

## COMMENT

# COMPULSORY LICENSING OF PATENTS IN AUSTRALIA: REFORMING THE LANDSCAPE OR FENCING US IN?

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*The Australian Productivity Commission released its final report to government into the compulsory licensing provisions of the Patents Act 1990 (Cth) on 28 March 2013. Its stated focus, however, is on the operation of compulsory licensing in Australia more broadly. Accordingly, it considered related parts of the Act, for example, the Crown use provisions and specific technology areas involving Standard Essential Patents, which have not undergone the same level of scrutiny in the past. One of the motivations for the inquiry was to assess whether the compulsory licensing provisions can be invoked efficiently and effectively, given the substantial costs and lengths of time associated with obtaining a Federal Court order. Despite the risk of significant barriers for potential applicants, the Commission found that there were no clear alternatives to the current arrangements, instead choosing to improve the criteria for granting a compulsory licence by introducing a public interest test. Before accepting the Commission's recommendations in their current form, it would be judicious for the Federal Government to ensure that the short-term interests of the public do not detract from the long-term objectives of the patent system.*

## I BACKGROUND

Once again there are calls for patent reform in Australia.<sup>1</sup> The Productivity Commission has recently released a report into the compulsory licensing provisions in the *Patents Act 1990* (Cth) (*'Patents Act'*).<sup>2</sup> Despite claims that the inquiry is largely in response to the findings of the Australian Law Reform

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1 One commentator recently said that there is a 'plethora of reviews into the Australian patent system': see Chris Dent, 'The Possibilities of a Regulatory Approach to Answer the Question: Should Genetic Inventions be Patentable?' (2012) 22(1) *Journal of Law, Information and Science* 16, 16.

2 Productivity Commission, 'Compulsory Licensing of Patents' (Inquiry Report No 61, 28 March 2013) (*'Final Report'*). Compulsory licensing is one of several mechanisms in the *Patents Act* that allows for a patented invention to be exploited without the authorisation of the patentee: at ss 133–136A. Other examples include Crown use and acquisition (at ss 163–71), seeking regulatory approval (at ss 119A–119B), experimental use (at s 119C), and use in or on foreign vessels, aircraft or vehicles temporarily in Australia (at s 118).

Commission's inquiry into gene patents,<sup>3</sup> its stated focus is on the operation of compulsory licensing in Australia more broadly.<sup>4</sup> As a consequence, this inquiry considered for review related parts of the *Patents Act*, for example, the Crown use provisions<sup>5</sup> and specific technology areas involving Standard Essential Patents (SEPs),<sup>6</sup> climate change and food security, which have not undergone the same level of scrutiny in the past.<sup>7</sup> Therefore the scope of the inquiry, as I will discuss, presented an opportunity to propose several reforms to both the *Patents Act* and *Competition and Consumer Act 2010* (Cth) ('CCA').<sup>8</sup> One of the motivations for the inquiry was to assess whether the compulsory licensing provisions can be invoked efficiently and effectively,<sup>9</sup> given the substantial costs and lengths of time

- 3 See David Bradbury and Mark Dreyfus, 'Balancing Access to Technology and Innovation' (Joint Media Release, 29 June 2012). In their statement, they said '[t]he compulsory licensing provisions are ... an important step in implementing the Government's Response to the Gene Patent Report'. In June 2004, the ALRC released its final report into gene patenting, *Genes and Ingenuity: Gene Patenting and Human Health*, which had as part of its Terms of Reference a focus on 'current patenting laws and practices — including licensing — related to genes and genetic and related technologies': Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) ('ALRC *Genes and Ingenuity Report*').
- 4 Productivity Commission, 'Compulsory Licensing of Patents' (Draft Report, December 2012) 5 ('*Draft Report*').
- 5 The Crown use provisions allow governments to exploit a patented invention without the patent holder's authorisation: see *Patents Act* ss 163–70. In circumstances where the government invokes its right, the patent holder is entitled to remuneration under s 165.
- 6 An SEP is, by definition, necessary for the implementation of a technical or industry standard: see Carl Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting' in Adam B Jaffe, Josh Lerner and Scott Stern (eds), *Innovation Policy and the Economy* (National Bureau of Economic Policy, 2000) vol 1, 119, 136 (noting that 'once a standard is picked, any patents (or copyrights) necessary to comply with that standard become truly essential'). As a result, downstream companies implementing an industry standard to manufacture goods would be required to seek authorisation from the patent holder to implement the standard.
- 7 For example, the Productivity Commission produced a research report into standard-setting activities in 2006, but it was restricted to laboratory accreditation arrangements in Australia: Productivity Commission, 'Standard Setting and Laboratory Accreditation' (Research Report, 2 November 2006). Prior to this, the Kean Inquiry in 1995 released a report into Australia's standards and conformance infrastructure, but did not address the issue of intellectual property rights and standards: see generally Committee of Inquiry into Australia's Standards and Conformance Infrastructure, 'Linking Industry Globally' (Report, 1995).
- 8 The *Patents Act* recognises that a failure to work a patent may give rise to a contravention of pt IV of the CCA: *Patents Act* s 133(2)(b). The inquiry is whether 'the patentee has contravened, or is contravening, Part IV of the *Competition and Consumer Act 2010* or an application law (as defined in section 150A of that Act) in connection with the patent': *Patents Act* ss 133(1), (2)(b). In practice, applications for compulsory licences would most likely fall under s 46 of the CCA, since the misuse of market power protections most directly apply to refusals to license.
- 9 See the 'Terms of Reference' in Bradbury and Dreyfus, above n 3. See generally Productivity Commission, 'On Efficiency and Effectiveness: Some Definitions' (Staff Research Note, May 2013).

