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# Medical law reporter

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## BALANCING PUBLIC HEALTH, TRADE AND INTELLECTUAL MONOPOLY PRIVILEGES: RECENT AUSTRALIAN IP LEGISLATION AND THE TPPA

*Over the past year, several significant reforms to Australia's intellectual property regime have been proposed and passed by Parliament. The Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth) made various improvements to Australian patent law, including an improved threshold for patentability, greater clarity around "usefulness" requirements, and the introduction of an experimental use exemption from infringement. Another Bill, the Intellectual Property Laws Amendment Bill 2012 (Cth), currently out for public consultation, would implement a 2003 decision of the World Trade Organisation (WTO) General Council and the 2005 Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration). If enacted, this Bill would facilitate equitable access to essential medicines by amending the compulsory licensing regime set out in the Patents Act 1990 (Cth). The underlying intention of this Bill – meeting public health goals outlined in the 2005 Doha Declaration – stands in juxtaposition to proposed reforms to intellectual property standards pursuant to the Trans-Pacific Partnership Trade and Investment Agreement (TPPA) that Australia is involved in. Although at a preliminary stage, leaked drafts of relevant intellectual property provisions in the TPPA suggest a privileging of patent monopoly privileges over public health goals. This column weighs the sentiments of the proposed Bill against those of the proposed provisions in the TPPA.*

### INTRODUCTION

Over the past decade, developing and transitional economies, NGOs and civil society have sought to ameliorate the negative impacts on public health policy of neo-liberal trade arrangements, including the World Trade Organisation (WTO) *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS Agreement) and various United States-led preferential trade and investment deals, so as to (re)establish the right of countries to "[take] measures to protect public health".<sup>1</sup> These efforts are viewed by many as culminating in the 2001 *Doha Declaration on the TRIPS Agreement and Public Health* (Doha Declaration),<sup>2</sup> which recognised that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health and in particular to promote access to medicines for all".<sup>3</sup>

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<sup>1</sup> WTO, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Conference, 4th Session, November 2001, WT/MIN(01)/DEC/2 at [4] (Doha Declaration), [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) viewed 25 August 2012. There is extensive debate over the extent to which the TRIPS Agreement, and the WTO rules-based system generally, has entrenched (or helped address) disadvantage and bargaining power imbalances between developed and developing countries. For an introduction see, generally, Henckels C, "The Ostensible 'Flexibilities' in TRIPS: Can Essential Pharmaceuticals be Excluded from Patentability in Public Health Crises?" (2006) 32(2) *Monash University Law Review* 335, <http://www.austlii.edu.au/cgi-bin/sinodisp/au/journals/MonashULawRw/2006/15.html> viewed 24 August 2012; cf the position of Mercurio B, "Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines" (2007) 5 *Northwestern University Journal of International Human Rights* 1, <http://www.austlii.edu.au/cgi-bin/sinodisp/au/journals/UNSWLRS/2007/23.html> viewed 23 August 2012; but also Faunce TA, "Global Intellectual Property

Almost one-third of the world's population lacks access to "essential medicines".<sup>4</sup> These are generally defined as those medicines (and medical preparations) "that satisfy the priority health care needs of the population".<sup>5</sup> Least-developed countries face special challenges combating infectious and chronic disease.<sup>6</sup> For them the societal burden of disease is compounded by the effects of low per capita income, weak institutional governance structures and poor access to health treatment and prevention.<sup>7</sup> With insufficient, or non-existent, manufacturing capacity to produce pharmaceutical products for their own populations, these countries rely on donations from pharmaceutical companies, or fund the import of pharmaceuticals via overseas aid or national debt.<sup>8</sup> International trade agreements, including the *Marrakesh Agreement establishing the World Trade Organisation* (WTO Agreement),<sup>9</sup> arguably restrict the ability of countries to export generic medicines under a compulsory licence, even to countries which lack the capacity to produce their own medical products.<sup>10</sup>

As a response to the challenge of improving access to essential medicines for least-developed and developing countries, the Australian Government has been consulting on a proposed Bill to amend Australia's compulsory licensing regime.<sup>11</sup> This would better allow the export of patented pharmaceutical products, under licence, to certain countries suffering a public health crisis. This Bill, the *Intellectual Property Laws Amendment Bill 2012* (Cth) (the *Proposed IP Bill*),<sup>12</sup> implements Australia's obligations under a 2003 decision of the Council of the World Trade Organisation and a 2005 protocol amending the TRIPS Agreement.<sup>13</sup>

To give context to the stifled passage of the Proposed IP Bill, this column sets out other recent public health-related reforms to the *Patents Act 1990* (Cth) contained within the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (*Raising the Bar Act*). In particular, the smooth implementation of the Raising the Bar reforms contrasts with the delayed passage of the Proposed IP Bill. The delay in the Proposed IP Bill, coupled with the exclusion in the *Raising the Bar Act* of

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Protection for Innovative Pharmaceuticals: Challenges for Bioethics and Health Law" in Bennett B and Tomossy GF (eds), *Globalisation and Health* (Springer, Dordrecht, 2006) pp 87-108.

<sup>2</sup> Doha Declaration; see also WTO, *Ministerial Declaration*, Ministerial Conference, 4th session, adopted 13 November 2001, WT/MIN(01)/DEC/1, [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.pdf](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf) viewed 24 August 2012.

<sup>3</sup> Doha Declaration at [4], [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) viewed 25 August 2012.

<sup>4</sup> "Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines", published in the report to the General Assembly of the United Nations, *Special Rapporteur on the Right to the Highest Attainable Standard of Health*, United Nations document A/63/263, 11 August 2008.

<sup>5</sup> World Health Organisation, *Essential Medicines* (2012), [http://www.who.int/medicines/services/essmedicines\\_def/en/index.html](http://www.who.int/medicines/services/essmedicines_def/en/index.html) viewed 24 August 2012.

<sup>6</sup> *Declaration on the TRIPS Agreement and Public Health* at [1], WT/MIN(01)/DEC/2 (20 November 2001) (Doha Declaration), [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) viewed 25 August 2012.

<sup>7</sup> For example, in only three of 14 surveyed Central African countries were "more than 50% of the drugs that are considered essential ... available from central medical stores": Dobson R, "Children in Central Africa have Access to Few Essential Drugs" (17 January 2009) 338 BMJ 129; UN-OHRLLS, *About LDCs* (2012), <http://www.unohrlls.org/en/ldc/25> viewed 24 August 2012; UN-OHRLLS, *Criteria for Identification and Graduation of LDCs* (2012), <http://www.unohrlls.org/en/ldc/164> viewed 24 August 2012.

<sup>8</sup> See eg Mercurio, n 1; see also Faunce, n 1.

<sup>9</sup> *Marrakesh Agreement establishing the World Trade Organization* (WTO Agreement) done at Marrakesh 1994 (entered into force in Australia 1 January 1995) [1995] ATS 8.

