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Compulsory licensing and like arrangements?**

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# Accessing and affording drugs despite the patent barrier: Compulsory licensing and like arrangements?

Charles Lawson\*

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*This article addresses the potential of compulsory licensing and like arrangements under the Patents Act 1990 (Cth) for pharmaceuticals that are not made available in Australia, or available at such a high price that they are effectively unavailable. The analysis shows that the existing compulsory licensing and like arrangements (the general third party non-voluntary licensing, government (Crown) use and government acquisition) appear to be credible possibilities for accessing patented pharmaceuticals, albeit there remain significant uncertainties about their deployment. The article concludes that compulsory licensing and like arrangements need to be a clear and present threat to patent holders to encourage them to voluntarily work their patents or license them (in Australia) on reasonable terms and conditions.*

## INTRODUCTION

At the fourth Ministerial Conference in Doha in 2001 the World Trade Organisation (WTO) adopted the *Declaration on the TRIPS Agreement and Public Health* that expressly reaffirmed the right of member states to “flexibly” apply compulsory licensing in their adoption of minimum standard intellectual property<sup>1</sup> required by the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS).<sup>2</sup> TRIPS itself sets out a general compulsory licensing provision for patents. This provides for the “other use of the subject matter of a patent without the authorisation of the right holder” subject to respecting various conditions and procedures that protect the “legitimate interests” of the rights holder.<sup>3</sup> This mechanism allows both government uses and third party uses that are authorised by government.<sup>4</sup>

At the same Ministerial Conference there was also recognition that some member states “with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement”.<sup>5</sup> To address this concern, a complex agreement was reached that waived certain TRIPS requirements and mandated a notification mechanism and certain additional conditions for compulsory licences issued according to the system.<sup>6</sup> An amendment to TRIPS has been proposed,<sup>7</sup> albeit the waiver continues in force until the amendment takes effect.<sup>8</sup> Several member states have modified their laws to allow for the export

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<sup>1</sup> *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (2001) at [4] and [5(b)].

<sup>2</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights* (Annex 1C to the *Marrakesh Agreement establishing the World Trade Organisation*), opened for signature 15 April 1994, 1869 UNTS 299 (entered into force 1 January 1995).

<sup>3</sup> TRIPS, Art 31.

<sup>4</sup> For an overview see, for example, Malbon J, Lawson C and Davison M, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary* (Edward Elgar, 2014) pp 491-506; Gervais D, *The TRIPS Agreement: Drafting History and Analysis* (3rd ed, Sweet & Maxwell, 2008) pp 384-401.

<sup>5</sup> *Declaration on the TRIPS Agreement*, n 1 at [6].

<sup>6</sup> *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (2003).

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of pharmaceuticals according to the interim waiver mechanism,<sup>9</sup> although only Rwanda has notified as an eligible importing country,<sup>10</sup> with Canada notifying authorisation of manufacture for export.<sup>11</sup> While the scheme may work, it is cumbersome and is unlikely to be readily embraced.<sup>12</sup> Perhaps surprisingly, Australia has notified its acceptance of the proposed scheme,<sup>13</sup> and has declared it will not import pharmaceuticals under the scheme.<sup>14</sup> The Australian government is presently developing amendments to the *Patents Act 1990* (Cth) to implement the waiver scheme for exports under the domestic laws.<sup>15</sup>

Apart from the specific compulsory licensing regime allowed through the outcomes of the *Declaration on the TRIPS Agreement and Public Health*, WTO member states are required to adopt at least the minimum standard TRIPS-mandated system. For Australia there are additional minimum standards established by the *Australia-United States Free Trade Agreement* (AUSFTA).<sup>16</sup> Australia therefore now has TRIPS-compliant and AUSFTA-compliant compulsory licensing and like arrangements (other use without the authorisation of the right holder) in the *Patents Act*:<sup>17</sup> general third party non-voluntary licensing,<sup>18</sup> government (Crown) use,<sup>19</sup> and government acquisition.<sup>20</sup>

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<sup>7</sup> See *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (2005). See also Council for Trade-Related Aspects of Intellectual Property Rights, *Protocol Amending the TRIPS Agreement: Status of Acceptances*, WTO Doc IP/C/W/490/Rev.9 (2012).

<sup>8</sup> *Implementation of Paragraph 6*, n 6 at [11].

<sup>9</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc IP/C/57 (2010).

<sup>10</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Rwanda*, WTO Doc IP/N/9/RWA/1 (2007). Notably Nepal is also reported as having lodged a notification: see Anderson E, “Unnecessary Deaths and Unnecessary Costs: Getting Patented Drugs to Patients most in Need” (2009) 29 BC Third World LJ 85 at 104-105 and the references therein.

<sup>11</sup> Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under Paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Canada*, WTO Doc IP/N/10/CAN/1 (2007). See generally Anderson, n 10 at 103-104 and the references therein; Rimmer M, “The John Chrétien Pledge to Africa: Patent Law and Humanitarian Aid” (2005) 15 *Expert Opinion on Therapeutic Patents* 889.

<sup>12</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, WTO Doc IP/C/M/62 (2010) at [168]-[212]. See also Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, WTO Doc IP/C/M/63 (2010) at [184]-[247]. See generally Abbott F and J Reichman, “The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provision” (2007) 10 J Int’l Econ L 921. See also Esmail L and J Kohler, “The Politics Behind the Implementation of the WTO Paragraph 6 Decision in Canada to Increase Global Drug Access” (2012) 8 *Globalization and Health* 7.

<sup>13</sup> See *Protocol Amending the TRIPS Agreement Done at Geneva on 6 December 2005 – Notification of Acceptance*, WTO Doc WT/Let/593 (2007).

<sup>14</sup> See IP Australia, *Implementing the TRIPS Protocol: Consultation Paper* (IP Australia, 2010) p 3.

<sup>15</sup> See *Intellectual Property Laws Amendment Bill 2013* (Cth), s 3 and Schs 2 and 3. See also Australia, House of Representatives, *Parliamentary Debates* (30 May 2013) p 4531 (Yvette D’Ath, Parliamentary Secretary for Climate Change, Industry and Innovation).

<sup>16</sup> *Australia-United States Free Trade Agreement*, signed 18 May 2004 (entered into force 1 January 2005).

<sup>17</sup> The *Patents Act 1990* (Cth) was amended to comply with TRIPS and AUSFTA: see *US Free Trade Agreement Implementation Act 2004* (Cth), s 3 and Sch 8; *Patents (World Trade Organization Amendments) Act 1994* (Cth).

<sup>18</sup> *Patents Act 1990* (Cth), ss 133-140.

<sup>19</sup> *Patents Act 1990* (Cth), ss 163-170.

<sup>20</sup> *Patents Act 1990* (Cth), s 171. There are also other provision in the *Patents Act 1990* (Cth) that limit an inventor’s entitlements include limiting inventions that might be “mischievous to the state by raising prices of commodities at home, or hurt trade, or generally inconvenient” (s 18(1) and Sch 1), revocations (ss 101, 134 and 138), limiting some conditions in contracts “relating to the sale or lease of, or a license to exploit, a patented invention” (ss 144-146) and certain dealings by generics manufacturers obtaining regulatory approval (s 119A).

