

AUSTRALIA'S POSITION ON MEDICINES POLICY IN INTERNATIONAL FORUMS: INTELLECTUAL PROPERTY PROTECTION AND PUBLIC HEALTH

**David G Legge, Deborah H Gleeson, Hans
Löfgren¹ and Belinda Townsend**

Universal access to affordable medicines, which are safe, efficacious and of high quality, and which are appropriately used, depends on national legislation that is in turn constrained by a range of international agreements. This regulatory configuration also affects the profitability of the pharmaceutical industry, domestic and international. Tensions and contradictions between industry profitability and public health objectives relate to access, innovation and regulation.

High levels of intellectual property (IP) protection (including easy patenting, generous privileges and strong enforcement) enable longer monopoly pricing which contributes to pharmaceutical industry revenues but increases the cost barriers to consumers and the cost burden on national health systems. The access barriers associated with monopoly pricing are particularly steep for poor people with little or no social protection and are particularly burdensome for developing countries (Abbott and Dukes 2009).

High levels of IP protection are said to be necessary to fund corporate research and development (PhRMA 2013). However, funding research and development (R&D) through monopoly pricing also means that investment is selectively directed to the development of drugs which promise high commercial returns. A WHO Commission concluded in

¹ Dr Hans Löfgren passed away unexpectedly while this paper was in press. Over the last decade, Hans' work was dedicated to advancing access to medicines in India and the developing world. He will be sorely missed: for his role in the global struggle for access to medicines, and as a teacher, research supervisor, mentor and friend.

2006 that the development of drugs for conditions which disproportionately affect people living in developing countries has been neglected because of poor expected returns (Commission on Intellectual Property Rights Innovation and Public Health 2006). High profit margins also support aggressive marketing which contributes to the over-use and misuse of medicines and further financial burdens on families and governments.

Since the advent of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1995 there has been a gradual but significant strengthening of IP protection, including for medicines, through successive bilateral and plurilateral free trade agreements (Lopert and Gleeson 2013; Roffe *et al.* 2007; Drahos 2002).

The TRIPS Agreement committed signatories to providing 20-year patent terms in all technology areas and for patents to be available for both products and processes (WTO 2010). Many developing countries resisted the new IP standards embedded in TRIPS but, as Drahos tells it (2002), they were ultimately coerced into agreeing. The principles enshrined in the agreement are implemented domestic legislation, which provides governments with some flexibility, as confirmed by the 2001 Doha Declaration on the TRIPS Agreement and Public Health (WTO Ministerial Council 2001; Scherer and Watal 2001). The term 'TRIPS flexibilities' refers to the discretion available to WTO members in amending domestic patent laws to conform to TRIPS. In particular, it is legal under TRIPS to legislate for the issuing of compulsory licenses and for 'parallel importation' (sourcing drugs available on the open market in other countries where these are available at lower prices than are charged by the domestic distributors). These are important flexibilities but they need to be articulated in domestic law for implementation.

There has been powerful opposition to developing countries seeking to utilise the flexibilities available under TRIPS, most famously when a consortium of 39 international pharmaceutical companies sued the government of South Africa over its use of parallel importing (Heywood 2009). This was at a time when HIV medications and other branded medicines were priced far out of the reach of patients in developing countries. The drug companies were supported by the Clinton administration, which also placed South Africa on its 301 Watch List as a precursor to trade sanctions. An international coalition of non-government groups mobilised in solidarity with South Africa. The

pharmaceutical companies were effectively shamed through bad publicity and the legal case was withdrawn (Gray and Vawda 2013). Yet their objectives remain unchanged and as recently as January 2014 it emerged that the international pharmaceutical industry was gearing up to launch a campaign against a new South African law establishing a domestic system for patent claim examination (Saez 2014).

The global pharmaceutical corporations, led by Pfizer, were early advocates of the TRIPS Agreement but since 1994 have pushed for even stronger IP protection. Starting with the North American Free Trade Agreement (NAFTA) in 1994, there has been a proliferation of bilateral and plurilateral trade agreements enshrining progressively stronger IP protection, commonly referred to as 'TRIPS Plus' provisions (Roffe *et al.* 2007).

The global IP system has evolved incrementally, with variations in conformity and resistance across the developing world and in different institutional contexts (Deere 2008; Williams and Lofgren 2013). Countries such as Brazil (Chaves *et al.* 2008), Thailand (Soontarajarn 2006) and India (India 2011) have sought to resist high levels of IP protection for public health reasons and to protect domestic generics manufacturers. They have been supported by civil society networks such as Médecins Sans Frontières (MSF), Third World Network (TWN) and Knowledge Ecology International (KEI) (Shashikant 2007). In their perspective, the harms resulting from excessive IP protection include: first, that monopoly pricing creates unacceptable price barriers to access; second, that funding R&D on the basis of anticipated profit distorts investment in new medicines; and third, that much of the revenue garnered through monopoly pricing is misused in marketing. Their policy positions are generally directed to delinking R&D from monopoly pricing (CEWG 2012). This would lead to lower prices, more rational R&D spending, and stem the flow of revenues into perverse and aggressive marketing (Moon *et al.* 2012; Soos and Lofgren 2013).

Three important areas of debate where these tensions between strong IP protection and public health objectives (access, quality and safety, rational use and innovation) can be clearly delineated: first, the pressures on countries to adopt levels of IP protection in excess of those required by the TRIPS Agreement; second, the policing of alleged infringements of IP rights (in particular the criminalisation of IP infringements including mandated in-transit seizures, and the industry demand that

medicines regulatory agencies assist in the policing of IP rights); and third, the regulation of over use and misuse of medicines in health care and in agriculture.

The purpose of this article is to describe and explain the role played by the Australian government in three forums where international norms and agreements affecting the pricing, innovation and regulation of medicines have been or are being negotiated: the World Health Organisation (WHO), the Anti-Counterfeiting Trade Agreement (ACTA), and current negotiations regarding IP provisions in the proposed Trans Pacific Partnership Agreement (TPPA).

The article is based on an analysis of Australian government policy statements, resolutions and summary records of the World Health Organisation, the text of the Anti-Counterfeiting Trade agreement, leaked draft chapters of the Trans Pacific Partnership trade agreement, and secondary sources and commentary in the refereed literature and civil society discussion.

In each of the three cases the context of negotiations is reviewed (including levels of transparency), the arguments at issue are explored and the position taken by the Australian government is analysed. Analysing the policies adopted in these forums has involved, first, evaluating the stated (or imputed) logic of the policies, having regard to broadly shared policy objectives and the different ideological world views in which such policy objectives are to be interpreted. Second, the political pressures and influences shaping the positions adopted have been reviewed, including the demands of the corporate world, the requirements of geopolitics and the concerns of different domestic constituencies that may have an interest in these debates.

IP and Medicines at the World Health Organisation

Within the WHO, tensions between IP protection and medicines policy have been prominent in three debates: WHO's role in evaluating the health implications of trade agreements (and in particular the full utilisation of TRIPS flexibilities); the funding of R&D for diseases predominantly affecting developing countries; and the conflation of medicines regulation with the policing of IP. In the context of these debates, Australia has sought to weaken the capacity of WHO to advise member states regarding the health implications of trade agreements, has

opposed WHO work towards delinking patents from medicines research through a global R&D treaty, and has sought to conflate quality of medicines issues with IP privileges and mandate the policing of pharmaceutical IP by medicines regulatory agencies. The analysis below is informed by materials assembled by WHO Watch (WHO Watch 2013a), a project of the global People's Health Movement (WHO Watch 2013b).

