

## Australia

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### I. The Pharmaceutical Industry and Competition Law

#### LEGISLATION

The federal legislation covering both competition-law and consumer-law issues arising, or potentially arising, in the pharmaceutical industry in Australia is the *Competition and Consumer Act 2010* (Cth) (CCA).<sup>1</sup> Competition law is primarily contained within Part IV.

Several forms of anticompetitive practices are expressly subject to *per se* prohibition:

- Cartels [Part IV, Division 1, ss 44ZZRA-44ZZRV];<sup>2</sup>
- Primary boycotts [s 4D, s 45(2)(a)(i) and s 45(2)(b)(i)];<sup>3</sup>
- Third line forcing (form of exclusive dealing) [s 47(6) and (7)];<sup>4</sup>
- Minimum resale price maintenance (including vertical price fixing) [s 4, s 48, ss 96-100].

Despite the *per se* prohibition, all of these forms of conduct may be authorised in advance<sup>5</sup> if the parties can demonstrate that there are public benefits arising from the conduct that would outweigh the likely anticompetitive detriment. Other forms of anticompetitive conduct, misuse of market power (s 46), exclusive dealing (s 47) and other restrictive horizontal arrangements than the above-mentioned (s 45) are not prohibited *per se*. Exclusive dealing and collective bargaining can be

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<sup>1</sup> The Act was previously named the *Trade Practices Act 1974* (Cth). The Australian Constitution, the *Commonwealth of Australia Constitution Act (1900)*, limits the extent to which the federal government can legislate. For that reason, states and territories enacted a 'schedule' version of the Part IV of the CCA, which contains core provisions on competition law. The CCA and the enacted schedule ensure a nationally consistent competition law.

<sup>2</sup> Part IV, Division 1 of the *Competition and Consumer Act 2010* (Cth). This incorporates price-fixing, output restrictions, allocation of customers, suppliers or territories and bid rigging. This conduct is both a criminal offence and subject to civil penalties. Certain joint venture activity is excluded from the scope of the *per se* prohibition, but remains subject to the general prohibition against anticompetitive agreements in s45.

<sup>3</sup> In Australia these are referred to as 'exclusionary provisions' and are *per se* prohibited where they involve an agreement between competitors having the purpose of preventing, restricting or limiting supply or acquisition to defined persons or classes of persons: ss 45 and 4D of the CCA. Joint ventures benefit from a limited competition defence: s 76C of the CCA.

<sup>4</sup> Unlike other forms of exclusive dealing, it is *per se* prohibited, but it is possible for the conduct to be 'notified' and receive immunity on public benefit grounds. This occurs when supply is made on the condition that goods or services are purchased from an unrelated third party (or there is a refusal to supply because of failure to agree to such a condition).

<sup>5</sup> It is not possible for conduct to be retrospectively authorised; approval must be provided in advance of the conduct occurring or it will contravene the Act notwithstanding any demonstrated public benefits.

individually exempted from prohibition through the 'notification' process, which is less demanding than authorisation. Both s 46 and s 47 are provisions on competition law that are highly relevant to the pharmaceutical sector as they could be applied to forms of 'evergreening' and other forms of facilitating the market position of products based on patents.<sup>6</sup>

The CCA does not include a special regime for the pharmaceutical industry (unlike, for instance, the telecommunication market). Therefore, the general provisions of the CCA on competition and consumer laws apply to the pharmaceutical sector.<sup>7</sup> Nevertheless, s 51, which provides exceptions from the application of competition law of the CCA, is of great importance to the pharmaceutical sector. Subsection 51(3) exempts intellectual property (IP), including licencing arrangements (in particular conditional licensing), from the application of competition law provisions in Part IV, other than misuse of market power (s 46) and resale price maintenance (s 48). It provides that

[a] contravention of a provision of [Part IV] other than section 46, 46A or 48 shall not be taken to have been committed by reason of:

- (a) the imposing of, or giving effect to, a condition of:
  - (i) a licence granted by the proprietor, licensee or owner of a patent, of a registered design, of a copyright or of EL rights within the meaning of the *Circuit Layouts Act 1989*, or by a person who has applied for a patent or for the registration of a design; or
  - (ii) an assignment of a patent, of a registered design, of a copyright or of such EL rights, or of the right to apply for a patent or for the registration of a design; to the extent that the condition relates to:
    - (iii) the invention to which the patent or application for a patent relates or articles made by the use of that invention;
    - (iv) goods in respect of which the design is, or is proposed to be, registered and to which it is applied;
    - (v) the work or other subject matter in which the copyright subsists; or
    - (vi) the eligible layout in which the EL rights subsist;
- (b) the inclusion in a contract, arrangement or understanding authorizing the use of a certification trade mark of a provision in accordance with rules applicable under Part XI of the *Trade Marks Act 1955*, or the giving effect to such a provision; or
- (c) the inclusion in a contract, arrangement or understanding between:
  - (i) the registered proprietor of a trade mark other than a certification trade mark; and
  - (ii) a person registered as a registered user of that trade mark under Part IX of the *Trade Marks Act 1955* or a person authorized by the contract to use the trade mark subject to his or her becoming registered as such a registered user;of a provision to the extent that it relates to the kinds, qualities or standards of goods bearing the mark that may be produced or supplied, or the giving effect to the provision to that extent.

Section 51(3) has been widely criticised. For instance, the Australian competition authority, the Australian Competition and Consumer Commission (ACCC), has expressed the view that s 51(3) should be repealed. First, the ACCC points out that despite the presumption, inherent in the exemption, that arrangements on licensing or assigning IP rights are procompetitive, this is not always the case, as some arrangements can damage competition in the form of decreased efficiency

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<sup>6</sup> See also Part III of this chapter.

<sup>7</sup> There is one key exception; Australia has recently introduced 'price signalling' laws which currently apply only to the banking sector. However, where price signalling constitutes cartel conduct it will be captured. The specific price signalling laws will not be discussed further as they currently have no application outside the banking sector. Outside the core competition provisions in Part IV, there are some competition provisions specific to certain industries; most notably, the telecommunications industry.

and welfare. Where licensing arrangements do not restrict competition the CCA does not prohibit them. In other cases, where competition could be restricted, but public benefits nevertheless justify the adoption of such arrangements, the general authorisation process could be utilised. Secondly, the ACCC notes that s 51(3)(a) is uncertain in scope because of the connotation 'to the extent that the condition relates to' that could be interpreted in different ways.<sup>8</sup>

A recent extensive independent review of competition policy and law, the 'Harper Review' (2015),<sup>9</sup> initiated by the Australian Government in 2014, found s 51(3) was unnecessary and proposed its immediate repeal. Conditional licensing, which is exempted under s 51(3), can, in the pharmaceutical sector, lead to a substantial lessening of competition, which would be prohibited in the CCA if not for the exemption under s 51. In this respect, the Harper Panel noted that '[i]n fields in which there are multiple and competing IP rights, such as the pharmaceutical or communications industries, cross-licensing arrangements can be entered into to resolve disputes but which impose anti-competitive restrictions on each licensee'.<sup>10</sup>

The Australian Government subsequently initiated a review of the IP arrangements, as proposed in the Harper Report, and is awaiting its final report and recommendations before making a final decision on s 51(3). The IP Draft Report, released as part of this review in April 2016, recommended that s 51(3) be repealed.<sup>11</sup> It is likely that this provision will be repealed.

#### CASES AND MISUSES OF MARKET POWER

There are a very limited number of competition law cases involving pharmaceutical companies in Australia, despite the fact that competition law can be enforced both privately and publicly. There are two key reasons that may explain the general absence of litigation. The first is the broad exemption under s 51(3). The second is that the provision dealing with abuse of dominant position (misuse of market power (s 46)), which is likely to be of most significance to anti-competitive conduct in the pharmaceutical industry, requires both proof of anticompetitive intent and that this intent is linked to the company's substantial market power. This has been difficult to prove in practice, both in pharmaceutical and other cases. The ACCC has succeeded on one occasion in

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<sup>8</sup> ACCC, *ACCC submission to the Productivity Commission Inquiry into Intellectual Property Arrangements in Australia* (November 2015), p 14, available at <<https://www.accc.gov.au/system/files/ACCC%20Submission%20-%20PC%20inquiry%20into%20IP%20arrangements%20in%20Australia%20-%2030%20November.pdf>> (11 May 2016).

<sup>9</sup> Ian Harper, Peter Anderson, Su McCluskey and Michael O'Bryan QC, 'Competition Policy Review: Final Report (March 2015), available at <<http://competitionpolicyreview.gov.au/final-report/>>, ('Harper Report').

<sup>10</sup> Harper Report, p 109.

<sup>11</sup> *Government Response to the Competition Policy Review* (2015), pp 9-10, available at <[http://www.treasury.gov.au/~media/Treasury/Publications%20and%20Media/Publications/2015/Government%20response%20to%20the%20Competition%20Policy%20Review/Downloads/PDF/Govt\\_response\\_CPR.ashx](http://www.treasury.gov.au/~media/Treasury/Publications%20and%20Media/Publications/2015/Government%20response%20to%20the%20Competition%20Policy%20Review/Downloads/PDF/Govt_response_CPR.ashx)> (11 May 2016), p 9; Productivity Commission, *Intellectual Property Arrangements, Draft Report* (Canberra, April 2016)) available at <<http://www.pc.gov.au/inquiries/current/intellectual-property>> pp 22-23, 36, 385-393 ('IP Draft Report').

proving misuse of market power in a pharmaceutical case,<sup>12</sup> but it failed in its most recent claim against a pharmaceutical company.<sup>13</sup>

The prohibition of misuse of market power is contained in s 46. Section 46(1) provides a general clause which prohibits a corporation with substantial market power from taking advantage of that power for one of the prohibited purposes. It states:

A corporation that has a substantial degree of power in a market shall not take advantage of that power in that or any other market for the purpose of:

- (a) eliminating or substantially damaging a competitor of the corporation or of a body corporate that is related to the corporation in that or any other market;
- (b) preventing the entry of a person into that or any other market; or
- (c) deterring or preventing a person from engaging in competitive conduct in that or any other market.

Subsections 46(6A) and (7) further explain the meaning of 'taking advantage',<sup>14</sup> subsections 46(3), (3A), (3B) and (3C) provide guidance on determining 'a substantial degree of power' and subsection 46(4) explains that 'power' means also bargaining power.<sup>15</sup> Section 46 also includes a specific prohibition against predatory pricing in sections 46(1AA) and 46(1AAA).

Although the prohibited purposes in subsection 46(1) are aimed at competitors, the underlying goal of Australian competition law, including the misuse of market power prohibition in s 46, is to protect competition.<sup>16</sup>

The wording of s 46 has been criticised and, in that context, the Harper Report proposed changing s 46 by removing the current requirement to establish a prohibited purpose and introducing a test focussing on conduct having the purpose or effect of substantially lessening competition.<sup>17</sup> It recommended that

[t]he primary prohibition in section 46 of the CCA should be re-framed to prohibit a corporation that has a substantial degree of power in a market from engaging in conduct if the proposed conduct has the purpose, or would have or be likely to have the effect, of substantially lessening competition in that or any other market...<sup>18</sup>

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<sup>12</sup> *ACCC v Baxter Healthcare* [2008] FCAFC 141.

<sup>13</sup> *ACCC v Pfizer* [2015] FCA 113 (*Pfizer*). See the discussion below.

<sup>14</sup> (6A) In determining for the purposes of this section whether, by engaging in conduct, a corporation has taken advantage of its substantial degree of power in a market, the court may have regard to any or all of the following:

- (a) whether the conduct was materially facilitated by the corporation's substantial degree of power in the market;
- (b) whether the corporation engaged in the conduct in reliance on its substantial degree of power in the market;
- (c) whether it is likely that the corporation would have engaged in the conduct if it did not have a substantial degree of power in the market;
- (d) whether the conduct is otherwise related to the corporation's substantial degree of power in the market.

This subsection does not limit the matters to which the court may have regard.

(7) Without in any way limiting the manner in which the purpose of a person may be established for the purposes of any other provision of this Act, a corporation may be taken to have taken advantage of its power for a purpose referred to in subsection (1) notwithstanding that, after all the evidence has been considered, the existence of that purpose is ascertainable only by inference from the conduct of the corporation or of any other person or from other relevant circumstances.

