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## EVERGREEN OR DECIDUOUS? AUSTRALIAN TRENDS IN RELATION TO THE ‘EVERGREENING’ OF PATENTS

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*[The so-called ‘evergreening’ of pharmaceutical patents has become an issue of major public concern in the wake of the Australia–United States Free Trade Agreement and the amendments it requires to the Therapeutics Goods Act 1989 (Cth). The effect of these amendments was to place additional obligations on manufacturers of generic (unpatented) pharmaceuticals. Some additional provisions were also included in an attempt to safeguard against potentially ‘illegitimate’ patent infringement action taken by patentees against such manufacturers. This article examines these provisions and their likely effect on the patent protection strategies adopted by the pharmaceutical industry. It also considers recent responses to these strategies by the patents administration system and the courts — in particular, the decision of Arrow Pharmaceuticals Ltd v Merck & Co Inc.]*

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### I INTRODUCTION

‘Evergreening’ refers to the strategy adopted by patentees who seek to extend their period of patent protection by applying for secondary patents over related or derivative technologies. At first blush, the idea of evergreening seems an anathema to central tenets of the patent system, which provide protection for a limited term to ‘novel’ inventions. Accordingly, the practice of evergreening has

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been criticised as effectively enabling protection beyond the initial term despite only trivial changes to the invention itself. Multinational pharmaceutical companies are most frequently accused of abusing the patent system in this way, and it was this concern that prompted such debate and interest in the lead-up to Australia's implementation of the *Australia–United States Free Trade Agreement*<sup>1</sup> and during the 2004 federal election campaign.

The *AUSFTA* made much more extensive alterations to copyright law than to the patent system. The duration of many copyrights was extended by a further 20 years<sup>2</sup> — the full term of a patent — a change much more amenable to the charge of evergreening than corresponding changes to patent law. Nevertheless, the changes to copyright did not capture the public's imagination in the same way, even though their consequences would be felt far more profoundly in the future. Rather, it was the changes to patents and therapeutic goods regulation that received widespread public and media attention. The availability and cost of pharmaceuticals are issues that have much greater visceral impact upon the public than access to and use of copyright works.

This recent attention in the Australian media reflects global concern about the manner in which the patent system is to strike a balance between the interests of inventors and the general public. On the one hand, incentives must exist for 'pioneering' or 'originator' drug companies to innovate. On the other hand, regard must be had for competing manufacturers of generic products ('generics companies') in order to facilitate their simultaneous creation of new therapies and efficient production of older drugs. This is, of course, not a concern isolated to Australia. Such issues, and concerns over potential abuses of evergreening, are widespread throughout the global community, including in the United States.<sup>3</sup> However, the balance is struck differently in each jurisdiction.<sup>4</sup> Unsurprisingly, some countries — notably those with a significant pioneering drug sector — are more favourably inclined to protect originator interests, whereas others — especially countries with poorer health and financial positions, and those with a significant generics industry — are less inclined. Additionally, world trade agreements are layered on top of all those interests and related debates have been playing out inside the Doha round of negotiations of the World Trade Organization ('WTO') in recent years.

This article reviews evergreening practices and related laws from an Australian perspective. First, it analyses the strategy and practice of evergreening in Australia, before outlining the backdrop provided by pre-existing patent and

<sup>1</sup> Opened for signature 18 May 2004, [2005] ATS 1 (entered into force 1 January 2005) ('*AUSFTA*').

<sup>2</sup> *Ibid* art 17.4.4.

<sup>3</sup> See, eg, discussion of the United States Federal Commission's 2002 inquiry into evergreening abuses: Thomas Faunce, 'The Awful Truth about Evergreening', *The Age* (Melbourne), 7 August 2004, 9.

<sup>4</sup> See, eg, the comparative regulatory discussion in Anita Nador and Melanie Szweras, *Comparing Canadian Notice of Compliance (NOC) Regulations for Patented Medicines with Corresponding United States and European Union Provisions* (4 March 2002) Bereskin and Parr Intellectual Property Law <[http://www.bereskinparr.com/English/publications/art\\_html/bio-noc-regul-nador.html](http://www.bereskinparr.com/English/publications/art_html/bio-noc-regul-nador.html)>. Although these jurisdictions differ considerably in their approaches, they are more homogenous than others.

Therapeutic Goods Administration ('TGA') systems. It then examines the changes introduced by the *AUSFTA*, identifying both 'pro-' and 'anti-' evergreening elements, and considers the effect of several recent cases.

The 'pro-evergreening' elements of the *AUSFTA* extend protection by creating peripheral mechanisms rather than making fundamental changes to patent laws. Specifically, the mechanisms introduce regulatory 'data exclusivity' and impose tightened controls over advertising by generics companies. The core obligation imposed by these changes is to require those seeking to market pharmaceuticals to certify their products as 'patent-friendly', under threat of significant penalty. As will be seen, the original provisions of the *US Free Trade Agreement Implementation Act 2004* (Cth) have already had to be amended to ameliorate unintended side effects for the 'over-the-counter' and complementary medicine sectors, where compliance costs were raised without any real benefit for consumers.<sup>5</sup> The 'anti-evergreening' provisions are also unlikely to have any significant effect. To the extent that they do prove to have teeth, they are likely to be 'pulled' at the insistence of the US, which indicated its grave reservations about their inclusion in the amending legislation.

There is clearly a large financial incentive for drug companies to push the boundary of protection systems, so it seems likely that evergreening in one form or another will continue. In light of Australia's obligations under the *AUSFTA*, legislative intervention appears unlikely. Consequently, the primary checks and balances on subversive evergreening practices in Australia remain those provided by IP Australia and the courts. Case law is, of course, very fact specific (as it must be). It is therefore difficult to draw any coherent principles from the decisions. Some courts continue to exhibit serious reservations about patenting methods of medical treatment — sometimes on philosophical grounds and especially where they perceive no real technical innovation but rather legal artifice. Other decisions, particularly those by appellate courts, appear quite 'patent-friendly' and seem less inclined to refuse protection unless a product or process clearly lacks novelty (attacks on 'obviousness' proving more problematic). Overall, the proprietary trend in intellectual property seems set to continue, with evergreening of pharmaceutical patents providing merely one more example.

## II PATENT STRATEGIES — EVERGREENING IN ACTION?

Clearly, it is fundamental to the patent system that applications relate to new inventions. However, in the context of pharmaceutical patents, the practice of evergreening does not simply refer to extending the original patent, but also includes strategies and practices used to protect a cluster of related, but arguably unoriginal, technologies through the filing of secondary applications. For example, a patentee may seek protection for novel uses of a drug, or new methods of administering or producing it, prior to the expiry of the original substance patent. The effect is to 'reset the clock' on the patentee's protection period, excluding potential competitors from the marketplace for another full

<sup>5</sup> See below Part IV(D)(4).

term. Generic drug companies, for example, are forced to decide whether to delay entry of their own products, challenge the secondary patent, or design around it.

With a number of ‘blockbuster’ substance patents due for expiry within the next few years, this practice has received a considerable amount of attention, both within and outside the pharmaceutical industry. As it is phrased in an article by Michael Burdon and Kristie Sloper:

In an environment where there is ever increasing pressure on innovator pharmaceutical companies to maximise return on investment and where share values may be substantially affected by court decisions in patent litigation between pharmaceutical innovators and generic companies, a key element of pharmaceutical life cycle management strategies is to extend patent protection for as long as possible by filing secondary patents to keep generics off the market.<sup>6</sup>

Burdon and Sloper’s article reviews the United Kingdom case law and attempts to extrapolate several lessons for ‘the development of a credible life cycle management strategy.’<sup>7</sup> The article concludes that:

secondary patents can be useful in extending patent protection in certain cases. Although it has often proved difficult to maintain the validity of such patents before the UK courts it is by no means impossible and there have been some significant victories for patentees in the UK courts in cases involving secondary patents in recent years. ...

Even where the final outcome of proceedings is that the patent is held invalid, the effect of the litigation will have been to delay the generics’ entry to the market. Fighting the litigation may also have ‘warned off’ other generic competition. In any event, for a successful product, the benefit of even a short time of additional proprietary sales may easily outweigh the costs of patent litigation.<sup>8</sup>

Similarly, it is instructive to consider various comments included in presentations by Andrew Teuten of Sagittarius Intellectual Property Consultants Ltd: ‘These days 20 years of patent life is not enough; there is a need to make protection “longer and stronger”’.<sup>9</sup> Such protection is further defined to include measures such as making best use of the *Paris Convention for the Protection of Industrial Property*,<sup>10</sup> the ‘patent term guarantee’ in the US and statutory patent term extension,<sup>11</sup> and taking advantage of opportunities for secondary patents as well as regulatory data exclusivity.<sup>12</sup>

<sup>6</sup> Michael Burdon and Kristie Sloper, ‘The Art of Using Secondary Patents to Improve Protection’ (2003) 3 *International Journal of Medical Marketing* 226, 226.