Lack of support in the WHO for full utilisation of TRIPS flexibilities

Shortly after the TRIPS agreement came into force in 1995, amidst rising tensions over patents and access to medicines, member states of the WHO, through resolution A52.19, requested that the Director General assist members in developing policies and regulations that assess the pharmaceutical and health policy implications of trade agreements and assist countries to 'maximize the positive and mitigate the negative impact of those agreements' (World Health Assembly 1999).

In May 2005, the WHO Secretariat submitted a report on trade and health to the WHO Executive Board (EB) (EB116/4, WHO 2005b). While it was praised by several developing countries, the United States delegation criticised the report, and accused the Secretariat of being 'against industry, free trade, and intellectual property' (WHO 2005a:41*ff.*). Thailand introduced a resolution 'International trade and health', on behalf of itself and thirteen countries, which urged member states to work towards policy coherence in trade and health, and to reduce the risks to health systems and health outcomes from trade agreements. The draft requested the Director-General to provide support to member states in relation to these goals. Australia was at this time a member of the EB (the US was not). Australia's representative (Ms Jane Halton) proposed a complex set of amendments (WHO 2005a:64-7) which sought to weaken the urgency of the resolution, rendering the analysis more bland and the recommendations more diffident, see also Khor (2005). The debate was deferred to the next EB meeting in January 2006 where a revised resolution was agreed for transmitting to the World Health Assembly (WHA).

At the subsequent WHA (May 2006) where the revised resolution was adopted, the US cautioned the Secretariat 'on its technical competency to advise member states accurately on the potential implications of trade

rules from a public health perspective' (WHO 2006:134-40*ff.*). In the weeks before the Assembly, the US had complained to the Director-General over advice which a senior WHO official (Dr William Aldis) had published, recommending that Thailand should be cautious about the implications for access to medicines of a mooted US-Thai free trade agreement (Williams 2006). Australia did not publicly speak out against developing countries using to the full the flexibilities of TRIPS and did not explicitly oppose the resolution on trade and health. But Australian representatives did seek to water down the text of the original Thai resolution. The strength of feeling exhibited by the US in denouncing the competence of the WHO Secretariat to advise on trade and health would have been clearly communicated to the Australian representatives. For a more detailed account of the trade and health resolution see Legge (2013).

Australia has also been among the cheerleaders for the continued freeze on mandatory member state contributions to WHO's budget which has undoubtedly limited the capacity of the WHO to undertake work in trade and health policy coherence. WHO is funded through mandatory formula based contributions ('assessed contributions' or ACs) and voluntary contributions (VCs which are either tied or untied). Since the late 1970s the proportion of the WHO budget which is met through ACs has fallen from 80 per cent to 25 per cent, owing partly to the freeze on ACs and partly to increasing voluntary contributions (Legge 2012). Australia, like many donor countries provides the bulk of its voluntary contribution as earmarked donations to particular programs. In 2010–11 Australia provided \$68.6 million to WHO, comprising \$18.0 million in voluntary untied funding, \$9.1 in assessed (or mandatory) contributions (untied), and a majority of the funding, \$41.5 million, in earmarked funding (Australian Government 2012b).

The freeze on ACs means that WHO's agenda is largely determined by the donors (rich countries, philanthropies, international financial institutions etc) on the basis of what they are willing to fund, rather than the member states through the World Health Assembly (WHA). Not only has this arrested action on resolutions of the Assembly on trade agreements and the use of TRIPS flexibilities but it has also led to gross under funding of medicines regulation and rational use of medicines.

IP, innovation and public health: Australia's role in delay and diversion tactics within WHO

A second debate within the WHO has been on the lack of R&D investments by global pharmaceutical companies to develop medicines for diseases specially needed for developing countries. Since 2003, a series of debates and intergovernmental and expert working groups have been commissioned by the WHO to investigate how to improve the financing and coordination of R&D for the purpose of developing much needed medicines at affordable prices. This culminated in the 2012 report to the WHA of the Consultative Expert Working Group on Research and Development: Financing and Coordination (A65/24, see WHO 2012a). This report explicitly and unambiguously recommended a binding treaty for the purposes of funding R&D for conditions disproportionately affecting developing countries.

The concept of a binding R&D treaty as proposed by the CEWG (WHO 2012a:Chapter 6) entails delinking the patent mechanism from the funding of R&D for diseases predominately affecting developing countries. R&D would be funded publicly on a contract or prize basis. This would remove the argument for monopoly pricing to recoup R&D costs. Under such circumstances, there would be no barrier to a competitive market in the generic production of such medicines. This would mean lower prices. The proposed treaty was supported by many developing countries but opposed by pharmaceutical corporations and their host governments. The opposition, led by the US and Europe and supported by Australia, has taken the form of the repeated re-examination of old proposals that have been discarded by CEWG experts, the continued assertion that other mechanisms to boost investment in drugs could be explored, and procedural delaying tactics.

The World Health Assembly (May 2012) was divided with resolutions for and against the proposed binding R&D treaty. Led by Brazil, India and Thailand, the case for delinking pharmaceutical R&D from IP protection and monopoly pricing was largely supported by Latin America, Africa and Asia. Australia (with the US, Canada and Japan) argued for more time, more options and further consultation (WHO 2012c:51ff.). A deal, brokered by Thailand, transferred the debate to an Open Ended Meeting of Member States (OEMS Meeting in November 2012) which at the final hour (and with few member states in the room), resolved to proceed with an R&D observatory and some selected

demonstration projects before reconsidering the binding treaty (WHO 2012b). The binding treaty has been shelved for the time being. Undoubtedly it will return.

The case for delinking and a binding agreement to meet the needs of developing countries is strong (Velásquez 2012). However, this would establish a precedent that could be extended to other medicines and the pharmaceutical corporations and their host countries are strongly opposed. The Australian government is part of this opposition, participating in delay and diversion tactics.

IMPACT and the role of medicines regulatory agencies in policing IP rights

A final debate in the WHO in which Australia has taken a position contrary to public health considerations concerns the role of medicines regulatory agencies in policing IP. Australia, along with Europe and the US, has repeatedly conflated, through the slippery use of the term ‘counterfeiting’, the regulation of quality of medicines with the regulation of IP infringement. In trade law ‘counterfeiting’ refers to trade mark infringements (WTO *nd*) but the WHO definition, adopted in the early 1990s, encompassed failings with respect to quality, safety and efficacy but was ambiguous with respect to intellectual property status. Thus, campaigning around ‘counterfeiting’ was able to harness government and public concern regarding substandard medications in the pursuit of industry objectives of stronger IP protection.

In 2006, Australia joined the European Commission, Germany, Italy and the Netherlands in funding the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). IMPACT was hosted by WHO, and WHO was a lead member of the taskforce, although this was never mandated by a resolution of the World Health Assembly; indeed it had been established without any reference to the governing bodies. IMPACT was funded (nearly US\$2.6 million) by contributions from the European Commission, Australia, Germany, Italy and the Netherlands (altogether 68%) and by WHO (28%). It also benefitted from significant in-kind support from the pharmaceutical industry. Two years after its establishment the World Health Assembly (in May 2008) was invited to endorse it.