<sup>15</sup> (4) In this section:

- (a) a reference to power is a reference to market power;
- (b) a reference to a market is a reference to a market for goods or services; and
- (c) a reference to power in relation to, or to conduct in, a market is a reference to power, or to conduct, in that market either as a supplier or as an acquirer of goods or services in that market.

<sup>16</sup> *Boral Besser Mansony Ltd v ACCC* (2003) 215 CLR 374, at [122].

<sup>17</sup> Harper Report, pp 334-348.

<sup>18</sup> Harper Report, p 348.

In March 2016, the government announced its support of the Harper recommendations with regards to s 46. It is, therefore, expected that s 46 will be amended to incorporate an effects-based test. This should lead to an increase in the number of cases regarding the misuse of market power, including cases in the pharmaceutical sector.

The recent case of *Pfizer*<sup>19</sup> illustrates the difficulties when applying s 46 and its application to the pharmaceutical industry. It is the first case taken by the ACCC dealing with conduct undertaken by a multinational pharmaceutical company that could be assigned to 'evergreening' tactics.

Pfizer was the owner of the patent for a highly-profitable drug called 'Lipitor' that expired in May 2012. Lipitor, whose active ingredient is atorvastatin, is used to treat high cholesterol. It is the most prescribed drug in Australia and was the drug with the highest Australian Government pharmaceutical-benefit expenditure from 2010 to 2012.<sup>20</sup> On a global scale, Lipitor was labelled 'the best-selling drug of all time'.<sup>21</sup>

Pfizer introduced a 'Project LEAP' in order to (as argued by the ACCC) maintain its exclusive position in the market after the expiry of its Lipitor patent in May 2012.<sup>22</sup> Project LEAP included a number of practices. In January 2011, Pfizer introduced an Accrual Fund Scheme set for every individual pharmacy, which was offered to over 5,000 pharmacies. Under the Fund Scheme, each pharmacy was given a monthly credit of 5% of its purchase value of Lipitor.<sup>23</sup> In April 2012, the value of the Fund was over AUD\$33.6 million.<sup>24</sup>

In January 2012, before the expiry of the Lipitor patent, Pfizer started to sell its own generic version of atorvastatin that was the same size, shape and colour as Lipitor<sup>25</sup> and also began to offer discounts on the purchase of both Lipitor and its generic product to individual pharmacies (since 2010, Pfizer has been supplying directly to pharmacies avoiding wholesale distribution<sup>26</sup>). In January 2012, it also opened the Accrual Funds to relevant pharmacies, on the condition that the pharmacy would stockpile a certain quantity of Pfizer's generic atorvastatin for a certain period of time prior to the expiry of the Lipitor patent. For instance, if a pharmacy agreed to stockpile 75% of the anticipated volume of atorvastatin for the period of one year, it was eligible for a Platinum Offer which covered 100% access to its Accrual Fund, between 75-60% discount on Pfizer generic atorvastatin and between 5-20% discount on Lipitor.<sup>27</sup>

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<sup>19</sup> *ACCC v Pfizer* [2015] FCA 113.

<sup>20</sup> *Pfizer*, at [110]; Thomas Faunce, 'Australian Competition and Consumer Commission v Pfizer: Evergreening and Market Power as Blockbuster Drug Goes off Patent' (2015) 22 *JLM* 771, 780.

<sup>21</sup> Robert Jones, 'Pfizer Moves Aggressively to Maintain Lipitor Sales' (2012) 647 *Pharmaco Economics and Outcomes News* 11, 11.

<sup>22</sup> *Pfizer*, at [6] and [186]; ACCC, 'Statement of Claim', Submission in *Pfizer* (Federal Court Proceeding NSD 146/2014, 13 February 2014) at [60(d)].

<sup>23</sup> *Pfizer*, [6]; ACCC, 'Statement of Claim', Submission in *Pfizer* (Federal Court Proceeding NSD 146/2014, 13 February 2014) at [47]-[49].

<sup>24</sup> *Pfizer*, at [305].

<sup>25</sup> *Pfizer*, at [228]; ACCC, 'Statement of Claim', Submission in *Pfizer* (Federal Court Proceeding NSD 146/2014, 13 February 2014) at [33].

<sup>26</sup> ACCC, 'Statement of Claim', Submission in *Pfizer* (Federal Court Proceeding NSD 146/2014, 13 February 2014) at [44]-[46].

<sup>27</sup> *Pfizer*, at [220]-[225]; ACCC, 'Statement of Claim', Submission in *Pfizer* (Federal Court Proceeding NSD 146/2014, 13 February 2014) at [51].

The ACCC alleged that Pfizer had contravened s 46, misuse of market power, and s 47, a form of exclusive dealing, by offering discounts and loyalty rebates. Pfizer disputed all claims made by the ACCC including all three requirements of s 46(1): the existence of substantial market power; taking advantage of that power; for a prescribed anticompetitive purpose.

The ACCC claimed that Pfizer's conduct was effective because Pfizer possessed substantial power; without the existence of substantial power Pfizer would not have succeeded to the same extent.<sup>28</sup> It further argued that Pfizer had initiated its conduct for the purposes of primarily deterring or preventing other suppliers of generic atorvastatin from engaging in competitive conduct [s 46(1)(c)] by engaging in practices which took advantage of its position as a first mover.<sup>29</sup> These included creating discounts and loyalty rebates, and were further facilitated by other practices, such as creating a generic product that looked very similar to the original Lipitor.

However, Pfizer argued that it had no substantial power and thus could not take advantage of that power<sup>30</sup> and that its conduct was legitimate because it simply wanted to maximise its sales. The Court agreed with Pfizer, concluding that selling below cost does not on its own constitute misuse of market power, particularly when the period is short and occurs while launching a new product. That was the case here, as Pfizer was offering discounts in connection with launching its generic atorvastatin.<sup>31</sup> The Court also agreed with Pfizer's claim that it had a 'legitimate' purpose of establishing 'a close relationship with pharmacies'<sup>32</sup> and creating 'a greater opportunity to sell its own generic product'.<sup>33</sup> In the Court's opinion, Pfizer was 'seeking to position itself to remain a viable supplier of atorvastatin into the future'.<sup>34</sup> The Court therefore refused the ACCC's claim that Pfizer had a prohibited purpose, notwithstanding evidence from Pfizer's internal documents, which stated, amongst other things, that

Second brands will be sold into pharmacy in bulk to 'block' other generic offers in the market.<sup>35</sup>

This case illustrates the difficulties that may be faced when attempting to prove intention under s 46. It also illustrates the narrow interpretation of s 46 which lead to the justification of potentially anticompetitive conduct on grounds which, arguably, would not have been considered legitimate in other jurisdictions, such as the EU. All anticompetitive conduct is designed to gain sales, improve and/or stabilize position in the market and thereby enhance profits, whether it takes the form of cartel conduct or misuse/abuse of market position. The distinguishing factor in most jurisdictions is whether the means adopted to achieve this end are competitive or restrictive and/or 'abusive'. This does not appear to have been distinguished in this case.

With regards to substantial market power, the Federal Court agreed with the ACCC that the relevant market was the market for the supply of atorvastatin, and disagreed with Pfizer's claim that the

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<sup>28</sup> *Pfizer*, at [292]

<sup>29</sup> See Thomas Faunce, 'Australian Competition and Consumer Commission v Pfizer: Evergreening and Market Power as Blockbuster Drug Goes off Patent' (2015) 22 *JLM* 771, 776-777.

<sup>30</sup> *Pfizer*, at [293].

<sup>31</sup> *Pfizer*, at [294]-[324]. Note that the ACCC did not claim s46 was contravened in the form of predatory pricing, but rather that Pfizer's rebate scheme was anticompetitive under s46.

<sup>32</sup> *Pfizer*, at [357], [360].

<sup>33</sup> *Ibid.*

<sup>34</sup> *Pfizer*, at [413].

<sup>35</sup> *Pfizer*, at [231].

relevant market should have been more broadly defined as the supply of pharmaceuticals.<sup>36</sup> However, when determining whether Pfizer had substantial power in the market, the Court disagreed with the ACCC. Notably, the Court held that the relevant time period for assessing market power was between January to May 2012 and that during this period Pfizer did not enjoy substantial market power.<sup>37</sup> The first requirement for a misuse of market power claim was, therefore, not established with the result that even if the anticompetitive intention had been proven the ACCC's claim would have failed.

The Court's conclusion that Pfizer did not possess substantial market power from January to May 2012 is surprising. The Court did not provide a detailed examination of market shares and barriers to entry<sup>38</sup> and its approach does not fully reflect previous judicial consideration of s46 with regards to the requirement of substantial market power.<sup>39</sup>

The ACCC also claimed that Pfizer's conduct contravened s 47 on exclusive dealing, in particular s 47(2)(d) and (e), in the form of restrictive supply conditions having the purpose of substantially lessening competition under s 47(10).<sup>40</sup> The ACCC did not argue that the conduct had an anti-competitive effect. The Court applied the same reasoning that it had adopted when considering the

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<sup>36</sup> There is no difference between determining the relevant market in the pharmaceutical industry in comparison with other industries.

<sup>37</sup> *Pfizer*, at [251].

<sup>38</sup> *Pfizer*, at [280]-[290]. The only company supplying atorvastatin in Australia during that period of time was Ranbaxy, which was allowed to launch its generic atorvastatin in Australia on 18 February and which also offered discounts on its product to pharmacies. See, *Pfizer*, at [271]-[272] and [289]; Thomas Faunce, 'Australian Competition and Consumer Commission v Pfizer: Evergreening and Market Power as Blockbuster Drug Goes off Patent' (2015) 22 *JLM* 771, 772, 775.

<sup>39</sup> See, eg, *Boral Besser Masonry Ltd v Australian Competition and Consumer Commission* (2003) 215 CLR 374 at [137]; *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177 at 189.

<sup>40</sup> Subsection 47(10) provides:

- (10) Subsection (1) does not apply to the practice of exclusive dealing constituted by a corporation engaging in conduct of a kind referred to in subsection (2), (3), (4) or (5) or paragraph (8)(a) or (b) or (9)(a), (b) or (c) unless:
- (a) the engaging by the corporation in that conduct has the purpose, or has or is likely to have the effect, of substantially lessening competition; or
  - (b) the engaging by the corporation in that conduct, and the engaging by the corporation, or by a body corporate related to the corporation, in other conduct of the same or a similar kind, together have or are likely to have the effect of substantially lessening competition.

Subsections 47(1) and (2) provide:

- (1) Subject to this section, a corporation shall not, in trade or commerce, engage in the practice of exclusive dealing.
- (2) A corporation engages in the practice of exclusive dealing if the corporation:
  - (a) supplies, or offers to supply, goods or services;
  - (b) supplies, or offers to supply, goods or services at a particular price; or
  - (c) gives or allows, or offers to give or allow, a discount, allowance, rebate or credit in relation to the supply or proposed supply of goods or services by the corporation; on the condition that the person to whom the corporation supplies, or offers or proposes to supply, the goods or services or, if that person is a body corporate, a body corporate related to that body corporate:
  - (d) will not, or will not except to a limited extent, acquire goods or services, or goods or services of a particular kind or description, directly or indirectly from a competitor of the corporation or from a competitor of a body corporate related to the corporation;
  - (e) will not, or will not except to a limited extent, re-supply goods or services, or goods or services of a particular kind or description, acquired directly or indirectly from a competitor of the corporation or from a competitor of a body corporate related to the corporation; or ...

misuse of market power claim under s 46, concluding that the ACCC had failed to establish anticompetitive purpose because the purpose was merely to increase sales and stay competitive.<sup>41</sup>

The ACCC appealed to the Full Federal Court on both s 46 and s 47. The appeal was heard in November 2015 and judgment has been reserved.

## II. Enforcement mechanisms, remedies and consumer protection

### ENFORCEMENT PATTERNS REGARDING PHARMACEUTICAL COMPETITION LAW ISSUES

Competition law enforcement is predominantly public in Australia. The only two significant competition law cases relating to the pharmaceutical industry, *Pfizer* and *Baxter Healthcare*, were both brought by the Australian Competition and Consumer Commission (ACCC). In relation to consumer and patent contraventions, however, enforcement is predominantly private. This also reflects the situation in other industries.