<sup>7</sup> *Ibid* 228.

<sup>8</sup> *Ibid* 238.

<sup>9</sup> Andrew Teuten, ‘Strategies for Extending the Period of Exclusivity of a Pharmaceutical Product’ (Paper presented at the Biotech and Pharmaceutical Patenting IBC USA Conference, Paris, 27 January 2004) [slide 2] <[http://www.sagittariusipc.co.uk/AT\\_presentation\\_Jan04.pdf](http://www.sagittariusipc.co.uk/AT_presentation_Jan04.pdf)>.

<sup>10</sup> Opened for signature 20 March 1883, 828 UNTS 305 (entered into force 19 May 1970).

<sup>11</sup> See, eg, the *Drug Price Competition and Patent Term Restoration Act of 1984*, 15 USC §§ 68b–68c, 70b (1994); 21 USC §§ 301 note, 355, 360cc (1994); 28 USC § 2201 (1994); 35 USC §§ 156, 271, 282 (1994) (*‘Hatch-Waxman Act’*) which provides for term extension for drug patents. The Australian laws provide more limited protection: see below Part IV(A)(1). See also Gerald J Mossinghoff, ‘Overview of the *Hatch-Waxman Act* and its Impact on the Drug Devel-

Teuten notes the controversial nature of secondary patents 'such as new polymorphs, salts, formulations, processes, uses etc',<sup>13</sup> but canvasses their advantages in extending the overall period of protection, and the dissuasive effect on generic drug companies. He comments further on the potential unattractiveness of designing around existing patents, which, even if technically feasible, may confront regulatory hurdles in trying to establish 'bio-equivalency' with the originator product.<sup>14</sup> It is this combination of strategies — in particular, an astute package of secondary patents and exclusivity over regulatory data — that Teuten refers to as 'total product protection'.<sup>15</sup> While he does caution as to the probability of validity challenges if secondary patents extend protection beyond the basic term (and the fact that they provide a target to be further designed around) he nonetheless concludes that such protection can be very valuable, a similar conclusion to that reached in the paper by Burdon and Sloper.

One example of the successful use of evergreening strategies to obtain extended protection is GlaxoSmithKline's version of the antidepressant, paroxetine. The 'base' patent expired in the late 1990s, but ancillary patents covering new forms, tablets, uses and processes will not expire until between 2006 and 2018.<sup>16</sup>

It seems uncontroversial that there is a significant incentive — indeed, significant commercial pressure — on the pharmaceutical industry to adopt whatever legitimate tactics it can to effectively extend monopoly rights. Further, it is undeniable that the industry does indeed adopt these practices in an attempt to 'evergreen', using that expression in a broad sense.<sup>17</sup> Some of the tactics employed have been mentioned briefly above, though there are of course many others.<sup>18</sup> The ingenuity of technical, patent and legal advisers will ensure that the options available continue to expand. While most of the authorities referenced above in relation to evergreening strategies are international, this reflects the nature of the global pharmaceutical industry, especially the so-called originator sector. Similar tactics are adopted in Australia, with adaptation to local circumstances and laws as appropriate.

opment Process' (1999) 54 *Food and Drug Law Journal* 187. See generally 'Symposium: Striking the Right Balance between Innovation and Drug Price Competition — Understanding the Hatch-Waxman Act' (1999) 54 *Food and Drug Law Journal* 185. For a discussion of US evergreening practice (and abuse), see Lara J Glasgow, 'Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?' (2001) 41 *IDEA: The Journal of Law and Technology* 227.

<sup>12</sup> See Teuten, above n 9, [slide 3].

<sup>13</sup> *Ibid* 1.

<sup>14</sup> For a discussion on the US procedures for obtaining regulatory approval for generic drugs, including the requirement that a generics company demonstrate bio-equivalency with the original drug, see below Part III(B).

<sup>15</sup> Teuten, above n 9, [slide 3].

<sup>16</sup> Mike Hutchins, 'Using Interlocking Additional Early Stage Patents to Improve and Extend Patent Protection' (2003) 3 *International Journal of Medical Marketing* 212, 215.

<sup>17</sup> See, eg, David Uren, 'Drug Industry Has Plenty of Dodges, That's Patently Obvious — Trade in the Balance', *The Australian* (Sydney), 5 August 2004, 4.

<sup>18</sup> The subject matter of other secondary pharmaceutical patents has included isomers, pill-mixing, changed indications, drug-device combinations, tablets and special coatings.

## III PRE-EXISTING LAW

## A Australia

Prior to the introduction of the *AUSFTA* it was already possible to engage in so-called evergreening and indeed to seek an extension of protection for the terms of the base patent. Limited term extension for drug patents has been a feature of the *Patents Act 1990* (Cth) since 1998,<sup>19</sup> with the ability to apply for extensions of up to five years for pharmaceutical substance patents.<sup>20</sup> This specific extension is regarded as some compensation for the extended regulatory approval process and safety trials to which new drugs are subjected, and is a common element of many patent systems. However, this extension was never available for a 'use' claim. This limitation stemmed from an interpretation by the Federal Court of Australia of the meaning of the phrase 'pharmaceutical per se' in *Boehringer Ingelheim International v Commissioner of Patents*.<sup>21</sup> Australian Patent Office procedures now explicitly reflect this, including some specific examples of claims to which applications for term extensions will be rejected as non-compliant.<sup>22</sup>

The application of these provisions was the subject of a recent hearing before the Deputy Commissioner of Patents in *Application by Pfizer Inc.*<sup>23</sup> In this case, the Patent Office refused an application for extension of term in relation to a patent on a general class of chemical compounds. One example within this class (voriconazole, which apparently had surprising properties not evident from the general class of compounds discussed in the first patent specification) had been the subject of a divisional selection patent<sup>24</sup> from the patent in question, and that patent had already been granted a term extension. It was held that the current application could not meet the requirement of *Patents Act 1990* (Cth) s 70(2)(a) that the relevant compound be disclosed in substance in the patent.<sup>25</sup> The Deputy Commissioner believed that there would be a fundamental difficulty if the parent standard patent did disclose the substance claimed by the divisional application,

<sup>19</sup> *Intellectual Property Laws Amendment Act 1998* (Cth) sch 1 div 2.

<sup>20</sup> *Patents Act 1990* (Cth) ss 70–9A.

<sup>21</sup> [2001] AIPC ¶91-670. An appeal from this decision was dismissed in *Boehringer Ingelheim International GmbH v Commissioner of Patents* (2001) 112 FCR 595.

<sup>22</sup> For details of patent extension grounds, see Australian Patent Office, *Manual of Practice and Procedure* (vol 3) (April 2006) IP Australia [3.23.2.2] <[http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent\\_Examiners\\_Manual.htm](http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm)> which provides: 'Examples of claims that are not directed to substances per se are ... use of substance X in the treatment of Y'.

<sup>23</sup> (2004) 62 IPR 627.

<sup>24</sup> Divisional applications are dealt with in *Patents Act 1990* (Cth) ch 6A. They permit a further complete application for an invention disclosed in the original application, provided that this is made, in the case of an original standard patent, prior to the grant of the original application: s 79B(1). Divisional applications may also be made from an innovation patent application and these can be made following the grant of that application, as long as they are made within the prescribed time: s 79C.

<sup>25</sup> The section in question provides that 'one or more pharmaceutical substances *per se* must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification': *Patents Act 1990* (Cth) s 70(2)(a).

as prima facie this would have deprived the selection patent of the requisite element of novelty for patentability, subject to additional evidence.<sup>26</sup>

However, this element of the decision was overturned on appeal in *Pfizer Inc v Commissioner of Patents*,<sup>27</sup> and the matter was remitted to the Commissioner of Patents for further determination. Bennett J found that the Deputy Commissioner had effectively and inappropriately taken into account the selection patent in the construction of the parent patent. In contrast, Bennett J decided that 'the selection patent either by reason of its existence or as evidence in the construction of the parent patent for the purpose of ascertaining disclosure within the meaning of s 70(2)(a), was irrelevant.'<sup>28</sup> His Honour further commented:

There may have been reasons why the patentee chose to file a second patent instead of seeking to amend the parent patent to include a specific claim to voriconazole. However, those issues play no part in the determination of whether s 70(2)(a) is satisfied, in the same way that issues of invalidity for lack of novelty or obviousness play no part in the determination of fair basis of the claims on the matter described in the specification.<sup>29</sup>

Warwick A Rothnie has described this outcome as a 'peculiar form of double dipping (perhaps bootstrapping rather than evergreening)'.<sup>30</sup>

In any event, a patentee may of course seek protection for further inventions, which might include claims to new uses for existing products. Obviously each new application must meet all the requirements for patentability in its own right, and will only receive protection to the extent its claims are valid. As Karin Innes states, '[p]atent evergreening will still be permitted to the extent that it does not transgress the law.'<sup>31</sup> She asserts that the practice of evergreening was 'effectively endorsed'<sup>32</sup> by the High Court of Australia in *Aktiebolaget Hässle v Alphapharm Pty Ltd*.<sup>33</sup>

At a technical level, this may seem to be overstating the effect of the case, which did not explicitly refer to evergreening and on its face was more concerned with the proper process to be undertaken in determining the issue of

<sup>26</sup> *Application by Pfizer Inc* (2004) 62 IPR 627, 634 (Deputy Commissioner Herald). Note that Deputy Commissioner Herald found that the *Patents Act 1990* (Cth) did not preclude the extension of term of more than one patent based on a single registration under the Australian Register of Therapeutic Goods: at 629.