These compulsory licensing and like arrangements are often cited as an avenue to avoid problematic patents and alleviate some of the harsher price and access consequences of patenting.<sup>21</sup> The purpose of this article is to assess the existing statutory compulsory licensing and like arrangements in Australia. This is particularly important as a complex regulatory framework is in place to control unreasonably high prices and improve consumer access to pharmaceuticals.<sup>22</sup> This is essentially the Pharmaceutical Benefits Scheme (PBS) under the *National Health Act 1953* (Cth) administered by Medicare Australia under the *Health Insurance Act 1973* (Cth). This regulation has been very successful in protecting Australians from high drug prices.<sup>23</sup> And critically, these price control measures are under attack from countries seeking to increasingly protect and enforce patents for their pharmaceutical corporations, and most particularly, by those based in the United States.<sup>24</sup> The mischief that compulsory licensing and like arrangements might address is the possible refusal of pharmaceutical patent holders to make their patent-protected pharmaceuticals available in Australia, or charge such high prices that these pharmaceuticals are effectively unavailable in Australia. In this sense these arrangements are, at the same time, a threat against patent holders controlling their pharmaceuticals and an incentive to make pharmaceuticals available at reasonable prices and on the patent holder's terms. In this context, compulsory licensing and like arrangements are a credible response to patented pharmaceuticals being actually or effectively withheld from the Australian market. But *only* if this really is a credible threat. This article therefore addresses the workability of these arrangements.

In addressing the workability of, and likely impediments to, desirable future reforms, this article first addresses the minimum standards of a compulsory licensing system required by Australia's international commitments to TRIPS and the AUSFTA. Next, it addresses, in order, the compulsory licensing system in Australia formed by (i) general third party non-voluntary licensing, (ii) government (Crown) use and (iii) government acquisition. The article then discusses the policy justifications for licensing systems, before concluding that while the existing compulsory licensing and like arrangements (the general third party non-voluntary licensing, government (Crown) use and government acquisition) appear to be credible possibilities for accessing patented pharmaceuticals, there remain significant uncertainties about their deployment.

## TRIPS AND AUSFTA MINIMUM REQUIREMENTS

Article 31 of TRIPS provides for a minimum standard system for "other use of the subject matter of a patent without the authorization of the right holder" that sets out conditions and procedures rather than threshold standards.<sup>25</sup> The Article addresses both government uses and uses by a third party that has been authorised by the government.<sup>26</sup> The "other use" refers to "use other than that allowed under Article 30" that, in turn, refers to limited exceptions to a patent's exclusive rights that "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the

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<sup>21</sup> See, for example, Senate Community Affairs References Committee, *Gene Patents* (Senate Printing, 2010) pp 122-124; Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (SOS Printing Group, 2004) p 617.

<sup>22</sup> See, for example, Doran E and Henry D, "Australian Pharmaceutical Policy: Price Control, Equity and Drug Innovation in Australia" (2008) 29 JPHP 106 at 108-114 and the references therein. See also Drahos P, Lokuge B, Faunce T, Goddard M and Henry D, "Pharmaceuticals, Intellectual Property and Free Trade: The Case of the US-Australia Free Trade Agreement" (2004) 22 *Prometheus* 243 at 244-249.

<sup>23</sup> See, for example, Dalton A, "Australia's Pharmaceutical Benefits System: Flawed but Improving, and Better than Anywhere Else" (2001) 24 *AHR* 7 at 12-13.

<sup>24</sup> See, for example, Pharmaceutical Research and Manufacturers of America, *Special 301 Submission 2012* (PhRMA, 2012) pp 14-17, 112-114, <http://www.phrma.org/sites/default/files/304/phrmaspecial301submission2012.pdf>.

<sup>25</sup> TRIPS, Art 31.

<sup>26</sup> For a summary of the negotiating history leading to the combining of these various schemes, see Watal J, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International, 2001) pp 320-321.

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legitimate interests of the patent owner taking account of the legitimate interests of third parties”.<sup>27</sup> The TRIPS system established under Art 31 falls neatly into three parts: general authorisation;<sup>28</sup> remedies to anti-competitive practices;<sup>29</sup> and dependent patents.<sup>30</sup> The conditions and procedures mandated for general authorisation by Art 31 are: each case is to be considered on its merits; reasonable efforts to obtain a voluntary licence should have failed (albeit this might be waived in case of emergency or government uses); the scope and duration of any uses should be limited; any uses should be non-exclusive, non-assignable and predominantly to supply the domestic market; adequate compensation should be paid; and decisions should be open to review.<sup>31</sup> Any disputes between member states, so far, have been resolved by negotiation.<sup>32</sup>

Following TRIPS, Australia also entered into the AUSFTA that reinforces and extends some of the TRIPS minimum requirements. AUSFTA provides:

A Party shall not permit the use<sup>33</sup> of the subject matter of a patent without the authorisation of the right holder except in the following circumstances:

- (a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party’s laws relating to prevention of anti-competitive practices;<sup>34</sup> or
- (b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that:
  - (i) the Party shall limit such use to use by the government or third persons authorised by the government;
  - (ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and
  - (iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph.<sup>35</sup>

The *Patents Act* as amended is considered to be consistent with both TRIPS<sup>36</sup> and AUSFTA.<sup>37</sup> The following parts consider the non-voluntary schemes under the *Patents Act* in turn and their shortcomings: general third party non-voluntary licensing, government (Crown) use and government acquisition.

### **GENERAL THIRD PARTY NON-VOLUNTARY LICENSING**

The *Patents Act* provision relating to voluntary third party licensing provides:

- (1) ... a person may apply<sup>[38]</sup> to the Federal Court, after the end of the prescribed period,<sup>[39]</sup> for an order<sup>[40]</sup> requiring the patentee to grant the applicant a licence to work<sup>[41]</sup> the patented invention<sup>[42]</sup> ...

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<sup>27</sup> TRIPS, Art 30.

<sup>28</sup> TRIPS, Art 31(a)-(j).

<sup>29</sup> TRIPS, Art 31(a), (c)-(e), (g)-(j).

<sup>30</sup> Patents that cannot be exploited without infringing another patent: TRIPS, Art 31(l).

<sup>31</sup> TRIPS, Art 31(a)-(j).

<sup>32</sup> See *Brazil – Measures Affecting Patent Protection*, WTO Doc WT/DS199/4 (2001); *Argentina – Certain Measures on the Protection of Patents and Test Data*, WTO Doc WT/DS196/4 (2000).

<sup>33</sup> The footnote providing, in part: “[u]se’ in this paragraph refers to use other than that allowed under paragraph 3 and Article 30 of the TRIPS Agreement”: AUSFTA, Art 17.7.7 fn 17-[22].

<sup>34</sup> The footnote providing, in part: “[w]ith respect to sub-paragraph (a), the Parties recognize that a patent does not necessarily confer market power”: AUSFTA, Art 17.7.7 fn 17-[23].

<sup>35</sup> AUSFTA, Art 17.9.7. Notably AUSFTA, Art 17.9.7(b) addresses Crown use: see Advisory Council on Intellectual Property, *Review of Crown Use Provisions for Patents and Designs* (IP Australia, 2005) pp 11-12.

<sup>36</sup> See *Patents (World Trade Organization Amendments) Act 1994* (Cth).