As a result of the limited number of competition cases in Australia relating to the pharmaceutical industry no pattern of enforcement has emerged. There have been only two significant competition law decisions relating to pharmaceuticals, both of which were based principally on Australia's misuse of market power (monopoly) laws. The most recent case (*Pfizer*) involved two claims under the CCA. The first alleged a misuse of market power.<sup>42</sup> The second alleged a form of exclusive dealing<sup>43</sup> which would typically be considered under abuse of power prohibitions in other jurisdictions. As noted in Part I, both claims failed. Importantly, and controversially, the Court concluded both that Pfizer lacked substantial market power at the relevant time and did not have an anti-competitive purpose. The case was appealed and heard before the Full Federal Court bench in November 2015. Judgment has been reserved; the success or otherwise of this appeal is likely to have a significant influence on the prospect for future competition based litigation, particularly as it relates to pay-for-delay or other evergreening tactics.

The second case involved a claim that Baxter Healthcare had leveraged its market power to harm competitors and substantially lessen competition by negotiating and entering into long term contracts with State Purchasing Authorities. These contracts bundled products over which it enjoyed significant market power with products for which it faced, or was likely to face, competition. The Federal Court held that Baxter's conduct constituted misuse of market power and unlawful exclusive dealing.

In addition to competition law litigation, there have been a number of informal merger reviews relating to the pharmaceutical industry over the last decade.<sup>44</sup> Although Australia has no mandatory merger notification requirement in its competition laws, the ACCC routinely 'informally' assesses mergers and acquisitions and indicates whether it will oppose, not oppose or not oppose subject to the provision of merger remedies. Most acquisitions of any significance are notified to the ACCC for consideration pursuant to this process, including in the pharmaceutical industry; notwithstanding

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<sup>41</sup> *Pfizer*, at [13] and [464].

<sup>42</sup> CCA, s 46.

<sup>43</sup> CCA, s 47.

<sup>44</sup> Since 2005 there have been 15 mergers informally reviewed by the ACCC, none of which were opposed and six not opposed subject to the provision of enforceable undertakings. Since 2010 there have been four not opposed and a further three not opposed subject to undertakings.

the voluntary nature of the process, many mergers and acquisitions are made conditional upon regulatory approval by the ACCC.<sup>45</sup>

The ACCC has not opposed any pharmaceutical mergers in the past decade, but has on five occasions since 2009 required merging parties to provide merger remedies (in the form of s 87B 'enforceable undertakings'<sup>46</sup>) in order to gain informal approval. The most notable recent mergers or acquisitions considered by the ACCC involved Pfizer's proposed acquisition of Hospira and GSK Consumer Healthcare's proposed acquisition of GlaxoSmithKline plc and Novartis AG.

In relation to the first, on 13 August 2015 the ACCC announced it would not oppose Pfizer Inc's acquisition of Hospira Inc, a global merger valued at approximately US\$17 billion. The ACCC noted that the parties either overlapped, or had the potential to overlap, 'for the supply of a number of small molecule drugs and had the potential to overlap for the supply of six biological pharmaceutical molecules and their biosimilars in the future'<sup>47</sup> and considered the effect of the proposed acquisition in the context of the national market for their supply. It concluded, in relation to small molecule drugs, that the merged firm would continue to be competitively constrained by alternative suppliers in the majority of relevant markets and there was limited competitive overlap between them, that there was 'little to no current competitive overlap' between the parties in some markets and that in relation to small molecule drugs listed on the Government's Pharmaceutical Benefits Scheme (PBS) that Scheme would provide some pricing constraint on the parties. In relation to biological pharmaceutical molecules and their biosimilars, the ACCC concluded that, by the time the parties brought their products to market, there would likely be sufficient competitors to constrain the merged entity.<sup>48</sup>

In relation to the proposed acquisition by GSK Consumer Healthcare of GlaxoSmithKline plc and Novartis AG, the ACCC expressed some concerns about its competitive impact. The parties provided the ACCC with a s 87B enforceable undertaking designed to address these concerns and this was accepted by the ACCC which then announced, on 18 December 2014, that it would not oppose the acquisition. The transaction involved a proposed Joint Venture, GSK Consumer Healthcare, with GlaxoSmithKline Plc and Novartis to acquire 63.5% and 36.5% of the shares respectively. The ACCC concluded that the acquisition was unlikely to substantially lessen competition in relation to the markets for manufacture and supply of 'cold sore, topical and systemic pain management, cold and flu' and anti-dermatological products'<sup>49</sup> because of the existence of a number of pharmaceutical companies likely to provide post-merger constraints. However, in relation to smoking cessation products, the ACCC considered the merger was likely to raise competition concerns, as GSK and

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<sup>45</sup> See, for example, 'Undertaking to the Australian Competition and Consumer Commission: given under section 87B of the *Competition and Consumer Act 2010* (Cth) by GlaxoSmithKline Plc and Novartis Consumer Health Australasia Pty Ltd (accepted by the ACCC on 17 December 2014) para 2.10, available at <<http://registers.accc.gov.au/content/trimFile.phtml?trimFileTitle=MER14+13069.pdf&trimFileFromVersionId=1183827&trimFileName=MER14+13069.pdf>>.

<sup>46</sup> These are known as s 87B enforceable undertakings; they cannot be imposed by the ACCC, but the ACCC may accept a written undertaking given by a party in relation to most competition and consumer matters under the CCA. If accepted any contravention of the undertaking can be taken to Court, which has considerable powers to make orders in respect of the contravention. This includes divesting any benefits obtained as a result of the contravention: s 87B(4) CCA.

<sup>47</sup> 'Pfizer Inc – proposed acquisition of Hospira Inc' (ACCC Merger Register, Reference 57422).

<sup>48</sup> 'Pfizer Inc – proposed acquisition of Hospira Inc' (ACCC Merger Register, Reference 57422).

<sup>49</sup> 'GSK Consumer Healthcare - proposed acquisition of GlaxoSmithKline plc and Novartis AG' (ACCC Merger Register, Reference 55931).

Novartis were particularly close competitors in relation to the supply of nicotine replacement patches and gums in Australia. As a result, the acquisition might have weakened 'competitive constraints on remaining suppliers'.<sup>50</sup> To address these concerns the parties offered a s 87B enforceable undertaking in which they proposed divesting 'smoking cessation products currently marketed and supplied by Novartis in Australia under the brand Nicotinell, and the smoking cessation products currently supplied by Novartis in Australia under private label arrangements'.<sup>51</sup> The ACCC was satisfied that these undertakings would resolve their competition concerns. Similar remedies were provided in a number of other jurisdictions which considered this deal.<sup>52</sup>

Beyond merger review and competition litigation, the ACCC may authorise, on public benefit grounds, certain conduct that might otherwise fall within the scope of the competition law prohibitions. Most notably, in relation to the pharmaceutical industry, the ACCC recently re-authorised the Medicines Australia Code of Conduct, which sets out marketing and promotion standards in relation to prescription pharmaceutical products.<sup>53</sup> The authorisation was granted subject to some additional conditions regarding transparency and despite considerable opposition to the code from a number of interested parties.<sup>54</sup> As a result, conduct set out in the Code will not be held to infringe the Act for the duration of the authorisation (currently five years from May 2015). The Code was originally established in 1960 and is currently in its 18<sup>th</sup> edition. It covers areas such as false and misleading claims, advertisements, brand name reminders, relationships with healthcare professionals (including travel, hospitality, remuneration and entertainment) and monitoring and reporting.

#### INTERACTION BETWEEN COMPETITION AND CONSUMER LAWS

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<sup>50</sup> 'GSK Consumer Healthcare - proposed acquisition of GlaxoSmithKline plc and Novartis AG' (ACCC Merger Register, Reference 55931).

<sup>51</sup> 'GSK Consumer Healthcare - proposed acquisition of GlaxoSmithKline plc and Novartis AG' (ACCC Merger Register, Reference 55931). See also 'Undertaking to the Australian Competition and Consumer Commission: Given under section 87B of the *Competition and Consumer Act 2010* (Cth) by GlaxoSmithKline Plc and Novartis Consumer Health Australasia Pty Ltd' (accepted by the ACCC on 17 December 2014).

<sup>52</sup> See, for example, Federal Trade Commission (US), 'Novartis AG, In the Matter of (GlaxoSmithKline)' (8 April 2015) available at <<https://www.ftc.gov/enforcement/cases-proceedings/141-0141-c-4510-c-4498/novartis-ag-matter-glaxosmithkline>> and European Commission, 'Mergers: Commission approves both GSK's acquisition of Novartis' vaccines business and a consumer healthcare joint venture between GSK and Novartis, subject to conditions' (Press Release, Brussels, 28 January 2015) available at [http://europa.eu/rapid/press-release\\_IP-15-3841\\_en.htm](http://europa.eu/rapid/press-release_IP-15-3841_en.htm).

<sup>53</sup> Medicines Australia, Code of Conduct, 18<sup>th</sup> edition, available at <<https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>>. See also ACCC, 'ACCC authorises Medicines Australia code subject to strengthening individual reporting' (ACCC Media Release, MR 66/15, 24 April 2015) and ACCC, 'Medicines Australia Limited - Revocation and Substitution - A91436 - A91440' (ACCC Authorisations and Notification Register, 24 April 2015) available at <<http://registers.accc.gov.au/content/index.php/itemId/1179619/fromItemId/278039/display/acccDecision>>).

<sup>54</sup> Ken Harvey, 'Pharmaceutical industry code of conduct fails to find favour' (The Conversation, 22 August 2014) available at <<http://theconversation.com/pharmaceutical-industry-code-of-conduct-fails-to-find-favour-30404>>.

The CCA contains Australia's competition laws and its primary federal consumer laws (The Australian Consumer Law).<sup>55</sup> It incorporates a single object provision, applicable to both competition and consumer laws; namely, that the object of the Act is to 'enhance the welfare of Australians through the promotion of competition and fair trading and provision for consumer protection'.<sup>56</sup>

Competition and consumer prohibitions are both administered by the ACCC, although state and territory consumer affairs bodies also play a role in consumer law advocacy and enforcement. Consumer laws may be enforced by state and territory courts in addition to federal courts; competition law cases may only be brought before the federal court (or, on appeal, the High Court).<sup>57</sup> There are no specialist bodies in Australia with responsibilities relating to pharmaceutical competition law or consumer law cases.

The consumer protection provisions in the CCA are collectively referred to as the Australian Consumer Law.<sup>58</sup> They include numerous protections including those relating to manufacturers' product liability, consumer guarantees relating to product quality and fitness. The most notable insofar as they might overlap with competition law prohibitions are the prohibitions on misleading or deceptive conduct (and other forms of false advertising), unconscionable conduct and unfair terms.

Although it is rare for a consumer and competition law matter to be brought together in a single proceeding, it is clear that consumer protection provisions play a role in facilitating fair competition and unconscionable conduct provisions, in particular, have recently been utilised as a cheaper and quicker method of pursuing conduct which might also have raised concerns under misuse of market power laws.

#### *Unfair terms legislation*

The Australian Consumer Law currently prohibits unfair terms in standard form consumer contracts and therefore has limited potential to overlap with the competition law prohibitions. However, in 2015<sup>59</sup> the Government legislated to extend existing unfair contract terms laws to apply unfair contract terms in standard form contracts with small business (employing less than 20 people and below a certain value threshold).<sup>60</sup> The new law will apply to contracts entered into or varied after 12 November 2016 and while it could, theoretically, apply to some pharmaceutical distribution arrangements, it is unlikely to play a significant role in protecting against anti-competitive distribution practices.

#### *Unconscionable conduct*

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<sup>55</sup> There are additional consumer laws in some jurisdictions. In the case of both consumer and competition laws state and territory legislation extends their coverage beyond the constitutionally limited scope of federal laws.

<sup>56</sup> CCA, s 22.

<sup>57</sup> Only the Federal Court of Australia (or High Court on appeal) may hear competition law matters.

<sup>58</sup> The Australian Consumer Law is currently under review by Consumer Affairs Australia and New Zealand, with a report expected in March 2017 (see Australian Consumer Law Review, available at <<http://consumerlaw.gov.au/review-of-the-australian-consumer-law/about-the-review/>>).

<sup>59</sup> *Treasury Legislation Amendment (Small Business and Unfair Contract Terms) Act 2015* (Cth).