<sup>27</sup> (2005) 141 FCR 413.

<sup>28</sup> *Ibid* 420.

<sup>29</sup> *Ibid* 421 (citations omitted). Note that Bennett J was not assessing issues of validity in relation to the selection patent. See also *Imperial Chemicals Industries Pty Ltd v Commissioner of Patents* (2004) 63 IPR 476 for the potential impact of such a situation on novelty. This case also involved a patent within the scope of a previous patent on the relevant general class of chemical compounds. An appeal against its rejection by the Patent Office was allowed: at 494–5 (Crennan J).

<sup>30</sup> Warwick A Rothnie, *Extending the Selected beyond the Extension* (8 March 2005) IPwar's Patents <<http://homepage.mac.com/wrothnie/iblog/C149316833/E2145394282/index.html>>.

<sup>31</sup> Karin Innes, 'The Impact of the Australia–United States Free Trade Agreement on Pharmaceutical Patents' (July 2005) *Blake Dawson Waldron: Life Sciences Update 7* <<http://www.bdw.com.au/publications/lifescience/lifescience072005.pdf>>.

<sup>32</sup> *Ibid*.

<sup>33</sup> (2002) 212 CLR 411.



‘inventive step’.<sup>34</sup> In a practical sense, however, the comment is accurate: the High Court decision overturned the ‘anti-evergreening’ approaches of lower courts. For example, the Federal Court had found the Losec patent — which did not claim the active substance (for which a prior patent had expired) but rather a coating system — to be obvious.<sup>35</sup> The majority of the High Court disagreed, allowing continued protection of the drug in question, despite it being noted to have cost the Pharmaceutical Benefits Scheme over \$141 million in the 1997–98 financial year.<sup>36</sup> However, there were some strong dissents from Kirby and McHugh JJ. Kirby J noted that the finding of obviousness was consistent with the approach of Laddie J on essentially the same subject matter in *Cairnstores Ltd v Aktiebolaget Hässle*.<sup>37</sup>

Another important decision in the field of secondary patents — in this case relating to a use patent — is that of the Full Federal Court in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*.<sup>38</sup> This was an appeal from the judgment of Heerey J in *Bristol-Myers Squibb Co v FH Faulding & Co Ltd*<sup>39</sup> in relation to a petty patent for a more efficient method of administering an anti-cancer drug. At first instance, Heerey J revoked the patent on various grounds, most controversially that it was a method of treatment, the patenting of which would be generally inconvenient.<sup>40</sup> Heerey J quoted Cooke J: “there remains ... a deep-seated sense that the art of the physician or the surgeon in alleviating human suffering does not belong to the area of economic endeavour or trade and commerce.”<sup>41</sup>

The Full Federal Court dismissed the appeal but reversed Heerey J’s decision on the method of medical treatment issue,<sup>42</sup> instead affirming the majority view from *Anaesthetic Supplies Pty Ltd v Rescare Ltd*.<sup>43</sup>

It is also possible to attempt to evergreen by filing innovation patents, which require a lower level of ‘innovative step’, rather than the same level of inventiveness required of standard patents. The term of protection is lower, but such patents can be used for ‘secondary’ protection of incremental innovation, or to enable ready enforcement by means of a divisional filing, pending grant of a parent standard patent.

The preceding analysis illustrates that, while not always successful, pharmaceutical companies often attempted to take advantage of the pre-*AUSFTA* Australian patent regime in order to engage in evergreening. In Part V, this article will consider in greater detail recent judicial criticism of one such attempt, *Arrow*

<sup>34</sup> Ibid 436–8 (Gleeson CJ, Gaudron, Gummow and Hayne JJ).

<sup>35</sup> *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375.

<sup>36</sup> *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 212 CLR 411, 449 (Kirby J).

<sup>37</sup> Ibid 450. See *Cairnstores Ltd v Aktiebolaget Hässle* [2002] EWHC 309 (Ch) (Unreported, Laddie J, 6 March 2002).

<sup>38</sup> (2000) 97 FCR 524 (‘*Faulding*’).

<sup>39</sup> (1998) 41 IPR 467.

<sup>40</sup> Ibid 479–82.

<sup>41</sup> Ibid 481, citing *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385, 388 (Cooke J).

<sup>42</sup> *Faulding* (2000) 97 FCR 524, 529–30 (Black CJ and Lehane J), 569–70 (Finkelstein J).

<sup>43</sup> (1994) 50 FCR 1.

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*Pharmaceuticals Ltd v Merck & Co Inc*,<sup>44</sup> as well as briefly look at some other current Australian decisions.

### B *United States*

This article will not attempt to provide a comprehensive overview of US evergreening practices and laws.<sup>45</sup> However, it is important to appreciate the basic principles governing the US system — in particular the *Hatch-Waxman Act*<sup>46</sup> — in order to understand the US negotiating position and the basis for the changes introduced by the *AUSFTA*. It is certainly true that the Australian regulatory framework is far from identical to its US counterpart. However, the US approach remains important in Australia, notwithstanding the protestations of domestic trade negotiators that it has successfully resisted introducing a *Hatch-Waxman* type system into Australian law.<sup>47</sup>

Like Australia, debates have taken place in the US about the dangers of evergreening and have attempted to strike a balance between the interests of originator and generics drug companies. This is done primarily within the framework of the *Hatch-Waxman Act*. This Act introduces a procedure for obtaining regulatory approval for generic drugs. An 'abbreviated new drug application' ('ANDA') can be made to the US Food and Drug Administration ('FDA') by generic drug manufacturers seeking approval for the release of their competing drugs. The rationale underlying this system is that if the original drug had already received regulatory approval then, in order to gain marketing approval for their drugs, all a generics company should be required to do is to demonstrate bio-equivalency with the original drug — that is to say, an identical biological effect — rather than demonstrate safety and efficacy independently.

To balance the interests of the originator industry, the *Hatch-Waxman Act* requires ANDA lodgements to make one of four certifications in relation to the patent status of the competing generic drug. The options are:

- (a) the drug is not patented;
- (b) relevant patents have expired;
- (c) relevant patents will expire by the time the generics drug hits the market; or
- (d) the patent won't be infringed or is invalid.<sup>48</sup>

The certification made by the ANDA applicant essentially provides a form of early warning system for the primary patentees, who can then seek an injunction to prevent the release of products which they believe are in violation of their patent claims.

<sup>44</sup> (2004) 63 IPR 85 (*'Arrow v Merck'*).

<sup>45</sup> For further information in relation to the United States systems, see references in above n 11.

<sup>46</sup> 15 USC §§ 68b–68c, 70b (1994); 21 USC §§ 301 note, 355, 360cc (1994); 28 USC § 2201 (1994); 35 USC §§ 156, 271, 282 (1994).

<sup>47</sup> See, eg, Evidence to Senate Select Committee on the Free Trade Agreement between Australia and the United States of America, Parliament of Australia, Canberra, 21 June 2004, 46, 48, 58 (Stephen Deady).

<sup>48</sup> *Federal Food, Drug, and Cosmetic Act*, 21 USC § 355(b)(2)(A) (2004).

In order to compile a centralised list of patents to which a generics competitor should have regard when making the required certifications, the so-called ‘Orange Book’ was created. The Orange Book contains this listing, to which the originator industry essentially adds in a self-nominating fashion. In theory, maintaining the list in a ‘closed’ form improves certainty for generics manufacturers. However, it now appears that the benefits of a more confined list have been eroded by astute use of the system by patent attorneys familiar with how to best combine patent drafting, filing and Orange Book listing: ‘With a greater understanding of how *Hatch-Waxman* and the patent laws interrelate, patent agents and attorneys can help maximize the future earnings of their clients’ drug patents.’<sup>49</sup>

The *Hatch-Waxman Act* contains several other important elements. First, it makes provision for periods of data exclusivity (for example, to an originator listing a new molecular entity). Second, it also grants patentees a more expeditious mechanism for obtaining stays on generic product releases. Finally, it further provides for term extensions in order to make up for delays caused by regulatory processes.<sup>50</sup> Overall, while the *Hatch-Waxman Act* was not stacked completely in favour of the originator drug company interests, its basic structure — especially as it came to be used over time — is on balance friendly to that sector.

