**Productivity Commission** 

Locked Bag 2 Collins Street East

Melbourne Victoria 8003

21 December 2012

Dear Commissioner's,

Re: Submission to the "Compulsory Licensing of Patents" Inquiry

My concern is that if the *Patents Act 1990* (Cth) is to have a compulsory licensing as an ex post safeguard then the measure needs 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. My submission is that the existing scheme set out in the *Patents Act 1990* (Cth) may not achieve this because of the complexity and ambiguity in the present statutory scheme. I have set out the reasoning the following pages. The immediate solution is to modify the *Patents Act 1990* (Cth) so that compulsory licensing is 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.

If you have any queries please do not hesitate to contact me.

Yours sincerely,

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# The Patents Act 1990 (Cth) provision, as amended, provides:

- (1) ... a person may apply<sup>[1]</sup> to the Federal Court, after the end of the prescribed period, <sup>[2]</sup> for an order<sup>[3]</sup> requiring the patentee to grant the applicant a licence to work<sup>[4]</sup> the patented invention<sup>[5]</sup> ...
- (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>[6]</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

<sup>&</sup>lt;sup>1</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 para 133(2)(a) 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 para 133(2)(b) of the Act – facts supporting the assertion that the patentee has contravened, or is contravening, pt 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)

applicant": *Patents Regulations 1991* (Cth) reg 12.1(2)(a) and (b).

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>&</sup>lt;sup>3</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>&</sup>lt;sup>4</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>5</sup> The chapeau of this subsection was also amended to address certified "innovation patents": *Patents* 

<sup>&</sup>lt;sup>5</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>&</sup>lt;sup>6</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.

(b) the patentee has contravened, or is contravening, Part IV of the *Competition and Consumer Act 2010* [(Cth)] <sup>[7]</sup> or an application law<sup>[8]</sup> ... in connection with the patent.

A further restriction on this system is the requirement that any decision to grant a compulsory license "must not be made ... that is inconsistent with a treaty between the Commonwealth and a foreign country". The meaning and application of this compulsory licensing system in Australia remains uncertain despite various reviews. While others have provided a comprehensive textual analysis of the existing compulsory licensing provisions, and the provisions in the *Patents Act 1990* (Cth) have been subjected to various reviews, the key uncertainties remain. The main uncertainties are set out below.

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<sup>&</sup>lt;sup>7</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>&</sup>lt;sup>8</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>9</sup> *Patents Act 1990* (Cth) s 136.

<sup>&</sup>lt;sup>10</sup> See Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, ALRC 99 (SOS Printing Group, 2004) 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 Sherer F and J Watal, "Post TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 *Journal of International Economic Law* 913.

<sup>5</sup> Journal of International Economic Law 913.

11 See, for recent examples, Nielsen J and D Nicol, "Whither Patent Use without Authorization in Australia" (2008) 36 Federal Law Review 333; Lawson C, "Public Interest Compulsory Licensing under the Patents Act 1990 (Cth): A Real Incentive or a Barrier to Working?" (2008a) 19 Australian Intellectual Property Journal 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 Australian Business Law Review 369.

<sup>&</sup>lt;sup>12</sup> Earlier reviews include Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, ALRC 99 (SOS Printing Group, 2004) pp 611-630; 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 27-31. See also Senate Economics Legislation Committee, *Provisions of the Intellectual Property Laws Amendment Bill 2006* (Senate Printing, 2006) pp 15-19 and 21 and Appendix 3 (p 14).

## "work" the invention (a)

The threshold limitation is that the *Patents Act 1990* (Cth) only 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" (emphasis added). <sup>13</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". 14 The concern 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". 15 These "exclusive rights" available to a patent holder include 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>16</sup>

In other words, a compulsory license 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>17</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. 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).

<sup>&</sup>lt;sup>13</sup> Patents Act 1990 (Cth) s 133(1).

<sup>&</sup>lt;sup>14</sup> Patents Act 1990 (Cth) Sch 1 ("work").

Patients Act 1990 (Cth) sch 1 ( work ).