<sup>60</sup> Initially the threshold applies to contracts where the upfront price payable is \$300,000 or less or \$1m or less if the contract is for more than 12 months. The legislation currently applies only to unfair terms in standard form consumer contracts.

The potential for greatest overlap between competition and consumer protection laws arises in relation to unconscionable dealings. The Australian Consumer Law prohibits unconscionable conduct in connection with the supply (or possible supply) or acquisition (or possible acquisition) of goods or services. It sets out a number of factors that may be considered when assessing whether conduct is unconscionable, including relative strengths of bargaining power and whether undue pressure was exerted or unfair tactics used.<sup>61</sup>

The unconscionable conduct provisions have not yet been utilised in the context of anti-competitive supplies of pharmaceuticals, but they have been used successfully in the grocery sector in relation to conduct that might also have attracted scrutiny under misuse of market power laws. It has been argued that the ACCC might be making strategic use of the unconscionable conduct provisions as an alternative to a misuse of market power claim in some cases given that the latter are more resource intensive and the ACCC's track record for success in misuse of market power cases has been poor.<sup>62</sup>

The most notable example of this occurred in 2014 when the ACCC commenced proceedings against Coles (one of the two major supermarket chains in Australia<sup>63</sup>) in relation to payments demanded from several of its smaller suppliers which were accompanied by threats to delist products or lose contracts if payments were not made. Despite several commentators pointing out that this looked a lot like a potential misuse of market power case,<sup>64</sup> the ACCC did not pursue a misuse of market power claim but rather instead alleged that Coles had engaged in unconscionable conduct contrary to the Australian Consumer Law.

The ACCC succeeded in its claim, with the Court holding, in 2015, that the conduct was unconscionable. Factors considered relevant in reaching this determination included the fact that Coles enjoyed substantially more bargaining strength than smaller suppliers and knowingly took advantage of that power.<sup>65</sup>

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<sup>61</sup> Section 21 of the Australian Consumer Law contains the relevant prohibition and section 22 sets out a non-exhaustive list of factors that may be taken into account in assessing whether conduct was unconscionable. At the time of these proceedings the relevant prohibition was contained in s 22, but the substance of the prohibition was the same.

<sup>62</sup> See, for example, Michael Bradley and Hannah Marshall, 'ACCC v Coles: Coles's lucky day' (June 2014) *Competition and Consumer Law News* 58 and Alexandra Merrett, 'ACCC signals strategic change in battle with supermarkets' (The Conversation, 6 May 2014) available at <<https://theconversation.com/accc-signals-strategic-change-in-battle-with-supermarkets-26288>>.

<sup>63</sup> At the time of the proceedings Coles was the second largest grocery retailer in Australia: *Australian Competition and Consumer Commission v Coles Supermarkets Australia Pty Ltd* [2014] FCA 1405 at para 1. The largest retailer is Woolworths. The ACCC has initiated separate proceedings against Woolworths alleging unconscionable conduct toward its suppliers: ACCC, 'ACCC takes action against Woolworths for alleged unconscionable conduct towards supermarket suppliers' (ACCC Media Release, MR 252/15, 10 December 2015).

<sup>64</sup> See, for example, Michael Bradley and Hannah Marshall, 'ACCC v Coles: Coles's lucky day' (June 2014) *Competition and Consumer Law News* 58; Alexandra Merrett, 'ACCC signals strategic change in battle with supermarkets' (The Conversation, 6 May 2014). See also Caron Beaton-Wells, 'Coles v ACCC: finding the balance between fair trading and competition' (The Conversation, 21 October 2014) available at <<https://theconversation.com/coles-v-accc-finding-the-balance-between-fair-trading-and-competition-33135>>.

<sup>65</sup> *Australian Competition and Consumer Commission v Coles Supermarkets Australia Pty Ltd* [2014] FCA 1405 at [202]. See also Alexandra Merrett, 'ACCC signals strategic change in battle with supermarkets' (The Conversation, 6 May 2014).

In their current form, the Australian Consumer Law's unconscionable conduct provisions are relatively new and relatively untested; there is, however, potential for them to be triggered by pharmaceutical supply arrangements in the future, particularly given likely disparity of bargaining power between the major suppliers and retailers.

However, one of the significant limitations of the Australian Consumer Law is that its penalty regime is modest when compared with that available for contraventions of the competition law provisions. The maximum civil penalty for each contravention of the unconscionable conduct prohibition in the Australian Consumer Law is AUS\$1.1 million,<sup>66</sup> compared with the competition law provisions for which the penalties available are AUS\$10m per contravention or a higher penalty based on percentage of turnover or three times the value of benefits obtained that are attributable to the breach.<sup>67</sup> Penalties at the level provided for in the Australian Consumer Law are unlikely to achieve sufficient deterrence against evergreening conduct by major pharmaceutical companies.<sup>68</sup>

### *Misleading conduct*

One area of consumer law which has been tested in relation to pharmaceutical products involves the prohibition on misleading and deceptive conduct occurring in trade or commerce. The prohibition on misleading and deceptive conduct in the Australian Consumer Law<sup>69</sup> is not limited to consumer transactions; it extends to all misleading or deceptive conduct which takes place in trade or commerce.

Although not an obvious mechanism by which firms might seek to 'evergreen' products and thereby restrict competition, a relatively recent case has demonstrated how advertising might be used to achieve this end. In particular, it was alleged certain forms of conduct and advertising misled pharmacists and patients into believing that certain branded products could not be substituted for generic alternatives, with the result that the originator company could continue to receive a 'brand premium' for sales.

It is necessary to understand something of Australia's pharmaceutical regulation in order to understand how misleading conduct was able to assist in product evergreening. In Australia, any new drug may be lawfully marketed and supplied only after evaluated and approved by the Therapeutic Goods Administration. If approved the drug will appear on the Australian Register of Therapeutic Goods (ARTG). ARTG registered drugs may then be considered for listing under the Pharmaceutical Benefits Scheme (PBS) and, if approved, will be listed on the PBS by brand name at a specific price.<sup>70</sup> Where a drug has been listed by an originator company, a supplier of an equivalent drug may apply to be listed on the PBS as a 'substitute' drug. Approval will be given only if the new brand has the same active ingredient as the listed brand and is sufficiently bioequivalent.<sup>71</sup> Listing of

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<sup>66</sup> Australian Consumer Law, s 224.

<sup>67</sup> CCA, s 76.

<sup>68</sup> See, for example, *Australian Competition and Consumer Commission v Coles Supermarkets Australia Pty Ltd* [2014] FCA 1405 at [106].

<sup>69</sup> Australian Consumer Law, s 18.

<sup>70</sup> The consequences of listing and price-setting mechanisms are discussed further in Part IV.

<sup>71</sup> *Apotex Pty Ltd (formerly GenRx Pty Ltd) v Les Laboratoires Servier (No 2)* [2008] FCA 607 at [3]-[7] (*'Apotex v Servier'*)

a substitute brand is known as ‘a’-flagging.<sup>72</sup> A pharmacy may supply a generic alternative to a branded drug provided it is ‘a’-flagged, the patient agrees, the prescriber (doctor) has not indicated that substitution is not to occur (which he or she may do at their absolute discretion) and substitution is permitted in the relevant jurisdiction.<sup>73</sup> Where the branded drug is supplied a patient may be required to pay a ‘brand premium’, which is passed on to the relevant pharmaceutical company, with the result that there is a clear commercial interest to pharmaceutical companies which list ‘brand drugs’ in having doctors prevent substitution.

Attempts to discourage brand substitution led to claims of misleading and deceptive conduct by Les Laboratoires Servier (‘Servier’) in respect of its medication, Coversyl. The Federal Court of Australia held that Servier’s campaign, designed to discourage substitution of generic substitutes for its product, constituted misleading or deceptive conduct.<sup>74</sup>

Servier was the originator company for the medication Coversyl and had been patent-holder and marketer since 1992.<sup>75</sup> Coversyl contains perindopril as its active ingredient and is used to treat high blood pressure, amongst other things. It was at the time the most prescribed ACE inhibitor on the Australian Pharmaceutical Benefits Scheme.<sup>76</sup> After Servier’s original patent expired GenRx, a rival company, distributed a generic form of the drug, which was listed in the ARTG as an ‘a’-flagged drug. However, before Servier’s main patent for perindopril expired, Servier substituted an equivalent salt form (‘perindopril arginine’) for the original perindopril erbumine salt (referred to by the Court as ‘the salt switch’).<sup>77</sup> This new product was subsequently approved by the Therapeutic Goods Administration.<sup>78</sup>

An issue arose over whether the ‘new’ Coversyl should be preferred over the ‘old’ Coversyl against which GenRx offered an ‘a’-flagged generic listing in the PBS. GenRx argued there was no clinical rationale for the ‘salt switch’ but rather it was motivated by Servier’s desire to protect its market from generic suppliers by making it difficult to supply products competing with Coversyl after the patent expiry date. The Court accepted that ‘commercial interests’ rather than ‘clinical rationale’ appeared to be the reason for the switch.<sup>79</sup> When Servier began to market the new product in 2006 it embarked on a marketing campaign which included explaining the biological equivalence of the products to doctors while also distinguishing between its ‘new’ and ‘old’ Coversyl product, promoting ‘the fact that its perindopril arginine was not substitutable for its perindopril erbumine’,<sup>80</sup> that old Coversyl would be removed from the PBS and that new and old Coversyl would be ‘a-

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<sup>72</sup> This is because the letter ‘a’ appears immediately before the brand name on the PBS schedule: see *Apotex v Servier*, at [5]

<sup>73</sup> *National Health Act 1953* (Cth), s 103.

<sup>74</sup> *Apotex v Servier*. At the time misleading and deceptive conduct was prohibited under s 52 of the Act. This became s 18 of the Australian Consumer Law when that was introduced in 2009, but it remained, in substance, the same prohibition.

<sup>75</sup> For more detail see Thomas Faunce, ‘New forms of evergreening in Australia: Misleading advertising, enantiomers and data exclusivity: *Apotex v Servier* and *Alphapharm v Lundbeck*’ (2008) 16 *JLM* 220 and *Apotex v Servier*.

<sup>76</sup> Thomas Faunce, ‘New forms of evergreening in Australia: Misleading advertising, enantiomers and data exclusivity: *Apotex v Servier* and *Alphapharm v Lundbeck*’ (2008) 16 *JLM* 220 at 220. ACE refers to angiotensin-converting enzyme. See also *Apotex v Servier*, at [11]

<sup>77</sup> *Apotex v Servier*, at [13]

<sup>78</sup> *Apotex v Servier*, at [14]

<sup>79</sup> *Apotex v Servier*, at [17]

<sup>80</sup> *Apotex v Servier*, at [22].

flagged' as substitutable with the result pharmacists could switch patients from the old to the new formulation.<sup>81</sup>

As part of its strategy Servier distributed a 'No Substitution' stamp to thousands of doctors as well as placing advertisements in medical publications that, it was alleged, asserted that brand substitution was not permitted for Coversyl. Although the Court found that doctors, as a sub-group, would not have been misled by the text of the stamp into believing Coversyl could never be substituted for an existing 'a'-flagged generic, it held that pharmacists confronted with a prescription bearing the stamp and patients prescribed perindopril could be misled into thinking there was a prohibition on substitution for Coversyl. The Court therefore concluded that the conduct contravened the misleading and deceptive conduct provisions of the CCA. The Court also considered advertisements placed in medical journals which claimed, amongst other things, that the new Coversyl had improved stability over perindopril erbumine products.<sup>82</sup> It concluded that, although it was technically true that the new Coversyl had improved stability and shelf life, as perindopril was a commonly prescribed drug and therefore unlikely to be stocked for more than 12 months, the 'improved stability' claimed offered no clinical benefit,<sup>83</sup> with the result that references suggesting new Coversyl's improved stability as a was a reason for not allowing substitution was 'misleading or likely to mislead medical practitioners.'<sup>84</sup>

#### SECTOR SPECIFIC REVIEWS OF COMPETITION LAW IN THE PHARMACEUTICAL SECTOR

There have been no sector specific reviews of competition law in the pharmaceutical sector. However, there have been a number of reviews of the pharmaceutical sector which have considered competition law issues and general reviews of competition and intellectual property laws which have dedicated sections to pharmaceutical competition.