In 2003, several amendments to the Act were made by the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*.<sup>51</sup> The relevant provisions are contained in Title XI, ‘Access to Affordable Pharmaceuticals’. One of the changes introduced was to correct abuses made possible where an innovator company progressively ‘late-listed’ patents in the Orange Book, creating successive 30-month stays on generic product releases in the event of related litigation, effectively stalling generic competition.<sup>52</sup> Another change provides a mechanism for an ANDA applicant that has been sued for patent infringement to counterclaim for correction or deletion of patents listed in the Orange Book.<sup>53</sup>

<sup>49</sup> Terry G Mahn, ‘Patenting Drug Products: Anticipating *Hatch-Waxman* Issues during the Claims Drafting Process’ (1999) 54 *Food and Drug Law Journal* 245, 253.

<sup>50</sup> For further discussion of the important and complex issue of data exclusivity, see, eg, Elizabeth H Dickinson, ‘FDA’s Role in Making Exclusivity Determinations’ (1999) 54 *Food and Drug Law Journal* 195.

<sup>51</sup> Pub L No 108-173, 117 Stat 2066. For a brief discussion of its features, see, eg, Richard J Berman and Janine A Carlan, ‘Changes to the *Hatch-Waxman Act* by the Recently Enacted Medicare Law: New Considerations for “Paragraph IV” Litigation’ (23 December 2003) *Arent Fox: Alert* <[http://www.arentfox.com/legal\\_updates/icontent493.pdf](http://www.arentfox.com/legal_updates/icontent493.pdf)>.

<sup>52</sup> *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Pub L No 108-173, § 1101, 117 Stat 2066, 2448.

<sup>53</sup> *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Pub L No 108-173, § 1101, 117 Stat 2066, 2448.

IV THE *AUSFTA* AND ITS IMPLEMENTATIONA *AUSFTA*

There is no radical change mandated by patent elements of the *AUSFTA*,<sup>54</sup> and in particular little that relates to potential evergreening. Most of the *AUSFTA* patent requirements simply reinforce aspects of the WTO's *Agreement on Trade-Related Aspects of Intellectual Property Rights*<sup>55</sup> and pre-existing patent law and practice in Australia. However, in some senses they can be described as strengthening this underlying protection afforded to patentees, and are sometimes characterised as 'TRIPS plus'. The core obligations under the *AUSFTA* involve changes such as allowing extensions of pharmaceutical patent terms to account for regulatory delays,<sup>56</sup> and restricting the ability of a generic competitor to use data relating to an originator's patent in its own marketing approval applications (improving so-called regulatory data exclusivity).<sup>57</sup>

These changes are examined in detail below and some other, perhaps unintended, side effects arising from interactions between the *AUSFTA* provisions and elements of pre-existing Australian patent law are also discussed.

1 *Time Extensions*

Article 17.9.8(b) of the *AUSFTA* requires each country to

make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process ... [required for drugs].

The pre-existing provisions in ss 70–9A of the *Patents Act 1990* (Cth) have been briefly mentioned above,<sup>58</sup> and they seem already to satisfy the requirements of this provision. There has been some speculation that this provision could provide a basis for further protection beyond that already provided under the *Patents Act 1990* (Cth):

Article 17.9.8 provides for the possibility of further extension of the patent term, including for pharmaceutical patents. This extension would be in addition to any extension that Australia already provides under section 70 of the *Patents Act* for pharmaceutical patents.<sup>59</sup>

I am not convinced that this is the case. Yet, given that there is an absolute cap on the extension under s 77 of five years, it is arguable that if a patent term was curtailed for more than five years as a result of a particular marketing approval

<sup>54</sup> Opened for signature 18 May 2004, [2005] ATS 1 (entered into force 1 January 2005).

<sup>55</sup> *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3, annex 1C (*Agreement on Trade-Related Aspects of Intellectual Property Rights*) (entered into force 1 January 1995) ('TRIPS').

<sup>56</sup> *AUSFTA*, opened for signature 18 May 2004, [2005] ATS 1, art 17.9.8 (entered into force 1 January 2005).

<sup>57</sup> *Ibid* art 17.9.6.

<sup>58</sup> See above n 20 and accompanying text.

<sup>59</sup> Submission to Senate Select Committee on the Free Trade Agreement between Australia and the United States of America, Parliament of Australia, 5 May 2004, Submission No 159, 18 (Peter Drahos, Thomas Faunce, Martyn Goddard and David Henry).

process then there may be some obligation to provide for a greater extension than the current five-year cap. However, the curtailment would still need to be ‘unreasonable’ and the *AUSFTA* does not specify that the effective patent term must be extended to 20 years, rather, simply that there be an unspecified adjustment available to the patentee.

Perhaps some indirect support for a proposition of a general term extension might be found in part of a US International Trade Commission report on the *AUSFTA*, which asserts that ‘the FTA goes further than *TRIPS* by ... extending the terms of protection for copyrights, trademarks, patents, and trade secrets’.<sup>60</sup> This same report also states that:

The FTA is expected to result in increased revenues for US industries dependent on copyrights, trademarks, patents, and trade secrets. ...

Industries that might benefit from the greater patent and trade secret protections, including the protection of confidential data, are the pharmaceutical and agricultural chemicals industries.<sup>61</sup>

Nevertheless, the more detailed and measured analyses prepared by the relevant industry consultation groups reporting to the President — the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (‘IFAC-3’) and the Industry Sector Advisory Committee for Chemicals and Allied Products (‘ISAC-3’) — only discuss term extension in the context of addressing regulatory market approval delays. Owing to their specificity and more relevant objectives, these analyses are to be preferred as background sources when trying to discern the implications of the *AUSFTA*.

## 2 Use of Patents for Marketing Approval

The only other provision of note is art 17.9.6, which provides that if a country allows a third person to use the subject matter of a patent to generate information necessary to support an application for marketing approval of a pharmaceutical product,<sup>62</sup> then any product produced under that limited authority cannot be used or sold other than to meet those marketing approval requirements.

This leads to the core of the US-advocated *AUSFTA* provisions, which are contained in the blandly designated art 17.10 (‘Measures Related to Certain Regulated Products’). These provisions attempt to strengthen various regulatory approval provisions relevant to pharmaceuticals (and agricultural chemicals) and to cut back on the practice of ‘springboarding’, which is said to occur when

<sup>60</sup> US International Trade Commission, *US–Australia Free Trade Agreement: Potential Economy-wide and Selected Sectoral Effects* (2004) 112–13 <<http://permanent.access.gpo.gov/websites/ftp.usitc.gov/ftp.usitc.gov/pub/reports/studies/pub3697.pdf>>.

<sup>61</sup> *Ibid* 116.

<sup>62</sup> This type of ‘pre-market’ use of the patent is commonly referred to as ‘*Bolar*-type’ or ‘*Roche-Bolar*-type’ use. The label arises from legislative amendments (for example in the US: 35 USC § 271(e)(1)) consequent to the case of *Roche Products Inc v Bolar Pharmaceuticals Co Inc*, 733 F 2d 858 (Fed Cir, 1984), which had produced an even more limiting construction of the scope of underlying exemptions to patent rights. The US commonly seeks to restrict the scope of *Bolar*-type use in the same fashion implemented here as in its other bilateral free trade agreements. See generally Office of the United States Trade Representative, *Trade Agreements Home* <[http://www.ustr.gov/Trade\\_Agreements/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Section_Index.html)>.

generics manufacturers use test data already provided by a primary patent holder to gain approval for their competing drug.<sup>63</sup>

Article 17.10.1(a) creates a five-year period of data exclusivity (in favour of the information provider) to previously undisclosed safety and efficacy test data and information, running from the date of marketing approval for that product (irrespective of whether it is patented). In other words, generic competitors cannot use that data without the data provider's consent to market 'the same or a similar product on the basis of that information' (or without the original market approval).<sup>64</sup> Article 17.10.1(c) extends similar exclusivity in relation to evidence about data, information and approvals submitted in other territories.