associated with obtaining a compulsory licence order from the Federal Court.<sup>10</sup> Despite the risk of significant barriers for potential applicants, the Commission found that there were ‘no clear alternatives’ to the current arrangements.<sup>11</sup> However, other recommendations from the Commission are more practical, for instance, improving the criteria for granting a compulsory licence.<sup>12</sup> In the end, the implementation of the Commission’s recommendations into primary legislation will ultimately be determined by the government’s agenda for reform, including its reliance on cross-bench support in the Federal Senate.

A compulsory patent licence may be warranted in situations where the parties are not able to achieve an agreement or, alternatively, situations in which non-voluntary access ‘acts as a pro-competitive remedy that tempers the exclusivity’ of a patent grant.<sup>13</sup> With regard to the latter, seeking an order for a compulsory licence was viewed by an earlier inquiry as an ex post mechanism or safeguard against a patent holder abusing its market power.<sup>14</sup> According to one set of commentators, compulsory licensing ‘seeks to promote competition rather than to address consumer welfare directly’.<sup>15</sup>

10 *Patents Act* s 133(1) states: ‘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’. One submission to the inquiry estimated that an application to the Federal Court, if contested, would generally ‘involve fees in the range of \$200,000 to \$500,000’: see Scott Bouvier, King & Wood Mallesons, Submission No 2 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 21 September 2012, 2. Other participants estimate that a dispute involving a pharmaceutical patent could be well in excess of \$1 million in costs: see Civil Liberties Australia, Submission No 12 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 28 September 2012, 6; Walter and Eliza Hall Institute of Medical Research, Submission No 13 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 28 September 2012, 6; Institute of Patent and Trade Mark Attorneys, Submission No 18 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 28 September 2012, 10 [44]. As for the length of time, Federal Court statistics indicate that it is not uncommon for legal matters to take longer than 12 months to finalise: see Federal Court of Australia, *Annual Report 2011–2012* (14 September 2012) 132.

11 *Final Report*, above n 2, 23 (Finding 6.1).

12 *Ibid* 24 (Recommendation 6.2).

13 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (September 2000) 162 (‘Ergas Committee Report’). It is well established, however, that the use of compulsory licensing in the pharmaceutical industry is primarily targeted at providing access to medicines, rather than seeking market efficiency: see Reiko Aoki and John Small, ‘Compulsory Licensing of Technology and the Essential Facilities Doctrine’ (2004) 16 *Information Economics and Policy* 13, 15.

14 *Ergas Committee Report*, above n 13, 162–3. There have been only a few applications where Australian courts have been asked to grant a compulsory licence, but none have been successful: see *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation* (1969) 119 CLR 572; *Wissen Pty Ltd v Kenneth Mervin Lown* (1987) 9 IPR 124; *Amrad Operations Pty Ltd v Genelabs Technologies Inc* (1999) 45 IPR 447. Nevertheless, the *Ergas Committee Report* characterises the compulsory licensing provisions of the *Patents Act* as a remedy for certain contraventions of the (then) *Trade Practices Act 1974* (Cth), albeit poorly executed: *Ergas Committee Report*, above n 13, 162.

15 Aoki and Small, above n 13, 15. Alternatively, a compulsory licence may be viewed as the state retaining some control over the way in which the patent holder uses his or her exclusive rights: see Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press, 1951) 162.

The rest of the review is set out as follows.<sup>16</sup> Part II discusses the *Issues Paper*<sup>17</sup> and public submissions, before providing a brief account of the *Draft Report*. Adopting the usual approach, the Commission asked for public submissions upon the release of the *Issues Paper*. Part III considers the Commission's recommendations in the *Final Report*. In the end, only five substantive recommendations, and a call for an 'awareness raising' campaign in the form of a plain English guide developed jointly by IP Australia and the Australian Competition and Consumer Commission (ACCC), were proposed by the Commission. Part IV concludes with some comments on how to think about the recommendations of this inquiry.

## II FROM THE GENERAL TO THE SPECIFIC

### A Issues Paper

As with similar inquiries, the public aspect is not effectively launched until the release of the *Issues Paper* — in this case, on 9 August 2012. Notably, the Terms of Reference named a number of specific areas relevant to this inquiry.<sup>18</sup> These include gene patents and access to healthcare, food security, climate change and alternative energies, and SEPs. The *Issues Paper* provides some background to each of these areas of concern.