##### *Pharmaceutical Patents Review 2012-2013*

In October 2012 a review of pharmaceutical patents was initiated by the Government. The stated objective included assessing 'whether the system for pharmaceutical patents is effectively balancing the objectives of securing timely access to competitively priced pharmaceuticals, while fostering innovation and supporting research'. In particular, the extension of term provisions will be reviewed.<sup>85</sup> A report was finalised in May 2013 and later made public. However, during this time there had been a change in government and the new government's response to the final report simply noted that the review was 'one of a number of reviews of the pharmaceutical system conducted during the term of the previous government' and that it has 'no plans to respond' to the report, but may consider the information in the report when considering future policy.<sup>86</sup>

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<sup>81</sup> *Apotex v Servier*, at [22].

<sup>82</sup> There was evidence that, because of changes to packaging, dosages and labels, between old and new Coversyl, the switch had caused confusion among patients who had previously been taking the old Coversyl product: *Apotex v Servier*, at [22].

<sup>83</sup> *Apotex v Servier*, at [120].

<sup>84</sup> *Apotex v Servier*, at [102].

<sup>85</sup> Pharmaceutical patents review, Terms of Reference (IP Australia, 16 October 2016) available at <<https://www.ipaustralia.gov.au/about-us/ip-legislation/pharmaceutical-patents-review>>.

<sup>86</sup> Government statement on the Pharmaceutical Patent Review Final Report (2014), available at <<https://www.ipaustralia.gov.au/about-us/ip-legislation/pharmaceutical-patents-review>>.. See also Mark Summerfield, 'Pharmaceutical Patents Review Buried by Successive Governments' (Patentology Blog, 16

The review has had no demonstrable impact on policy or enforcement in the pharmaceutical sector.

#### *Competition Policy Review 2014-2015 (Harper Review)*

In 2014 an independent review of competition law and policy commenced. The final report, released in March 2015, noted 'Pharmacy' as an area for immediate reform and made recommendations in relation to intellectual property relevant to the pharmaceutical sector.

- Pharmacy

The Harper Panel accepted that some ongoing regulation of pharmacy was justified, but that the current regulations restricting pharmacy location and ownership were not and should be removed. These restrictions are strongly defended by the Pharmacy Guild of Australia<sup>87</sup> and Pharmaceutical Society of Australia, but labelled as 'redundant and ineffective'<sup>88</sup> by many others.

With limited exceptions, legislation limits ownership of community pharmacies to pharmacists and limits the number of pharmacies each pharmacist can own.<sup>89</sup> In addition, Pharmacy Location Rules, originally introduced in 1990<sup>90</sup> 'to address perceived inefficiencies in the community pharmacy sector and the oversupply and sustainability of pharmacy services in particular geographic areas' and accompanied by incentive payments to facilitate closure or merger,<sup>91</sup> have been retained, although incentive payments have ceased. These impact on the ability to relocate and establish new pharmacies in particular areas.

The Harper Report recommended removal of regulations which restrict the location of pharmacies and require (with limited exceptions) that only pharmacists own pharmacies,<sup>92</sup> noting that Governments 'do not need anti-competitive regulation to ensure pharmacies meet community expectations of safety, access and standard of care'.<sup>93</sup>

The Harper Panel noted that the renegotiation of the Australian Community Pharmacy Agreement (an agreement between the Australian Government and the Pharmacy Guild of Australia which has, since, 1990, governed 'remuneration pharmacists receive for dispensing Pharmaceutical Benefit Scheme (PBS) medicines on behalf of government, and regulations governing the location of

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February 2014) available at <<http://blog.patentology.com.au/2014/02/pharmaceutical-patents-review-buried-by.html>>.

<sup>87</sup> David Quilty, 'Evidence supports the pharmacy model' (Pharmacy Guild of Australia, 25 November 2015) in which Executive Director, David Quilty, claims the Harper Review's recommendations on pharmacy deregulation were 'deeply flawed and bereft of evidence'.

<sup>88</sup> Harper Report, p 180.

<sup>89</sup> Harper Report, p 179.

<sup>90</sup> See also Australian Government Department of Health 2014, Pharmacy Locations Rules Applicant's Handbook, Canberra, available at <<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pharmacy-acpa-acpainro.htm>>.

<sup>91</sup> Urbis, 'Review of the Pharmacy Location Rules under the Fourth Community Pharmacy Agreement, Final Report' (June 2010), p 1, available at <[http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pharmacy-acpa-index.htm/\\$File/review-report-fourth-pharmacy-location-rules.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pharmacy-acpa-index.htm/$File/review-report-fourth-pharmacy-location-rules.pdf)>.

<sup>92</sup> Harper Report, p 48 and recommendation 14

<sup>93</sup> Harper Report, p 48 and recommendation 14

pharmacies’<sup>94</sup> would provide an opportune time for implementation of a ‘targeted relaxation of the location rules, as part of a transition to their eventual removal’.<sup>95</sup>

Changes to the pharmacy rules are, however, politically sensitive and unlikely to be achieved in the short term, notwithstanding successive reviews recommending change.<sup>96</sup> In its response to the Harper Report, the Government ‘noted’ these recommendations but has not moved to implement them. The 6<sup>th</sup> Pharmacy Agreement was signed after the Harper Report was released<sup>97</sup> and without implementing any changes to the location rules. In response to questions about this, Health Minister Susan Lee responded that the pharmacy sector and government have agreed to ‘have a two-year review of both remuneration and location rules’.<sup>98</sup>

- Intellectual property

In addition to its recommendations relating to restrictive pharmacy rules, the Harper Report also recommended that s 51(3), which provides an intellectual property exemption from many of the competition law prohibitions in the CCA, should be repealed so that commercial transactions involving IP rights, including their assignment and licencing, be subject to the CCA in the same way as transactions involving other property and assets.<sup>99</sup>

The Harper Report further recommended a Productivity Commission review of intellectual property<sup>100</sup> to assess the appropriate extent of IP protection.<sup>101</sup> This was expressly stated to be separate from its recommendation to repeal s 51(3), which it argued should not be delayed pending the Productivity Commission Review.<sup>102</sup> The Panel also recommended an independent review to assess Australian Government processes ‘for establishing negotiating mandates to incorporate intellectual property provisions in international trade agreements.’<sup>103</sup>

The Government ‘noted’ the recommendation to repeal s 51(3) and, contrary to the recommendations contained in the Harper Report, indicated it would have regard to the findings of

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<sup>94</sup> Harper Report, p 181.

<sup>95</sup> Harper Report, p 189.

<sup>96</sup> See, for example, Urbis, ‘Review of the Pharmacy Location Rules under the Fourth Community Pharmacy Agreement, Final Report’ (June 2010), p 1. The National Commission of Audit also recommended ‘opening up the pharmacy sector to competition, including through the deregulation of ownership and location rules’: Australian Government 2014, *Towards Responsible Government - The Report of the National Commission of Audit Phase One*, Canberra, page xlii, available at <[http://www.ncoa.gov.au/report/docs/phase\\_one\\_report.pdf](http://www.ncoa.gov.au/report/docs/phase_one_report.pdf)>.

<sup>97</sup> The Pharmacy Agreement expired 1 July 2015 (after the Harper Report was published). The sixth community pharmacy agreement was finalised in May 2015. It includes provision of approximately AUS\$18.9 billion to community pharmacies for dispensing PBS medicines: 6<sup>th</sup> Community Pharmacy Agreement.

<sup>98</sup> The Hon Sussan Ley MP, Minister for Health, Minister for Aged Care, Minister for Sport, ‘Press Conference updating on the 6<sup>th</sup> Community Pharmacy Agreement’ (18 May 2015) available at <<http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2015-ley150518.htm>>. This is discussed further, below.

<sup>99</sup> Harper Report, p 41.

<sup>100</sup> Harper Report, p 112.

<sup>101</sup> Harper Report, p 41, recommendation 6

<sup>102</sup> Harper Report, p 41, recommendation 7

<sup>103</sup> Harper Report, recommendation 6

the Productivity Commission when deciding whether to repeal or retain the exemption.<sup>104</sup> The Government supported the broader Harper Report recommendation for a Productivity Commission to undertake an overarching review of intellectual property and subsequently commissioned such a review in August 2015.<sup>105</sup> The Government rejected the recommendation to separately review its process in relation to establishing negotiating mandates to incorporate IP provisions in international trade agreements, arguing it already had robust arrangements in place.<sup>106</sup>

To date the Harper Report has not resulted in any increased enforcement activities.

### *Productivity Commission Review of Intellectual Property*

In accordance with recommendations made in the Harper Report, Australia's Productivity Commission (PC)<sup>107</sup> is currently undertaking a 12 month public inquiry into Australia's intellectual property system.<sup>108</sup> The inquiry was instigated at the request of the Australian Government. The PC released a Draft Report<sup>109</sup> on 29 April 2016 with a final report expected by 18 August 2016.

Although not focussed on pharmaceuticals, the Draft Report included a chapter dedicated to pharmaceuticals and included a recommendation for the redesign of extensions of term for pharmaceutical patents<sup>110</sup> and a recommendation that there be no extension of the period of data protection.<sup>111</sup> The Draft Report also addressed evergreening and pay-for-delay tactics and made broad recommendations to raise the inventive step for patents<sup>112</sup> and to follow international examples and introduce monitoring to detect pay-for-delay arrangements to be administered by the ACCC.<sup>113</sup> More generally, the draft report addressed the current exemption from most of the competition provisions of the CCA for the licensing or assignment of intellectual property.<sup>114</sup> It

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<sup>104</sup> Australian Government, 'Government Response to the Competition Policy Review' (24 November 2015) available at <<http://treasury.gov.au/harperreview>>.

<sup>105</sup> Productivity Commission, *Intellectual Property Arrangements*, Public Inquiry (2015-2016) available at <<http://www.pc.gov.au/inquiries/current/intellectual-property>> (IP Inquiry). See also 'Pharmaceutical Patents – A Targeted Policy Prescription' (Productivity Commission Fact Sheet) available at <<http://www.pc.gov.au/inquiries/currenrt/intellectual-property/draft/pharma-factsheet.pdf>>.

<sup>106</sup> Australian Government, 'Government Response to the Competition Policy Review' (24 November 2015) available at <<http://treasury.gov.au/harperreview>>.

<sup>107</sup> The Productivity Commission is an agency of the Australian Government which provides independent advice to all levels of Government. Its core function is to conduct public inquiries at the request of the Government.

<sup>108</sup> IP Inquiry . See also 'Pharmaceutical Patents – A Targeted Policy Prescription' (Productivity Commission Fact Sheet).

<sup>109</sup> Productivity Commission, *Intellectual Property Arrangements, Draft Report* (Canberra, April 2016) ('IP Draft Report').

<sup>110</sup> IP Draft Report, draft recommendations 9.1 and 9.2. The Productivity Commission expressed concern that extensions of term (up to five years) for pharmaceutical patents had not attracted investment in research and development, as had been intended when they were introduced.

<sup>111</sup> IP Draft Report, draft recommendation 9.3. Currently data submitted to support regulatory approval is protected for a period of five years, during which any generic entrants must independently test and prove the safety of their pharmaceuticals: see *Pharmaceutical Patents – A Targeted Policy Prescription* (Productivity Commission Fact Sheet). The PC noted that there was no evidence patents do not provide sufficient protection on investment and that public availability of data could provide substantial health benefits and avoid costs of duplication.

<sup>112</sup> IP Draft Report, draft recommendation 6.1.

<sup>113</sup> IP Draft Report, draft recommendation 9.4.

<sup>114</sup> These are contained in s 51(3) of the CCA and were discussed in Part I.

noted the rationale for the exemption had ‘largely fallen away’<sup>115</sup> and concluded that, although the benefits and costs of removing the exemption under s 51(3) were ‘finely balanced’, it should nevertheless be repealed and the ACCC should issue guidance on the application of Part IV of the Act to IP.<sup>116</sup>

#### *Review of Pharmacy Remuneration and Regulation 2015-2017*

An independent review of pharmacy remuneration and regulation was formally announced in November 2015 together with terms of reference. The Panel is being chaired by former ACCC Commissioner and economist, Prof Stephen King. Its terms of reference include consideration of the ‘appropriate regulation of pharmacy and pharmacy distribution, including the role of Pharmacy Location Rules in supporting access to medicines in Australia’.<sup>117</sup> (The review is expected to be completed by March 2017.)