Under art 17.10.2, if either Australia or the US requires the submission of new clinical information (other than in relation to bio-equivalency) as an essential element for the approval of a pharmaceutical product — or alternatively, requires evidence of prior approval in another country that also requires such information — then competitors are blocked for three years from marketing the same or a similar product on the basis of the marketing approval for the original product unless they have the consent of the original information provider.<sup>65</sup> The periods of data exclusivity continue in this fashion even if the period of patent protection terminates prior to the end of the period of data exclusivity.<sup>66</sup> ISAC-3 was particularly pleased with this outcome,<sup>67</sup> though IFAC-3 was more measured in its assessment.<sup>68</sup>

Article 17.10.4 is the provision described by the authors of *How to Kill a Country: Australia's Devastating Trade Deal with the United States* as 'the most egregious case of extending monopoly rights ... which could be called "the

<sup>63</sup> Note, however, that the Intellectual Property Laws Amendment Bill 2006 (Cth) has recently been tabled before the House of Representatives, which makes, inter alia, significant amendments to the *Patents Act 1990* (Cth). Schedule 7 of the Bill amends the *Patents Act 1990* (Cth) to allow springboarding as an express exception to patent infringement at any time for the sole purpose of obtaining regulatory approval in Australia or a foreign territory. According to the Explanatory Memorandum, the purpose of the exception is to bring Australia's pharmaceutical patents regime closer into line with that of other jurisdictions such as the US and the European Union, thereby maintaining Australia's competitiveness as an investment for generics research and development: Explanatory Memorandum, Intellectual Property Laws Amendment Bill 2006 (Cth) 23.

<sup>64</sup> *AUSFTA*, opened for signature 18 May 2004, [2005] ATS 1, art 17.10.1(a) (entered into force 1 January 2005).

<sup>65</sup> *Ibid* ch 17 n 17 [26], which creates an alternative that permits parties to retain 'a system for protecting information ... that utilizes a previously approved chemical component from unfair commercial use'.

<sup>66</sup> *Ibid* art 17.10.3.

<sup>67</sup> See ISAC-3, *The US–Australia Free Trade Agreement (FTA): Report of the Industry Sector Advisory Committee for Chemicals and Allied Products (ISAC-3)* (2004) 10 <[http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Australia\\_FTA/Reports/asset\\_upload\\_file180\\_3402.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Reports/asset_upload_file180_3402.pdf)> which states: 'We are particularly pleased to see that the Agreement unambiguously prevents Australia from arbitrarily terminating the data protection period at the time of the expiration of the underlying patent.'

<sup>68</sup> IFAC-3 states in its report that '[w]hile these provisions on data exclusivity do not impose any additional obligations beyond those contained in *TRIPS* Article 39.3, they do serve to clarify the intent of the negotiators of the *TRIPS* Agreement': IFAC-3, *The US–Australia Free Trade Agreement (FTA) — The Intellectual Property Provisions: Report of the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3)* (2004) 15 <[http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Australia\\_FTA/Reports/asset\\_upload\\_file813\\_3398.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Reports/asset_upload_file813_3398.pdf)>.

Evergreening Article”’.<sup>69</sup> Even the Australian special negotiator, Stephen Deady, while holding a very different opinion on its impact, admitted that the specifics of art 17.10.4 involved ‘very tough negotiation’.<sup>70</sup> So what does this supposedly heinous provision actually do?

Article 17.10.4(a) applies to the extent that Australia permits third parties to seek approval for marketing a pharmaceutical product by relying on safety or efficacy information about a previously approved product. In such cases, Australia is obliged to include measures in its regulatory process — that is, the TGA system — to prevent the applicant from marketing a product, or a product for an approved use, under patent. This obligation extends to cover the entire term of the patent, but naturally does not apply where the patent owner has consented to, or acquiesced in, the use of the information.

Further, under art 17.10.4(b), even a request from a third party for marketing approval for a product or a product for an approved use under patent must trigger a notification to the patent owner. However, if a patent for a pharmaceutical product has had its term extended, Australia may permit export of a product covered by that patent, but only for the purposes of meeting the marketing approval requirements of Australia or another territory.

One possible limitation on evergreening abuses might be found in competition laws. This is certainly an approach being pursued or discussed overseas.<sup>71</sup> Indeed, under one of the many side letters to the *AUSFTA*, Australia is permitted to allow revocation on the grounds that a patent has been determined in a judicial proceeding to have been used in an anti-competitive manner.<sup>72</sup> However, the nexus between intellectual property and competition laws in Australia remains poorly developed and regulated, despite the attempts of numerous reviews and committees to suggest improvements.<sup>73</sup> Nonetheless, this is likely to become a more significant counterbalance in the future, assuming legislative reform to the underlying competition framework along the lines previously recommended.

<sup>69</sup> Linda Weiss, Elizabeth Thurbon and John Mathews, *How to Kill a Country: Australia's Devastating Trade Deal with the United States* (2004) 131.

<sup>70</sup> Evidence to Senate Select Committee on the Free Trade Agreement between Australia and the United States of America, Parliament of Australia, Canberra, 21 June 2004, 31 (Stephen Deady).

<sup>71</sup> See, eg, Christine S Paine, ‘Brand-Name Drug Manufacturers Risk Antitrust Violations by Slowing Generic Production through Patent Layering’ (2003) 33 *Seton Hall Law Review* 479; Decision News Media, *EU Antitrust Ruling Leads to AstraZeneca Fine* (16 June 2005) in-Pharma Technologist.com <<http://www.in-pharmatechnologist.com/news/ng.asp?n=60702>>. The author wishes to thank Alison Roy for this second reference.

<sup>72</sup> Letter from Mark Vaile (Minister for Trade) to Robert Zoellick (United States Trade Representative), 18 May 2004, 2 <[http://www.dfat.gov.au/trade/negotiations/us\\_fta/final-text/letters/17\\_ip\\_patents.pdf](http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/letters/17_ip_patents.pdf)>.

<sup>73</sup> See, eg, Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement: Final Report* (2000) 13–19; National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999) 233–46.

### 3 *Grace Periods*

One final issue to consider is a problem arising from the interplay of art 17.9.9<sup>74</sup> and the pre-existing grace period provisions<sup>75</sup> — a 'potential anomaly' highlighted in the recent IP Australia report, *Review of Patent Grace Period*.<sup>76</sup> Grace periods have applied in Australia since 1 April 2002 and permit certain prior publications made with the authority of the patentee within 12 months of the application date to be disregarded when assessing validity.<sup>77</sup> The potentially problematic situation contemplated by the report is one where an applicant files a complete application which is subsequently published, and then, less than 12 months later, they refile a second patent in reliance upon the grace period. This process is termed 'double patenting' by the report.<sup>78</sup>

The report observes that this type of publication should arguably be excluded from the grace period safe harbour, but then states that the '*AUSFTA* appears to prevent such an exclusion'.<sup>79</sup> Surely this shocking 'double-dipping' potential, which on its face is more blatant and pernicious than evergreening, is not what was intended by the *AUSFTA*. An attempt to exploit art 17.9.9 would undoubtedly bring the patent system into disrepute, and it is hard to see even the US raising an *AUSFTA* violation complaint against any legislative or judicial moves to shut it down. Further, at a technical level, art 17.9.9 only discounts use of information in determining novelty and inventive step, but does not operate in relation to the threshold question of 'manner of new manufacture'. If indeed there is any meaning left in that threshold test, it should be sufficient to knock out a double-dipping patent, which on its face is after all not *new*.

In its concluding comments, the *Review of Patent Grace Period* report again refers to the *AUSFTA* and makes the obvious point that 'any changes made to the grace period provisions would need to be considered in light of Article 17.9.9 of the *AUSFTA*'.<sup>80</sup> No immediate change is flagged to the provisions. Rather, a continued programme of monitoring and influencing global developments seems to be contemplated, with any change delayed at least until there is further adoption of grace periods in the (tautologically described) 'critical key markets'.<sup>81</sup> If this interpretation stands, then it provides a very tangible, if limited, mechanism for practically achieving a further extension of protection for the subject matter of the base patent. It arguably represents a far more significant development than other more well-known changes imposed by the *AUSFTA*.

<sup>74</sup> This article provides that:

Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure (a) was made or authorised by, or derived from, the patent applicant, and (b) occurs within 12 months prior to the date of filing of the application in the territory of the Party.

<sup>75</sup> *Patents Act 1990* (Cth) ss 24–5.

<sup>76</sup> IP Australia, *Review of Patent Grace Period* (2005) 7 <<http://www.ipaustralia.gov.au/pdfs/patents/specific/Review%20of%20the%20Patent%20Grace%20Period.pdf>>.

<sup>77</sup> *Patents Act 1990* (Cth) s 24(1)(a); *Patents Regulations 1991* (Cth) regs 2.2(1A), 2.3(1A).

<sup>78</sup> IP Australia, above n 76, 7.