Two of the main ex post safeguards associated with the *Patents Act* are the compulsory licensing and the Crown use and acquisition provisions. The compulsory licensing provisions have been a feature of the Australian patents system since the first Commonwealth patents legislation,<sup>19</sup> and are currently embodied in ss 133–136A. In practice, the granting of a compulsory licence is subject to satisfying either a competition test or a 'reasonable requirements of the public' test.<sup>20</sup> Section 135 sets out the circumstances in which the 'reasonable requirements of the public' test will be satisfied. Generally speaking, the test is

16 There is a reviewer's discretion not to go over ground that has, in this author's opinion, been dealt with sufficiently by past inquiries: for example, an objects clause for the *Patents Act* and s 51(3) of the *CCA*. In both instances, a clear case for reform has been established elsewhere: see Advisory Council on Intellectual Property, 'Patentable Subject Matter' (Final Report, December 2010) 22–30; *ALRC Genes and Ingenuity Report*, above n 3, 570–2 [24.65]–[24.71].

17 Productivity Commission, 'Compulsory Licensing of Patents' (Issues Paper, August 2012) ('*Issues Paper*').

18 Ibid 20–4.

19 *Patents Act 1903* (Cth) s 87.

20 It should be noted that prior to any successful application to the Federal Court based on the reasonable requirements test, an applicant must have tried for a reasonable period to obtain authorisation from the patentee, but without success; and, the patentee has given no satisfactory reason for not exploiting the patented invention: see *Patents Act* s 133(2)(a). This test, according to one submission, has been mischaracterised by the Commission as a public interest test. The Centre for Law and Genetics noted that '[t]he focus of this ground for application has always been domestic manufacture and industry': Jane Nielsen, Dianne Nicol and John Liddicoat, Centre for Law and Genetics, Submission No 3 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 26 September 2012, 13. Nevertheless, if an application for a compulsory licence order is granted under either test, the patentee is to paid an agreed amount with the applicant, or a 'just and reasonable' amount to be determined by the court: see *Patents Act* s 133(5).

satisfied after establishing whether a trade or industry in Australia is unfairly prejudiced, or whether demand for the patented product in Australia has not been reasonably met.<sup>21</sup> The Crown use and acquisition provisions provide for the Commonwealth or State Government to exploit (or acquire) a patent without the patentee's authorisation for the services of the Commonwealth or state. The scope and terms of such use or acquisition are embodied in ss 163–71. Again, if these provisions are invoked, the patentee is entitled to compensation under ss 165(2) or 171(4) respectively.

Commentators in this debate have tended to focus on two themes: access to, and price for, a given technology or technological solution. The granting of gene patents, for example, has raised concerns about access to affordable healthcare, while other concerns centre on the ethical grounds for gene patenting itself. As noted by the Commission, 'gene patents remain a contentious issue',<sup>22</sup> which comes after two significant government reviews of this topic.<sup>23</sup> In both cases, the reviews concluded that reforms to specifically exclude human genes and genetic materials from the patent system were unwarranted. In response, the Australian Government said that it agreed in principle with the recommendations.<sup>24</sup>

## B What the Submissions Say

As of 4 March 2013, there were 35 submissions and 17 post-*Draft-Report* submissions in response to the Commission's request for comment.<sup>25</sup> Despite the fact that no applications for a compulsory licence have been granted in Australia,<sup>26</sup> the majority of submissions on this issue claimed that a 'lack of use' should not be an indication of its importance as an ex post safeguard.<sup>27</sup>

Unsurprisingly, many of the participants responded to the inquiry on issues relevant to their organisation or members. For example, a number of contributions came from the healthcare sector, where concerns were about gene patenting and

21 *Patents Act* s 135(1).

22 *Issues Paper*, above n 17, 22.

23 See generally *ALRC Genes and Ingenuity Report*, above n 3; Senate Community Affairs References Committee, Parliament of Australia, *Gene Patents Report* (2010).

24 See, eg, Australian Government, *Australian Government Response to Senate Community Affairs References Committee: Gene Patents Report* (November 2011) 10–11.

25 All public submissions to the inquiry are available on the Commission's website: Productivity Commission, *Compulsory Licensing of Patents: Submissions* <<http://www.pc.gov.au/projects/inquiry/patents/submissions>>. In addition, one public hearing was conducted after the issue of the *Draft Report* on 20 February 2013: Transcript of Proceedings, *Inquiry into Compulsory Licensing of Patents* (Productivity Commission, Presiding Commissioner A McClelland and Commissioner W Mundy, 20 February 2013). The transcript is available on the Commission's website: <[http://www.pc.gov.au/data/assets/pdf\\_file/0011/122204/20130220-melbourne-transcript.pdf](http://www.pc.gov.au/data/assets/pdf_file/0011/122204/20130220-melbourne-transcript.pdf)>. This Part of the Comment will highlight content from the initial submissions, unless indicated otherwise.

26 *Issues Paper*, above n 17, 11–12. See also above n 14.

27 Institute of Patent and Trade Mark Attorneys, above n 10, 11; Law Council of Australia, Submission No 32 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 15 October 2012, 1; Advisory Council on Intellectual Property, Submission No 35 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 23 October 2012, 1.

easing of the compulsory licensing provisions.<sup>28</sup> The majority of comments were directed at the detrimental effects on affordable healthcare, and on research and development in the sector. Similar concerns were also pressed by other technology sectors.<sup>29</sup> As a consequence, several organisations advocated for no change to the current arrangements, or supported only amendments to clarify the scope and purpose of the current provisions.