Although none of the recent reviews which have dedicated sections to pharmacy or the pharmaceutical sector generally have led to increased enforcement activity, should s 51(3) be repealed as proposed by the Harper Panel and the IP Draft Report, there is the potential for increased competition law enforcement in the future.

#### COMPETITION LAW GUIDELINES RELEVANT TO PHARMACEUTICAL INDUSTRY

There are no guidelines specifically related to pharmaceutical competition law cases. Medicines Australia does, however, have a Code of Conduct which sets standards for marketing and promoting prescription pharmaceuticals by member companies. In 2015 the ACCC authorised, on public benefit grounds, the continuation of this code, which will remain in place for five years until 16 May 2020. Authorisation was granted subject to additional transparency obligations, including a condition enabling reporting of all relevant transfers of value.<sup>118</sup>

### **III. Patent Protection and Competition**

#### PATENT OWNERS AND GENERIC DRUGS IN AUSTRALIA

Australia would benefit from a more competitive pharmaceutical market. There is currently too much protection of the patent owners - multinational pharmaceutical companies – which is reflected in the patent protection itself, as well as evergreening and other tactics and opportunities available within the limits of the current law.

The Australian pharmaceutical patent protection lasts for 20 years,<sup>119</sup> but this can be extended for a further five years for pharmaceutical substances in accordance with international agreements.<sup>120</sup> An

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<sup>115</sup> IP Draft Report, p 385.

<sup>116</sup> IP Draft Report, p 23 and draft recommendation 14.1.

<sup>117</sup> Department of Health, ‘Review of Pharmacy Remuneration and Regulation’, available at <<http://www.health.gov.au/pharmacyreview>>.

<sup>118</sup> See ACCC, ‘ACCC authorises Medicines Australia code subject to strengthening individual reporting’ (Media release MR 66/15, 24 April 2016) available at <<https://www.accc.gov.au/media-release/accc-authorises-medicines-australia-code-subject-to-strengthening-individual-reporting>>.

<sup>119</sup> *Patents Act 1990* (Cth), ss 67 and 67; *Patent Regulations 1991* (Cth), Div 6.

<sup>120</sup> *Patents Act 1990* (Cth), s 70; *Intellectual Property Laws Amendment Act 1998* (Cth). The extension can be opposed based on s 75. See, eg, *Australia-United States Free Trade Agreement* (signed 18 May 2004, entered into force 1 January 2005), Article 17.10; *Agreement on Trade-Related Aspects of Intellectual*

applicant can apply for an extension once the patent is granted and before it expires. It can be extended only once. The reason for this 'special treatment' was to ensure and encourage research and development in the pharmaceutical industry and to unify the patent protection for pharmaceutical substances with countries such as the United States, as well as the European Union.<sup>121</sup>

This period has been criticised as too long for patent protection given that Australia is a patent-protected pharmaceuticals importer. Indeed, pharmaceutical companies earn great revenue in Australia. This is further facilitated by the high prices of pharmaceuticals, especially patented pharmaceuticals, in Australia compared to other developed countries.<sup>122</sup> Australia does not use competition law to prevent excessive prices; on the contrary, the current law and regulations aimed at and/or covering the pharmaceutical sector lead to higher prices than those paid in other developed countries. This is to the great detriment of the Australian economy considering that pharmaceutical patents represent the third largest intellectual property protection applications. These applications are predominantly being filled by multinational pharmaceutical companies, which are not Australian companies.<sup>123</sup>

The strong position of the pharmaceutical companies that hold patents is further facilitated by barriers to entry and other disadvantages for companies selling or wanting to sell generic products. Indeed, it is the owners of the patents and not the producers of the generic products that benefit from the extra protection, to the detriment of competition. Better treatment of the patent owners to the detriment of generic-drug producers has been highlighted and criticised in the 2013 Pharmaceutical Patent Review<sup>124</sup> and the current Intellectual Property Arrangements Review.<sup>125</sup>

This situation is illustrated by a number of examples. For instance, in 2007, new sections, ss 85AB and 85AC, were added to the *National Health Act 1953* (Cth).<sup>126</sup> These sections divide Australia's Pharmaceutical Benefits Scheme into two formularies: F1 – mostly single brand pharmaceuticals and F2 – mainly multiple brand pharmaceuticals – which are common for generic medicine. Faunce (and others) criticised this change, arguing that this division has a negative impact on pricing. It inflates the price charged by the patent holders from the F1 category, and it protects the price level of F1 category pharmaceuticals from competition with primarily generic pharmaceuticals with similar

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*Property Rights* (Annex 1C to the Marrakesh Agreement establishing the World Trade Organization), 1864 UNTS 299 (entered into force 1 January 1995), Article 33.

<sup>121</sup> *Alphapharm Pty Ltd v Lundbeck A/S* [2014] HCA 42, at [57]-[58]; Revised Explanatory Memorandum for the 1998 Intellectual Property Laws Amendment Act, available at <[http://www.aph.gov.au/Parliamentary\\_Business/Bills\\_Legislation/Bills\\_Search\\_Results/Result?bld=r397](http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bld=r397)>.

<sup>122</sup> See, Thomas Faunce, 'Australian Competition and Consumer Commission v Pfizer: Evergreening and Market Power as Blockbuster Drug Goes Off Patent' (2015) 22 *JLM* 771, 780-786; Duckett S et al, *Australia's Bad Drug Deal: High Pharmaceutical Prices* (Grattan Institute, 2013), available at <[http://grattan.edu.au/wp-content/uploads/2014/04/Australias\\_Bad\\_Drug\\_Deal\\_FINAL.pdf](http://grattan.edu.au/wp-content/uploads/2014/04/Australias_Bad_Drug_Deal_FINAL.pdf)>.

<sup>123</sup> Tony Harris, Dianne Nicol and Nicholas Gruen, *Pharmaceutical Patents Review Report* (2013, Canberra), pp 29-30, available at <[https://www.ipaustralia.gov.au/sites/g/files/net856/f/2013-05-27\\_ppr\\_final\\_report.pdf](https://www.ipaustralia.gov.au/sites/g/files/net856/f/2013-05-27_ppr_final_report.pdf)>.

<sup>124</sup> Tony Harris, Nicholas Gruen, Dianne Nicol, *Pharmaceutical Patents Review Report* (2013, Canberra), available at <<https://www.ipaustralia.gov.au/about-us/ip-legislation/pharmaceutical-patents-review>>.

<sup>125</sup> IP Draft Report.

<sup>126</sup> *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* (Cth).

therapeutic effects compared with that which it might have faced had the pharmaceuticals not been divided.<sup>127</sup>

Other barriers to entry arise from the commitment Australia made in Article 17.10.4 of the *Australia-United States Free Trade Agreement 2004*.<sup>128</sup> In this agreement, Australia agreed to implement measures as part of its approval marketing process which would forbid the marketing of pharmaceutical generic products before the expiry of relevant patents and thus prevent a generic-product competitor from entering the market before the patent has expired.<sup>129</sup>

This commitment was implemented by the *US Free Trade Agreement Implementation Act 2004* (Cth) which amended ss 25(3), 26(1)(a) and 26A(1)(a) of the *Therapeutic Goods Act 1989* (Cth) (TGA) and inserted ss 26A(1), 26B, 26C and 26(D) into the TGA. The TGA requires generic drug producers to search for information, at their own expense, as to whether there exists or could exist<sup>130</sup> a relevant patent and certify with the Therapeutic Goods Administration if they believe 'on reasonable grounds' that there is no patent; or, alternatively, if there is a patented product, certify that they notified the patentee of the registrations of their generic product. The generic drug producers face fines if they provide a false or misleading certificate. This places extra cost and risk on the generic producers. Furthermore, these provisions have been seen by some authors as incentives for patent holders to generate additional patent claims<sup>131</sup> – situations commonly called 'evergreening'. There is, however, no evidence of that have occurred to date.

Follow-on patents require fulfilment of the same requirements as the original patents. In general, decisions as to whether patents should be granted are based on an objective test, meaning that motives for patent applications, such as gaining an unfair advantage in the market, are not examined.<sup>132</sup>

The limits of what is patentable have been clarified by the High Court and include, among others, new uses for existing products.<sup>133</sup> With regards to pharmaceuticals, the High Court confirmed that a different and innovative coating of an old drug was patentable.<sup>134</sup> However, 'new uses' does not

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<sup>127</sup> Thomas Faunce, 'Australian Competition and Consumer Commission v Pfizer: Evergreening and Market Power as Blockbuster Drug Goes off Patent' (2015) 22 *JLM* 771, 785-786; Thomas Faunce, Jimmy Bai and Duy Nguyen, 'Impact of the Australia-US Free Trade Agreement on Australian Medicines Regulation and Prices' (2009) *J Gen Med* 18, 24.

<sup>128</sup> It came into effect on 1 January 2005 and is available at <<http://dfat.gov.au/trade/agreements/ausfta/pages/australia-united-states-fta.aspx>>.

<sup>129</sup> See, Stephanie Crosbie, 'The Limited Impact of Evergreening Practices In Australia' (2014-2015) 23(2) *Journal of Law, Information and Science* 83.

<sup>130</sup> In situations where a patent is expiring but the owner of the patent or another company applies for a new patent.

<sup>131</sup> Peter Drahos, Buddhima Lokuge, Thomas Faunce, Martyn Goddard and David Henry, 'Pharmaceuticals, Intellectual Property and Free Trade: the Case of the US-Australia Free Trade Agreement' (2004) 22(3) *Prometheus* 243, 250; see, also, Rhonda Chesmond, 'Patent Evergreening in Australia after the Australia-United States Free Trade Agreement: Floodgates or Fallacy?' (2006) 9 *Flinders JL Reform* 51.

<sup>132</sup> See the *Patent Act 1990* (Cth).

<sup>133</sup> *Foundation Ltd v Commissioner of Patents* (1980) 1A IPR 261; *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, at [265].

<sup>134</sup> *Aktiebolaget Hassle v Alphapharm Pty Ltd* [2002] HCA 59; 212 CLR 411.

cover a different dosage of the same drug, as considered in *Merck v Arrow Pharmaceuticals*<sup>135</sup> where the court of first instance, Gyles J, recognised such practices as a form of evergreening.<sup>136</sup>

Indeed, tendencies to evergreen patents are not uncommon in Australia. A recent study from 2013 that surveyed 15 of the most expensive drugs in Australia discovered that the number of patents per one analysed drug was between 22 and 121.<sup>137</sup> The same study also found that it was more common that the owners of the additional patents were not the originators. In particular, the study found that three quarters of the owners of these patents did not own the original patent for the substance in question.<sup>138</sup>

Although follow-up patents extend the length and broaden the scope of patent protection, a generic company, if it overcomes the aforementioned barriers to entry, can enter the market and offer generic products, which will not include new uses or other elements protected by patents.

Another form of practice which would restrict competition if used as a tactical practice and not genuine innovation, involves ‘pay-for-delay’ schemes. There has, however, been no study undertaken in Australia or any case<sup>139</sup> which has dealt with this practice. Nevertheless, as pointed out in the 2016 Draft Report on Intellectual Property Arrangements, this does not mean that such practices do not occur in Australia.<sup>140</sup> The Draft Report recommends that the ACCC starts monitoring such practices<sup>141</sup> and that the Australian Government institutes a review of pay-for-delay arrangements, as well as any other potentially anticompetitive practices arising in the pharmaceutical sector.<sup>142</sup>

### *Interlocutory Injunction*

Another example of the protection of patent owners involves applications for interlocutory injunctions. For instance, in *Abbot v Apotex*,<sup>143</sup> the Court considered the entering of the market by a company wanting to sell a generic drug as tactical and granted interlocutory injunction. The Court held that

...it should not expect that the court would be unsympathetic to an application for an interlocutory injunction in circumstances where [Apotex, the generic-drug producer] has, it seems, consciously held back from making a timely challenge to the validity of the patent in suit. It seems that [Apotex’s] decision to proceed in that way was essentially a tactical one.... Remain of the view that [Abbott’s] discretionary case for interlocutory relief has made the more persuasive by reason of [Apotex] having acted as it has.<sup>144</sup>

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<sup>135</sup> *Merck & Co Inc v Arrow Pharmaceuticals Ltd* [2006] FCAFC 91.