<sup>79</sup> *Ibid.*

<sup>80</sup> *Ibid.* 11.

<sup>81</sup> *Ibid.*



B US Free Trade Agreement Implementation Act 2004 (*Cth*)

The relevant obligations imposed by the *AUSFTA* were implemented by the *US Free Trade Agreement Implementation Act 2004* (*Cth*), which amended the *Therapeutic Goods Act 1989* (*Cth*), but not the *Patents Act 1990* (*Cth*). During the lead up to the 2004 election campaign, the Australian Labor Party successfully made a public issue out of the alleged improper use of the patent system by drug companies intent on delaying the entry of competing generic products (with consequent impacts on prices and market share) as long as possible.

In the political skirmish that followed, a number of proposals were put forward. Ultimately, the federal government agreed to include certain provisions in the implementing legislation designed to provide additional safeguards against evergreening practices. Arguably the most prominent (though not necessarily the most effective) of these ‘anti-evergreening’ provisions are those certificates from patentees wishing to enforce their rights against generics producers seeking marketing approval. These provisions are considered below, following an analysis of the potentially ‘pro-evergreening’ effect of certificates that are now required from persons seeking marketing approval under *Therapeutic Goods Act 1989* (*Cth*) s 26B.

1 *The Certification Regime*

As discussed, art 17.10.4 of the *AUSFTA* requires Australia to ‘provide measures in its marketing approval process to prevent’ generic producers from marketing a product, or a product for an approved use, if the product or use is covered by a patent.<sup>82</sup> It also requires Australia to ‘provide for the patent owner to be notified’ of any request for marketing approval of a product or use during the term of the patent. This vetting of applications on patent grounds, rather than purely in relation to safety and efficacy, is achieved by requiring an application for marketing approval to make a certification under s 26B(1) either:

- (a) signifying no infringement of a valid claim;<sup>83</sup> or
- (b) indicating that the patent holder has been notified of the intended marketing activities (thus enabling that party to bring infringement proceedings).

As Christopher Arup has observed, there has been commentary as to whether this purely ‘procedural’ implementation of the *AUSFTA* obligation — which does not

<sup>82</sup> See above Part IV(A)(2).

<sup>83</sup> Note that the qualifier ‘valid’ was introduced following submissions made via the Australian Labor Party. Like the US system, s 26B(1)(a) provides applicants with an opportunity to self-assess claim validity. Naturally, these certifications are required to be made on reasonable grounds, and so presumably the formation of such an opinion about validity would entail professional advice to that effect. This may be well within the means of the generics drug industry but is a different matter for the over-the-counter and complementary healthcare sectors, whose particular problems with the system of certification are discussed further below: see below Part IV(D)(4). This ‘validity’ element parallels one aspect of the options open to generics companies under the US system: a ‘paragraph IV’ certification under the *Hatch-Waxman Act*, 15 USC §§ 68b–68c, 70b (1994); 21 USC §§ 301 note, 355, 360cc (1994); 28 USC § 2201 (1994); 35 USC §§ 156, 271, 282 (1994).

require any further substantive checking by the TGA — really satisfies the requirement to prevent patent infringement contained in art 17.10.4.<sup>84</sup>

It is important to note that the special certificates required in relation to patent infringement proceedings under s 26C only apply in a situation where a certificate has been provided under s 26B(1).<sup>85</sup> This fact may in part explain the approach taken in *Hexal Australia Pty Ltd v Roche Therapeutics Inc*,<sup>86</sup> where Roche Therapeutics Inc sought an interlocutory injunction even before regulatory approval had been sought by the generic company, on the basis of an (accepted) intention to apply. This procedure would sidestep the triggering of the s 26B certificate and hence remove the need for any s 26C certificates, along with the significant potential complications and damages that may flow from such a certificate.

If a s 26B(1) certificate has been given, then a patent holder wanting to sue for infringement must first give a certificate in accordance with s 26C(3) of the *Therapeutic Goods Act 1989* (Cth) that the proceedings:

- (a) are to be commenced in good faith; and
- (b) have reasonable prospects of success; and
- (c) will be conducted without unreasonable delay.

Section 26C(4) allows 'reasonable prospects of success' to be deemed in a situation where three further sub-conditions are met by the patentee. First, the person must have had reasonable grounds in all the circumstances known to them (or which ought reasonably to have been known) for believing that he or she would be entitled to be granted final relief for infringement by the court. Second, they must also have had reasonable grounds in all the circumstances known to them (or which ought reasonably to have been known) for believing that each of the claims, in respect of which infringement is alleged, is valid. Third, the proceedings must not otherwise be vexatious or unreasonably pursued.

Given that s 26C(4) does not formally and exclusively define 'reasonable prospects of success', this expression might be open to a broader construction in the circumstances of a particular case. The language of the section is inclusive and does not indicate that the conditions outlined provide the only examples of 'reasonable prospects of success'.

A disincentive against improper use of certifications is provided in the form of s 26C(5), which imposes a penalty of up to \$10 million for a certificate under s 26C which is false or misleading in a material particular, or if an undertaking in such a certificate is breached. In fixing the extent of the penalty to be imposed in any particular case, the court must have regard to any profit obtained by the provider of the certificate, and to any loss or damage suffered by any person.<sup>87</sup>

If a person seeking marketing approval has notified a patentee of potential infringement by means of a s 26B(1) certificate, and the patentee or licensee

<sup>84</sup> Christopher Arup, 'The United States–Australia Free Trade Agreement — The Intellectual Property Chapter' (2004) 15 *Australian Intellectual Property Journal* 205, 225.

<sup>85</sup> *Therapeutic Goods Act 1989* (Cth) s 26C(1)(a).

<sup>86</sup> (2005) 66 IPR 325.

<sup>87</sup> *Therapeutic Goods Act 1989* (Cth) s 26C(6).

subsequently seeks an interlocutory injunction to stop that person marketing the therapeutic goods on the basis of threatened patent infringement, several additional requirements apply. These are set out in s 26D, and include notification of a Commonwealth or state or territory Attorney-General.<sup>88</sup> Further, a patentee or licensee in such a situation may be exposed to special damages and orders.<sup>89</sup> However, these punitive provisions apply only in the very particular circumstances where an interlocutory injunction is granted, but the main proceedings are later discontinued without consent of all parties, or are dismissed.<sup>90</sup> Further, before the special provisions can come into operation, the court must have made a specific declaration that:

- the patentee did not have reasonable grounds to believe it would be granted final relief for patent infringement;
- the patentee did not have reasonable grounds to believe it had a reasonable prospect of having the claims it was attempting to enforce held valid if challenged; or
- the injunction application was ‘otherwise vexatious or not reasonably made or pursued’.<sup>91</sup>

Only then is the court given the discretionary power to make the special further orders set out in s 26D(5). These permit awards of compensation to the applicant for marketing approval, either on the basis of an account of the Australian derived gross profits of the patentee during the period of the injunction, or on any other basis.<sup>92</sup> In addition, the court may award compensation to the Commonwealth or state or territory, to offset increased health care costs for purchase of relevant drugs from the patentee (as opposed to cheaper generic alternatives).<sup>93</sup>

In the scheme of the overall system, the ‘anti-evergreening’ provisions seem a pyrrhic victory, useful as a media stunt but not achieving any fundamental reform to the system. It is hard to envision these provisions, with their multiple qualifications and standards, ever being effectively used against a drug company to impose a significant penalty, though they may result in greater internal scrutiny by a patentee of the merits of its case — in particular, in relation to which of its claims it will seek a remedy. Further, there is a serious question as to whether the provisions are compliant with Australia’s obligations under *TRIPS* and the *AUSFTA* to provide patent rights without discrimination. Article 27(1) of *TRIPS* provides in relation to patentable subject matter that: ‘patents shall be available *and patent rights enjoyable without discrimination as to ... the field of*

<sup>88</sup> *Therapeutic Goods Act 1989* (Cth) s 26D(2). The Commonwealth Attorney-General is then deemed to be a party to the proceedings unless he or she gives written notice opting out: s 26D(3).

<sup>89</sup> *Therapeutic Goods Act 1989* (Cth) s 26D(4)–(5).

<sup>90</sup> *Therapeutic Goods Act 1989* (Cth) s 26D(4)(a)–(b).

<sup>91</sup> *Therapeutic Goods Act 1989* (Cth) s 26D(4)(c).

<sup>92</sup> *Therapeutic Goods Act 1989* (Cth) s 26D(5)(a).

<sup>93</sup> *Therapeutic Goods Act 1989* (Cth) s 26D(5)(b)–(c).