<sup>37</sup> *US Free Trade Agreement Implementation Act 2004* (Cth), s 3 and Sch 8.

<sup>38</sup> The application must include “(i) the name and address of the applicant; and (ii) the address for service in relation to the application; and (iii) the identity of the patent; and (iv) if the applicant relies on the ground mentioned in paragraph 133(2)(a)

- (2) After hearing the application, the court may, subject to this section, make the order if satisfied that:
- (a) all the following conditions exist:
    - (i) the applicant has tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions;
    - (ii) the reasonable requirements of the public<sup>[43]</sup> with respect to the patented invention have not been satisfied;
    - (iii) the patentee has given no satisfactory reason for failing to exploit the patent; or
  - (b) the patentee has contravened, or is contravening, Part IV of the *Competition and Consumer Act 2010* [(Cth)] <sup>[44]</sup> or an application law<sup>[45]</sup> ... in connection with the patent.

A further restriction on this system is the requirement that any decision to grant a compulsory licence “must not be made ... that is inconsistent with a treaty between the Commonwealth and a foreign country”.<sup>46</sup> The meaning and application of this compulsory licensing system in Australia remains uncertain despite various reviews.<sup>47</sup> While others have provided a comprehensive textual

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of the Act – facts supporting the assertion that the reasonable requirements of the public with respect to the patented invention have not been satisfied; and (iva) if the applicant relies on the ground mentioned in paragraph 133(2)(b) of the Act – facts supporting the assertion that the patentee has contravened, or is contravening, Part IV of the *Trade Practices Act 1974* [(Cth)] or an application law (as defined in section 150A of that Act) in connection with the patent; and (v) for an innovation patent – the date that the patent was certified”, and “a declaration by the applicant to the effect that the facts in the statement are true to the best of the knowledge of the applicant”: *Patents Regulations 1991* (Cth), reg 12.1(2)(a) and (b).

<sup>39</sup> This is “the period of 3 years after the date of sealing of the patent to which the application relates”: *Patents Regulations 1991* (Cth), reg 12.1(1).

<sup>40</sup> Noting that “[a]n order operates, without prejudice to any other method of enforcement, as if it were embodied in a deed granting a licence and executed by the patentee and all other necessary parties”: *Patents Act 1990* (Cth), s 133(4).

<sup>41</sup> The term “work”, in relation to a patented invention, means: (a) where the invention is a product – make or import the product; or (b) where the invention is a method or process – use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use”: *Patents Act 1990* (Cth), Sch 1.

<sup>42</sup> The chapeau of this subsection was also amended to address certified “innovation patents”: *Patents Amendment (Innovation Patents) Act 2000* (Cth), s 3 and Sch 1 (item 66).

<sup>43</sup> This means “(1) (a) an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee’s failure: (i) to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or (ii) to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or (iii) to carry on the patented process to a reasonable extent; or (iv) to grant licenses on reasonable terms; or (b) a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or (c) if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia”: *Patents Act 1990* (Cth), s 135.

<sup>44</sup> These are the laws addressing restrictive trade practices such as unlawful cartel conduct, anti-competitive disclosure of pricing and other information, and other unlawful practices such as contracts, arrangements or understandings that restrict dealings or affect competition, covenants affecting competition and prices, contracts, arrangements or understandings affecting the supply or acquisition of goods or services, misuse of market power, various exclusive dealings, resale price maintenance, and so on: *Competition and Consumer Act 2010* (Cth), ss 44ZZS-51AAA.

<sup>45</sup> Being “(a) a law of a participating jurisdiction that applies the Competition Code, either with or without modifications, as a law of the participating jurisdiction; or (b) any regulations or other legislative instrument made under a law described in paragraph (a); or (c) the Competition Code, applying as a law of the participating jurisdiction, either with or without modifications”: *Competition and Consumer Act 2010* (Cth), s 150A (“application law”). See also *Patents Act 1990* (Cth), s 136A.

<sup>46</sup> *Patents Act 1990* (Cth), s 136.

<sup>47</sup> See Australian Law Reform Commission, n 21, pp 612-625; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (IP Australia, 2000) pp 162-163; Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (AGPS, 1984) pp 27-32. For an overview of broader practices, see Scherer F and Watal J, “Post-TRIPS Options for Access to Patented Medicines in Developing Countries” (2002) 5 J Int’l Econ L 913.

analysis of the existing compulsory licensing provisions,<sup>48</sup> and the provisions in the *Patents Act* have been subjected to various reviews,<sup>49</sup> the key uncertainties remain and include the following.

### “Work” the invention

The threshold limitation is that the *Patents Act* provides that “a person may apply to the Federal Court ... for an order requiring the patentee to grant the applicant a licence to *work* the patented invention”.<sup>50</sup> The term “work” is defined to mean “make or import the product”, “use the method or process” and “make or import” the product of the “method or process”.<sup>51</sup> The concern within this limitation is that the scope of activities open to a successful applicant to “work” the patent-protected invention is significantly narrower than the other essential elements of a patentee’s “exclusive rights”.<sup>52</sup> These “exclusive rights” available to a patent holder include the right to “exploit” the invention:

- (a) where the invention is a product – make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
- (b) where the invention is a method or process – use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.<sup>53</sup>

In other words, a compulsory licence will not include the opportunity to “hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use ... it, or keep it for the purpose of doing any of those things”.<sup>54</sup> According to this statutory scheme, a court can *only* grant a compulsory licence to make or import the patent-protected product (including the product of a process or method) and use the method or process. But in many instances the usefulness of a compulsory licence is likely to be of very little value without the ability to also keep, sell or “otherwise dispose” of the patent protected product (that includes the product of a patented process or method).

### AUSFTA limitations

The *Patents Act* expressly requires that a compulsory licence order be consistent with the AUSFTA,<sup>55</sup> as a treaty between “the Commonwealth and a foreign country”.<sup>56</sup> The AUSFTA obligations have been reflected in the *Patents Act* as two circumstances when a compulsory licence might be granted (the provision is set out above). These two circumstances are: (i) as a remedy to an anti-competitive practice addressed in the *Patents Act* and the *Competition and Consumer Act 2010* (Cth);<sup>57</sup> and (ii) government use according to the Crown use provisions<sup>58</sup> or government acquisition provisions<sup>59</sup> in

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<sup>48</sup> See, for recent examples, Nielsen J and Nicol D, “Whither Patent Use without Authorization in Australia” (2008) 36 FL Rev 333; Lawson C, “Public Interest Compulsory Licensing under the Patents Act 1990 (Cth): A Real Incentive or a Barrier to Working?” (2008a) 19 AIPJ 129; Lawson C, “Compulsory Licensing under the Patents Act 1990 (Cth) to Remedy Anti-competitive Conduct under the Trade Practices Act 1974 (Cth)” (2008b) 36 ABLR 369.

<sup>49</sup> Earlier reviews include Australian Law Reform Commission, n 21, pp 611-630; Intellectual Property and Competition Review Committee, n 47, pp 162-163; Industrial Property Advisory Committee, n 47, pp 27-31. See also Senate Economics Legislation Committee, *Provisions of the Intellectual Property Laws Amendment Bill 2006* (Senate Printing, 2006) pp 15-19, 21 and Appendix 3 (p 14).

<sup>50</sup> *Patents Act 1990* (Cth), s 133(1) (emphasis added).

