for Humanity fast-track patent mechanism in the United States Patent and Trademark Office should be reviewed. At present, though, it seems to be a minor incentive in respect of humanitarian research and inventions with humanitarian applications. It is no substitute for substantive reform in respect of patent law and global health.

Recommendation 3.15

There has been much enthusiasm for forms of 'creative capitalism' – such as those promoted by the (RED) Campaign, the Gates Foundation, and the Clinton Foundation. While recognising the significant role that such organisations play, 'creative capitalism' is not an alternative or a substitute for a *World Health Organization Framework Convention on Research and Development*.

Recommendation 3.16

Caution also needs to be shown in respect of corporate social responsibility initiatives. Such measures are neither an alternative or a

substitute for a *World Health Organization Framework Convention on Research and Development*.