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*technology*'.<sup>94</sup> Arguably these provisions, in mounting additional hurdles for patentees seeking to enforce their rights over pharmaceutical inventions, do discriminate in relation to the enjoyment of patent rights.<sup>95</sup>

### C US Views

The US did not appreciate the introduction of the Australian Labor Party-sponsored changes, imposing special requirements and burdens on pharmaceutical companies seeking to enforce their patent rights. Indeed, the United States Trade Representative Robert Zoellick referred to them with disapproval in his exchange of letters with Minister for Trade, Mark Vaile, on the implementation of the *AUSFTA* in Australian legislation, and expressly reserved US rights:

If Australia's law is not sufficient to prevent the marketing of a product, or a product for an approved use, where the product or use is covered by a patent, Australia will have acted inconsistently with the Agreement. We will be monitoring this matter closely, and reserve all rights and remedies as discussed below.

We also remain concerned about recent amendments to sections 26B(1)(a), 26C and 26D of the *Therapeutic Goods Act of 1989*. Under these amendments, pharmaceutical patent owners risk incurring significant penalties when they seek to enforce their patent rights. These provisions impose a potentially significant, unjustifiable, and discriminatory burden on the enjoyment of patent rights, specifically on owners of pharmaceutical patents. I urge the Australian Government to review this matter, particularly in the light of Australia's international legal obligations. The United States reserves its rights to challenge the consistency of these amendments with such obligations.<sup>96</sup>

In the concluding paragraphs of his letter, Zoellick stated:

bringing the Agreement into effect is without prejudice to any future action the US Government may take regarding compliance of Australia's laws and other measures with the Agreement ... If subsequent practice reveals problems with the full exercise of US rights I have discussed above, Australia should expect that we will take appropriate remedial action.<sup>97</sup>

Zoellick has indicated that if a problem did emerge in the practical operation of these 'anti-evergreening' provisions, the US would first attempt bilateral resolution with Australia, but failing that would litigate the matter before the WTO.<sup>98</sup> Both the International Federation of Pharmaceutical Manufacturing Associations and the US Pharmaceutical Research and Manufacturers Associa-

<sup>94</sup> *TRIPS*, opened for signature 15 April 1994, 1867 UNTS 3, annex 1C, art 27(1) (entered into force 1 January 1995) (emphasis added).

<sup>95</sup> The obligation is subject to various other provisions, but these are all directed to issues of exclusion from patentable subject matter rather than enjoyment of the rights: see *ibid* arts 27(3), 65(4), 70(8).

<sup>96</sup> Letter from Robert Zoellick to Mark Vaile, 17 November 2004, 3 <[http://www.dfat.gov.au/trade/negotiations/us\\_fta/final-text/letters/ip\\_zoellick\\_vaile.pdf](http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/letters/ip_zoellick_vaile.pdf)>.

<sup>97</sup> *Ibid* 4.

<sup>98</sup> Lush Media, *US Still Watchful on FTA* (22 November 2004) Pharma in Focus <<http://www.pharmainfocus.com.au/news.asp?newsid=517>>.

tion have reportedly commented that they view these provisions as being inconsistent with Australia's obligations under *TRIPS*.<sup>99</sup>

By contrast, the core body that advises the President on the acceptability of the intellectual property related aspects of free trade agreements, IFAC-3, reported very favourably on the '*TRIPS plus*' provisions of the *AUSFTA*, and with an isolated exception,<sup>100</sup> recommended that they form a new model for future free trade negotiations with other countries.<sup>101</sup> IFAC-3 contains a high proportion of originator pharmaceutical company representatives,<sup>102</sup> and others have written elsewhere of the key role of pharmaceutical companies and executives in promoting the cause of intellectual property protection on a global basis, including in the genesis of *TRIPS*.<sup>103</sup> However, these groups are also represented in the elaborate internal structures of US free trade negotiations by another collective, ISAC-3, which made similar comments to IFAC-3.<sup>104</sup>

#### D Australian Views

What of Australian views? This article now considers the comments from the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America ('Senate Committee'),<sup>105</sup> parliamentary researchers, academics, practitioners and local industry groups.

##### 1 Senate Committee

The Senate Committee expressed concern at the prospect of escalating drug costs caused by the changes that further delay the entry of generics into the marketplace.<sup>106</sup> Two possible problems were identified. First, that imposing further restrictions on generic producers might provide new methods for patent holders to block their entry using litigation. Second, the concern that extending greater data exclusivity to a patentee over test data would in practice delay regulatory approval for generic products.

<sup>99</sup> Lush Media, *International Pharma Crits FTA* (25 October 2004) Pharma in Focus <<http://www.pharmainfocus.com.au/news.asp?newsid=469>>.

<sup>100</sup> See IFAC-3, above n 68, 15:

IFAC-3 is, however, troubled, by the recognition, in paragraph 1 of Side Letter 2, of Australia's current practice to permit the export by a third party of a pharmaceutical product covered by a patent during the period of patent term extension permitted under Article 17.10.4 for purposes of meeting the marketing approval requirements of another territory as well as of Australia. IFAC-3 believes that there should not be any differentiation between the protections provided pharmaceutical patents during the initial patent term or during the extension, as is the current practice in the United States.

<sup>101</sup> *Ibid*: 'IFAC-3 welcomes these provisions with respect to certain regulated products contained in AFTA and urges that they be retained in all future FTAs.'

<sup>102</sup> At the time of publication of the report, members of IFAC-3 included: Dr Joseph A Imler, Director, Public Policy, Merck & Company Inc; Susan K Finston, Associate Vice-President for IP and Middle East/Africa Affairs, Pharmaceutical Research and Manufacturers of America; Catherine P Bennett, Vice-President, Federal Tax and Trade Legislation, Pfizer Inc.

<sup>103</sup> See, eg, Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (2002) 147–8, 160–1.

<sup>104</sup> ISAC-3, above n 67.

<sup>105</sup> See Senate Committee, Parliament of Australia, *Final Report* (2004).

<sup>106</sup> *Ibid* [4.64]–[4.65].

The Senate Committee did find that the *AUSFTA* may not have gone as far down the 'pro-pharmaceutical' industry road as US negotiators originally intended.<sup>107</sup> It also commented favourably on the good intentions behind the implementing legislation.<sup>108</sup> Nevertheless, it expressed misgivings about the uncertainty and potential adverse impact of the new requirements and administrative procedures for generic manufacturers.

An uncontroversial conclusion was reached: 'Any delay to the marketing of generic drugs as a consequence of these changes, however slight, will have a cost to the PBS, state governments and consumers.'<sup>109</sup> It also expressed concern that there were no future plans to monitor actively the impact of these changes.<sup>110</sup> Earlier, the government's special negotiator to the *AUSFTA* accepted that delaying generic market entry could increase cost, but was at great pains to stress that (in his opinion) nothing agreed to in the *AUSFTA* would lead to such an outcome. The negotiator made numerous commitments to that effect and appeared insulted at the suggestion that there could be any substantive effect on delay as a consequence of the *AUSFTA*.<sup>111</sup>

## 2 *Parliamentary Researchers*

The Senate Committee cited a paper by parliamentary researchers, Dr Kate Burton and Jacob Varghese, on this point, which identifies several possible complications for determining patent infringement, given the potential issues associated with a claim's validity and the prospect of multiple patents covering different uses.<sup>112</sup> After briefly mentioning those complications, the paper discusses the tactical options that generic manufacturers have under the certification scheme before springboarding:

Taking [the] first option [certifying non-infringement] would risk a fine if the certification is later found to be false or misleading. However, it might be a safe option where the patent has clearly expired, or where other generics are on the market already.

Where the issue is particularly complex, the last two may be the only options. The second option [applying for a court declaration to settle uncertainty before certifying] involves the commencement of litigation. The third option [notifying the patent holder of the application and certifying accordingly] allows the patent holder to consider litigation. In either case, litigation of these matters would be happening before rather than after the generic has entered the market. Currently, generic manufacturers have much more control over when any litigation takes place, with the option to enter the market first.<sup>113</sup>

<sup>107</sup> Ibid [4.73].

<sup>108</sup> Ibid [4.88], [4.102].

<sup>109</sup> Ibid [4.102] (emphasis in original).

<sup>110</sup> Ibid [4.103].

<sup>111</sup> See, eg, Evidence to Senate Select Committee on the Free Trade Agreement between Australia and the United States of America, Parliament of Australia, Canberra, 21 June 2004, 48, 58, 63–4 (Stephen Deady).

<sup>112</sup> See Senate Committee, above n 105, [4.97], citing Kate Burton and Jacob Varghese, 'The PBS and the Australia-US Free Trade Agreement' (Research Note No 3, Parliamentary Library, Parliament of Australia, 2004).

<sup>113</sup> Burton and Varghese, above n 112, 3.