<sup>51</sup> *Patents Act 1990* (Cth), Sch 1 (“work”).

<sup>52</sup> *Patents Act 1990* (Cth), s 13(1).

<sup>53</sup> *Patents Act 1990* (Cth), s 13(1) and Sch 1 (“exploit”).

<sup>54</sup> See *Patents Act 1990* (Cth), s 13(1) and Sch 1 (“exploit”).

<sup>55</sup> AUSFTA, Arts 17.1.1 and 17.1.6.

<sup>56</sup> *Patents Act 1990* (Cth), s 136.

<sup>57</sup> *Patents Act 1990* (Cth), s 133(2)(b); *Competition and Consumer Act 2010* (Cth), s 87. Notably the *Competition and Consumer Act 2010* (Cth), s 87 provides for a remedy in the form of ancillary relief being “such order or orders as it [the court] thinks appropriate” that can include, in effect, a compulsory license: see Further Explanatory Memorandum, *Intellectual Property Laws Amendment Bill 2006* (Cth) p 4.

<sup>58</sup> *Patents Act 1990* (Cth), ss 163-172. See also Advisory Council on Intellectual Property, n 35, pp 9-12.

“cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency”.<sup>60</sup> Notably absent from the AUSFTA scheme is the possibility in the existing *Patents Act* scheme for a compulsory licence to be granted to a non-government applicant where the applicant has unsuccessfully tried for a reasonable period to get permission on reasonable terms, “the reasonable requirements of the public” are not satisfied, and there is “no satisfactory reason for failing to exploit the patent”.<sup>61</sup> This would appear to be a significant reduction in the apparent scope of the *Patents Act* compulsory licensing scheme. The term “anti-competitive practices” in AUSFTA could, however, be interpreted as including the current *Patents Act* provisions, including the “the reasonable requirements of the public”. This is the position presently supported by the Australian government.<sup>62</sup> This may well be so where dealings with a pharmaceutical are conducted by a corporation taking advantage of substantial market power (such as denying access of a pharmaceutical composition) – that is presently unlawful under s 46 of the *Competition and Consumer Act 2010* (Cth) – but seems unlikely in the vast majority of circumstances where a patent protected product is withheld from the market by a corporation without substantial market power. In short, the AUSFTA provision appears to neutralise the broad public interest standard captured by the terminology of “the reasonable requirements of the public”, and so on.

### Uncertain interpretations

The *Patents Act* threshold statutory requirements for the grant of a compulsory licence are extraordinarily complex and difficult to interpret. The main concern is the requirement that “the reasonable requirements of the public with respect to the patented invention have not been satisfied”.<sup>63</sup> The key phrase “reasonable requirements of the public with respect to the patented invention” is qualified in the *Patents Act*:

the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied if:

- (a) an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee’s failure:
  - (i) to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or
  - (ii) to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or
  - (iii) to carry on the patented process to a reasonable extent; or
  - (iv) to grant licences on reasonable terms; or
- (b) a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or
- (c) if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.<sup>64</sup>

The range of vague concepts captured by these words opens them to uncertain interpretation. While there is some authority to assist in interpreting some of these legislative standards, this is not definitive, tends to be old authority and does not address many of the words and phrases that appear in the standard.<sup>65</sup>

<sup>59</sup> *Patents Act 1990* (Cth), s 171.

<sup>60</sup> AUSFTA, Art 17.9.7.

<sup>61</sup> *Patents Act 1990* (Cth), s 133(2)(a).

<sup>62</sup> See Senate Economics Legislation Committee, n 49, Appendix 3 (p 14).

<sup>63</sup> *Patents Act 1990* (Cth), s 133(2)(a)(ii).

<sup>64</sup> *Patents Act 1990* (Cth), s 135(1).

<sup>65</sup> See, for an analysis of the legislative standards, Lawson (2008a), n 48 at 130-145. See also Intellectual Property and Competition Review Committee, n 47, pp 162-163.



## Court discretions in assessing applications

Whether the court grants a compulsory licence on an application is a discretion, with s 133(2) providing that “the court may, subject to this section, make the order if satisfied that”.<sup>66</sup> The exercise of a similarly worded discretion in the former *Patents Act 1952* (Cth) was considered in *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp.*<sup>67</sup> There Menzies J stated:

As, however, the discretionary power is conferred for the public good, it seems to me that an order should follow an affirmative finding [that the reasonable requirements of the public with reference to the patented invention have not been satisfied] unless the Court is satisfied that there is some sound reason for declining to make the order. Such a reason would, I think, be that local manufacture has been established by the patentee and a satisfactory reason has been given for delay in fulfilling a long-standing intention to establish such manufacture or that the applicant for a compulsory licence is not a person fitted to be a licensee. The capacity of a prospective licensee to maintain the reputation of the patented article is a matter of legitimate concern to the patentee and to the Court.<sup>68</sup>

Menzies J’s approach was to determine whether one of the deeming circumstances for the “reasonable requirements of the public” under the former Act had been satisfied, and then to exercise the discretion in favour of the applicant *unless* there was some reason, determined at the time of the hearing and *not* at the time of lodging the application,<sup>69</sup> for declining to make the order.<sup>70</sup> The concern about this approach is that an applicant for a compulsory licence cannot know why a patent holder (or the licensee or assignee) has refused a licence, and so cannot assess the likely potential for lodging an application. Further, the assessment of the merits of the matter at the time of the hearing rather than at application means the patent holder (or the licensee or assignee) has an opportunity after the application is lodged to remedy their activities and confound the application up to the date of the hearing.

## GOVERNMENT (CROWN) USE

Government (Crown) use is essentially exploitation of the patented invention by the Commonwealth or State government, or a person or organisation authorised by the Commonwealth or State.<sup>71</sup> The *Patents Act* provides:

- (1) Where, at any time after a patent application has been made, the invention concerned is exploited by the Commonwealth or a State (or by a person authorised in writing by the Commonwealth or a State) for the services of the Commonwealth or the State, the exploitation is not an infringement:
  - (a) if the application is pending – of the nominated person’s rights in the invention; or
  - (b) if a patent has been granted for the invention – of the patent.
- (2) A person may be authorised for the purposes of subsection (1):
  - (a) before or after any act for which the authorisation is given has been done; and
  - (b) before or after a patent has been granted for the invention; and
  - (c) even if the person is directly or indirectly authorised by the nominated person or patentee to exploit the invention.<sup>72</sup>

This scheme essentially allows government uses subject to notification<sup>73</sup> and adequate compensation.<sup>74</sup> The Advisory Council on Intellectual Property (ACIP) reviewed the scheme in

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<sup>66</sup> *Patents Act 1990* (Cth), s 133(2).

<sup>67</sup> See *Patents Act 1952* (Cth), s 108(3).

<sup>68</sup> *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp* (1969) 119 CLR 572 at 574-575 (Menzies J).

<sup>69</sup> *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp* (1969) 119 CLR 572 at 575 (Menzies J).

<sup>70</sup> *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp* (1969) 119 CLR 572 at 574-575 (Menzies J).

<sup>71</sup> Reported cases include *Stack v Brisbane City Council* (1995) 32 IPR 69; *General Steel Industries Inc v Commissioner of Railways (NSW)* (1964) 112 CLR 125. See also Australian Law Reform Commission, n 21, pp 593-610; Advisory Council on Intellectual Property, n 35.