IMPACT's program included publicising vigorously the dangers of 'counterfeit' medicines and advising countries, particularly in Africa, on the principles to be enshrined in national legislation against 'counterfeit' medical products (IMPACT 2007). The principles which it recommended be enacted in legislation included references to ensuring that pharmaceuticals are appropriately licensed and authorised as well as mandating the seizure of 'counterfeit' medicines in transit. The references to licensing and other provisions in the principles document can be interpreted as recommending 'patent linkage' whereby marketing approval becomes dependent upon the applicant demonstrating that the product is not under patent (see Shashikant 2010 for a detailed discussion of the conflation of IPRs and quality, safety and efficacy in the IMPACT principles). Harnessing medicines regulatory authorities in the policing of what had previously been a civil wrong (IP infringement) would be a significant coup for the international pharmaceutical corporations.

The establishment of IMPACT needs to be seen in conjunction with a number of parallel events including the negotiation of the Anti-Counterfeiting Trade Agreement (ACTA, see below), the seizures of generic medicines in transit through European ports and the patent law reform initiatives in Kenya and Uganda and the East African Community. Between October 2008 and May 2009 there were at least six seizures of Indian generic drugs in transit through European ports destined for Colombia, Peru, Brazil, Nigeria and Vanuatu (Khor 2009). These were drugs that were legitimate in both source and destination country and were not destined for import into the country of transit. The EU claimed that the seizures were required under a 2003 regulation and agreed to amend the regulations only after India took the EU to the WTO (Anonymous 2010). Around the same time (2008) the Kenyan Patent Act was adopted making the manufacturing, import or sale of 'counterfeit goods' a criminal matter rather than a matter for civil proceedings. In April 2012 the Kenya High Court ruled that the Act was too broad and vague with respect to counterfeit and generic medicines (IP-Watch 2012).

When IMPACT was finally introduced to the World Health Assembly (two years after it had been established) reservations were expressed by many developing countries about the presence of the pharmaceutical industry in its management group and associated conflicts of interest and the lack of a formal mandate. Levels of suspicion were heightened by the concurrent seizures of Indian generics by European customs.

WHO's involvement in IMPACT and the wider questions regarding medicines regulation were vigorously contested in the World Health Assembly and the Executive Board from this time on. In the course of these debates it became clear that the ambiguity regarding the meaning of 'counterfeit' was creating confusion, perhaps intentionally so. WHO had adopted its definition of 'counterfeit' in 1992 in the context of a workshop involving the pharmaceutical industry (Shashikant 2010) at a time when the industry, led by Pfizer, was lobbying intensively around the drafting of what was to become the TRIPS Agreement (Paine and Santoro 1992; Drahos 2002).

Subsequently the distinction between IP infringements and issues of quality, safety and efficacy has become clearer and mechanisms for dealing more effectively with the latter are being developed. But rather than drop the use of 'counterfeit' in relation to substandard medicines WHO has adopted the portmanteau term 'substandard/spurious/falsely-labelled/falsified/counterfeit medical products' (or SSFFCMP) in its deliberations on these matters. Australia and other supporters of IMPACT continue to conflate 'counterfeit' with substandard medicines. During the debate in the Executive Board in January 2013, Jane Halton (speaking for Australia) argued that 'the consequences for individuals who purchased *counterfeit or substandard medicines*, sometimes at great cost, should not be underestimated; such behaviour was, moreover, potentially very dangerous for the global health community, particularly in terms of increasing antimicrobial resistance' (WHO 2013:205).

There are two major issues at stake here: first, the industry project of tightening IP protection and enforcement; and second, the regulation of medicines supply to guarantee affordability, quality, safety and efficacy (QSE) and rational use. There is general agreement that national and regional medicines regulatory agencies (MRAs) should have responsibility for regulating for QSandE and that WHO, in association with the International Conference of Drug Regulatory Authorities, has responsibility to support the development of MRAs. However, the pharmaceutical industry has reason to be cautious about WHO's rational use of medicines objective and its ethical marketing practices policy. The attraction of IMPACT, from the point of view of the industry, was that it looked towards harnessing MRAs to progress the IP agenda without any focus on marketing practices or the challenge of over-prescribing.

In conclusion, Australia has taken a strong IP stance with respect to medicines policy at the WHO. It has contributed to a weakening of the capacity/authority of the WHO to advise on the health implications of trade agreements, opposed/restricted the WHO from progressing on a substantive biomedical R&D treaty, and supported mechanisms that conflate quality of medicines issues with IP privileges. These positions reflect an imbalance in favour of IP over effective medicines policy. In these three cases, Australia's position has been aligned with that of the United States, which suggests that Australia's position has been shaped at least in part by this geopolitical alliance. Notably, there is little awareness of Australia's position at the WHO in the wider Australian community, including those involved in development assistance.

Anti-Counterfeiting Trade Agreement (ACTA)

In addition to its pro IP stance within the WHO, Australia was supportive of the United States and its allies in proposing the Anti-Counterfeiting Trade Agreement (ACTA) as a means of strengthening the global system for the policing and enforcement of IP rights, focusing in particular (but not restricted to) on trademarks and copyright.

The US and Japan commenced work on ACTA in 2006. Negotiations involving the US, Australia, Canada, the EU and its 27 member states, Japan, South Korea, Mexico, Morocco, New Zealand, Singapore, and Switzerland were launched in October 2007; and a final text was released in May 2011 (Joint Standing Committee on Treaties 2012). The section in the proposed Agreement on civil enforcement required parties to make provision for injunctions to be issued and damages awarded in relation to infringements. Parties to the Agreement would have to legislate for courts to be able to order alleged infringers to provide information to the rights holder or to the court about the production and distribution of the allegedly infringing product. The section on border measures authorised seizures by customs officials including the seizure of goods in transit. Such seizures may be instituted at the request of the claimant rights holder. The section on enforcement provided for criminal procedures and penalties for counterfeit trademarks and copyright piracy on a commercial scale.

The proposed Agreement triggered opposition by internet users and widespread concerns about the implications for generic medicines. An

online petition following the release of the final treaty text in April 2011 collected 2.8 million signatures (Baraliuc *et al.* 2013). The secrecy of the process was a central theme in the global opposition to ACTA. The public had no access to a full draft of the Agreement until 2010, while US-based multinational corporations were consulted on the content of the draft treaty through an advisory committee. The Pharmaceutical Research and Manufacturers Association (PhRMA), representing the US pharmaceutical industry, was among those providing input to the draft text (Love 2009). In Australia, the Joint Committee on Treaties described the 'level of secrecy' maintained by the Department of Foreign Affairs and Trade (DFAT) as the 'most troubling aspect throughout the development of ACTA' (Joint Standing Committee on Treaties 2012).

ACTA was ostensibly concerned with copyright and counterfeiting, that is, protection for content producers such as musicians and filmmakers. But 'intellectual property' was not defined clearly and was widely understood to cover patents more broadly, including pharmaceutical patents. Of particular concern to public health advocates was that ACTA seemed to leave open the possibility of conflating generic drugs with 'counterfeit' products, as per the precedent of IMPACT (India 2011). Médecins Sans Frontières issued a report titled *A blank cheque for abuse: ACTA and its impact on access to medicines* (Médecins Sans Frontières 2012). Reinforcing such concerns was the repeated seizure in 2008-09 of shipments of generic drugs in transit through Europe, as mentioned above (Arkininstall *et al.* 2011).

In Australia, the Joint Standing Committee on Treaties (JSCOT) was critical of ACTA in its report of November 2011, recommending that the agreement 'not be ratified' pending clarification on key points (Joint Standing Committee on Treaties 2012). JSCOT was critical of secrecy, the lack of evidence of benefit to Australia, vague terminology, lack of balance (sole focus on the interests of rights holders) and lack of any attention to the wider development issues of technology transfer and access to knowledge. The JSCOT referred to the 'club approach' that had been taken to the negotiation of ACTA under which a group of IP exporters agree upon enforcement principles and then expected other countries, including developing countries that are IP importers, to accede to the agreement.