<sup>10</sup> For example, Art 31(f), 31(h), *Annex 1C to the WTO Agreement – Agreement on Trade Related Aspects of Intellectual Property Rights* [1995] ATS 8 (TRIPS Agreement); cf *Doha Ministerial Declaration*, at [6], WT/MIN(01)/DEC/1 (20 November 2001), [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm) viewed 25 August 2012.

<sup>11</sup> Submissions closed on 1 October 2012. However, for reasons discussed below, the Bill is unlikely to undergo significant redrafting prior to its introduction to Parliament.

<sup>12</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth) (Exposure Draft), <http://www.ipaustralia.gov.au/about-us/public-consultations/ip-laws-amendment-bill> viewed 23 August 2012. The Bill also introduces some reforms to the *Plant Breeder's Rights Act 1994* (Cth) that are unrelated to the TRIPS Protocol and are not considered further.

<sup>13</sup> The Protocol Amending the TRIPS Agreement, adopted by the WTO General Assembly WT/L/641 (6 December 2005), [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm) viewed 24 August 2012 (TRIPS Protocol).

compulsory licensing reforms to meet public health goals (despite Australia's agreement to ratify the 2005 *Protocol Amending the TRIPS Agreement* (TRIPS Protocol), suggests there may be persisting ideological opposition to the sentiments within the Proposed IP Bill. The Australian generic medicines industry has lobbied hard for the right to export patented drugs under licence as necessary for its economic survival in the face of imposed compulsory price drops that have advantaged the patented pharmaceutical industry as championed in Australia by the lobby group Medicines Australia.<sup>14</sup> Support for the Proposed IP Bill particularly may wane if Australia chooses to support proposed provisions contained within the *Trans-Pacific Partnership Trade and Investment Agreement* (TPPA) that valorise enhanced intellectual monopoly privileges (IMPs) over obligations to national and global public health contained within the Doha Declaration.<sup>15</sup> This column explores the tensions implicit in achieving a better balance between public health, trade and intellectual property in this context.

## RECENT REFORM OF THE AUSTRALIAN INTELLECTUAL PROPERTY SYSTEM

The *Raising the Bar Act* passed into law with the Governor-General's assent on 15 April 2012. Most provisions in the *Raising the Bar Act* come into effect on 15 April 2013; however, exemptions for researchers and regulatory use apply from 16 April 2012.<sup>16</sup>

A key feature of the reforms is an "experimental use" exemption that allows researchers to conduct genuine scientific inquiry without worrying about patent infringement.<sup>17</sup> This includes work on improving a patented invention (but does not include commercialisation until the patent expires or lapses). A research exemption in Australia, whether it exists under common law, requires legislative form or might be influenced by apparently contrary developments in the United States, has long been discussed in the literature.<sup>18</sup> The ability of publicly funded Australian scientists, or those working for Australian companies, to experiment free from the threat of patent infringement or from the tax of patent licences is critical to their capacity to develop innovation that can be scientifically proven to benefit the community and its environment, as well as creating the preconditions for a robust science and industrial sector. The notion particularly to be opposed was that universities were primarily profit-making institutions and so any research by their employees on a patented substance (even if in no way designed to produce a marketable product) was in fact a compensable exploitation of the patent. Such a view, achieving some currency in the United States,<sup>19</sup> disregards the trade-off of rapid distribution of knowledge to the public that has always been central to the accord of intellectual monopoly privileges such as patents.

To provide clarity for researchers, an inclusive list of activities that are deemed to be experimental has been included in s 119C of the *Patents Act 1990* (Cth). The following activities are exempt:

- determining the properties of the invention;
- determining the scope of a patent claim relating to the invention;
- improving or modifying the invention;
- determining the validity of the patent or of a patent claim relating to the invention; and
- determining whether the patent for the invention would be, or has been, infringed by the doing of an act.

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<sup>14</sup> Faunce TA, Bai J and Nguyen D, "Impact of the Australia-US Free Trade Agreement on Australian Medicines Regulation and Prices" (2010) 7(1) *Journal of Generic Medicines* 18.

<sup>15</sup> Text purporting to be the draft IP chapter can be found at <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf> while the purported draft investment chapter can be found at <http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf> viewed 24 September 2012.

<sup>16</sup> *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth), s 2.

<sup>17</sup> New s 119C, *Patents Act 1990* (Cth). See also *Patents Act 1990* (Cth), s 119B.

<sup>18</sup> Nicol D and Nielsen J, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (Centre for Law and Genetics, Occasional Paper No 6, 2003); Faunce, n 1, p 97; *Madey v Duke University* 307 F 3d 1351 (2002).

<sup>19</sup> But see *University of Western Australia v Gray (No 20)* [2008] FCA 498 at [160] (French J); Vines T and Faunce T, "University of Western Australia v Gray: An Academic Duty to Commercialise Research?" in "Medical Law Reporter" (2008) 16 JLM 419.

This list is not intended to be exhaustive. A court may find other activities also fall within the meaning of “experimental”. The exemption does not apply to research tools.<sup>20</sup>

The experimental use exemption was a recommendation of the Australian Law Reform Commission’s *Genes and Ingenuity: Gene Patenting and Human Health* report (2004) and the Senate Community Affairs Reference Committee inquiry into Gene Patents (2010).<sup>21</sup> The enacted exemption can be seen as a response, in part, to the ongoing gene patent debate and the attention this debate has drawn to academic freedom.<sup>22</sup> It is important to note that the experimental use exemption does not excuse potentially infringing acts that occurred prior to 16 April 2012.<sup>23</sup> Moreover, commentators and politicians have also expressed concerns that, despite the best intentions of IP Australia, the experimental use exemption as drafted may not be sufficiently broad to protect all research and educational activities in Australian publicly funded universities.<sup>24</sup>

The *Raising the Bar Act* also introduced a higher threshold of patentability by

- broadening the “prior art base” from Australia to the world;<sup>25</sup>
- improving the definition of the term “useful” so that an invention “is taken not to be useful unless a specific, substantial and credible use for the invention (so far as claimed) is disclosed in the complete specification”;<sup>26</sup> and
- providing that the Commissioner for Patents must only accept an application for a standard patent if satisfied of several factors “on the balance of probabilities”.<sup>27</sup>

It is to be hoped that these changes, not due to commence until April 2013, will have a more immediate impact on Australian public health than the new experimental use exemption, given the taxpayer largesse now accorded patent medicines since the splitting of the Pharmaceutical Benefits Scheme (PBS) formulary into F1 (patented) and F2 (generic categories) with restricted reference pricing between them.<sup>28</sup> While the stated aim of the *Raising the Bar Act* reforms is to “raise patent standards”,<sup>29</sup> the reforms themselves appear not to go as far as they could in preventing evergreening

<sup>20</sup> “Research tools” can be defined as “resources used by scientists, where those resources have no immediate therapeutic or diagnostic values”: Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (Canberra, 2004). IP Australia defines “Research tools” as something that “facilitates an experiment, and is not the subject of the experiment”: IP Australia, *Experimental Use Exemption from Patent Infringement* (15 September 2012), <http://www.ipaustralia.gov.au/about-us/public-consultations/ip-reforms/factsheet-experimental-use> viewed 22 September 2012.