<sup>72</sup> *Patents Act 1990* (Cth), s 163.

<sup>73</sup> *Patents Act 1990* (Cth), s 164.

<sup>74</sup> *Patents Act 1990* (Cth), s 165.

2005<sup>75</sup> and found that the increasing privatisation of government meant this scheme was open “to be abused in the absence of increased checks and balances which provide transparency and accountability”.<sup>76</sup> ACIP recommended, subject to emergency and non-commercial uses, government uses should only follow “genuine efforts to obtain authorisation from the right holder” within “a reasonable period of time” and on “reasonable commercial terms”.<sup>77</sup> Further recommendations included obtaining ministerial approval for uses and “just and reasonable [remuneration] taking into consideration the circumstances of the case”.<sup>78</sup> The Australian government has not yet responded to this report, with the provision last being amended in 1994.<sup>79</sup> The ongoing concern is what quantum of remuneration is payable and how this will be calculated?<sup>80</sup> There is presently no consensus on establishing the value of a patent.<sup>81</sup>

## GOVERNMENT ACQUISITION

Section 171 of the *Patents Act* provides:

- (1) The Governor-General may direct that a patent, or an invention that is the subject of a patent application, be acquired by the Commonwealth.
- (2) When a direction is given, all rights in respect of the patent or the invention are, by force of this subsection, transferred to and vested in the Commonwealth.<sup>82</sup>

The Governor-General must make the direction on the advice of the Minister administering the *Patents Act*.<sup>83</sup> In making the direction, the patent holder must be notified<sup>84</sup> and remuneration agreed or otherwise determined by a court.<sup>85</sup> Importantly, acquisition for use is confined to the Commonwealth and does not extend to the States and Territories.<sup>86</sup> Recent reviews of government acquisition tend to merge this avenue of non-voluntary uses with government (Crown) use (addressed above).<sup>87</sup>

The concerns with s 171 seem to be, first, about the patent holder having an opportunity to negotiate before the Commonwealth use and, secondly, that the remuneration be “just and reasonable taking into consideration the circumstances of the case”.<sup>88</sup> The remaining uncertainty is about what quantum of remuneration is payable and how this will be calculated? As explained above, there is presently no consensus on establishing the value of a patent.<sup>89</sup>

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<sup>75</sup> Earlier reviews include Australian Law Reform Commission, n 21, pp 593-602 and 605-608. Notably earlier reviews that did not address these issues included the Intellectual Property and Competition Review Committee, n 47; Industrial Property Advisory Committee, n 47.

<sup>76</sup> Advisory Council on Intellectual Property, n 35, p 1.

<sup>77</sup> Advisory Council on Intellectual Property, n 35, p 3.

<sup>78</sup> Advisory Council on Intellectual Property, n 35, pp 4-5.

<sup>79</sup> See *Patents (World Trade Organization Amendments) Act 1994* (Cth), ss 14-17.

<sup>80</sup> Advisory Council on Intellectual Property, n 35, pp 28-36; Australian Law Reform Commission, n 21, pp 599, 608.

<sup>81</sup> See, for example, Wu L and Wu L, “Pharmaceutical Patent Evaluation and Licensing Using a Stochastic Model and Monte Carlo Simulations” (2011) 29 *Nature Biotechnology* 798. See also Sherer and Watal, n 47 at 920-924.

<sup>82</sup> *Patents Act 1990* (Cth), s 171.

<sup>83</sup> See *Administrative Arrangements Order, 9 February 2012* (Cth), Pt 13 (Department of Industry, Innovation, Science, Research and Tertiary Education).

<sup>84</sup> *Patents Act 1990* (Cth), s 171(3).

<sup>85</sup> *Patents Act 1990* (Cth), s 171(4) and Sch 1 (“prescribed court”).

<sup>86</sup> See *Patents Act 1990* (Cth), s 171(1).

<sup>87</sup> See, for example, Advisory Council on Intellectual Property, n 35, p 9; Australian Law Reform Commission, n 21, pp 603-608.

<sup>88</sup> Advisory Council on Intellectual Property, n 35, pp 4-5. See also Australian Law Reform Commission, n 21, p 608.

<sup>89</sup> See, for example, Wu and Wu, n 81.

## THE POLICY JUSTIFICATIONS FOR A LICENSING SYSTEM

The mischief that a compulsory licence in the *Patents Act* seeks to address is:

A granted patent is essentially a right to exclude others from using the patented invention. The patentee also has the right to choose not to exploit the invention. However, if their failure to use the invention at all, or to a sufficient extent, is contrary to the public interest then access to the invention can be obtained in certain circumstances.<sup>90</sup>

The accepted justification for compulsory licensing in the *Patents Act* then appears to be that the threat of compulsion encourages voluntary licensing and the working of inventions in Australia sooner through the incentive to licence voluntarily and on the patent holder's own terms.<sup>91</sup> The policy problem is how to frame the "public interest" that justifies trampling on the patent holder's exclusive rights to exploit the invention according to the statutory privileges in the *Patents Act*? This is a problem with no rational or reasonable answer, and has continued to plague patent debates over the decades. The various contenders assert, as a generalisation the following arguments.

### Complete right to exclude

One view is that patent practices and exploitation should be unrestricted when they are enabling the patent holder to garner the monopoly benefits inherent in their superior invention. On this view, any restrictions, including limiting otherwise prohibited practices such as certain vertical and horizontal restraints on competition, merely undermines the incentives inherent in the statutory patent scheme. As a consequence, compulsory licensing is antithetical to maintaining the incentives to invest in invention and will result in less invention. In the context of cost containment regulation, for example, the United States' Pharmaceutical Research and Manufacturers of America asserts:

Such cost containment policies typically put short-term government objectives ahead of long-term strategies and ultimately impede the flow of medicines to patients, undercut return on investment for developers over a product's life cycle, which effectively diminishes the value of patent protection, and slows future innovation.<sup>92</sup>

### Limited right to exclude

An alternate view is that a patent's exclusive rights need to be ameliorated to address certain economic, social and ethical concerns, with there being no settled perspective on the extent to which the exclusive rights might be avoided to address the many and varied economic, social and ethical concerns. There seems little doubt now that establishing TRIPS minimum patent standards have led to the shutting down of some of the local manufacturing capacity of global pharmaceutical corporations<sup>93</sup> and have led also to a substantial increase in the price of pharmaceuticals.<sup>94</sup> Added to this are the considerable government (taxpayer) subsidies provided to pharmaceutical corporations (including direct grants, tax breaks and so on), the weak record of invention among the large

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<sup>90</sup> Explanatory Memorandum, *Intellectual Property Laws Amendment Bill 2006* (Cth) p 11. See also Intellectual Property and Competition Review Committee, n 47, p 162; Industrial Property Advisory Committee, n 47, p 29.

<sup>91</sup> See, for example, Explanatory Memorandum, n 90, p 12; Senate Economics Legislation Committee, n 49, pp 14-15; Australian Law Reform Commission, n 21, p 613; Intellectual Property and Competition Review Committee, n 47, p 162; and so on. There are other justifications: see, for example, Merges R, "Of Property Rules, Coase, and Intellectual Property" (1994) 94 *Colum L Rev* 2655, addressing compulsory licensing in the presence of high transaction costs.