<sup>136</sup> *Arrow Pharmaceuticals Ltd v Merck & Co Inc v* [2004] FCA 1282, at [1].

<sup>137</sup> Andrew Christie, Chris Dent, Peter McIntyre, Lacklan Wilson and Davis Studdert, ‘Patents associated with high-cost drugs in Australia’ (2013) 8(4) *PLoS ONE* 1.

<sup>138</sup> Andrew Christie, Chris Dent, Peter McIntyre, Lacklan Wilson and Davis Studdert, ‘Patents Associated with High-Cost Drugs in Australia’ (2013) 8 *PLoS ONE* 1.

<sup>139</sup> Such practices could potentially contravene s 45(2) of the CCA if proved that they substantially lessened competition.

<sup>140</sup> IP Draft Report, pp 287-288.

<sup>141</sup> There is no public mechanism for monitoring patent settlements in the pharmaceutical sector.

<sup>142</sup> IP Draft Report, p 289.

<sup>143</sup> *Abbot GmbH & Co KG v Apotex Pty Ltd* (2009) 83 IPR 373.

<sup>144</sup> *Abbot v Apotex*, at [42].

Indeed, with regards to interlocutory injunction cases linked to patent-infringement cases and/or patent-invalidity cases, there is a tendency to protect the owners of patent to the detriment of the producers of generic drugs who want to enter the market. This was also the case in *Alphapharm v Wyeth*<sup>145</sup> where the generic producer of drugs (Alphapharm) made a case about the benefits to competition that come from the entering of generic drug producers, and restriction of competition arising from potential 'evergreening' of the originator. In this case, Wyeth's patent for the drug (venlafaxine hydrochloride) had expired. Alphapharm proposed releasing its generic drug; however, it was at that time that they became aware of Wyeth's patent claim for the dosage method of using venlafaxine hydrochloride. Moreover, Wyeth made another patent claim for a chemical including metabolite of venlafaxine hydrochloride and thus, according to Alphapharm, Wyeth's market was shifting.<sup>146</sup> Alphapharm claimed that Wyeth's method patent was invalid while Wyeth made a claim for the infringement of its patent and applied for an interlocutory injunction to stop Alphapharm from entering the market.

Alphapharm's arguments centred on competition and the changing of Wyeth's position in the market due to applying for new chemical patent. Alphapharm argued:

Wyeth could not assert a stable status quo warranting protection by an interlocutory injunction. Second, the public interest in competition is a discretionary factor weighing in Alphapharm's favour. Third, Wyeth is seeking an interlocutory injunction for a purpose outside the scope of the protection of the method patent, namely, to shelter itself from competition, a factor which also weighed in Alphapharm's favour.<sup>147</sup>

However, the Court held that Alphapharm's claims were 'substantially overstated'<sup>148</sup> and approved the interlocutory injunction. This indicates that the balance between encouragement and protection of competition and the protection of patent ownership is perhaps not established properly by the court in interlocutory injunction cases. The primary reasons for favouring the drug owners in interlocutory injunction cases are 'adequacy of damages' and 'balance of convenience' if there are serious cases of both infringement and invalidity.<sup>149</sup> The Court has expressed the view that calculating damages for the originator is more difficult due to its established monopoly position and reputation than for a generic company who is just trying to enter the market,<sup>150</sup> and that the originator would suffer more than the generic-drug producer if the interlocutory injunction was not approved.<sup>151</sup>

From the competition point of view, especially when considering evergreening tactics such as in the case of Alphapharm, reputation and calculating damages seem to be insufficient reasons not to refuse an interlocutory injunction. The interlocutory injunction protects the owner of the patent and can unnecessarily prevent competition if the application is based on situations that appear to be tactical on behalf of the patent holder facilitating its market position.

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<sup>145</sup> *Alphapharm Pty Ltd v Wyeth* [2009] FCA 945.

<sup>146</sup> *Alphapharm v Wyeth*, at [73]-[74].

<sup>147</sup> *Alphapharm v Wyeth*, at [111].

<sup>148</sup> *Alphapharm v Wyeth*, at [127].

<sup>149</sup> See, eg, *Alphapharm v Wyeth*, at [127]-[128], [131].

<sup>150</sup> See, e.g., *Abbot v Apotex*, at [46].

<sup>151</sup> See, e.g., *Alphapharm v Wyeth*, [131]; *Sigma Pharmaceuticals (Aust) Pty Ltd v Wyeth* [2009] FCA 595, at [58], [65]; *Interpharma Pty Ltd v Commissioner of Patents* [2008] FCA 1498, at [279]-[282].

## COMPULSORY LICENCING AND EXPORT OF GENERIC DRUGS

International agreements<sup>152</sup> signed by Australia also place restrictions on the export of generic drugs where Australian patent law prevents producers of generic drugs from stockpiling generic drugs for both future export and future sale in Australia (which also constitutes another form of barrier to entry for the Australian market). The detriment to the Australian economy resulting from these export restrictions is obvious, especially when considering that Australian pharmaceutical producers focus on the production of generic drugs, unlike multinational pharmaceutical companies that hold patents but are not based in Australia. The export restriction has a significant impact on Australian producers of generic drugs as it prevents them from being the first in the market. The delayed entry of the foreign market deters producers from entering the market because of lost first-mover opportunity and the cost and high risk associated with entering a foreign market after others have already started to sell their competing products.<sup>153</sup> For these reasons, this restriction was criticised in the 2013 Pharmaceutical Patent Review, the 2016 drafted report on Intellectual Property Arrangements<sup>154</sup> and in earlier reviews.<sup>155</sup>

This absolute restriction of export in cases where there is a valid Australian patent to countries where the patent has expired or was never granted, was partly limited recently by the amendment of the *Patents Act 1990* (Cth).<sup>156</sup> Under Chapter 12, Part 3 of the *Patents Act*, producers of generic drugs can, 'in good faith', apply to the Federal Court for a compulsory licence after they have unsuccessfully asked the patentee for a voluntary authorisation, in situations where the generic drug in question is proposed to be exported to a least developed country 'in need' to address a 'public health problem'.<sup>157</sup>

The *Patents Act* also provides other reasons for granting compulsory licences in Chapter 12, Part 2. The Federal Court can grant a compulsory licence if the patented invention does not meet 'reasonable requirements of the public'. The *Patents Act* also expressly states that a compulsory licence can be granted in situations where the patentee has contravened the CCA. The court can even revoke a patent on these grounds.<sup>158</sup> However, a compulsory licence has not yet been granted in the pharmaceutical sector.<sup>159</sup>

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<sup>152</sup> *Australia-United States Free Trade Agreement 2004; Trans-Pacific Partnership Agreement 2015* (signed in February 2016), available at <<http://dfat.gov.au/trade/agreements/tpp/pages/trans-pacific-partnership-agreement-tpp.aspx>>.

<sup>153</sup> IP Draft Report, pp 271-272.

<sup>154</sup> IP Draft Report, pp 271-274.

<sup>155</sup> The Productivity Commission, *Study on Evaluation of the Pharmaceuticals Industry Investment Program* (February 2003), available at <<http://www.pc.gov.au/inquiries/completed/pharmaceutical-investment>>.

<sup>156</sup> *IP Laws Amendment Act 2015* (Cth).

<sup>157</sup> The primary reason for the introduction of this compulsory export licencing was the Australian obligation arising from the TRIPS Protocol.

<sup>158</sup> There are also a few specific situations under Chapter 12, Part 4, where the Commissioner of Patents can revoke a patent. These are if there was no entitlement to the patent, the invention is not a patentable invention or the patent was not obtained in the right way.

<sup>159</sup> The recent government inquiry into compulsory licensing summarised that there have been only a few applications across different industries; however, none of them were successful. The fact that these applications are costly and time consuming has led to this situation. Productivity Commission, *Compulsory Licensing of Patents* (2013, Inquiry Report No 6). In this report, the Productivity Commission also considered mechanisms which would encourage voluntary licensing.

#### IV. Public Finance Considerations

The pharmaceutical sector is subject to significant regulatory obligations and, in the case of PBS listed drugs, significant price regulation. Most notably, regardless of any price agreed by the Government for supply of goods under the PBS, patients pay a capped fee on individual prescriptions and are protected by a 'safety net' which caps or limits the amount payable for PBS products once a set threshold is reached.<sup>160</sup>

However, beyond the market distortions created by this level of price and non-price regulation, there are no points of differentiation relevant to the *competition law* treatment of pharmaceutical products in Australia made on the basis that public funds are involved.

#### EXEMPTIONS FROM COMPETITION LAWS

Competition law is applied consistently to healthcare purchasers and providers. There are broad exemptions from the CCA for intellectual property. These are not, however, restricted to healthcare, although the healthcare industry is likely to enjoy considerable benefits from the exemptions.

There are also broad exemptions from the CCA for public bodies which are not 'carrying on a business' when engaging in relevant activities. In such cases the public bodies enjoy Crown immunity from Part IV of the CCA.<sup>161</sup> The relevant provisions are contained in section 2A of the Act which collectively provide that the CCA binds the Crown and local government bodies insofar as they carry on a business, either directly or by an authority of the Commonwealth, State or Territory or, in the case of local government, by an incorporated company in which it has a controlling interest.<sup>162</sup> This applies generally to the Crown and is not restricted to health-related public bodies, although they may be less likely to be found to be 'carrying on business' than others.

#### PUBLIC OR PRIVATE ENFORCEMENT ON BEHALF OF THIRD PARTY PAYERS OR PUBLIC FUNDING BODIES

Enforcement of competition law prohibitions relating to third party payers or public funding bodies tends to be public in nature, although there are few examples of competition law based enforcement relating to the healthcare industry.

One (relatively) recent example involved a claim by the ACCC that Baxter Healthcare Pty Ltd had misused its market power and engaged in unlawful exclusive dealing in relation to its supply agreements with State purchasing authorities. The relevant conduct involved Baxter negotiating, tendering for and entering into of long-term contracts with State Purchasing Authorities in five Australian states and territories<sup>163</sup> for the sale of certain sterile fluids.

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<sup>160</sup> See Australian Government, 'Pharmaceutical Benefits Scheme (PBS) Safety Net', available at <<https://www.humanservices.gov.au/customer/services/medicare/pharmaceutical-benefits-scheme-pbs-safety-net>>. When the threshold is met concession card holders receive all subsequent PBS prescribed drugs for free for the remainder of the year; general patients receive subsequent PBS prescribed drugs at the concessional rate.

<sup>161</sup> Sections 2A, 2B and 2C of the CCA. See, for example, *ACCC v Baxter Healthcare* [2007] HCA 38.

<sup>162</sup> The Crown in right of the Commonwealth is not, however, liable for pecuniary penalties or to be prosecuted for an offence: s 2A(3) CCA.

<sup>163</sup> *ACCC v Baxter Healthcare* [2008] FCAFC 141 (per Mansfield J), at [2].

In relation to the misuse of market power claim, it was alleged by the ACCC that Baxter had taken advantage of its 'substantial market power in the sterile fluids market for the purpose of harming competitors or preventing competition in the PD fluids market' by entering into the long-term contracts which required each of the states and territories 'to acquire sterile fluids exclusively from Baxter and between 90 and 100 per cent of its PD fluids from Baxter'. States were effectively compelled to agree to the 'exclusive supply contracts for the supply of sterile fluids, bundled with PD products' because Baxter offered 'prohibitively high item-by-item prices' on sterile fluids, over which it held a virtual monopoly.<sup>164</sup> In so doing it was alleged that Baxter harmed actual and potential competition in the PD fluids market, because companies operating in the PD fluid market were not able to compete in the market or markets for sterile fluids.<sup>165</sup>

The allegations relating to exclusive dealing involved essentially the same conduct which, it was alleged, has the purpose, effect or likely effect of 'substantially preventing, hindering or lessening competition'<sup>166</sup> in several markets.

The ACCC was successful in its claims, with the majority of the Full Federal Court holding Baxter had contravened s 47 of the CCA by engaging in exclusive dealing conduct having the purpose and effect of substantially lessening competition and that it had contravened the prohibition against misuse of market power.

Although this case involved State Purchasing Authorities, the action was not taken on their behalf and, indeed, it is likely that they would also have been subject to proceedings if not for the fact that it was conceded that they were not 'carrying on a business' when engaging in the relevant conduct and therefore benefitted from Crown immunity.