India criticised the neglect of the development dimension in ACTA in a discussion at the TRIPS Council of the WTO (India 2011). India was

concerned that ACTA would be used to target generic medicines, and was particularly apprehensive about the provisions for seizures in transit by customs authorities. India demonstrated how provisions of the Agreement could be used to attack the trade in generic pharmaceuticals, and compared the absence of a development dimension in ACTA with the provisions in TRIPS dealing with the transfer of technology, socio-economic development, promotion of innovation and access to knowledge.

In contrast, the Australian government provided wholehearted support. According to the then Trade Minister, Craig Emerson, 'Australia played a leading role in the negotiation process' (Emerson 2011). On the occasion of its launch, Dr Emerson announced: 'This Treaty will help stem the burgeoning global trade in counterfeit and pirate materials, worth many billions annually' (Emerson 2011). That Australia's position was one of strong support is evident from interaction between DFAT and the parliamentary committee, the government's response to the committee report, and media releases by the Trade Minister (Australian Government 2012a). Indeed, it has been observed that '(DFAT) emerged as ACTA's cheerleader-in-chief in Australia, trumpeting the benefits of the treaty...' (External Contributor 2012).

ACTA was envisaged as a new mechanism, separate from existing international organisations already dealing with IP such as the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), to strengthen the enforcement of intellectual property rights. ACTA was to be administered by a new governing body for the purpose of providing IP holders with 'unprecedented protection' (Flint and Payne 2013). Thus ACTA was one of a range of 'forum shifting' initiatives, to ratchet up IP protection, by the United States and allies, including a raft of bilateral and regional 'TRIPS-Plus' trade agreements such as the Trans-Pacific Partnership (Sell 2011).

ACTA was signed by Australia, Canada, Japan, Morocco, New Zealand, Singapore, South Korea and the US in October 2011. In 2012, Mexico, the EU and 22 EU members also signed but only one country – Japan – has ratified the agreement, which will come into force after ratification by six countries. In reality, however, ACTA appears to have failed with its rejection by the European parliament in July 2012, following a global and particularly European civil society mobilisation (Anonymous 2012). Shortly before the vote in the European Parliament Germany's Justice

Minister criticised ACTA as ‘very inexact, very porous and with a very incorrect formulation’ (Anonymous 2012). In contrast, Australia, a core member of the ‘exclusive club’ headed by the US, appears to have taken no other position than support for the US and the objective of stronger enforcement of IP protection. The concerns of developing countries (excluded from the ACTA process) with regard to the potential implications for generics elicited no support from Australia. The development of ACTA and the establishment of IMPACT occurred in the same period and Australia was actively involved in both. Australia was promoting the conflation of ‘counterfeit’ with substandard medical products in the WHO while negotiating a treaty which explicitly defined counterfeit as a trademark infringement.

Trans Pacific Partnership Agreement Negotiations

The Trans Pacific Partnership Agreement (TPPA) negotiations, which are ongoing at the time of writing, represent a third forum in which Australia may take a position in support of extending the period of monopoly pricing of medicines (particularly in developing countries) and stronger enforcement of IP privileges.

Australia has a long-standing commitment to trade liberalisation pursued through trade negotiations as well as unilateral reforms to reduce trade barriers. It was no surprise that when plans were announced to extend the P4 (Pacific 4) trade agreement between Brunei, New Zealand, Chile and Singapore into a larger regional free trade bloc, Australia was at the table. Nor was it a surprise that the US would drive the agenda for the TPPA and seek to apply templates from other trade agreements as starting point for negotiations, including the bilateral agreement with South Korea (KORUS) (Flynn *et al.* 2012).

The TPPA negotiating parties are a curious assortment of nations with widely varying export industries, trade policy priorities and levels of development. The US agenda has in many areas clashed with the positions of other countries and key areas of the text, including the IP chapter, have been highly controversial. The US is seeking to pursue the interests of its IP exporting industries, including the pharmaceutical industry, while most of the other TPPA parties, including Australia, are net IP importers. These tensions have been reflected in Australia’s

position through the negotiations, which has not been one of unqualified support to the US.

The former Labor Government's 2011 Trade Policy Statement identified the TPPA as Australia's highest trade priority (Australian Government Department of Foreign Affairs and Trade 2011). This policy statement, which followed on the heels of the Productivity Commission's (2010) Review of Bilateral and Regional Free Trade Agreements, also marked out some 'red lines' with respect to the government's policy priorities for this and other trade agreements. While the Trade Policy Statement (*Trading our Way to More Jobs and Prosperity*) demonstrated a commitment to trade liberalisation, it also contained strong commitments regarding 'non-trade' objectives including labour standards, environmental protection, and public health. Furthermore, it included explicit commitments not to accept provisions that would 'limit its capacity to put health warnings or plain packaging requirements on tobacco products or its ability to continue the Pharmaceutical Benefits Scheme' (DFAT 2011:14).

In the earlier bilateral negotiations for the Australia–US Free Trade Agreement (AUSFTA), which entered into force in 2005, the Howard Government agreed to IP provisions that were not in Australia's interests, such as restrictions on compulsory licensing, and some provisions which, while not extending IP rights beyond existing levels, did effectively 'lock in' relatively high levels of IP protection for the future (Lopert and Gleeson 2013). Australia also agreed to the inclusion of an annex on pharmaceutical pricing and reimbursement (Australian Government Department of Foreign Affairs and Trade 2005). While Australia appears to have successfully fended off US attempts to use this annex to modify processes for listing and pricing pharmaceuticals in ways that would advantage patent holders, the fact that this annex was included in the agreement at all set an unfortunate precedent. The next bilateral trade agreement negotiated by the United States (with South Korea) included a far more onerous set of provisions applying to Korea's programs for subsidising medicines and medical devices (Lopert and Gleeson 2013).

In the Trans Pacific Partnership negotiations, leaked documents (United States Trade Representative 2011b; United States Trade Representative 2011a) show that the US tabled a set of extreme intellectual property provisions in 2011 that extend well beyond those included in previous trade agreements, including the AUSFTA (Lopert and Gleeson 2013).

These proposals (Lopert and Gleeson 2013; Flynn *et al.* 2011) would extend the market exclusivity period for new drugs in all of the TPPA countries through a range of provisions including:

- expanding patentability to new forms, uses and methods of using a known product;
- providing for patent term extensions to compensate for delays in granting patents or marketing approval;
- implementing a patent linkage mechanism requiring regulatory authorities to scan for existing patents, notify patent holders where a patent is in place and delay marketing approval until any disputes are settled;
- eliminating the legal safeguard of pre-grant opposition; and
- extending data exclusivity periods (five years for new pharmaceutical products, a further three years for new uses of existing products and potentially up to twelve years for biologics).

Furthermore, the 2011 US proposals would require countries to allow patents for diagnostic, therapeutic and surgical methods. In each of these areas, the US TPPA proposals extend well beyond the TRIPS Agreement and would limit the flexibilities available under TRIPS, re-affirmed in the Doha Declaration, for countries to limit IP rights in order to protect the health of their populations (Lopert and Gleeson 2013). The 2011 leaked US proposal for the IP chapter also included a set of enforcement obligations similar to the most controversial provisions originally proposed for ACTA (Flynn *et al.* 2012).