<sup>92</sup> Pharmaceutical Research and Manufacturers of America, n 24, p 15.

<sup>93</sup> See, for example, Kaplan W and Laing R, "Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines – An Overview of Key Concepts, Issues and Opportunities for Future Research", Health, Nutrition and Population (HNP) Discussion Paper (World Bank, 2005) p 14, [http://www.who.int/medicines/technical\\_briefing/tbs/KaplanLocalProductionFinal5b15d.pdf](http://www.who.int/medicines/technical_briefing/tbs/KaplanLocalProductionFinal5b15d.pdf).

<sup>94</sup> See, for example, Malpani R, "All Costs, No Benefits: How the US-Jordan Free Trade Agreement Affects Access to Medicines" (2009) 6 *Journal of Generic Medicine* 206; El-Said H and El-Said M, "TRIPS-Plus Implications for Access to Medicines in Developing Countries: Lessons from Jordan-United States Free Trade Agreement" (2007) 10 *Journal of World Intellectual Property* 438. See also Productivity Commission, *International Pharmaceutical Price Differences*, Research Report (Productivity Commission, 2001), [http://www.pc.gov.au/data/assets/pdf\\_file/0018/18153/pbsprices.pdf](http://www.pc.gov.au/data/assets/pdf_file/0018/18153/pbsprices.pdf).

pharmaceutical corporations, and that the risk of investment for pharmaceuticals is in the clinical trial stages and not the basic research.<sup>95</sup> All together these factors suggest that various economic, social and ethical concerns might credibly justify limiting a patent holder's exclusive rights. How these might be limited and the extent to which they might be limited is uncertain and contested.

### Other arguments

Another important argument against compulsory licensing as a means of limiting a patent holder's exclusive rights arises from the ongoing national concerns of those countries that benefit from high levels of intellectual property protection and enforcement. There is no doubt now that establishing TRIPS minimum patent standards has substantially increased the financial returns to some technology exporting countries.<sup>96</sup> So, for example, the United States' Pharmaceutical Research and Manufacturers of America asserts:

Because of the United States' pre-eminence in the life-sciences sector, foreign cost containment measures create market access barriers that pose a significant threat to the [United States] based biopharmaceutical industry, and in turn the [United States'] economy. More specifically, these policies have the ability to dramatically impact the industry's ability to gain market access to and compete in new and existing markets thereby harming the ability to sustain and create exports, maintain and develop jobs, stimulate future innovation, and more.<sup>97</sup>

### DISCUSSION AND CONCLUSIONS

The analysis in this article so far demonstrates that Australia has implemented a TRIPS and AUSFTA-consistent *Patents Act* that allows for the compulsory licensing and like arrangements through general third party non-voluntary licensing,<sup>98</sup> government (Crown) use<sup>99</sup> and government acquisition.<sup>100</sup> Unfortunately, each of these systems retains uncertainties and needs further clarification about their operation and the likely circumstances in which they will be deployed. In the context of dealing with maintaining price controls and improving consumer access to pharmaceuticals, the uncertainties in the existing systems do not appear to be a credible threat to either addressing an incentive to license and work inventions or as a means to dealing with problem patents. Perhaps disappointingly, and despite recent reviews, the Australian government has not yet addressed many of the criticisms of these systems,<sup>101</sup> so that uncertainty about the scheme's operation and effectiveness remain.

The first step in addressing the weaknesses of the current scheme requires the Australian government to clarify the exiting arrangements. This probably requires further research and policy development to set out how and when the existing arrangements might be deployed. The recent Productivity Commission Inquiry is a welcome first step.<sup>102</sup> There the Productivity Commission undertook a comprehensive review of the operation of the *Patents Act* compulsory licensing provisions and recommended substantial changes to the existing scheme:

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<sup>95</sup> Abbott F, "Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism" (2005) 8 J Int'l Econ L 77 at 91-92.

<sup>96</sup> See, for example, Abbott, n 95 at 81-82 and the references therein.

<sup>97</sup> Pharmaceutical Research and Manufacturers of America, n 24.

<sup>98</sup> *Patents Act 1990* (Cth), ss 133-140.

<sup>99</sup> *Patents Act 1990* (Cth), ss 163-170.

<sup>100</sup> *Patents Act 1990* (Cth), s 171.

<sup>101</sup> See, for example, Advisory Council on Intellectual Property, n 35, pp 4-5, 28-36; Intellectual Property and Competition Review Committee, n 47, pp 162-163.

<sup>102</sup> See Productivity Commission, *Compulsory Licensing of Patents*, Inquiry Report No 61 (Productivity Commission, 2013).

## Accessing and affording drugs despite the patent barrier: Compulsory licensing and like arrangements?

- (a) To remove the *Patents Act* as a source of power for compulsory licence to remedy anti-competitive conduct and explicitly recognise compulsory licensing as a remedy in the *Competition and Consumer Act 2010* (Cth).<sup>103</sup>
- (b) To replace the “reasonable requirements of the public” standard with a “public interest” test that would be available if:
  - Australian demand for a product or service is not being met on reasonable terms, and access to the patented invention is essential for meeting this demand.
  - The applicant has tried for a reasonable period, but without success, to obtain access from the patentee on reasonable terms and conditions.
  - There is a substantial public interest in providing access to the applicant, having regard to:
    - benefits to the community from meeting the relevant unmet demand.
    - commercial costs and benefits to the patent holder and licensee from granting access to the patented invention.
    - other impacts on community wellbeing, including those resulting from greater competition and from the overall effect on innovation.<sup>104</sup>
- (c) To empower the Federal Court to set the terms of the licence, including where the parties cannot reach agreement determine “any remuneration, consistent with the public interest” taking into account the interests of “the patentee to obtain a return on investment commensurate with the regulatory and commercial risks involved” and “the public to the efficient exploitation of the invention”.<sup>105</sup>
- (d) To clearly set out in the *Patents Act* the obligations imposed by international agreements such as AUSFTA.
- (e) To amend the *Patents Act* to extend the scope of government (Crown) use to States and Territories requiring a prior attempt to negotiate with the patent holder, a statement of reasons for the decision, and remuneration set taking into account the interests of “the patentee to obtain a return on investment commensurate with the regulatory and commercial risks involved” and “the public to the efficient exploitation of the invention”.<sup>106</sup>

With the growing pressure against Australia maintaining its price controls under the PBS and access to affordable pharmaceuticals, these compulsory licensing and like arrangements face considerable barriers. These are considered in turn, albeit not exhaustively.

The first likely barrier is the portfolio allocation within the Australian government itself. In the late 1980s, the Australian government shifted its policy focus away from consumer welfare as a priority to a greater focus and preference for maintaining a pharmaceutical industry.<sup>107</sup> This was in response to an “industry perception” that the “Australian operating environment is ‘hostile’” in part because of the apparently low prices paid for pharmaceuticals under the PBS.<sup>108</sup> The policy response involved favouring the Department of Industry over the Department of Health in setting pharmaceutical policy and increasingly including pharmaceutical industry participation (generally through its industry representative body Medicines Australia)<sup>109</sup> in decisions about policy and regulation.<sup>110</sup> The outcome over time has been to expressly accommodate a “viable industry” with the Australian government’s *National Medicines Policy* providing, in part, that:

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<sup>103</sup> Productivity Commission, n 102, pp 23, 138.