<sup>21</sup> Australian Law Reform Commission, n 20, Recommendation 13-1; Australian Parliament, Senate Community Affairs Reference Committee, *Gene Patents* (Canberra, 2010) at [5.195].

<sup>22</sup> See eg Australian Law Reform Commission, n 20; Australian Parliament, Senate Community Affairs Reference Committee, n 21. Some supporters of gene patenting see the *Raising the Bar Act* as the solution to the gene patents debate. This in contrast to the position of IP Australia which stated that the *Raising the Bar Act* “does not deal with gene specific issues”: *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* (Cth), Explanatory Memorandum; cf the statements of witnesses before the Senate Legal and Constitutional Affairs Legislation Committee, *Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010*, [http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Committees?url=legcon\\_ctte/patent\\_amendment/hearings/index.htm](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Committees?url=legcon_ctte/patent_amendment/hearings/index.htm) viewed 22 September 2012.

<sup>23</sup> Infringement proceedings must be started within six years of the day on which the infringing activity was done: *Patents Act 1990* (Cth), s 120(4)(b).

<sup>24</sup> For example, House of Representatives, *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*, Second Reading Speech (Melissa Parke MP) (19 March 2012) p 3422.

<sup>25</sup> See *Patents Act 1990* (Cth), Sch 1.

<sup>26</sup> *Patents Act 1990* (Cth), s 7A.

<sup>27</sup> *Patents Act 1990* (Cth), s 49(1) (not commenced). This amendment introduces the “balance of probabilities” test for the first time; currently the Act implies that a patent application must be presumed valid.

<sup>28</sup> See Faunce et al, n 14.

<sup>29</sup> Senate, *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* (Cth), Second Reading Speech (Senator Kim Carr, Minister for Innovation, Industry, Science and Research) (22 June 2011) p 3485.

strategies by patent holders, especially in the pharmaceutical space, as they do not restrict patents for new forms, uses or packaging.<sup>30</sup> This is an important limitation that is explored below in the context of the proposed IP chapter of the TPPA.

The *Raising the Bar Act* introduces much-needed, albeit prospective, reforms to Australia's patents and the regulation of patent attorneys, but does not alter the existing arrangements for the non-voluntary use or acquisition of patents, such as compulsory licensing.<sup>31</sup> By contrast, the Proposed IP Bill will introduce a new form of compulsory licence: one designed to address the needs of least-developed and developing countries better, particularly those that lack their own generic medicines manufacturing capacity and one which might yet provide a spur to a revival in the economic fortunes and health security afforded by a robust generic manufacturing industry in this nation.

## THE INTELLECTUAL PROPERTY LAWS AMENDMENT BILL 2012 (CTH)

The Proposed IP Bill was a long time in the making. Australia accepted the TRIPS Protocol in September 2007 and the Parliamentary Joint Standing Committee on Treaties (JSCOT) supported future efforts to implement appropriate legislation. In April 2010, IP Australia released an options paper, with submissions due by October 2010.<sup>32</sup> In March 2011, then Minister for Innovation Senator Kim Carr and the Minister for Trade Dr Craig Emerson MP announced that the Labor Government would introduce legislation to give effect to the TRIPS Protocol by the end of 2011.<sup>33</sup>

This announcement appeared to surprise the pharmaceutical industry and patent attorneys,<sup>34</sup> which may explain why the draft legislation did not eventuate until August 2012. "Originator" pharmaceutical companies and the United States Government, while not opposing the TRIPS Protocol outright, have previously sought to restrict the possible therapeutic products available under the scheme<sup>35</sup> – an approach rejected by NGOs and generic pharmaceutical companies as inflexible and unwieldy. The domestic patented pharmaceutical industry's lobbying may have delayed the preparation of the final draft Bill. Alternatively, the 2012 ministerial reshuffle (which saw Senator Kim Carr demoted from the ministry) may have been pivotal to the delay. It is notable, however, that efforts by the Australian generic pharmaceutical industry to expand overseas markets in patent-expired jurisdictions by introducing a provision allowing manufacture here for export there, had been rebuffed prior to the proposed Bill.

Submissions on the current Exposure Draft closed on 1 October 2012 with "no extensions possible".<sup>36</sup> In light of the previous consultation rounds, an inflexible timetable for submissions on the Exposure Draft, the political capital required to seek government approval to any further amendments,

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<sup>30</sup> Faunce TA, Vines T and Gibbons H, "New Forms of Evergreening in Australia: Misleading Advertising, Enantiomers and Data Exclusivity" in "Medical Law Reporter" (2008) 16 JLM 220.

<sup>31</sup> For an introduction to Australia's compulsory licensing regime see Nielsen J and Nicol D, "Whither Patent Use Without Authorisation in Australia?" (2008) 36(3) Fed L Rev 331, <http://www.austlii.edu.au/cgi-bin/sinodisp/au/journals/FedLawRw/2008/14.html> viewed 24 August 2012; Lawson C, "Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition" (2002) 30 Fed L Rev 97, <http://www.austlii.edu.au/cgi-bin/sinodisp/au/journals/FedLawRw/2002/4.html> viewed 23 August 2012. The compulsory licence regime is currently under review by Australia's Productivity Commission: Bradbury D (MP) and Dreyfus M (MP), "Balancing Access to Technology and Innovation", *Media Release* (29 June 2012), <http://ministers.treasury.gov.au/DisplayDocs.aspx?doc=pressreleases/2012/059.htm&pageID=003&min=djba&Year=&DocType=0> viewed 25 August 2012.

<sup>32</sup> IP Australia, *IP Laws Amendment Bill* (2012), <http://www.ipaustralia.gov.au/about-us/public-consultations/ip-laws-amendment-bill> viewed 25 August 2012.

<sup>33</sup> Carr, Senator Kim, "Better Access to Medicines for Countries in Need", *Media Release* (22 March 2011), <http://archive.innovation.gov.au/ministersarchive2011/carr/MediaReleases/Pages/BETTERACCESSTOMEDICINESFORCOUNTRIESINNEED.html> viewed 25 August 2012.

<sup>34</sup> Summerfield M, "Surprise! New Pharmaceutical Compulsory Licenses Proposed" (23 March 2011) *Patentology*, <http://blog.patentology.com.au/2011/03/surprise-new-pharmaceutical-compulsory.html> viewed 25 August 2012.

<sup>35</sup> Henckels, n 1 at 354.

<sup>36</sup> IP Australia, n 32.

and the desire to pass the Bill before the 2013 federal election, it is unlikely that the Bill will change significantly prior to its tabling in Parliament early in 2013.