The US proposals have attracted stringent criticism from international health, development and consumer and human rights organisations such as Medecins Sans Frontieres (2012), Oxfam (2013), Public Citizen (2013a) and Third World Network (2013) for the effects they would be likely to have on access to affordable medicines in developing countries. The bulk of the 2011 US proposals were opposed by all the other TPPA countries (Inside U.S. Trade 2012), and the IP chapter was widely reported as one of the key sticking points in the negotiations (Inside U.S. Trade 2013b).

Australian health, development and fair trade NGOs also opposed the US IP proposals for the TPPA. This opposition was expressed in various submissions, including to the Department of Foreign Affairs and Trade (DFAT) (Public Health Association of Australia *et al.* 2013) and many letters to politicians (Baum *et al.* 2013; Moore 2013), media releases

(Public Health Association of Australia 2013) and other advocacy documents (Hirono *et al.* 2014). Organisations involved in this advocacy effort included the Public Health Association of Australia, the Australian Fair Trade and Investment Network, the Australian Federation of AIDS Organisations, the Australian Healthcare and Hospitals Association, Palliative Care Australia, the Australian Medical Students' Association, the Australian Health Promotion Association and many others. As well as written submissions and letters, many of these organisations also had frequent discussions with trade negotiators and in some cases attended stakeholder events at TPPA negotiating rounds. The advocacy undertaken by these organisations focused on the risks the US IP proposals presented for the affordability of medicines both for Australians and for those in developing countries.

Documents released by the Department of Foreign Affairs and Trade under Freedom of Information (FOI), although heavily redacted, confirm that trade officials were cognisant that existing IP standards in Australia are inappropriately high for some of the other TPPA parties, and suggest that some of these advocacy messages had been taken up to a certain degree in the Australian negotiating position. Briefing material prepared by DFAT for a meeting with PhRMA and Biotechnology Industry Association (BIO) included the following points (Department of Foreign Affairs and Trade 2012a):

Possible “development” impact of the US proposals

- The Australian government, and our stakeholders, are also concerned that the US proposals may increase the cost of medicines, and delay the introduction of generic medicines, for developing countries in the region
 - this could make it harder for the poorest in developing countries to access necessary treatment
 - and limit the current reach of Australia’s aid expenditure on medicines and vaccines.

Yet, the former Labor Government’s position was essentially defensive, seeking to maintain the domestic status quo (which has often been referred to as a ‘balance’ between the interests of IP rights holders and the community). For example, briefing material for stakeholder meetings

conducted by DFAT on the Trans Pacific Partnership Agreement and Intellectual Property (2012b), released under FOI, includes the statement:

The Government is aiming to develop a high-quality IP chapter that deals with recent developments in international IP, but does not go beyond Australia's existing domestic regime or require legislative change

- we are seeking provisions that allow us to maintain the flexibilities in our IP system, and that strike an appropriate balance between the interests of right holders, users and the community.

In November 2013, Wikileaks published a leaked consolidated draft of the IP chapter of the TPPA, dated 30 August 2013, documenting the negotiating positions of all twelve TPPA parties at the end of the most recent official round of the negotiations (Trans Pacific Partnership 2013). The draft chapter showed that the US was continuing to push for the same extreme IP provisions, with a couple of exceptions (*e.g.* the clause eliminating pre-grant opposition that had appeared in earlier drafts was missing from the 2013 draft) (Public Citizen 2013b). The draft chapter also includes a set of border enforcement provisions of sufficiently broad scope to enable the seizure of legitimate generic pharmaceuticals (Weatherall 2013:32).

It is clear from this draft text that the Australian Government of the day opposed many of the worst US proposals for pharmaceutical patents. For example, the text indicates that before the 2013 election, Australia rejected proposals to extend patent periods to compensate for delays in regulatory approval and to extend data exclusivity periods (Trans Pacific Partnership 2013).

It is not so clear, however, whether the Labor Government was supporting the efforts of other countries to strike a better balance between intellectual property privileges and the public interest. The leaked draft showed that five countries (New Zealand, Canada, Chile, Singapore and Malaysia) had made a counter-proposal which presented a more flexible approach that would largely protect access to affordable medicines in the region (Cox 2013). This text does not indicate Australia's position on most provisions in this counter-proposal.

Inside US Trade (2013a) reported that Australia was involved in the early development of this proposal, and it is likely that Australia's silence on

key elements in the draft was due to the caretaker period before the election (Cox 2013). But Australia appears to have supported a US proposal to require countries to allow patents for new uses and new methods of using existing drugs (Trans Pacific Partnership 2013). This calls into question the previous Government's commitment to preserving access to medicines in the region. The US proposal for new uses and methods is consistent with current Australian law and the provisions of the AUSFTA, but would encourage evergreening of patents (extending the monopoly term by gaining additional patents for minor, therapeutically insignificant variations to existing products) in other TPPA countries, including Vietnam, which already has significant problems providing access to medicines for much of its population.

The trade policy of the Liberal-National Coalition Government elected in September 2013 (Coalition Government 2013) raised concerns in the Australian public health community. It expressed a strong commitment to concluding trade deals, increasing foreign investment and reducing risk for investors, and indicated that the new government was open to investor-state dispute settlement mechanisms in trade agreements. There was an emphasis on greater consultation with industry, and no mention of civil society stakeholders or of health, medicines or the environment. The Minister for Trade and Investment, however, issued a statement soon after the release of the November 2013 leak that reiterated the previous government's commitment to avoiding provisions that would undermine the PBS or the health system (Janda 2013), and these types of statements have been repeatedly made by the new government.

The TPPA negotiations have been shrouded in secrecy, illuminated by occasional leaks, and we can only speculate on what level of IP protection Australia will be prepared to settle for. At the time of writing, there is little public evidence of Australia's current position. Media reports during TPPA ministerial meetings in December 2013 (Expose the TPPA 2013) suggest that Australia, among other countries, may have given in to some of the US demands for IP and medicines but these reports have not been verified.

Past experience (including at WHO and ACTA) suggest that Australia may end up supporting the US position or seeking some middle ground, rather than supporting the position of the developing countries. This is particularly likely if such support is perceived to compromise Australia's interests in other areas (*e.g.* agricultural market access) in the final stages

of the negotiations. However, a key difference in Australia's approach in the TPPA, compared to the internal debates within the WHO and its position on ACTA, is that it has encountered intense domestic criticism and advocacy.

Conclusions

This article has explored Australia's role in three areas of global medicines policy relating to IP protection: within the WHO (access, innovation and regulation) and in the negotiations for ACTA and the TPPA.

In the World Health Assembly Australia has: first, failed to support a role for WHO in encouraging developing countries to adopt legislation which takes full advantage of flexibilities available under the TRIPS Agreement; second, failed to support the delinking of monopoly pricing from R&D for diseases which disproportionately affect developing countries; and third, has supported the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) which has promoted the criminalisation of IP infringements and has sought to require medicines regulatory authorities to take on a policing role with respect to IP and medicines.

In the negotiations around ACTA, Australia supported attempts to establish a reinforced IP enforcement regime, in the expectation that developing countries, urgently needing technology transfer and access to knowledge, would eventually be forced to join. In this context, Australia sanctioned the possibility that ACTA would open the way for the in-transit seizure of generic medical products deemed to be 'counterfeit'. In its support for IMPACT and ACTA and in contributions to WHO debates Australia has consistently supported the agenda for stronger IP protection and supported the US in its opposition to WHO playing a role in promoting trade and health policy coherence.

In its participation in the 'exclusive club' that developed ACTA, Australia placed no value on the role of technology transfer and access to knowledge in social and economic development. In both ACTA and the TPPA Australia appears to have expressed little concern regarding monopoly pricing as a barrier to access in developing countries.