<sup>104</sup> Productivity Commission, n 102, pp 24, 154.

<sup>105</sup> Productivity Commission, n 102, pp 24, 155.

<sup>106</sup> Productivity Commission, n 102, pp 25, 181.

<sup>107</sup> See Industry Commission, *The Pharmaceutical Industry* (AGPS, 1996) Vol 1, pp 95-101.

<sup>108</sup> Industry Commission, n 107, Vol 1, pp 95-96.

<sup>109</sup> See Medicines Australia, *Annual Report 2010-2011* (Medicines Australia, 2010) p 3, [http://medicinesaustralia.com.au/files/2010/01/MedicinesAustralia\\_AnnualReport2010-11\\_.pdf](http://medicinesaustralia.com.au/files/2010/01/MedicinesAustralia_AnnualReport2010-11_.pdf).

<sup>110</sup> This evolution is set out in Lofgren H and de Boer R, “Pharmaceuticals in Australia: Developments in Regulation and Governance” (2004) 58 *Social Science and Medicine* 2397 at 2400-2401.

It is essential that industry policy and health policy be coordinated, providing a consistent and supportive environment for the industry, and appropriate returns for the research and development, manufacture, and supply of medicines.<sup>111</sup>

Perhaps the main accommodation has been in consultative arrangements. As a demonstration of this accommodation has been the *Memorandum of Understanding* reached between the Australian government (represented by the Minister for Health and Aging) and Medicines Australia.<sup>112</sup> Here the Australian government undertook “not to implement new policy to generate price-related savings from the PBS during the period of agreement”.<sup>113</sup> These measures were then implemented through the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010* (Cth).<sup>114</sup> The success of this arrangement for the pharmaceutical industry has been that the federal budget has subsequently not had any PBS-related savings.<sup>115</sup> Despite Australia being only a minor participant in global pharmaceuticals (having approximately one per cent of global sales),<sup>116</sup> the pharmaceutical industry is well organised and well funded and likely to be a significant and influential critic of any attempts to clarify compulsory licensing and like arrangements as they might affect the PBS.<sup>117</sup>

The next likely barrier to reform is the proliferation of bilateral, plurilateral and regional trade agreements where TRIPS-plus measures have been, at least in part, an attempt to globalise and strengthen intellectual property generally and patents in particular.<sup>118</sup> For example, the AUSFTA specifically extends the TRIPS patenting minimum standards to allow for the “new uses” of known compounds,<sup>119</sup> prohibiting parallel importing,<sup>120</sup> limited compulsory licensing and like arrangements,<sup>121</sup> patent term extensions for regulatory delays,<sup>122</sup> data exclusivity extensions to coincide with patent terms,<sup>123</sup> and allows non-violation claims.<sup>124</sup> The AUSFTA also specifically addresses the PBS with measures to limit its regulatory authority<sup>125</sup> and a means of threat and coercion as a way of raising prices through an “independent review body” to examine drugs rejected by the price-determining

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<sup>111</sup> Department of Health and Aging, *National Medicines Policy* (Department of Health and Aging, 2000) p 4, [http://www.health.gov.au/internet/publications/publishing.nsf/Content/CA25774C001857CACA2574FC0079DC1A/\\$File/nmp2000.pdf](http://www.health.gov.au/internet/publications/publishing.nsf/Content/CA25774C001857CACA2574FC0079DC1A/$File/nmp2000.pdf).

<sup>112</sup> Department of Health and Aging and Medicines Australia, *Memorandum of Understanding* (Department of Health and Aging and Medicines Australia, 2010), [http://medicinesaustralia.com.au/files/2010/09/APLHGR14@health-gov-au\\_20100929\\_093746.pdf](http://medicinesaustralia.com.au/files/2010/09/APLHGR14@health-gov-au_20100929_093746.pdf).

<sup>113</sup> Department of Health and Aging and Medicines Australia, n 112, cl 4.

<sup>114</sup> A minor hiccup was the Cabinet decision in 2011 to defer the listing of some new medicines on the PBS: see, for example, Australia, House of Representatives, *Parliamentary Debates* (30 May 2011) p 5169 (Mal Washer). This has now been resolved: see Minister for Health and Ageing, *Pharmaceutical Benefits Scheme (PBS) Deferrals Statement of Principles of Commitment between Stakeholders* (Department of Health and Ageing, 2011), <http://www.pbs.gov.au/news/2011/09/pbs-deferrals-statement-of-principles.pdf>.

<sup>115</sup> See Medicines Australia, n 109.

<sup>116</sup> See Economics Intelligence Unit, *Benchmarking Study of the Characteristics of the Australian and International Pharmaceuticals Industries* (Economics Intelligence Unit, 2005) p 15, [http://www.qctn.com.au/Portals/0/Main\\_Body\\_Economist%20Benchmarking%20Report\\_Pharma.pdf](http://www.qctn.com.au/Portals/0/Main_Body_Economist%20Benchmarking%20Report_Pharma.pdf).

<sup>117</sup> For an example of these activities in respect of the AUSFTA, see Harvey K, “Patents, Pills and Politics: The Australia-United States Free Trade Agreement and the Pharmaceutical Benefits Scheme” (2004) 28 AHR 218.

<sup>118</sup> See, for example, Drahos et al, n 22 at 246-247, 252-255.

<sup>119</sup> AUSFTA, Art 17.9.1.

<sup>120</sup> AUSFTA, Art 17.9.4.

<sup>121</sup> AUSFTA, Art 17.9.7.

<sup>122</sup> AUSFTA, Art 17.9.8.

<sup>123</sup> AUSFTA, Art 17.10.3.

<sup>124</sup> AUSFTA, Art 21.2(c).

<sup>125</sup> AUSFTA, Annex 2-C.

## Accessing and affording drugs despite the patent barrier: Compulsory licensing and like arrangements?

Pharmaceutical Benefits Advisory Committee.<sup>126</sup> The ongoing negotiation of the *Trans-Pacific Partnership Agreement* (TPP), currently under secret negotiations, promises to entrench patent standards affecting pharmaceuticals.<sup>127</sup> Leaked materials from the TPP negotiations show that the United States is seeking to restrict the PBS assessment process according to the principle of:<sup>128</sup>

sound economic incentives and the operation of competitive markets, or the adoption or maintenance by a Party of procedures that appropriately value objectively demonstrated therapeutic significance of high quality patented and generic pharmaceutical products and medical devices, for the efficient development of and access to such products and devices.<sup>129</sup>

This is a shift away from the AUSFTA principle of:

the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.<sup>130</sup>

While subtle, the change in language reflects a change in reference from the “therapeutic significance of a pharmaceutical” in AUSFTA to the “therapeutic significance of high quality patented and generic pharmaceutical products” in the TPP.<sup>131</sup> This appears to be an attempt to value patented pharmaceuticals as a special case, presumably deserving special financial treatment by paying higher prices under the PBS. The TPP also appears to extend the scope of patent (and data exclusivity) beyond that established by AUSFTA.<sup>132</sup>

The effect of these various proliferating bilateral, plurilateral and regional trade agreements are to “ratchet” increasingly stronger intellectual property standards.<sup>133</sup> In the case of compulsory and like arrangements, this means that products and processes are being patented that previously could not be patented,<sup>134</sup> and the provisions to trample the exclusive rights through compulsory licensing are being reduced.