Of the other major themes to come through from the submissions, several inquiry participants raised concerns about the operation of s 133 in the context of the *Australian-United States Free Trade Agreement*.<sup>30</sup> At the heart of the problem lies the fact that both Australia and the United States have agreed to limit the grounds for compulsory licences to situations provided under art 17.9.7 of the *AUSFTA*.<sup>31</sup>

### C Draft Report

The *Draft Report* (spanning 306 pages) was released on 14 December 2012, with the early chapters devoted to the rationale for patents, and the key features and utilisation of the patent system.<sup>32</sup> Notably, the Commission found that Australia has rarely granted compulsory licences, in line with most other countries except for the United States.<sup>33</sup>

Concerns raised in the *Issues Paper* about access, cost and timeliness were the subject of discussions in chs 5–6. A central question of the debate was whether human genes should be patentable. The uncertainty surrounding this issue has had a significant impact on particular industries, such as the biotechnology

28 See, eg, Medicines Australia, Submission No 10 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 28 September 2012; Walter and Eliza Hall Institute of Medical Research, above n 10; Peter MacCullum Cancer Centre, Submission No 14 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 28 September 2012; National Health and Medical Research Council, Submission No 33 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 22 October 2012.

29 See, eg, CSL, Submission No 5 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 27 September 2012; CropLife, Submission No 6 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 27 September 2012; Alliance for Clean Technology Innovation, Submission No 9 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 28 September 2012.

30 *Australian-United States Free Trade Agreement*, opened for signature 18 May 2004, [2005] ATS 1 (entered into force 1 January 2005) ('*AUSFTA*'). The *AUSFTA* 'came into effect on 1 January 2005, and primarily ensures greater access to the United States of America market for Australian products': Law Council of Australia, above n 27, 6. The Law Council of Australia says '[t]he implications for Australia from entering this bilateral agreement is that not only does any domestic patent legislation have to comply with the minimum standards set by TRIPS, but it must also comply with the much higher standards agreed to under *AUSFTA*'. The relevance of this issue is provided in s 136 of the *Patents Act*, which specifies that an order for a compulsory licence must not be inconsistent with international agreements.

31 Centre for Law and Genetics, above n 20, 12, 16–17; Law Council of Australia, above n 27, 6. See also Charles Lawson, Submission No 36 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 21 December 2012, 5 (submitted post-Draft-Report).

32 *Draft Report*, above n 4, chs 2–4.

33 Ibid 56–7. See also at app C, which details the common features of compulsory licences in comparable markets, including the United States. Since the Commission's draft recommendations are reproduced in full in the *Final Report*, discussion of their substance will be left for Part III.

and pharmaceutical industries, and with access to healthcare more generally.<sup>34</sup> Although the Commission supports the conclusions of past reviews, in that a gene patent exclusion is considered unwarranted, it did venture into the area of healthcare access.<sup>35</sup> More specifically, the Commission considered other mechanisms, such as exclusions and exemptions for healthcare, public-health-specific compulsory licensing arrangements, and the use of government purchasing power to control the cost of patented healthcare products.<sup>36</sup>

Another area deemed worthy of attention is that of technical or industry standards.<sup>37</sup> Following on from the *Issues Paper*, the Commission focused its inquiry on SEPs, which are important to technologies in the telecommunications, information technology and consumer electronics industries.<sup>38</sup> The main concern raised by the Commission relates to the risk of market power abuse by patent holders when SEPs are adopted in a standard.<sup>39</sup> But even faced with considerable evidence of litigation activity involving SEPs in other jurisdictions, the Commission was quick to alleviate any further concerns by advocating pt IV of the *CCA* as a catch-all remedy.<sup>40</sup> Beyond this the Commission ‘does not agree that specific measures aimed at these industries are necessary’.<sup>41</sup>

The Commission does advocate for change in ch 6 of the *Draft Report*. In unequivocal terms, the Commission stated that there is a case for reforming the criteria for ordering a compulsory licence.<sup>42</sup> One of the grounds for a compulsory licence order is satisfied if a patentee contravenes pt IV of the *CCA* after a prescribed period.<sup>43</sup> The government introduced this competition-based test in 2006 as an additional ground to s 133 of the *Patents Act* with cross-referencing to the *CCA*.<sup>44</sup> According to the Commission’s findings, the cross-reference to the *CCA* in s 133(2)(b) of the *Patents Act* undermines the effectiveness of the *Patents Act*, since the *CCA* provides a broader and lower-cost alternative for potential applicants.<sup>45</sup>

34 The normative debate being had over whether genetic material should be patentable is beyond the scope of this review.

35 *Draft Report*, above n 4, ch 9.

36 *Ibid* 188–208.

37 Industry standards are developed for a number of purposes, including to achieve minimum objectives of safety, quality or performance for a product or service, or to promote interoperability across a range of industries and new technologies.

38 Since products in these industries may require market participants to acquire hundreds, if not thousands of patent licences, the risk of patent hold-up is more pronounced with SEPs: see, eg, Telstra Corporation Ltd, Submission No 8 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, September 2012, 2–3.

39 *Draft Report*, above n 4, 102.

40 *Ibid* 102–3. According to the Commission, competitors or potential competitors can rely on s 46 of the *CCA* for any market power abuses generally, or s 133(2)(b) *Patents Act* (‘competition test’) specifically if a compulsory licence is sought.