Australia's ultimate stance in the TPPA negotiations is yet to be determined. The provisions proposed for the TPPA in relation to IP protection and its policing are far more extreme than those accepted by Australia in the AUSFTA in 2005. It is unlikely that Australia will agree to extremely high standards of IP protection that would be disadvantageous domestically. It is more likely that Australia will acquiesce to provisions that will result in higher levels of IP protection in some of the less developed countries that form part of the TPPA process.

The Australian government's apparent willingness to defend the PBS in the TPPA negotiations may reflect its fiscal exposure (as funder of the PBS) or voter concern or both. Certainly the leaked texts, the rising public awareness of the risks of the TPPA and the advocacy of civil society organisations appear to have contributed to some caution with respect to domestic sensitivities. It seems that the development implications of the TPPA proposals are being given less weight. Australia's initial support for ACTA during its highly secretive negotiation appears to have shown no concern for either public health or development implications. However, its rejection by JSCOT show that parliamentary scrutiny was able to give some weight to such considerations, albeit at the eleventh hour.

In both the TPPA and ACTA cases it is striking that while public and parliament were kept in the dark during the negotiations, the corporations that stood to gain from stronger IP protection had privileged access to draft text during the negotiations. The privileging of the transnational corporations over democratic accountability is concerning.

The positions adopted by Australia in WHO debates over TRIPS flexibilities, trade and health policy coherence, delinking R&D from monopoly pricing and the IMPACT agenda were broadly consistent with the corporate interest, with the US position and with neoliberal ideology. Australia's position at WHO has been less secretive but unaccountable regarding its development implications. In the TPPA negotiations, the implications for the PBS are clearly being given some weight although it seems that Australia has not taken a strong position on the development issues. The added dimension of market access bargaining in the TPPA negotiations adds a further complexity; Australia's ultimate position on IP and medicines may be shaped as much by trade-offs to gain better terms for its exports than by particular commitments regarding intellectual property.

The secrecy of international negotiations and lack of public accountability for the position taken by Australia in these negotiations appears to have contributed to the neglect of public health and development solidarity.

In important respects the pharmaceutical industry stands opposed to development objectives such as technology transfer and access to knowledge. Maximising profits and shareholder value depends on high levels of IP protection and strong enforcement, but loose regulation of pricing, marketing and utilisation. Standing with the transnational pharmaceutical industry is an array of corporations in other knowledge intensive industries (including entertainment, electronics and computing) looking to benefit from high IP protection and strong enforcement.

There is a need for closer monitoring of Australia's official position in these and similar negotiations and stronger demand for policies informed by public health objectives and development solidarity. This might involve better informed, better organised public health advocacy, closer links between public health advocates and other civil society movements committed to knowledge access, and closer liaison with social movements and governments in the global South.

David Legge is Scholar Emeritus in the School of Public Health and Human Biosciences at La Trobe University.

d.legge@latrobe.edu.au

Deborah Gleeson is a lecturer in the School of Public Health and Human Biosciences at La Trobe University.

d.gleeson@latrobe.edu.au

Hans Löfgren was Associate Professor in Politics and Policy Studies in the School of Humanities and Social Sciences at Deakin University.

hans.lofgren@deakin.edu.au

Belinda Townsend is a doctoral candidate in the School of Humanities and Social Sciences at Deakin University.

bel.townsend@deakin.edu.au

References

Abbott, F. M. and Dukes, M. N. G. 2009. *Global pharmaceutical policy: ensuring medicines for tomorrow's world*, Cheltenham, UK, Edward Elgar Publishing.

Anonymous. 2010. Drug seizure issue settled, EU agrees to amend laws. *Economic Times*, 8 October.

Anonymous. 2012. The Last ACTA: Intellectual Property Treaty Dies in European Parliament *Spiegel Online International* (Online), available online: <http://www.spiegel.de/international/europe/acta-international-property-treaty-voted-down-by-european-parliament-a-842583.html> (accessed 6 August 2013).

Arkininstall, J., Childs, M., Menghaney, L., Ford, N. and von Schoen-Angerer, T. 2011. The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries. *Journal of Generic Medicines*, 8, 14-22.

Australian Government. 2012a. *Australian Government response to the Joint Standing Committee on Treaties Report: Report 126 Review of treaty tabled on 21 November 2011: Anti-Counterfeiting Trade Agreement* (Online). Canberra, available online: <http://www.dfat.gov.au/ip/downloads/government-response-to-jscot-report-on-acta.pdf>.

Australian Government. 2012b. *Australian Multilateral Assessment: World Health Organisation*, Canberra, available online: <http://www.ausaid.gov.au/partner/Documents/who-assessment.pdf> (accessed: 28 May 2013).

Australian Government Department of Foreign Affairs and Trade. 2005. *Australia-United States Free Trade Agreement* (Online), available online: <http://www.dfat.gov.au/fta/ausfta/final-text/> (accessed 13 September, 2013).

Australian Government Department of Foreign Affairs and Trade. 2011. *Gillard Government Trade Policy Statement: Trading Our Way to More Jobs and Prosperity* (Online). Canberra, available online: <http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.pdf> (accessed 19 October 2012).

Baraliuc, I., Depreeuw, S. and Gutwirth, S. 2013. Copyright enforcement in the digital age: A post-ACTA view on the balancing of fundamental rights. *International Journal of Law and Information Technology*, 21, 92-104.

Baum, F., Yeatman, H., Daube, M., Willis, E. and Sainsbury, P. 2013. *Joint letter to minister*, Canberra, available online: http://www.phaa.net.au/documents/131209_joint%20letter%20to%20Minister%20Dutton%20re%20TPPA.pdf (accessed 7 April 2014)

CEWG. 2012. *Consultative Expert Working Group on Research and Development: Financing and Coordination (A65/24)*, Geneva, available online: http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_24-en.pdf (accessed 8 January 2013)

Chaves, G. C., Vieira, M. F. and Reis, R. 2008. Access to medicines and intellectual property in Brazil: Reflections and strategies of civil society. *Sur - International Journal on Human Rights* 5, 163-189.

Coalition Government. 2013. *The Coalition's Policy for Trade* (Online), available online: <http://lpaweb-static.s3.amazonaws.com/Coalition%202013%20Election%20Policy%20%E2%80%93%20Trade%20%E2%80%93%20final.pdf> (accessed 13 October 2013).

Commission on Intellectual Property Rights Innovation and Public Health. 2006. *Public health, innovation and intellectual property rights*, Geneva, available online: <http://www.who.int/intellectualproperty/en/>

Cox, K. 2013. *TPP Negotiating Parties' Counterproposal to the US on Medicines Represents a More Flexible Approach* (Online). Knowledge Ecology International, available online: <http://www.keionline.org/node/1826> (accessed 24 November, 2013).

Deere, C. 2008. *The implementation game: the TRIPS agreement and the global politics of intellectual property reform in developing countries*, Oxford, Oxford University Press.

Department of Foreign Affairs and Trade. 2012a. *TPP Briefing for (s22 1(a)(ii)) Meeting with PhRMA and BIO - July 2012. Released under Freedom of Information, FOI request 1302-F501.*

Department of Foreign Affairs and Trade. 2012b. *Trans-Pacific Partnership Agreement: Intellectual Property Stakeholder Meetings. 14, 15, 16 and 19 November 2012: Sydney, Brisbane, Melbourne, Canberra. Briefing material released under Freedom of Information. FOI Request 1302-F501.*

Drahos, P. 2002. *Developing countries and international intellectual property standard-setting* available online: <http://www.anu.edu.au/jellows/pdrahos/articles/pdfs/2002devcountriesandipstandards.pdf>

Emerson, C. 2011. Australia to sign Anti-Counterfeiting Trade Agreement (ACTA). Canberra Department of Foreign Affairs and Trade.