The proposed Bill appears cognisant of the interminable process of multilateral trade negotiations. Schedule 1 of the Bill implements the – still in force – WTO General Council Decision of 30 August 2003 and comes into force approximately six months after the day the Act receives Royal Assent.<sup>37</sup> Schedule 2 of the Bill would implement the TRIPS Protocol but only commences on “the later of”:

- (a) immediately after the start of the day after the end of the period of 6 months beginning on the day this Act receives the Royal Assent; and
- (b) immediately after Article 31*bis* of the Agreement on Trade-Related Aspects of Intellectual Property Rights set out in Annex 1C to the Marrakesh Agreement establishing the World Trade Organization, done at Marrakesh on 15 April 1994, enters into force for Australia.

However, the provision(s) do not commence *at all* if the event mentioned in paragraph (b) does not occur.<sup>38</sup>

Given action to date on the international scene, it is possible, even likely, that Sch 2 to the Bill will never come into force.

Key to the proposed reforms is the introduction of the concept of a “patented pharmaceutical invention” (PPI), which means:

- (a) if the product is a patented product – the patented product; or
- (b) if the product results from the use of a patented process – the patented process.<sup>39</sup>

“Pharmaceutical product” is exhaustively defined under the Proposed IP Bill as “any patented product, or product manufactured through a patented process, of the pharmaceutical sector”.<sup>40</sup> The TRIPS Protocol clarifies that members “understand” that the term “pharmaceutical products” includes “active ingredients necessary for its manufacture and diagnostic kits needed for its use”.<sup>41</sup> The Proposed IP Bill does not replicate this understanding in the legislative provision, but lists “active ingredients” and “diagnostic kits” as examples of pharmaceutical products.<sup>42</sup>

Similar to Australia’s existing compulsory licence regime, under the proposed s 136(C) a “person” (the “PPI order applicant”) applies to the Federal Court for a “PPI order” to grant a “PPI compulsory licence” to “work the invention for the purposes of manufacturing a pharmaceutical product in Australia for export to an eligible importing country”.<sup>43</sup>

Perhaps motivated by a desire to ensure Australia’s regime is seen to comply with the TRIPS Protocol, a PPI order applicant must furnish the court with

a statement made by or on behalf of, and with the authorisation of, the eligible importing country to the effect that it will take reasonable measures within its means, proportionate to its administrative capacities and to the risk of trade diversion, to prevent re-exportation from its territory of a pharmaceutical product imported into its territory in accordance with a PPI compulsory licence.<sup>44</sup>

How a court treats this statement remains a matter for conjecture. Presumably any statement will be by way of affidavit but, if it is made by a (presumably authorised) member of the “eligible importing country”, there may not be an opportunity for the court or patentee to cross-examine or interrogate the statement-maker. How will the truth of the attested facts be determined?<sup>45</sup> Would the Federal Court be willing to determine, for instance, whether measures proposed by Rwanda to prevent

<sup>37</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), s 2(1) (Exposure Draft).

<sup>38</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), s 2(1) (Exposure Draft) (emphasis added).

<sup>39</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 27 (Exposure Draft).

<sup>40</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 28 (Exposure Draft).

<sup>41</sup> Annex to the TRIPS Agreement, at [1(a)].

<sup>42</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 28 (Exposure Draft).

<sup>43</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136C(1) (Exposure Draft).

<sup>44</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136C(3) (Exposure Draft).

<sup>45</sup> For instance, would it be sufficient to table any relevant foreign laws and by-laws? See eg *Evidence Act 1995* (Cth), s 174.

re-exportation are “reasonable” and “proportionate to its administrative capacity”?<sup>46</sup> Commentators have questioned the expertise, and enthusiasm, of the Federal Court to determine appropriate royalty rates in other intellectual property matters;<sup>47</sup> the determination of a country’s financial and administrative capabilities would appear even less evidence-based and, indeed, a much more arbitrary and abstract concept.

Moreover, the need to call expert witnesses or the representatives of foreign governments, assuming they are willing to testify,<sup>48</sup> will delay the application process, increase the cost and complexity of the application, potentially expose foreign governments to embarrassment and undermine the intent of the scheme. A hypothetical example might involve struggling country X struck by epidemic Y, but its administrators being too proud to testify that Y is greater than X, thus causing the scheme to not succeed in distributing required essential medications.

While it may be tempting to dismiss s 136C as a “tick-and-flick” exercise, this seems inconsistent with the Bill’s language. First, proposed s 136D of the Bill requires the Federal Court to be “satisfied” that the application is, among other things, “made in good faith”.<sup>49</sup> This finding can only occur “after hearing an application under section 136C”,<sup>50</sup> suggesting that the statement in s 136C has a significant role in determining the question of whether the application is in good faith.

There are several options open to Parliament – or IP Australia – to clarify the intent of the Bill. For example, s 136C of the Bill could be amended to provide a rebuttable presumption that, first, the statement was made “by or on behalf of, and with the authorisation of” an “eligible importing country”; and, secondly, that a statement about a fact relating to the “administrative capacities” of an eligible importing country is evidence of those facts.

Alternatively, s 136C could be deleted from the Bill and, instead, introduced, in a modified form, in the regulations prescribed under s 136D(2). This would allow the court to consider the matters raised in the statement but reduce its salience in determining whether an application was made “in good faith”.<sup>51</sup>

A final option is for the Federal Court to develop a rule or practice direction to guide practitioners and applicants (who may be NGOs acting on behalf of the eligible importing country) on both the form and expected content of a statement made under s 136C.

Section 136D(1) of the Bill sets out other matters on which the court must be satisfied, including:

- (a) the application is made in good faith;
- (b) the pharmaceutical product is to be imported:
  - i. by the eligible importing country; or
  - ii. on behalf of, and with the authorisation of, the eligible importing country;
- (c) the proposed use of the pharmaceutical product is to address a public health problem in the eligible importing country:
  - i. in circumstances of national emergency, or other circumstances of extreme urgency, in that country; or
  - ii. in other circumstances – by the public non-commercial use of the pharmaceutical product in that country;

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<sup>46</sup> Rwanda was the first country to use the 2003 waiver to import Apo-TriAvir, manufactured and exported under a compulsory licence issued in Canada. The licence was granted in September 2007, although it took another 12 months before the drugs were shipped: Canadian Department of Foreign Affairs and International Trade, *Trade and Intellectual Property* (January 2012), [http://www.international.gc.ca/trade-agreements-accords-commerciaux/fo/trips\\_agree.aspx](http://www.international.gc.ca/trade-agreements-accords-commerciaux/fo/trips_agree.aspx) viewed 27 August 2012. The Canadian reforms allow the Commissioner for Patents, rather than a judicial officer, to grant the required compulsory licence.

<sup>47</sup> Nielsen and Nicol, n 31.

<sup>48</sup> It is optional – at the election of the country – for the eligible importing country to be a party to an application under s 136C: *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136C(4) (Exposure Draft).