41 *Draft Report*, above n 4, 104. A similar view is held by the Commission with regard to climate change and alternative energies, and food security: at 106, 109.

42 *Draft Report*, above n 4, 13.

43 *Patents Act* s 133(2)(b). *Patent Regulations 1991* (Cth) reg 12.1 specifies that the prescribed period is a period of 3 years after the date of granting the patent.

44 *Intellectual Property Laws Amendment Act 2006* (Cth) sch 8 item 2, amending *Patents Act* s 133(2).

45 *Draft Report*, above n 4, 135.

It is also apparent that the Commission is in favour of clarifying when the Crown use provisions can be utilised, in particular in relation to healthcare.<sup>46</sup> One motive for this position is, perhaps, that the Crown use provisions are seen as a less costly and timelier option than a compulsory license, where governments can access patents specifically for healthcare purposes. To assist this practice, some inquiry participants would like to see the *Patents Act* explicitly state that Crown use is applicable to healthcare.<sup>47</sup> However, singling out healthcare as a special case in the Act would be contrary to the widely supported approach of having a technology-neutral patents system.<sup>48</sup>

Finally, the *Draft Report* briefly discusses two exemptions associated with the non-voluntary access to patents in Australia — the experimental exemption and regulatory approval exemption.<sup>49</sup> The ‘Raising the Bar’ legislation introduced in 2012 amended the *Patents Act* by inserting s 119C to allow the use of a patented invention for experimental purposes.<sup>50</sup> A series of past reviews highlighted how the absence of a research exemption inhibited follow-on innovation and caused uncertainty concerning patent infringement.<sup>51</sup> The regulatory approval exemption in s 119A was introduced in 2006 to provide an exemption from infringement for use of a pharmaceutical patent for the purposes of regulatory approval.<sup>52</sup> The Raising the Bar reforms extended the exemption to a ‘product, method or process’ that requires approval by a law of the Commonwealth, or of a state or territory.<sup>53</sup> In effect, this exemption allows generic pharmaceutical manufacturers to bring their products to market sooner.<sup>54</sup>

46 Ibid 168.

47 See Centre for Law and Genetics, above n 20, 10; Civil Liberties Australia, above n 10, 6–7; Department of Health and Ageing (Cth), Submission No 22 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, September 2012, 3, 6. A similar proposal was endorsed by the ALRC in its review of gene patents: see *ALRC Genes and Ingenuity Report*, above n 3, 33.

48 See Centre for Law and Genetics, above n 20, 19; Medicines Australia, above n 28, 2; Civil Liberties Australia, above n 10, 9; Walter and Eliza Hall Institute of Medical Research, above n 10, 7; Institute of Patent and Trade Mark Attorneys, above n 10, 13 [56]; Advisory Council on Intellectual Property, Submission No 35, above n 27, 2. For a contrary position, see Hazel Moir, Submission No 46 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 8 February 2013, 12 (submitted post-*Draft-Report*).

49 *Draft Report*, above n 4, ch 8. These legislative exemptions allow third parties to exploit a patented invention without the patentee’s authorisation under certain circumstances.

50 *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) sch 2 item 1, inserting *Patents Act* s 119C.

51 See generally *ALRC Genes and Ingenuity Report*, above n 3, ch 13; Advisory Council on Intellectual Property, ‘Patents and Experimental Use’ (Final Report, October 2005). For example, there is evidence that researchers have held the view that an implicit or practice-based exemption already exists under Australian patent law: see Centre for Law and Genetics, above n 20, 8.

52 *Patents Act* s 119A, as inserted by *Intellectual Property Laws Amendment Act 2006* (Cth) sch 7 item 3, exempts a person exploiting a pharmaceutical patent for the purposes of obtaining inclusion in the Australian Register of Therapeutic Goods, or a similar regulatory approval under a foreign law.

53 *Patents Act* s 119B, as inserted by *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) sch 2 item 1.

54 *Draft Report*, above n 4, 182.



### III FINAL REPORT AND RECOMMENDATIONS

The *Final Report* (spanning 316 pages) was delivered to the government on 28 March 2013. In large part, the report duplicates the contents of the *Draft Report*, with chs 1–10 (including the appendices) reproduced in full.<sup>55</sup> As for the rest, there were slight changes to the Overview and some amendments taken into the Final Recommendations.

First, to the Overview and the Commission's comments. The language of the report locates compulsory licensing as an ex post safeguard,<sup>56</sup> and asks whether such a safeguard is needed. Based on evidence and feedback from inquiry participants, Australia's compulsory licensing provisions have been rarely used.<sup>57</sup> Amongst the explanations put forward by commentators were the following reasons:

1. compulsory licensing acts as an effective deterrent;
2. it is only needed in exceptional circumstances; and
3. the process of obtaining a compulsory licence remains costly and time consuming.<sup>58</sup>

The Commission suggests that only the third explanation warrants a case for reform, but, in the end, determines that there are 'no clear alternatives to the Federal Court'.<sup>59</sup>