15 Patents Act 1990 (Cth) s 13(1).

16 Patents Act 1990 (Cth) s 13(1) and Sch 1 ("exploit").

17 See Patents Act 1990 (Cth) s 13(1) and Sch 1 ("exploit").

### **(b) AUSFTA** limitations

The Patents Act 1990 (Cth) expressly requires that a compulsory license order be consistent with the AUSFTA. 18 as a treaty between "the Commonwealth and a foreign country". 19 The AUSFTA then provides *only* 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 1990 (Cth) and the Competition and Consumer Act 2010 (Cth);<sup>20</sup> and (ii) government use according to the Crown use provisions<sup>21</sup> or government acquisition provisions<sup>22</sup> in "cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency". 23 Notably absent from the AUSFTA scheme is the possibility in the existing Patents Act 1990 (Cth) scheme for a compulsory license 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>24</sup> This would appear to be a significant reduction in the apparent scope of the *Patents Act* compulsory licensing scheme.<sup>25</sup>

### (c) Uncertain interpretations

The Patents Act 1990 (Cth) threshold statutory requirements for the grant of a compulsory license are extraordinarily complex and difficult to interpret. The main concern is the requirement that "the reasonable requirements of the public with

<sup>&</sup>lt;sup>18</sup> Australia-United States Free Trade Agreement, Arts 17.1.1 and 17.1.6. <sup>19</sup> Patents Act 1990 (Cth) s 136.

<sup>&</sup>lt;sup>20</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* (Senate Printing, 2006) p 4.

<sup>21</sup> Patents Act 1990 (Cth) ss 163-172. See also Advisory Council on Intellectual Property, Review of Crown Use Provisions for Patents and Designs (IP Australia, 2005) pp 9-12.

<sup>&</sup>lt;sup>22</sup> Patents Act 1990 (Cth) s 171.

<sup>&</sup>lt;sup>23</sup> Australia-United States Free Trade Agreement, Art 17.9.7.

<sup>&</sup>lt;sup>24</sup> Patents Act 1990 (Cth) s 133(2)(a).

<sup>&</sup>lt;sup>25</sup> The term "anti-competitive practices" in AUSFTA could be interpreted as including the current Patents Act provisions, including the "the reasonable requirements of the public". This is the position advocated by the Australian Government: see Senate Economics Legislation Committee, Provisions of the Intellectual Property Laws Amendment Bill 2006 (Senate Printing, 2006) Appendix 3 (p 14). This may well be so where dealings with a pharmaceutical (such as denying access) are conducted by a corporation taking advantage of substantial market power, 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: see Competition and Consumer Act 2010 (Cth) s 46.

respect to the patented invention have not been satisfied". <sup>26</sup> The key phrase "reasonable requirements of the public with respect to the patented invention" is qualified in the *Patents Act 1990* (Cth):

... 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
  - (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>27</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>28</sup>

### (d) Court discretions in assessing applications

Whether the court grants a compulsory license on an application is a discretion – "the court may, subject to this section, make the order if satisfied that ...". <sup>29</sup> The exercise

<sup>27</sup> Patents Act 1990 (Cth) s135(1).

<sup>&</sup>lt;sup>26</sup> Patents Act 1990 (Cth) s 133(2)(a)(ii).

<sup>&</sup>lt;sup>28</sup> See, for an analysis of the legislative standards, Lawson C, "Public Interest Compulsory Licensing under the Patents Act 1990 (Cth): A Real Incentive or a Barrier to Working?" (2008a) 19 Australian Intellectual Property Journal 129, 130-145. See also Intellectual Property and Competition Review Committee, Review of Intellectual Property Legislation under the Competition Principles Agreement (IP Australia, 2000) pp 162-163.

<sup>&</sup>lt;sup>9</sup> Patents Act 1990 (Cth) s 133(2).

of a similarly worded discretion in the *Patents Act 1952* (Cth) was considered in *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation* (1969) 119 CLR 572.<sup>30</sup> There Justice Menzies 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 license 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>31</sup>

Justice Menzies approach was to determine whether one of the deeming circumstances for the *Patents Act 1952* (Cth) "reasonable requirements of the public" 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>32</sup> for declining to make the order.<sup>33</sup> The concern about this approach is that an applicant for a compulsory license cannot know why a patent holder (or their licensee or assignee) has refused a license so assessing the likely potential for lodging an application, and the patent holder (or their licensee or assignee) then has an opportunity after the application is lodged to remedy their activities to confound the application up to the date of the hearing.

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<sup>&</sup>lt;sup>30</sup> See *Patents Act 1952* (Cth) s 108(3).

<sup>&</sup>lt;sup>31</sup> Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation (1969) 119 CLR 572 at 574-575 (Menzies J).

<sup>&</sup>lt;sup>32</sup> Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation (1969) 119 CLR 572 at 575 (Menzies J).

<sup>&</sup>lt;sup>33</sup> Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation (1969) 119 CLR 572 at 574-575 (Menzies J).