<sup>49</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136D(1)(a) (Exposure Draft).

<sup>50</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136D(1) (Exposure Draft) (emphasis added).

<sup>51</sup> This would also support the objective of the *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136D(1)(g) (Exposure Draft).

(d) working the patented pharmaceutical invention is necessary to enable the import and proposed use of the pharmaceutical product as mentioned in paragraphs (b) and (c);

...

(e) the PPI order applicant and the eligible importing country will take reasonable measures to prevent a pharmaceutical product that is exported from Australia in accordance with a PPI compulsory licence from being used for a purpose other than the purpose of addressing the public health problem mentioned in paragraph (c).

Except in “circumstances of national emergency, or other circumstances of extreme urgency”, a PPI applicant must attempt to negotiate a voluntary licence with the patentee on “reasonable terms and conditions”.<sup>52</sup>

If granted, a PPI compulsory licence is subject to stringent, minimum conditions, including that:

- (a) no more than the quantity of the pharmaceutical product that is determined by the Federal Court to be necessary to meet the needs of the eligible importing country is manufactured;
- (b) the entirety of the pharmaceutical product manufactured for that purpose is exported to that country;
- (c) the pharmaceutical product is labelled and marked in accordance with the regulations;
- (d) before shipment of the pharmaceutical product begins, the shipment information prescribed by the regulations is made available on a website by, or on behalf of, the licensee for a minimum period prescribed by the regulations;
- (e) the duration of the licence is only for the period of time determined by the Federal Court to be necessary to address the public health problem concerned;
- (f) the licence does not give the licensee, or a person authorised by the licensee, the exclusive right to work the patented pharmaceutical invention;
- (g) the licence is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used;
- (h) the licensee must give the Commissioner the information prescribed by the regulations in relation to the licence in accordance with the regulations.<sup>53</sup>

A “person” may apply to the Federal Court to revoke a PPI compulsory licence,<sup>54</sup> and the court may revoke the licence if “satisfied” that:

- (a) either:
  - i. the substantive circumstances that justified the grant of the licence have ceased to exist and are unlikely to recur; or
  - ii. the licensee has not complied with the terms of the licence; and
- (b) the legitimate interests of the licensee or the eligible importing country are not likely to be adversely affected by the revocation.

It is worth noting that, while there is a nexus between a breach of licence conditions imposed under proposed s 136E and revocation, no such connection exists in relation to the statement required under s 136C(1). Thus, the value of that statement appears even further reduced.

Imposing conditions on the PPI compulsory licence will require the court to stray into the fields of public health, including epidemiology, and humanitarian development and to engage in forecasting, as it determines the appropriate quantity of pharmaceutical products to be exported under the licence. Failure by the court to determine an appropriate quantity may have significant financial impacts on the applicant (and disastrous impacts on a population), as a new application would be required to amend the terms of a PPI compulsory licence relating to, among other things “the quantity of the pharmaceutical product concerned ... and the duration of the licence”.<sup>55</sup> An amendment would only be granted where the court was satisfied that

- (a) it is just to do so in all the circumstances; and

<sup>52</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136D(1)(e) (Exposure Draft). See *Intellectual Property Laws Amendment Bill 2012* (Cth), proposed s 136P (Exposure Draft). A PPI order cannot be sought until the end of 30 days after the service of notice under proposed s 136D(1)(e).

<sup>53</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136E(1) (Exposure Draft).

<sup>54</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136L(1) (Exposure Draft).

<sup>55</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136G(1)(a), (c) (Exposure Draft).



- (b) the legitimate interests of the following are not likely to be adversely affected by the amendment of the term:
- i. the patentee;
  - ii. any person claiming an interest in the patent as exclusive licensee or otherwise;
  - iii. the licensee;
  - iv. the eligible importing country.<sup>56</sup>

Remuneration is payable to the patentee, with the parties to attempt to negotiate an agreed fee.<sup>57</sup> In the event of a disagreement, the Federal Court is to determine “adequate remuneration taking into account the economic value to the eligible importing country of the use authorised by the PPI compulsory licence”.<sup>58</sup> In the event of a PPI application, there will be considerable interest in what constitutes “adequate” remuneration: in particular, whether it differs from the requirement for “just and reasonable” terms payable by a licensee seeking a non-PPI compulsory licence;<sup>59</sup> and the extent to which the court takes account of the margin profit usually enjoyed by patentees.

In line with the existing compulsory licensing regime, an order cannot be made under this Part that is “inconsistent with a treaty between the Commonwealth and a foreign country”.<sup>60</sup> This means the court will need to consider current treaties, including the TRIPS Agreement, the *Australia–United States Free Trade Agreement* (AUSFTA)<sup>61</sup> and any future trade agreement. AUSFTA included provision which actually restricted Australia’s ability to reform compulsory licensing, limiting their grant to situations of “public health emergency” or anti-competitive behaviour. AUSFTA also included ambiguous data exclusivity provisions (all backed by a non-violation nullification of benefits clause) in provisions of Ch 17. As a post-Doha Declaration agreement, it is disappointing (but not surprising) that AUSFTA does not reference the broader, pro-public health provisions of the Declaration.<sup>62</sup>

Finally, an amendment to the *Patents Act 1990* (Cth) is to be introduced via the Proposed IP Bill to preserve the ability of a pharmaceutical company to seek patent extension under the *Patents Act 1990* (Cth), where the first inclusion of “goods that contain, or consist of, a pharmaceutical substance” on the Australian Register of Therapeutic Goods was for the sole purpose of exporting the goods from Australia under the TRIPS Protocol system.<sup>63</sup>

## THE NEED FOR REFORM: BACKGROUND TO THE 2005 PROTOCOL TO THE TRIPS AGREEMENT

The merits of the Proposed IP Bill can be evaluated by looking at more detail in its public health background in the Doha Declaration and its associated texts. For public health advocates, the Doha Declaration’s significance comes from its impact on WTO law and, perhaps more keenly, its symbolism. The Doha Declaration “recognized that public health issues can take precedence over the rights of private intellectual property holders” and, according to one commentator, this was the first time “international health and development was discussed at every level of WTO governance”.<sup>64</sup> For least-developed, developing and middle-income economies, the Doha Declaration provided a mechanism to address the excesses of TRIPS and the WTO rules-based regime.<sup>65</sup> India heralded the adoption of the Doha Declaration as the “the most important single achievement of the Doha Round”,

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<sup>56</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136G(2) (Exposure Draft).

<sup>57</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136P(3)(a) (Exposure Draft).

<sup>58</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136P(3)(b) (Exposure Draft) (emphasis added).

<sup>59</sup> *Patents Act 1990* (Cth), s 133(5)(a), (b).

<sup>60</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136R (Exposure Draft).

<sup>61</sup> *Australia–United States Free Trade Agreement* done at Washington, 18 May 2004 (entered into force in Australia 1 January 2005) [2005] ATS 1 (AUSFTA).