Where the inquiry does take the current arrangements to task is with the criteria for granting a compulsory licence. The Commission recommends there is a 'clear case to strengthen the criteria for granting a compulsory licence, and to remove overlap and inconsistency across different pieces of legislation'.<sup>60</sup> As discussed above, there are essentially two grounds for granting a compulsory licence — the 'reasonable requirements of the public' test<sup>61</sup> and the competition test.<sup>62</sup> In response, the Commission proposes to replace the former with a new 'public interest' test, which would be assessed according to whether the patented invention delivers a substantial net benefit to the community as a whole.<sup>63</sup> The other ground for a compulsory licence aims to address anti-competitive behaviour. It does so by cross-referencing the *Patents Act* with pt IV of the *CCA*. However, the Commission believes this 'creates overlap and inconsistency' because different

55 On one hand, these background chapters (constituting over 90 per cent of the report) together may be the only document readers encounter; then perhaps, it serves to repeat the efforts of the inquiry in the final report: see *Final Report*, above n 2, 29. Some slight textual changes exist to align it with the final recommendations and findings.

56 *Ibid* 7.

57 Since first appearing in the *Patents Act 1903* (Cth), only three applications for a compulsory licence order have been made, with none being successful: see above n 14.

58 *Final Report*, above n 2, 12.

59 *Ibid* 13.

60 *Ibid* 14.

61 *Patents Act* s 133(2)(a).

62 *Ibid* s 133(2)(b).

63 *Final Report*, above n 2, 24 (Recommendation 6.2).

remedies and litigation pathways are available to prospective applicants.<sup>64</sup> As a consequence, the Commission recommends removing s 133(2)(b) (competition test), and amending the *CCA* to explicitly make compulsory licences available as a remedy for breaches of pt IV of the *CCA*.<sup>65</sup>

The third criticism directed towards the compulsory licensing provisions involves clarifying the international treaty obligations contained in s 136 of the *Patents Act*.<sup>66</sup> At present, Australian courts must not make an order for a compulsory licence ‘that is inconsistent with a treaty between the Commonwealth and a foreign country’.<sup>67</sup> One of the predictable outcomes from the inquiry has been to expose the restrictive nature of this obligation on the part of the Federal Court.<sup>68</sup> As noted by the Commission, there are widely held views that the *AUSFTA* creates inconsistencies with the granting of compulsory licences under s 133(2)(a).<sup>69</sup> Additionally, there is no certainty that the Commission’s proposed public interest test would satisfy the *AUSFTA*.<sup>70</sup> Despite the Australian Government publicly stating that the existing compulsory licensing is compliant with the *AUSFTA*,<sup>71</sup> to remove any doubt, the Commission recommends repealing s 136 and proposes that any treaty obligations with respect to compulsory licensing should be incorporated directly into the Act.<sup>72</sup>

The second grouping of provisions that fall within the scope of the inquiry are the Crown use and acquisition provisions.<sup>73</sup> These provisions allow Australian and state governments to exploit a patented invention, or acquire it, for the services

64 Ibid 15.

65 Ibid 23 (Recommendation 6.1). A similar, but apathetic conclusion, was arrived at by an earlier inquiry: Industrial Property Advisory Committee, ‘Patents, Innovation and Competition in Australia’ (Report, 29 August 1984) 30.

66 *Final Report*, above n 2, 16.

67 *Patents Act* s 136.

68 A number of academic commentators have long held this view. Nielsen and Nicol suggest that the Federal Court ‘will be restricted in its interpretation of [s 133] to the *AUSFTA* grounds’: Jane Nielsen and Dianne Nicol, ‘Whither Patent Use Without Authorisation in Australia?’ (2008) 36 *Federal Law Review* 333, 358. They also question the validity of the reasonable requirements of the public test. Similarly, Lawson has said ‘the *AUSFTA* provision would appear to expressly exclude the operation of s 133(2)(a)’: Charles Lawson, ‘Public Interest Compulsory Licensing under the *Patents Act* 1990 (Cth): Real Incentive or a Barrier to Working?’ (2008) 19 *Australian Intellectual Property Journal* 129, 146.

69 *Final Report*, above n 2, 16. See also Civil Liberties Australia, above n 10, 7; Institute of Patent and Trade Mark Attorneys, above n 10, 12 [53]; Alphapharm, Submission No 48 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 8 February 2013, 2 (submitted post-Draft-Report); Public Health Association of Australia, Submission No 52 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 4 March 2013, 6–7 (submitted post-Draft-Report).

70 *Final Report*, above n 2, 16. See also Alphapharm, Submission No 51 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 26 February 2013, 2 (submitted post-Draft-Report).

71 *ALRC Genes and Ingenuity Report*, above n 3, 617 [27.22].

72 *Final Report*, above n 2, 25 (Recommendation 6.3).