Despite the apparent uncertainties to granting compulsory licences (“work” the invention, uncertain interpretations, and so on), there remains the real possibility that such licences might be granted and that they can address the price and access issues. This is demonstrated by the recent decision of India’s Controller General of Patents, Designs and Trade Marks to issue the first-ever compulsory licence to the Indian corporation Natco Pharma Ltd for the manufacture of the patented pharmaceutical *Naxever* (for the treatment of liver and kidney cancers), which is owned by the global pharmaceutical corporation Bayer Corporation.<sup>135</sup> The Controller General concluded on the evidence

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<sup>126</sup> Drahos P and Henry D, “The Free Trade Agreement between Australia and the United States” (2004) 328 *BMJ* 1271. See also Drahos et al, n 22 at 246; Faunce T, “Reference Pricing for Pharmaceuticals: Is the Australia-United States Free Trade Agreement Affecting Australia’s Pharmaceutical Benefits Scheme?” (2007) 187 *MJA* 240.

<sup>127</sup> See Maxmen A, “Trade Deal to Curb Generic-drug Use” (2012) 489 *Nature* 16 at 16-17; Gordon B, “Trading Up in Asia: Why the United States Needs the Trans-Pacific Partnership – Comment” (2012) 91 *Foreign Affairs* 17 at 20-22; Faunce T and Townsend R, “The Trans-Pacific Partnership Agreement: Challenges for Australian Health and Medicine Policies” (2011) 194 *MJA* 83.

<sup>128</sup> See Gleeson D, Tienhaara K and Faunce T, “Challenges to Australia’s National Health Policy from Trade and Investment Agreements” (2012) 5 *MJA* 354 at 355.

<sup>129</sup> *Trans-Pacific Partnership: Transparency Chapter – Annex on Transparency and Procedural Fairness for Healthcare Technologies* (2011) Art X.1(c), <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificTransparency.pdf>.

<sup>130</sup> AUSFTA, Annex 2-C, Art 1(d).

<sup>131</sup> See also Gleeson et al, n 128 at 355.

<sup>132</sup> Gleeson et al, n 128 at 355-356 and the references therein.

<sup>133</sup> Drahos et al, n 22 at 252-255.

<sup>134</sup> For example, the patentability of new uses of known compounds: AUSFTA, Art 17.9.1. See also Lawson C and Pickering C, “TRIPS-Plus’ Patent Privileges – An Intellectual Property ‘Cargo Cult’ in Australia” (2004) 22 *Prometheus* 355 at 357-361.

<sup>135</sup> *Natco Pharma Ltd v Bayer Corporation – Application for Compulsory License under Section 84(1) of the Patents Act 1970 in respect of Patent No 215758* (unreported, Controller General of Patents, Mumbai, CLA No 1 of 2011) pp 4-5, <http://patentdocs.typepad.com/files/compulsory-license-application.pdf>. See also Bonadio E, “Compulsory Licensing of Patents: The Bayer-Natco Case” (2012) 34 *EIPR* 719.

that the patented invention was “not available to the public at a reasonably affordable price”,<sup>136</sup> was not manufactured in India,<sup>137</sup> and the patent holder “failed to grant a voluntary license on reasonable terms to anyone”.<sup>138</sup> As a consequence a compulsory licence was issued to Natco Pharma Ltd.<sup>139</sup> The licence authorised Natco Pharma Ltd to manufacture the pharmaceutical in its own facilities and to sell the drug with a royalty payment to the Bayer Corporation of six per cent.<sup>140</sup>

This was the first such compulsory licence granted in India and will undoubtedly attract significant controversy particularly from patent holders. Perhaps the three main issues in restricting a patent owner’s interests in a patent protected product are: (i) the quantum of a fair royalty; (ii) creating a grey market; and (iii) dulling the incentive to invent.<sup>141</sup> These issues were addressed in India by adopting an internationally recognised royalty rate that took into account an additional amount because of the drug’s therapeutic value,<sup>142</sup> and other measures to confine manufacture and limit distribution for specific treatments and within a specific territory.<sup>143</sup> The question of dulling the incentive to invent, however, remains unanswerable and will continue to be controversial – this is a matter that cannot be independently tested and measured.<sup>144</sup> Undoubtedly those nations looking to the positive export earnings from patent-protected pharmaceuticals will press the case for higher prices to avoid the postulated dulling effect of limiting patents.

The likely solution, however, to the apparent conflict between price controls, patents and access to patent-protected pharmaceuticals is not simply a matter of the automatic compulsory licensing of pharmaceuticals that are not made available in Australia, or at such a high price they are effectively unavailable. The solution is likely to be a more nuanced combination of mechanisms that recognises the need for the Australian community to fund the development of new pharmaceuticals while balancing the likely costs with research subsidies, manufacturing subsidies, some price controls, and managing the enforcement of patents, including through some compulsory licensing (whether general third party non-voluntary licensing, government (Crown) use or government acquisition).<sup>145</sup> This requires, however, a compulsory licensing system that can credibly work. As the analysis in this article has demonstrated, the compulsory licensing and like arrangements as they are presently configured retain significant uncertainties and this needs to be addressed. Most importantly, this is not so that these measures can be necessarily implemented immediately, but rather, that they are a clear and present threat to encourage patent holders to voluntarily work their patents or license them (in Australia) on reasonable terms and conditions.

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<sup>136</sup> *Natco Pharma Ltd v Bayer Corporation* (unreported, Controller General of Patents, Mumbai, CLA No 1 of 2011) p 35.

<sup>137</sup> *Natco Pharma Ltd v Bayer Corporation* (unreported, Controller General of Patents, Mumbai, CLA No 1 of 2011) p 45.

<sup>138</sup> *Natco Pharma Ltd v Bayer Corporation* (unreported, Controller General of Patents, Mumbai, CLA No 1 of 2011) p 45.

<sup>139</sup> *Natco Pharma Ltd v Bayer Corporation* (unreported, Controller General of Patents, Mumbai, CLA No 1 of 2011) p 45.

<sup>140</sup> *Natco Pharma Ltd v Bayer Corporation* (unreported, Controller General of Patents, Mumbai, CLA No 1 of 2011) pp 60-61.

<sup>141</sup> See Yang D, “Compulsory Licensing: For Better or For Worse, the Done Deal Lies in the Balance” (2012) 17 JIPR 76 at 77.

<sup>142</sup> *Natco Pharma Ltd v Bayer Corporation* (unreported, Controller General of Patents, Mumbai, CLA No 1 of 2011) p 60.

<sup>143</sup> *Natco Pharma Ltd v Bayer Corporation* (unreported, Controller General of Patents, Mumbai, CLA No 1 of 2011) p 61.

<sup>144</sup> Generalising about incentives is plagued by circumstances, context, time, countries, levels of development, firm size, and so on: see, for example, Moser P and Voena A, “Compulsory Licensing: Evidence From the Trading with the Enemy Act” (2012) 102 AER 396; Scherer F, *Competition Policy, Domestic and International* (Edward Elgar Publishing, 2000).

<sup>145</sup> See also Abbott, n 95 at 92-93.