<sup>62</sup> Faunce et al, n 14.

<sup>63</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 70(5) (Exposure Draft).

<sup>64</sup> Mercurio, n 1; and see also Faunce, n 1.

<sup>65</sup> Henckels, n 1.

while the Philippines effusively called it “the crowning glory of the WTO’s contribution to global welfare and humanitarian concerns”.<sup>66</sup> The Doha Declaration has been called “a bill of rights for the public health regulation of medicines”.<sup>67</sup> Yet it has also been termed “an exercise in civil society distraction from the fundamental lack of involvement of WTO processes and texts in the great public health crises that currently confront humanity”.<sup>68</sup>

Indeed, while posterity may reflect favourably on the ideals behind the Doha Declaration, its highly contentious birth highlights the ongoing normative strength of multinational corporate interests within the international-trade space. Its development was spurred by a legal dispute between South Africa and 39 pharmaceutical companies over the legality of the Republic of South Africa’s *Medicines Act 1997*.<sup>69</sup> The South African *Medicines Act* allowed parallel importation of generic medicines to address, among other matters, South Africa’s HIV/AIDS epidemic. In one of the great public relations disasters of all time, South African President Nelson Mandela was named as a defendant. The United States Government initially supported this action, but later withdrew its support in the face of public criticism. In a twist of fate, the United States Democratic Party, members of which initially supported the lawsuit against South Africa, are now pushing again for stronger patent rights at the expense of developing countries.<sup>70</sup>

Moreover, a last-minute deadlock between developed economies and other WTO members was, reportedly, only broken after African nations mounted a highly public campaign whose centrepiece was statistics outlining the number of children in least-developed and developing countries who had died from treatable diseases during the overdrawn negotiations.<sup>71</sup>

The Canadian Ambassador’s statement that “[The African countries] showed that the poorest among us do make a difference in this organization ... [t]hey helped the WTO find its heart and soul”<sup>72</sup> was perhaps also a reflection on the cold and impersonal nature of a rules-based free trade system, which can – at least out of the public eye – sustain “a crude balancing test weighing up the relative value of the lives of HIV-AIDS sufferers in sub-Saharan Africa versus the economic interests of the corporation that invented the pharmaceutical”.<sup>73</sup>

Notwithstanding its controversial origins, the Doha Declaration reinforces the “flexibility” provisions of TRIPS, recognising that:

- (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

<sup>66</sup> Quoted in Mercurio, n 1; see also Faunce, n 1.

<sup>67</sup> Drahos P and Henry D, “The Free Trade Agreement Between Australia and the United States” [2004] 328 BMJ 1271 (Editorial). Of course, a Bill of Rights does not, by itself, overcome entrenched discrimination and inequality without political will to implement its provisions.

<sup>68</sup> Faunce T, “Innovation and Insufficient Evidence: The Case for a WTO Agreement on Health Technology Safety and Cost-effectiveness Evaluation” in Rubenstein K, Pogge T and Rimmer M (eds), *Incentives for Global Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, Melbourne, 2010) p 227.

<sup>69</sup> t Hoen EFM, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, <http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf> viewed 27 August 2012; Rimmer M, Submission to the Joint Standing Committee on Treaties Inquiry into the Hong Kong Amendment to the TRIPS Agreement, [http://www.aph.gov.au/Parliamentary\\_Business/Committees/House\\_of\\_Representatives\\_Committees?url=jsct/9may2007/subs/sub2.pdf](http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=jsct/9may2007/subs/sub2.pdf) viewed 27 August 2012.

<sup>70</sup> Rimmer M, “A Mercurial Treaty: The Trans-Pacific Partnership and the United States”, *The Conversation* (15 June 2012), <http://theconversation.edu.au/a-mercurial-treaty-the-trans-pacific-partnership-and-the-united-states-7471> viewed 22 September 2012).

<sup>71</sup> Faunce, n 1.

<sup>72</sup> Quoted in Mercurio, n 1.

<sup>73</sup> Henckels, n 1 at 351.

- (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN [most favoured nation] and national treatment provisions of Articles 3 and 4.<sup>74</sup>

Further, the Ministerial Conference instructed the TRIPS Council to determine an “expeditious solution” for countries facing difficulties in making “effective use” of compulsory licensing. The need for a solution arises because, while Art 31 of TRIPS recognises the right of countries to issue compulsory licences, Art 31(f) imposes a restriction that “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”. This creates uncertainty for countries seeking to export a pharmaceutical product to a third country under a compulsory licence.<sup>75</sup> In 2003, the WTO General Council agreed to an interim waiver of Art 31(f) and (h), to enable pharmaceuticals to be exported under compulsory licence to least-developed countries and other eligible countries.<sup>76</sup> In 2005 the General Council made this waiver permanent via the TRIPS Protocol, and referred the amendment of the TRIPS Agreement to members for “acceptance”.<sup>77</sup>

The TRIPS Protocol would amend the compulsory licensing flexibilities established under Art 31(f) of the TRIPS Agreement by introducing a new Art 31*bis* and Annex to the TRIPS Agreement.<sup>78</sup> Under the TRIPS protocol, a compulsory licence for export may be issued for “products of the pharmaceutical sector” needed to address the public health concerns or for “non-commercial public use”.<sup>79</sup> Export of the licensed product must be to least-developed countries or a country that has notified the Council of TRIPS of its intention to access the system and lacks sufficient manufacturing capacity of its own.<sup>80</sup> Both importing and exporting countries are required to supply various details to the TRIPS Council, including the name of the licensee, the pharmaceutical product and the quantities required and any conditions imposed on the licence.<sup>81</sup>

To reduce the likelihood that imported pharmaceuticals are redirected to other markets – ie re-exported to a country that is not an eligible importing country – the TRIPS protocol requires that:

eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system.<sup>82</sup>

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<sup>74</sup> Doha Declaration, at [5], [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) viewed 25 August 2012.

<sup>75</sup> This uncertainty was also identified in, inter alia, Nielsen and Nicol, n 31.

<sup>76</sup> *General Council Decision of 30 August 2003 on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 and Corr 1, [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm) viewed 16 August 2012. A brief chronology is set out in Commonwealth of Australia, *Regulatory Impact Statement – Export of Patented Pharmaceuticals to Countries Experiencing a Health Crisis* (August 2011), <http://ris.finance.gov.au/2011/08/15/export-of-patented-pharmaceuticals-to-countries-experiencing-a-health-crisis-%E2%80%93-regulation-impact-statement-ip-australia> viewed 27 August 2012.

<sup>77</sup> Protocol Amending the TRIPS Agreement, WT/L/641 (8 December 2005).

<sup>78</sup> WTO, *Amendment of the TRIPS Agreement*, [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm) viewed 25 August 2012.

<sup>79</sup> Annex to the TRIPS Agreement, at [1(a)], [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm) viewed 25 August 2012.