73 *Patents Act* ss 163–71. The Terms of Reference asked the Commission to ‘[r]ecommend any alternative mechanisms deemed necessary’ to ensure reasonable access to healthcare services: see *Final Report*, above n 2, vi.

of the Crown without the patentee's authorisation.<sup>74</sup> Unlike the compulsory licensing provisions, governments do not need to negotiate with the patentee before exploiting the patent, which may provide a less costly and time-consuming alternative.<sup>75</sup>

One of the key issues arising from the inquiry was whether Crown use provisions could be applied to patented healthcare products given that governments are responsible for the supply of many healthcare services.<sup>76</sup> However, inquiry participants raised several concerns about the legitimacy of such use.<sup>77</sup> First, the Act can only be used 'for the services of' a government, which may be narrowly construed by the courts to exclude healthcare.<sup>78</sup> Second, some healthcare services are supplied by non-government organisations, for example, testing laboratories, which may be considered outside the scope of the Crown use provisions.<sup>79</sup> And third, there were some concerns about whether individual states could authorise such use outside their borders.<sup>80</sup> Taken as a whole, the Commission proposes that any 'uncertainty [should] be addressed by clarifying the scope of Crown use'.<sup>81</sup>

In particular, the Commission recommends amending s 163 to make it clear that Crown use can be invoked for services that all levels of government have primary responsibility for providing or funding.<sup>82</sup> The second recommendation offered in relation to Crown use is more procedural in nature: it adds the conditions that the Crown should attempt prior negotiations with the patentee before invoking Crown use,<sup>83</sup> and that any exercise of Crown use must be approved by the relevant Minister.<sup>84</sup> This proposal aligns with previous concerns about the protection of patentees' rights.<sup>85</sup>

Finally, in less enthusiastic terms, the Commission suggests: 'there may be a case for some awareness-raising initiatives about compulsory licensing'.<sup>86</sup> The Commission's evaluation on the subject is to recommend a jointly authored plain English guide by IP Australia and the ACCC.<sup>87</sup>

74 The Commission reports that only two cases of Crown use have reached the courts, both of which were allowed, but no cases of patent acquisition are known to the Commission: see *Final Report*, above n 2, 164–6. See also *General Steel Industries Inc v Commissioner for Railways (NSW)* (1964) 112 CLR 125; *Stack v Brisbane City Council* (1995) 59 FCR 71.

75 See *Patents Act* s 164: 'after an invention has been exploited under subsection 163(1), the relevant authority must inform the applicant'.

76 See *Final Report*, above n 2, 169–74.

77 Ibid 170.

78 Ibid 171.

79 Department of Health and Ageing (Cth), above n 47, 5.

80 See Civil Liberties Australia, above n 10, 6; Royal College of Pathologists of Australasia, Submission No 16 to Productivity Commission, *Compulsory Licensing of Patents Inquiry*, 28 September 2012, 2; Department of Health and Ageing (Cth), above n 47, 6.

81 *Final Report*, above n 2, 18.

82 Ibid 25 (Recommendation 7.1).

83 The Commission stipulates that this should be waived in emergencies: ibid 25 (Recommendation 7.2).

84 Ibid 25 (Recommendation 7.2).

85 See, eg, Advisory Council on Intellectual Property, 'Review of Crown Use Provisions for Patents and Designs' (Final Report, November 2005) 3 (Recommendation 1).

86 *Final Report*, above n 2, 228.

87 Ibid 25 (Recommendation 10.1).

#### IV REFORMING THE LANDSCAPE OR FENCING US IN?

The Commission's inquiry into the compulsory licensing of patents has now drawn to a close, but as I indicated above, the task of integrating these proposed reforms into legislation is far from guaranteed. At the time of writing, the headlines across the nation's media must read like a hurricane warning for the new Federal Coalition Government.<sup>88</sup> So, perhaps now is a good time to reflect and briefly consider the policy context of the inquiry.

The notion of a compulsory patent licence arose from the historical requirement that a patentee must locally work a patented product or process.<sup>89</sup> This meant that the patentee was required to use the patented invention in the country where the patent was granted. In some cases where a patentee failed to work the invention locally, the patent was subject to revocation.<sup>90</sup>

Switch to today: one of the criticisms to come out of the inquiry is the use of protectionist language in s 135(1) (the 'reasonable requirements of the public' test).<sup>91</sup> As mentioned earlier, one of the grounds for a court to grant a compulsory license order is that it finds 'the reasonable requirements of the public with respect to the patented invention have not been satisfied'.<sup>92</sup> The ground is qualified by a range of criteria in s 135. Relevantly, s 135(1)(a) of the *Patents Act* suggests that the requirements are not satisfied if 'an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or demand in Australia for the patented product ... is not reasonably met'.

With reference to s 135(1) of the *Patents Act*, the Commission explicitly stated that 'the conflation of the reasonable requirements of the public with the interests of the Australian industry is problematic'.<sup>93</sup> It believes '[t]he purpose of the reasonable requirements ... test should not be to protect the interests of a particular trade or industry, if this comes at a net cost to the broader community'.<sup>94</sup> A salient example is where providing a compulsory licence for the benefit of an Australian industry (ie to the applicant company) will over time act as a disincentive for

88 See, eg, Katharine Murphy, 'Clive Palmer Forms Senate Alliance with Motoring Enthusiast Party's Ricky Muir', *The Guardian* (online), 10 October 2013 <<http://www.theguardian.com/world/2013/oct/10/clive-palmer-senate-alliance-ricky-muir>>; James Massola, Mathew Dunkley and Joanna Mather, 'Palmer's Party Unites with Muir in Senate Bloc', *The Australian Financial Review* (online), 10 October 2013 <[http://www.afr.com/p/national/palmer\\_party\\_unites\\_with\\_muir\\_in\\_0KCYL41amw6TSBGOLDZACM](http://www.afr.com/p/national/palmer_party_unites_with_muir_in_0KCYL41amw6TSBGOLDZACM)>. The subtext to these reports is a prediction that the Senate will shift to the right: see Nick Economou, 'The 2013 Senate Contest: Australia Lurches to the Right', *The Conversation* (online), 3 October 2013 <<http://theconversation.com/the-2013-senate-contest-australia-lurches-to-the-right-17535>>.