Expose the TPP. 2013. *Closing in a TPP Deal* (Online), available online: <http://exposethepp.tumblr.com/post/69585545815/closing-in-on-a-tpp-deal-washington-trade-daily> (accessed 31 March 2014).

External Contributor. 2012. *The Department for ACTA* (Online). Sydney: LeMay and Galt Media, available online: <http://delimiter.com.au/2012/03/26/the-department-for-acta/> (accessed 7 August 2013).

Flint, A. and Payne, J. 2013. Intellectual property rights and the potential for universal access to treatment: TRIPS, ACTA and HIV/AIDS medicines. *Third World Quarterly*, 34, 500-515.

Flynn, S., Baker, B., Kaminski, M. and Koo, J. 2012. The U.S. proposal for an intellectual property chapter in the Trans-Pacific Partnership Agreement. *American University International Law Review*, 28, 105-202.

Flynn, S., Kaminski, M., Baker, B. K. and Koo, J. H. 2011. *Public Interest Analysis of the US TPP Proposal for an IP Chapter. Draft Version 1.3* (Online). Program on Information Justice and Intellectual Property, American University Washington College of Law, available online: <http://infojustice.org/wp-content/uploads/2011/12/TPP-Analysis-12062011.pdf> (accessed 11 July 2012).

Gray, A. L. and Vawda, Y. A. 2013. TRIPS, Access to Medicines, and Local Production in South Africa. In: Lofgren, H. and Williams, O. (eds.) *The New Political Economy of Drugs: Production, Innovation and TRIPS in the Global South*. London: Palgrave Macmillan.

Heywood, M. 2009. South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health. *J Human Rights Practice*, 1, 14-36.

Hirono, K., Gleeson, D., Haigh, F. and Harris, P. 2014. *The Trans Pacific Partnership Agreement Negotiations and the Health of Australians: A policy brief*. Sydney, available online: <http://www.phaa.net.au/documents/140217%20TPP-policy%20brief%20FINAL.pdf> (accessed 7 April 2014)

IMPACT. 2007. *Principles and elements for national legislation against counterfeit medical products* (Online). WHO, available online: <http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf> (accessed 25 October 2013).

India 2011. Trends in the enforcement of intellectual property rights. *TRIPS Council 26 October 2011*.

Inside U.S. Trade. 2012. U.S. Mulls Strategy On TPP Medicines Proposal In Light Of Stiff Resistance.

Inside U.S. Trade. 2013a. Several TPP countries table alternative pharma IP text ahead of Mexico intersessional. *Inside U.S. Trade, September 11 2013*.

Inside U.S. Trade. 2013b. TPP work on key issues remains slow, resolution by APEC doubtful. *Inside U.S. Trade*. Posted September 26, 2013.

IP-Watch. 2012. *Kenyan High Court's Overturning Of Anti-Counterfeit Law Hailed* (Online). IP-Watch, available online: <http://www.ip-watch.org/2012/04/21/kenyan-high-courts-overturning-of-anti-counterfeit-law-hailed/> (accessed 24 August 2013).

Janda, M. 2013. *ABC Radio: Leaked Document Shows Big Rifts in Pacific Trade Deal. Thursday November 14 2013*. (Online), available online: <http://www.abc.net.au/pm/content/2013/s3891114.htm>.

Joint Standing Committee on Treaties. 2012. *Report 125, Treaty tabled on 21 November 2011, Anti-Counterfeiting Trade Agreement (Tokyo on 1 October 2011)*, Canberra, available online: http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=jsct/21november2011/report.htm (accessed 24 October 2013)

Khor, M. 2005. *WHO Board debates and defers decision on trade and health*, Penang, available online: <http://www.twinside.org.sg/title2/health.info/twinfohealth010.htm> (accessed 9 January, 2013)

Khor, M. 2009. *Row over European seizures of low-cost drugs* (Online), available online: <http://www.twinside.org.sg/title2/resurgence/2009/228-229/health1.htm> (accessed 24 August 2013).

Legge, D. G. 2012. Future of WHO hangs in the balance. *BMJ*, 345, e6877.

Legge, D. G. 2013. *Trade and Health: An Enquiry into the Role of the World Health Organisation in promoting Policy Coherence across the fields of Trade and Health and in particular, the Origins, Implementation and Effectiveness of World Health Assembly Resolution 59.26 on International Trade and Health*, Oslo, available online: <https://www.med.uio.no/helsam/english/research/global-governance-health/background-papers/who-trade.pdf> (accessed March 6, 2014)

Lopert, R. and Gleeson, D. 2013. The high price of "free" trade: US trade agreements and access to medicines. *Journal of Law, Medicine and Ethics*, 41, 199-223.

Love, J. 2009. Who are the cleared advisors that have access to secret ACTA documents?, available online: <http://www.keionline.org/blogs/2009/03/13/who-are-cleared-advisors>.

Medecins Sans Frontieres. 2012. *Trading Away Health: How the U.S.'s Intellectual Property Demands for the Trans-Pacific Partnership Agreement Threaten Access to Medicines. MSF Access Campaign Issue Brief* (Online), available online: http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_TP_P_ENG_2012_update.pdf (accessed 28 May, 2013).

Médecins Sans Frontières 2012. Blank Cheque for Abuse: ACTA and its Impact on Access to Medicines. *MSF Briefing document*.

Moon, S., Bermudez, J. and Hoen, E. t. 2012. Innovation and access to medicines for neglected populations: Could a treaty address a broken pharmaceutical R&D system? *PLoS Med*, 9, e1001218.

Moore, M. 2013. *Trans Pacific Partnership Agreement and public health* Canberra, available online: <http://www.phaa.net.au/documents/131003%20Letter%20to%20Tony%20Abbott%20TPPA.pdf> (accessed 7 April 2014)

Oxfam. 2013. *Putting Public Health at Risk: US Proposals Under the Trans Pacific Partnership Agreement (TPPA) to Exacerbate Vietnam's Access to Medicines Crisis. Ref 05/2013, 4 March 2013.* (Online), available online: <http://www.oxfam.org/sites/www.oxfam.org/files/vietnam-trans-pacific-partnership-agreement-oxfam-mb-040313.pdf> (accessed 11 October 2013).

Paine, L. S. and Santoro, M. 1992. *Pfizer: Global Protection of Intellectual Property*, Harvard Business School.

PhRMA. 2013. *Intellectual property protections are vital to continuing innovation in the biopharmaceutical industry* (Online). Pharmaceutical Research and Manufacturers of America, available online: <http://www.phrma.org/innovation/intellectual-property> (accessed 22 October, 2013).

Productivity Commission. 2010. *Bilateral and Regional Trade Agreements: Productivity Commission Research Report*, Canberra, available online: <http://www.pc.gov.au/projects/study/trade-agreements/report> (accessed 10 October, 2011)

Public Citizen. 2013a. *How the TPP Endangers Access to Affordable Medicines* (Online), available online: <http://www.citizen.org/documents/TPPonepagerfinalmostrecent.pdf> (accessed 11 October 2013).

Public Citizen. 2013b. *What's New in the Wikileaks TPP Text?* (Online). Public Citizen's Global Access to Medicines Program, available online: <http://www.citizen.org/documents/Whats%20New%20in%20the%20WikiLeaks%20TPP%20Text-11.pdf> (accessed 24 November, 2013).