<sup>80</sup> Annex to the TRIPS Agreement, Appendix, [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm) viewed 25 August 2012.

<sup>81</sup> Annex to the TRIPS Agreement, at [2].

<sup>82</sup> Annex to the TRIPS Agreement, at [3].

This final obligation is already reflected in the TRIPS Agreement and, in a previous form, has been criticised by NGOs, including Médecins Sans Frontières, as an onerous requirement that is a further disincentive for companies seeking to pursue compulsory licences under the regime.<sup>83</sup>

To date, the European Union, Norway, The Netherlands, Switzerland, Canada, China, India and South Korea have accepted the TRIPS Protocol.<sup>84</sup> The Protocol will come into force when two-thirds of WTO members have accepted the amendment.<sup>85</sup> Following public consultation, and an inquiry by the Joint Standing Committee on Treaties (JSCOT), Australia accepted the terms of the TRIPS Protocol in September 2007.<sup>86</sup> IP Australia then began a consultation process on the *Proposed IP Bill* that would allow Australia to be an eligible “exporting country” under the TRIPS Protocol.

## A STILLBORN REFORM? IMPACTS OF “TRIPS-PLUS” AGREEMENTS ON THE PROPOSED BILL

It is anticipated that the Proposed IP Bill will pass into law some time in 2013. Less certain is whether it or the TRIPS Protocol system as a whole will deliver more affordable medicines and address the growing burden on non-communicable disease in developing countries, while protecting Australia’s health security by spurring a competitive domestic generic pharmaceutical industry. To be successful, the new compulsory licensing system must not only operate more effectively than the existing compulsory licensing regime, it must also accommodate a change in focus from responding to malaria, HIV/AIDS and tuberculosis epidemics to assisting least-developed and developing countries to deal with hypertension, asthma, diabetes and other chronic, non-communicable diseases.<sup>87</sup>

An initial hurdle is the compulsory licence regime itself. Academics,<sup>88</sup> the Productivity Commission,<sup>89</sup> Australian Law Reform Commission<sup>90</sup> and judicial officers have all identified the weaknesses in Australia’s compulsory licence provisions, namely that they are “cumbersome and expensive to apply”.<sup>91</sup> There is a view that the compulsory licence provisions do not need to be used to be effective; rather, the threat of them is enough to achieve a positive outcome.<sup>92</sup> This argument has been challenged on the basis that, because compulsory licence provisions have never been successfully invoked in Australia (and rarely in comparable jurisdictions),<sup>93</sup> the threat they represent is illusory.<sup>94</sup> This may not always be the case, as threats such as bioterrorist attack, SARS, and avian influenza soon may render them of critical public health significance.

<sup>83</sup> Joint Standing Committee on Treaties (JSCOT), *Report 86: Treaties tabled on 27 March and 9 May 2007*, Ch 9, Protocol amending the TRIPS Agreement (Geneva, 6 December 2005) at [9.17], [9.18] (August 2007), [http://www.aph.gov.au/Parliamentary\\_Business/Committees/House\\_of\\_Representatives\\_Committees?url=jscot/9may2007/report/chapter9.pdf](http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=jscot/9may2007/report/chapter9.pdf) viewed 25 August 2012.

<sup>84</sup> Commonwealth of Australia, n 76 at [39]. The European Parliament, however, expressed concern over the effectiveness of the Protocol and deferred its acceptance: JSCOT, n 83 at [9.28].

<sup>85</sup> WTO Treaty, Art X, at [(3)].

<sup>86</sup> The Committee did, however, accept the criticism of the Protocol’s effectiveness put forward by Dr Matthew Rimmer of the Australian National University: JSCOT, n 83 at [9.40]; Commonwealth of Australia, n 76 at [14], [15].

<sup>87</sup> “90% of deaths from non-communicable diseases now occur in low and middle income countries” and “more people in developing countries currently die from chronic diseases ... than from infectious diseases such as AIDS, malaria, and tuberculosis”: Moszynski P, “High Cost of Essential Drugs Forces Millions into Poverty Every Year” (13 December 2011) 343 *BMJ* d8108 (News).

<sup>88</sup> Nielsen and Nicol, n 31.

<sup>89</sup> Productivity Commission, *Compulsory Licensing of Patents – Issue Paper* (9 August 2012), <http://www.pc.gov.au/projects/inquiry/patents/issues> viewed 19 November 2012.

<sup>90</sup> The Australian Law Reform Commission was unaware of any compulsory licences that had been granted since Federation: Australian Law Reform Commission, n 20 at [27.10].

<sup>91</sup> *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 97 FCR 524; [2000] FCA 316 at [137] (Finkelstein J).

<sup>92</sup> ALRC, n 20 at [27.11], fn 15.

<sup>93</sup> ALRC, n 20 at [27.18].

<sup>94</sup> ALRC, n 20 at [27.12].

There is little reason to expect the dismal record of compulsory licensing in Australia to change rapidly after the passage of the *Intellectual Property Laws Amendment Bill 2012* – a prediction based on the global record of successful applications made under the 2003 WTO General Council waiver and 2005 TRIPS Protocol.<sup>95</sup>

Of greater concern is the desire of the Australian Government to commit to the TPPA, an agreement that (according to leaked IP provisions) will limit the ability of Australia, and developing countries in the Asia-Pacific region, to introduce public health policies that conflict with the private, commercial interests of patent holders. This has already been seen in the fact that a multinational tobacco company, having lost a constitutional claim concerned with acquisition of property in the Australian High Court, is seeking to insert in the TPPA an investor-state dispute settlement system that would bypass such domestic courts in favour of a panel of three trade arbitrators construing narrowly drafted provisions related to protection of investment. Those investments are defined broadly enough in draft TPPA provisions to include IP.<sup>96</sup>

The TPPA is a regional trade agreement currently being negotiated between Australia, Brunei, Chile, Malaysia, Peru, Singapore, New Zealand, the United States and Vietnam.<sup>97</sup> Japan has expressed interest in joining the Agreement and it has been announced that Mexico and Canada will soon join.

Recently a majority of Democrat representatives of the United States House of Representatives and a number of Senators have gone on record criticising the secretive negotiating process and expressing concern about TPPA proposals that could allow governments to be sued before foreign tribunals for doing no more than protecting the public or environmental interest.<sup>98</sup> Although the negotiating parties appear to have signed a confidentiality agreement in 2010, leaks of the TPPA intellectual property and investment chapters have occurred, exposing the extent to which the provisions represent a shift of the locus of governance offshore in a direct corporate challenge to national sovereignty, particularly by those nations that have invested heavily in developing a sound rule of law.<sup>99</sup> Concerns have already been expressed about the impact of these on drug prices and internet access.<sup>100</sup>

Relevantly, the proposed language of the TPPA undermines the spirit of the *Raising the Bar Act* reforms and the proposed compulsory licensing regime for export to least-developed countries.