There is no reason to believe that, where a public body is carrying on business and either engages in or is the victim of anti-competitive behaviour, that the enforcement pattern would be any different.

#### PRICING CONTROLS OF PHARMACEUTICALS IN AUSTRALIA

All prescription medicine supplied in Australia must be approved and registered by the Therapeutic Goods Administration pursuant to the *Therapeutic Goods Act 1989* (Cth). Once approved they are listed on the Australian Register of Therapeutic Goods (ARTG) and may then be supplied in Australia.<sup>167</sup>

In addition, suppliers may apply to have their product listed on the Pharmaceutical Benefits Scheme (PBS) which means that they are supplied at a subsidised cost to Australian Residents and visitors who enjoy benefits under the Reciprocal Health Care Agreement. Once a drug is approved for listing in the PBS it is included in the Schedule of Pharmaceutical Benefits.

Subsidies fall into two categories; general and concessional, with patients paying a capped fee for PBS listed products and the Government paying the remainder of the cost. In 2016 the maximum

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<sup>164</sup> *ACCC v Baxter Healthcare* [2008] FCAFC 141 (per Mansfield J), at [5].

<sup>165</sup> *ACCC v Baxter Healthcare* [2008] FCAFC 141 (per Mansfield J), at [5].

<sup>166</sup> *ACCC v Baxter Healthcare* [2008] FCAFC 141 (per Mansfield J), at [5].

<sup>167</sup> Therapeutic Goods Administration, 'Australian Register of Therapeutic Goods', available at <<https://www.tga.gov.au/australian-register-therapeutic-goods>>.

'co-payment' for PBS medicine is AUS\$38.30 for general patients and AUS\$6.10 for concessional patients. The level of co-payment is indexed annually in line with the Consumer Price Index (CPI).

Over the counter medicines (which do not require prescriptions and are not listed on the PBS) are not price-regulated.<sup>168</sup>

The price of drugs listed on the PBS is regulated by the *National Health Act 1953* (Cth). To be listed on the PBS a supplier must apply to Pharmaceutical Benefits Advisory Committee (PBAC). If PBAC recommends listing the government will then consider the matter and may refer it to the Pharmaceutical Benefits Pricing Authority (PBTA) to calculate the price to the Government would be willing to pay the manufacturer. On the basis of PBAC recommendations the Department of Health undertakes price negotiations with the supplier. When agreement is reached it is sent to the Minister for approval.<sup>169</sup> If the expected cost is more than AU\$5m annually it is also considered by the Commonwealth Department of Finance and Administration and, if expected to cost more than \$20m it is considered by Cabinet.<sup>170</sup>

Where agreement cannot be reached the Minister may make a price determination. Patients may then be required to pay the difference between the price determined by the Minister and the price claimed by the supplier (known as the 'special patent contribution'), although in some cases the Commonwealth may pay the special patient contribution.<sup>171</sup>

Where two or more brands of the same medicine are listed under the PBS, the Government subsidises up to the price of the lowest price brand; where a higher cost brand is dispensed a pharmacist is required to charge a 'brand premium' which is remitted to the supplier. Pharmacists may (and should) substitute cheaper generic brands provided the patient agrees, the brands are bioequivalent, the prescriber has not indicated that substitution is not to occur and substitution is permitted under relevant state or territory legislation.

Entry of the first generic competitor triggers an automatic statutory price reduction of 16% under the PBS,<sup>172</sup> considerably less than many other jurisdictions.

Where PBS listed drugs are supplied by a pharmacist the Government reimburses the pharmacist the cost of the drug. Drugs used in public hospitals are largely funded through agreements between states, territories and Commonwealth governments.<sup>173</sup>

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<sup>168</sup> Simone Mitchell, Nicholas Tyacke, Simon Uthmeyer, Kieran O'Brien, Rohan Singh, Eliza Mallon, Rob McMaster and Anna Parker (DLA Piper), *Medicinal product regulation and product liability in Australia: overview* (Practical Law, Thomson Reuters) available at <<http://uk.practicallaw.com/0-500-7384>>.

<sup>169</sup> *National Health Act 1953* (Cth) s 85AD.

<sup>170</sup> Simone Mitchell, Nicholas Tyacke, Simon Uthmeyer, Kieran O'Brien, Rohan Singh, Eliza Mallon, Rob McMaster and Anna Parker (DLA Piper), *Medicinal product regulation and product liability in Australia: overview* (Practical Law, Thomson Reuters).

<sup>171</sup> *National Health Act 1953* (Cth) s 85B.

<sup>172</sup> Memorandum of Understanding between the Australian Government and Medicines Australia 2010 (September 2010) available at <<http://www.pbs.gov.au/info/industry/useful-resources/memorandum>>. See also s 99ACB *National Health Act 1953* (Cth)

<sup>173</sup> Simone Mitchell, Nicholas Tyacke, Simon Uthmeyer, Kieran O'Brien, Rohan Singh, Eliza Mallon, Rob McMaster and Anna Parker (DLA Piper), *Medicinal product regulation and product liability in Australia: overview* (Practical Law, Thomson Reuters).

Pharmacists are paid by the Government to dispense PBS items. The PBS-dispensed price received by pharmacist includes the cost to the pharmacist (manufacturer's price plus specified wholesale mark-up), an administration, handing and infrastructure (AHI),<sup>174</sup> a dispensing fee and any other fee to which the pharmacist is entitled. The Pharmaceutical Benefits Remuneration Tribunal implements agreements between the Minister for Health and Pharmacy Guild of Australia as to how this price is to be established, pursuant to s 98BAA of the *National Health Act 1953* (Cth). This applies only to pharmacy dispensed items and not to medicines acquired or dispensed through hospitals.<sup>175</sup>

From 1 August 2015 pharmacists may charge patients an additional fee of up to AUS\$1.17 for ready-prepared items and AUS\$1.53 for extemporaneously prepared items, provided the total cost does not exceed the AUS\$38.30 threshold<sup>176</sup> and, as part of the Sixth Pharmacy Agreement it may charge an additional extra fee of up to AUS\$4.33, provided the total cost does not exceed AUS\$38.30.<sup>177</sup>

Conversely, in an attempt to improve pharmacy competition, and despite opposition from the Pharmacy Guild of Australia,<sup>178</sup> from 1 January 2016 pharmacists have had the option of discounting the patient co-payment for most PBS medicines by up to AUS\$1.<sup>179</sup>

### ***Obligation to make available pharmaceutical products***

Pharmaceutical suppliers of originator drugs are obliged to supply certain branded products listed on the PBS. This is designed to deter suppliers entering the Australian market 'without a viable business model able to support their long term participation in the market'.<sup>180</sup>

The guarantee of supply obligation, contained in an almost impenetrable provision of the *National Health Act 1953* (Cth), states: "The responsible person for a guaranteed brand of a guaranteed item must supply the guaranteed brand of the guaranteed item during the guaranteed period for the guaranteed brand of the guaranteed item."<sup>181</sup> A 'guaranteed brand of a guaranteed item' is defined<sup>182</sup> to include two categories of product; 'new brands' and 'first brand to offer a lower price'.<sup>183</sup> In relation to new brands, the guarantee of supply applies to brands that are newly listed and bioequivalent or biosimilar to an existing listed brand and have the same drug and manner of administration.<sup>184</sup> In relation to existing brands, the guarantee of supply applies to certain brands of

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<sup>174</sup> Agreed as part of the 6<sup>th</sup> Community Pharmacy Agreement. See further Australian Government, 'PBS Access and Sustainability Package including the Sixth Community Pharmacy Agreement', available at <<http://www.pbs.gov.au/info/general/pbs-access-sustainability-package>>.

<sup>175</sup> The dispensed price for medicines supplied by approved hospital authorities is determined by the Minister under s 98C(1)(a) and 99(4) of the *National Health Act* and associated regulations.

<sup>176</sup> Australian Government, *The Pharmaceutical Benefits Scheme: PBS Frequently Asked Questions*, available at <<http://www.pbs.gov.au/info/general/faq>>.

<sup>177</sup> Ibid.

<sup>178</sup> See, for example, Sue Dunlevy, 'Prescription medicine row: 'There is always one or two who will do the wrong thing'' (news.com.au, 22 December 2015).

<sup>179</sup> The Hon Sussan Ley MP, 'Discount PBS prescriptions start today' (Media Release, 1 January 2016).

<sup>180</sup> Australian Government, 'Guarantee of Supply' Pharmaceutical Benefits Scheme website, available at <<http://www.pbs.gov.au/info/industry/listing/elements/guarantee-of-supply>>.

<sup>181</sup> *National Health Act 1953* (Cth), s 99AEB.

<sup>182</sup> *National Health Act 1953* (Cth), s 99AEA.

<sup>183</sup> *National Health Act 1953* (Cth), ss 99AEC(2) and 99AED(2) set out the full criteria for classifying products as guaranteed brands of guaranteed items.

<sup>184</sup> *National Health Act 1953* (Cth), s 99AEC(2)

F2 listed items which offer a voluntary price reduction which has been accepted by the minister and published on the Schedule of Pharmaceutical benefits.<sup>185</sup>

The guarantee of supply runs for 24 months or until a new bioequivalent or biosimilar brand of that drug lists or an existing bioequivalent or biosimilar brand lists at a lower price.<sup>186</sup>

The guarantee requires the responsible person<sup>187</sup> for the brand to supply it within a reasonable period, or a prescribed period, after receiving a supply request.<sup>188</sup> The responsible person for a brand is required to notify the Minister in the event of failure to supply.<sup>189</sup> The Minister has the power to revoke or vary determinations in relation to the brand as a result of such a failure.<sup>190</sup> Although it is not an offence to fail to supply, it is an offence to fail to notify the Minister of such a failure, for which the responsible person may face a maximum penalty of 60 penalty units<sup>191</sup> (currently equivalent to AUS\$10,800).<sup>192</sup>

## PARALLEL TRADE RESTRICTIONS

Parallel importation of pharmaceutical products is not prohibited, but must comply with all relevant regulation, including Therapeutic Goods Administration approval to sell and PBS listing if the importer is seeking to qualify for government reimbursement. There have been no competition law cases relating to parallel imports of pharmaceutical products.

### V. Conclusion

There is a lack of competition law cases in the pharmaceutical sector in Australia. The primary reason is that competition law has not been used, other than in the cases of *Pfizer* and *Baxter Healthcare*, to address potentially anticompetitive practices where pharmaceuticals are involved. The proposed change to Australia's misuse of market power provision to incorporate an 'effects' based test and the proposed repeal of s 51(3) will, if implemented, go some way to facilitating the use of competition law to address anti-competitive conduct in the pharmaceutical industry.

Pharmaceuticals, most notably patented pharmaceuticals, are expensive in Australia. The current law and policy tend to favour and overprotect patented drugs over the generics. From social welfare and the Australian economy perspectives, it would be preferable if a balance was established and, thus, if the pharmaceutical market was more open to competition from generic-drug producers.

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<sup>185</sup> *National Health Act 1953 (Cth)*, s 99AED(2). See also Australian Government, 'Guarantee of Supply' Pharmaceutical Benefits Scheme website, available at <<http://www.pbs.gov.au/info/industry/listing/elements/guarantee-of-supply>>.

<sup>186</sup> *National Health Act 1953 (Cth)*, s 99AEC(3) and 99AED(3). This is the 'guaranteed period'. See also Australian Government, 'Guarantee of Supply' Pharmaceutical Benefits Scheme website, available at <<http://www.pbs.gov.au/info/industry/listing/elements/guarantee-of-supply>>

<sup>187</sup> The responsible person is the registered person or corporation that supplies the particular brand of medicine on the PBS *National Health Act 1953 (Cth)*, ss 84 and 84AF.

<sup>188</sup> *National Health Act 1953 (Cth)*, s 99AEE.

<sup>189</sup> *National Health Act 1953 (Cth)*, s 99AEG(1)(2).

<sup>190</sup> *National Health Act 1953 (Cth)*, s 99AEH.

<sup>191</sup> *National Health Act 1953 (Cth)*, s 99AEG(3).

<sup>192</sup> The value of a penalty unit is set out in the *Crimes Act 1914 (Cth)* s 4AA and is currently set at AUS\$180. It is subject to indexation.