89 Penrose, above n 15, 140–1.

90 Ibid 159.

91 *Final Report*, above n 2, 148–9. Such observations about the compulsory licensing provisions are not new, 'they hark back to a period where the primary concern was the promotion of domestic industry, rather than securing the best use of resources and achieving high levels of productivity': *Ergas Committee Report*, above n 13, 162.

92 *Patents Act* s 133(2)(a)(ii).

93 *Final Report*, above n 2, 148.

94 Ibid.

foreign entities to market their products locally. This is one of the reasons why the Commission has recommended a new 'public interest' test to replace the current reasonable requirements test.<sup>95</sup> In proposing a public interest test, the Commission seems mindful of the trade-off between the rights of the patentee and the interests of the broader public, but the conditions precedent specified in its recommendations are less than novel.<sup>96</sup>

The other policy context in which this inquiry should be considered is the purpose of the compulsory licensing provisions. There have been several assertions about how compulsory licensing encourages the licensing and working of patented inventions sooner.<sup>97</sup> It does so by serving as an incentive (or threat) for patentees to grant a voluntarily licence on agreed terms.<sup>98</sup> However, there is scant anecdotal and no empirical evidence regarding the use of compulsory licensing in Australia and its efficiency and effectiveness. Joined with other criticisms, such as ill-defined language and the considerable expense associated with obtaining an order under s 133, it seems unlikely the current thresholds will encourage potential applicants, local or otherwise. The policy question then is whether these barriers have been appropriately addressed by the inquiry, such that compulsory licensing may 'promote the efficient use of patents and promote competition'.<sup>99</sup> Before accepting the Commission's recommendations in their current form, it would be judicious for the government to ensure that the short-term interests of the public do not detract from the long-term objectives of the patent system.<sup>100</sup>

## V POSTSCRIPT

Since the conclusion of the inquiry in March 2013, the Federal Government issued a new amendment Bill, entitled the Intellectual Property Laws Amendment Bill 2013 (Cth), which was introduced to Parliament on 30 May 2013. The Bill includes amendments to clarify that the Crown use provisions can be used, under appropriate circumstances, to enable the provision of services that the relevant governments have primary responsibility for funding or providing.<sup>101</sup> The Bill also seeks to improve transparency and accountability in the process for using

95 Ibid 24 (Recommendation 6.2). Other concerns identified by the Commission about s 133(2)(a) were its unclear purpose, ill-defined language and the construction of s 135 generally: at 147–8.

96 Ibid 151. For instance, a compulsory licence shall be made available if national demand for a product or service has not been met on reasonable terms: a residual element of *Patents Act* s 135(1)(a).

97 See *Ergas Committee Report*, above n 13, 162; Charles Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97, 114; Dianne Nicol and Jane Nielsen, 'Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry' (Occasional Paper No 6, Centre for Law and Genetics, 2003) 238; Explanatory Memorandum, Intellectual Property Laws Amendment Bill 2006 (Cth) 12.

98 Lawson, 'Public Interest Compulsory Licensing', above n 68, 145.

99 Explanatory Memorandum, Intellectual Property Laws Amendment Bill 2006 (Cth) 1.

100 See Advisory Council on Intellectual Property, 'Patentable Subject Matter', above n 16, 5 (Recommendation 2).

101 Intellectual Property Laws Amendment Bill 2013 (Cth) sch 1 item 4.

the Crown use provisions.<sup>102</sup> Both of these proposed amendments effectively implement the Commission's recommendations in full.<sup>103</sup>

Following on from a government announcement in 2011 to improve access to medicines,<sup>104</sup> the Bill also seeks to introduce compulsory licences for pharmaceutical exports to developing countries.<sup>105</sup> In sum, the reforms aim to enable Australian courts to issue compulsory licences to generic manufacturers to produce and export pharmaceutical products to eligible importing countries, compliant with Australia's obligations under the *TRIPS Agreement* and the *TRIPS Protocol*.<sup>106</sup>

The Bill passed the House of Representatives without amendment on 25 June 2013. It then moved to the Senate and was introduced on 28 June 2013. On 4 August 2013, Prime Minister Kevin Rudd announced a federal election for 7 September 2013, causing all legislation not yet passed in both houses of Parliament to lapse. As a consequence, the Bill will need to begin the process all over again in the current Parliament.

102 Ibid sch 1 item 5.

103 See *Final Report*, above n 2, 25 (Recommendations 7.1, 7.2).

104 Kim Carr and Craig Emerson, 'Better Access to Medicines for Countries in Need' (Joint Media Release, 22 March 2011).

105 Intellectual Property Laws Amendment Bill 2013 (Cth) sch 2 item 19.

106 *Draft Report*, above n 4, 183. See *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) annex 1C ('*TRIPS Agreement*'); *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (8 December 2005) (Decision of 6 December 2005) annex ('*TRIPS Protocol*').