Public Health Association of Australia. 2013. *High stakes for public health in final Trans Pacific trade talks*, Canberra, available online: http://www.phaa.net.au/documents/131203_High%20stakes%20for%20public%20health%20in%20final%20Trans%20Pacific%20trade%20talks.pdf (accessed 7 April 2014)

Public Health Association of Australia, Australian Fair Trade and Investment Network, Australian Federation of AIDS Organisations, Medecins Sans Frontieres Australia, Asia Pacific Network of People Living with HIV/AIDS, Palliative Care Australia and Australian Medical Students' Association. 2013. *Submission to the Department of Foreign Affairs and Trade: The Trans Pacific Partnership Agreement, Intellectual Property and Medicines. 1 October 2013.* available online:

http://www.dfat.gov.au/fta/tpp/subs/tpp_sub_multi_NGO_on_IP.pdf (accessed 11 October 2013).

Roffe, P., Braun, J. V. and Vivas-Eugui, D. 2007. A new generation of regional and bilateral trade agreements: lessons from the US-CAFTA-DR agreement. In: Blouin, C., Heymann, J. and Drager, N. (eds.) *Trade and Health: Seeking Common Ground*. Montreal, Kingston, London, Ithaca: McGill-Queen's University Press.

Saez, C. 2014. *WHO Chief: No Government Should Be Intimidated For Doing "Right Thing"* In *Public Health* (Online). Intellectual Property Watch, available online: <http://www.ip-watch.org/2014/01/24/who-director-general-no-government-should-be-intimidated-by-interested-parties/> (accessed March 30 2014).

Scherer, F. and Watal, J. 2001. Post-TRIPS options for access to patented medicines in developing countries. *Journal of International Economic Law*, Vol. 5, No. 4, pp. 913-939.

Sell, S. K. 2011. TRIPS was Never Enough: Vertical Forum Shifting, FTAs, ACTA and TPP. *Journal of Intellectual Property Law*, 18, 447-478.

Shashikant, S. 2007. *Thailand issues 3 licenses to promote access to medicines* (Online). Third World Network, available online: http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.020705.htm (accessed 22 October 2013).

Shashikant, S. (ed.) 2010. *The IMPACT counterfeit taskforce, intellectual property rights enforcement and seizure of medicines*, Geneva: Third World Network.

Soontarajarn, T. 2006. *Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the Public use of patent for Pharmaceutical Products* (Online). Third World Network, available online: http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.020705.htm (accessed 22 October 2013).

Soos, P. and Lofgren, H. 2013. Financing Pharmaceutical Research and Development: Alternatives to the Patent System. In: Lofgren, H. (ed.) *The Politics of the Pharmaceutical Industry and Access to Medicines: World Pharmacy and India*. New Delhi: Social Science Press.

Third World Network. 2013. *What to expect in TPPA talks* (Online). TWN, available online: <http://www.twinside.org.sg/title2/wto.info/2013/twninfo130702.htm> (accessed 25 October 2013).

Trans Pacific Partnership. 2013. *Intellectual Property (Rights) Chapter - Consolidated Text. Wikileaks Release, November 13, 2013.* (Online), available online: <http://wikileaks.org/tpp/static/pdf/Wikileaks-secret-TPP-treaty-IP-chapter.pdf> (accessed 24 November 2013).

United States Trade Representative. 2011a. *Trans-Pacific Partnership Intellectual Property Rights Chapter (Selected Provisions). September 2011*, available online: <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf> (accessed 18 October 2011)

United States Trade Representative. 2011b. *Trans-Pacific Partnership Intellectual Property Rights Chapter, Draft - February 10, 2011*, available online: <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf> (accessed 14 September 2011)

- Velásquez, G. 2012. *Rethinking The R&D Model for Pharmaceutical Products: A Binding Global Convention*, Policy Brief 8, South Centre, Geneva, available online: <http://www.southcentre.int/policy-brief-8-april-2012/#more-1995> (accessed 28 May, 2014).
- Weatherall, K. G. 2013. *TPP – Australian Section-by-Section Analysis of the Enforcement Provisions of the August Leaked Draft. The Selected Works of Kimberley G Weatherall*. (Online), available online: <http://works.bepress.com/kimweatherall/27/> (accessed 24 November 2013).
- WHO. *Executive Board, 132nd Session, Geneva, 21–29 January 2013, Summary Records, List of Participants* (Online). Geneva: WHO, available online: http://apps.who.int/gb/ebwha/pdf_files/EB132-REC2/B132_REC2-en.pdf (accessed 12 November 2013).
- WHO. 2005a. *Executive Board, 116th Session, Geneva, 26-27 May 2005, Decisions, Summary Records* (Online). Geneva: WHO, available online: http://apps.who.int/gb/ebwha/pdf_files/EB116-REC1/B116_2005_REC1-en.pdf (accessed 12 November 2013).
- WHO. 2005b. *International trade and health* (Online). Geneva: WHO, available online: http://apps.who.int/gb/archive/pdf_files/EB116/B116_4-en.pdf (accessed 12 November 2013).
- WHO. 2006. *Fifty-ninth World Health Assembly, Geneva, 22-27 May 2006, Summary records of committees, reports of committees* (Online). Geneva: WHO, available online: http://apps.who.int/gb/ebwha/pdf_files/WHA59-REC3/WHA59_REC3-en.pdf (accessed 12 November 2013).
- WHO. 2012a. *A65/24. Consultative Expert Working Group on Research and Development: Financing and Coordination* (Online). Geneva: WHO, available online: http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_24-en.pdf (accessed 12 November 2013).
- WHO. 2012b. *EB132/21 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination* (Online), available online: http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_21-en.pdf (accessed 12 November 2013).
- WHO. 2012c. *Sixty-Fifth World Health Assembly, Geneva, 21–26 May 2012, Summary Records of Committees* (Online). Geneva: WHO, available online: http://apps.who.int/gb/ebwha/pdf_files/WHA65-REC3/A65_REC3-en.pdf (accessed 12 November 2013).
- WHO Watch. 2013a. *Medicines and IPRs: access, safety and innovation* (Online). People's Health Movement, available online: <http://www.ghwatch.org/who-watch/topics/ipr> (accessed 22 October 2013).
- WHO Watch. 2013b. *WHO Watch* (Online), available online: <http://www.ghwatch.org/who-watch/about> (accessed 8 April 2013).
- Williams, D. C. 2006. *World health: A lethal dose of US politics* (Online). Asia Times, available online: http://www.atimes.com/atimes/Southeast_Asia/HF17Ae01.html (accessed 25 October 2013).

Williams, O. and Lofgren, H. 2013. The New Political Economy of Pharmaceuticals: Conformity and Resistance in the Global South. In: Lofgren, H. and O., W. (eds.) *The New Political Economy of Drugs: Production, Innovation and TRIPS in the Global South*. London: Palgrave Macmillan.

World Health Assembly. 1999. *WHA52.19 Revised drug strategy* (Online). Geneva: WHO, available online: <http://www.who.int/phi/WHA52.19.pdf> (accessed 12 November 2013).

WTO. 2010. *TRIPS material on the WTO website* (Online), available online: http://www.wto.org/english/tratop_e/trips_e/trips_e.htm (accessed 29 March 2010).

WTO. nd. *Counterfeit* (Online). WTO, available online: http://www.wto.org/english/thewto_e/glossary_e/counterfeit_e.htm (accessed 12 November 2013).

WTO Ministerial Council. 2001. *Declaration on the TRIPS agreement and public health* (Online). WTO, available online: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 30 August 2013).



*Intellectual Property Rights (IPR)