First, the draft language of the IP chapter suggests the United States seeks to ensure patent protection for new “forms, uses or methods” of using known products. These types of patents are commonly sought as part of an overall evergreen strategy and undermine *Raising the Bar Act’s* efforts to improve the “innovative step” and “usefulness” criteria under the *Patents Act 1990*. Moreover, a

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<sup>95</sup> For example, Canadian Department of Foreign Affairs and International Trade, n 46.

<sup>96</sup> A recent High Court challenge by large tobacco companies of Australia’s *Tobacco Plain Packaging Act 2011* (Cth) highlights this conflict between the vested property interests of multinational trading corporations and domestic laws which seek to promote the right to the “highest attainable standard of physical and mental health”: *International Covenant on Economic, Social and Cultural Rights*, Art 12 (opened for signature in New York, 16 December 1966) (entered into force for Australia 10 March 1976) [1976] ATS 5; see also *WHO Framework Convention on Tobacco Control*, Arts 5, 10, 11, 13 (opened for signature in Geneva, 21 May 2003) (entered into force for Australia 27 February 2005) [2005] ATS 7; *JT International SA v Commonwealth* (2012) 86 ALJR 1297; Faunce T, “An Affront to the Rule of Law: International Tribunals to Decide on Plain Packaging”, *The Conversation* (29 August 2012), <http://theconversation.edu.au/an-affront-to-the-rule-of-law-international-tribunals-to-decide-on-plain-packaging-8968> viewed 22 September 2012.

<sup>97</sup> Department of Foreign Affairs and Trade, *Trans-Pacific Partnership Agreement Negotiations*, <http://www.dfat.gov.au/fta/tpp/index.html> viewed 22 September 2012.

<sup>98</sup> Carter Z, “Trans-Pacific Partnership Talks: Senators Demand Access to Controversial Documents After Leak”, *Huffington Post* (25 June 2012), [http://www.huffingtonpost.com/2012/06/25/trans-pacific-partnership-documents-sherrod-brown-jeff-merkley-ron-wyden-robert-menendez\\_n\\_1624956.html](http://www.huffingtonpost.com/2012/06/25/trans-pacific-partnership-documents-sherrod-brown-jeff-merkley-ron-wyden-robert-menendez_n_1624956.html) viewed 24 September 2012.

<sup>99</sup> Text purporting to be the draft IP chapter can be found at <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf> while the purported draft investment chapter can be found at <http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf> viewed 24 September 2012.

<sup>100</sup> Gleeson DH, Tienhaara KS and Faunce TA, “Challenges to Australia’s National Health Policy from Trade and Investment Agreements” (2012) 196(5) MJA 354; Electronic Frontiers Foundation, *Trans Pacific Partnership Agreement*, <https://www.eff.org/issues/tpp> viewed 24 September 2012.

PPI applicant seeking to use the new compulsory licence regime to export a patented product to a least-developed country may be confronted with a “patent thicket”, requiring the filing of multiple applications before an licence to export is eventually granted. Secondly, United States TPPA proposals have called for an extension of data exclusivity rights restricting access by generic competitors to the safety data (including stage III and IV clinical trial data) whose prompt distribution should have been the trade off for the monopoly privilege and its approval for distribution under patent.

Thirdly, as with normal compulsory licences, the proposed Bill prohibits a court from making an order inconsistent with Australia’s international treaty obligations.<sup>101</sup> Thus, tighter restrictions in the TPPA on the use of TRIPS flexibilities or extensions of data exclusivity could limit the ability of an Australian court to grant a PPI compulsory licence.

Finally, the draft investment chapter of the TPPA calls for the introduction of an investor-state dispute settlement clause. If accepted, this would allow foreign pharmaceutical companies to sue the Australian Government for compensation should a court decision (or Act of Parliament) that promoted access to essential medicine constitute “indirect expropriation”.<sup>102</sup>

The Australian Government considers that “Australia’s highest trade priority at the moment is to conclude a Trans-Pacific Partnership Agreement”<sup>103</sup> and, despite its own trade policy statement providing that “transparency” is a guiding principle, continues to negotiate the TPPA in secret. Nevertheless, it has stated that neither the PBS nor an investor-state dispute settlement system will be included in any TPPA deal Australia signs.<sup>104</sup> Its negotiators have also stated that Australia will not be agreeing to any extension of IP away from its current domestic arrangements and that the Doha Declaration will be explicitly included in the TPPA.<sup>105</sup>

## CONCLUSION

The 2001 Doha Declaration affirmed the capacity of WTO members to use the full flexibilities in the TRIPS Agreement “to protect public health and, in particular, to promote access to medicines for all”. Passage of the *Intellectual Property Laws Amendment Bill 2012* (Cth) would represent an important step in realising the goal of the Doha Declaration. Building upon the reforms introduced by the *Raising the Bar Act*, it continues a recent trend to improve Australia’s patent system by rebalancing IP policy in favour of the community and open access. However, Australia also appears to be pursuing a trade agreement that would further entrench the rights of patent holders at the expense of populations and public health policies,

It remains to be seen how Australia resolves its apparent desire to do right by the developing world and the great public health challenges of our time, while also appeasing its major trading partners and their powerful investors. It is encouraging that the Department of Foreign Affairs and Trade appears less willing to accede to United States efforts to incorporate so-called “Doha Declaration-Minus” IP chapters into new bilateral and plurilateral regional trade agreements, especially given strong advice from Australia’s Productivity Commission to take just such a position.<sup>106</sup>

Should the TPPA come into effect in terms similar to those previously revealed, it is almost certain that the intellectual property and public health policy space of future governments, both Australian and foreign, will be further constrained. Should this come to pass, the Doha Declaration

<sup>101</sup> *Intellectual Property Laws Amendment Bill 2012* (Cth), Item 19, proposed s 136R (Exposure Draft).

<sup>102</sup> Gleeson, Tienhaara and Faunce, n 100.

<sup>103</sup> Commonwealth of Australia, *Gillard Government Trade Policy Statement* (April 2011), <http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.html> viewed 22 September 2012.

<sup>104</sup> Commonwealth of Australia, n 103. The Statement also states that “The public will be well informed about negotiations for, and the content of, proposed trade agreements and have an opportunity for input”.

<sup>105</sup> Commonwealth of Australia, *Briefing on TPPA* (RG Casey Blg, Canberra, 19 November 2012).

<sup>106</sup> Productivity Commission, *Bilateral and Regional Trade Agreements* (2010) pp 262-264. In particular, the Productivity Commission noted (p 263): “The Commission is not convinced, however, that the approach adopted by Australia in relation to IP in trade agreements has always been in the best interests of either Australia or (most of) its trading partners.”

and this attempt by an Australian government to implement it will be seen, not as a “bill of rights for public health”, but, rather, yet another manufactured distraction from the inexorable extension of intellectual monopolies at the expense of civil society, trade and public health.

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