Burton and Varghese acknowledge that the new provisions have adverse consequences for generic manufacturers and exert some dissuasive or delaying effect,<sup>114</sup> but are unclear as to whether it would make a significant practical difference or just present a fairly small technical change to an already complex regulatory system. Commenting on the *AUSFTA* changes prior to the adoption of the Australian Labor Party-inspired ‘anti-evergreening’ amendments, they also observe that the new processes might encourage evergreening. In particular, they commented on the complications posed by ‘new use’ patents, where generics might be sold for some applications but not others, making the determination of infringement quite difficult and further deterring generics competitors, potentially even from competing against the ‘old use’ market.<sup>115</sup>

### 3 Practitioners and Academics

Peter Drahos, when asked whether the changes proposed by the Australian Labor Party would prevent evergreening, commented that they would not,

because evergreening takes place in the Patent Office ... [s]o companies [will continue to] apply for patents on drugs in the Patent Office, in order to try and increase the web of patents they have around a particular compound, and that web of patents [will continue to act] as a deterrent.<sup>116</sup>

Drahos went on to observe that these amendments do not address the initial build-up of patent rights at all, but rather may deter the use of those patents in litigation.

Andrew Christie and Sally Pryor observed that an attempt to target so-called ‘dodgy’ patent claims was good in theory but ‘impossible in practice’.<sup>117</sup> While acknowledging the potential for the blight of evergreening to spread further in Australia, they felt that the changes being introduced avoided the worst elements of implementation of similar requirements in the US, despite imposing some extra burdens on generic manufacturers. As they further commented:

The trouble is that dodgy is not a ground for examination under patent law. It is a subjective term, and one that exists only in the eye of the beholder, so to speak ... An evergreen patent may well pass the standard of innovation, even though it contributes little or nothing to social welfare. So long as there is an invention, the law is blind to the purpose for which it is being patented, and social and economic issues don’t get a look-in.<sup>118</sup>

Innes anticipated little change in the ability to evergreen in Australia as a result of implementing the *AUSFTA* and displayed more faith than Drahos in the ability of the existing patent examination, opposition and revocation systems to stifle ‘dodgy’ patents.<sup>119</sup> However, Innes did appear to have an open mind about

<sup>114</sup> Ibid.

<sup>115</sup> Ibid.

<sup>116</sup> Australian Broadcasting Corporation, ‘Home Detention’, *The Law Report*, 10 August 2004 <<http://www.abc.net.au/rn/talks/8.30/lawrpt/stories/s1267686.htm>>.

<sup>117</sup> Andrew Christie and Sally Pryor, *Evergreen Dilemma: Law Blind to Patent’s Purpose* (17 August 2004) On Line Opinion <<http://www.onlineopinion.com.au/view.asp?article=2457>>.

<sup>118</sup> Ibid.

<sup>119</sup> Innes, above n 31, 7.

possible consequences for the frequency with which pharmaceutical patents are litigated.<sup>120</sup>

Are there any practical changes to the use of the patent system that are likely to arise in reaction to the *AUSFTA*? As observed above, it may be that advisers will increase the level of scrutiny of claims upon which reliance will be placed in litigation, but it is unlikely that the Australian Labor Party-sponsored 'safeguards' will have any significant effect on the ability of companies to gain patent rights. Indeed, the overall impact of the changes may be a more extensive use of particular elements of the patent system. Richard Hamer and Tom Reid have advised innovators to ensure that any secondary or formulation patents are granted prior to the expiry of the original or base patent, or alternatively — if there is some delay in obtaining a standard patent — to file a divisional innovation patent so that they will be able to benefit from the immediate grant of such innovation patents.<sup>121</sup> This feature has been available since the introduction of the innovation patent system, but the *AUSFTA* changes now extend the advantages of such an approach by enabling patents to be obtained immediately, thus triggering further complications for a generics competitor.

#### 4 *Industry Groups*

How has the Australian pharmaceutical industry reacted to these changes? The chair of the Generic Medicines Industry Association<sup>122</sup> was reportedly satisfied that the *AUSFTA* would not encourage evergreening, but remained alert to the possible expansion of evergreening practices:

The Government has repeatedly assured us there will be no delay to the market entry of generic medicines and we believe that the legislation is consistent with this ... [h]owever, irrespective of the FTA, spurious patent claims, or 'evergreening', is a growing trend outside of Australia, which we must ensure does not occur here.<sup>123</sup>

However there were reports in early 2005 that the *AUSFTA* was having unintended and nasty side effects on the over-the-counter and complementary medicine industries and those industry groups were much less sanguine than the Generic Medicines Industry Association.<sup>124</sup> Concerns were raised with Parliamentary Secretary to the Minister for Health and Ageing, Christopher Pyne, by the Complementary Healthcare Council and others. It was asserted that there was a considerable new compliance burden as a result of the certification requirements, which have been imposed not simply on the generics industry but also the on complementary medicines sector, the latter not having troubled itself much in

<sup>120</sup> Ibid.

<sup>121</sup> Richard Hamer and Tom Reid, 'FTA Impact on Pharmaceuticals' (April 2004) *Allens Arthur Robinson: Focus 2* <<http://www.aar.com.au/pubs/pdf/ip/foftapr04.pdf>>.

<sup>122</sup> John Montgomery, Chief Executive Officer of Alphapharm Pty Ltd ('Alphapharm'), holds the position. Note that Alphapharm is part of the Merck KGaA group of companies which specialises in pharmaceuticals and chemicals.

<sup>123</sup> David Wroe, 'Drug Groups Cool on Labor Safeguards', *The Age* (Melbourne), 4 August 2004, 4, quoting John Montgomery.

<sup>124</sup> See, eg. Lush Media, *FTA Compliance Costing Millions, Industry Calls for a Rethink* (21 March 2005) *Pharma in Focus* <<http://www.pharmainfocus.com.au/news.asp?newsid=646>>.



relation to patent matters in the past. Original estimates of cost increases for each application (as a result of legal and patent checks) were of the order of \$8000, with an industry-wide cost increase of \$16 million. Secondary costs were estimated to cost downstream consumers some \$64–80 million. Apparently there was also an early implementation problem: the TGA was alleged not to have notified the industry of the certification requirement until mid-February, but the automatic lodgement system had apparently continued to accept uncertified applications until that point. Companies had relied on those acceptances in taking their products to market, creating a regulatory ‘no man’s land’ that the TGA was insisting be rectified by retrospective provision of certificates.

More recent contact with the Complementary Healthcare Council indicates that the changes are still causing considerable problems within this sector, with an estimated cost increase of \$5000 per application.<sup>125</sup> Given the difficulty of searching the patent databases and the literature more generally, and the considerable resources required to challenge validity, reportedly ‘most companies would rather just shy away from the product opportunity’.<sup>126</sup>

The Therapeutic Goods Amendment Bill [No 2] 2005 (Cth) was introduced on 14 September 2005 to try to address some of these concerns. It refers to the existing two-tiered approach to pharmaceutical regulation of drugs, which discriminates between registered and listed medicines. The latter category, which comprises most complementary medicines and some over-the-counter products (such as sunscreens), is viewed as low risk and does not require submission of safety or efficacy data. The proposed amendments to the *Therapeutic Goods Act 1989* (Cth) would mean that the patent certification requirements under s 26B(1) would only apply to someone seeking to rely on safety or efficacy data previously submitted to the TGA. For those people simply applying for the listing of therapeutic goods such as complementary medicines, there would still be a requirement to provide a notice stating that the patent certification requirements did not apply.<sup>127</sup>

#### V RECENT AUSTRALIAN EVERGREENING CASES

One of the most recent cases dealing with evergreening in Australia is *Arrow v Merck*.<sup>128</sup> In this decision, Gyles J comprehensively found in favour of Arrow Pharmaceuticals Ltd (‘Arrow’) and revoked Merck & Co Inc’s (‘Merck’) patent, which involved the use of alendronate to treat osteoporosis in a way that minimised the potential for adverse gastrointestinal effects. The outcome is apparent in the first few sentences: ‘The case involves what would now colloquially be called an attempt to “evergreen” a pharmaceutical patent. I find that the application for revocation succeeds.’<sup>129</sup>

<sup>125</sup> Email from Anna Day (Communications and Media Manager, Complementary Healthcare Council) to Robert Chalmers, 8 September 2005.

<sup>126</sup> Email from Attila Pataki (Product Development Manager — Technical, Blackmores Ltd) to Robert Chalmers, 14 September 2005.

<sup>127</sup> *Therapeutic Goods Act 1989* (Cth) s 26(1)(aa)(ii).

<sup>128</sup> (2004) 63 IPR 85.

<sup>129</sup> *Ibid* 87 (Gyles J).

The original or base patent, which had no Australian equivalent, claimed priority back to 1982. Essentially, it disclosed alendronic acid, compositions of this acid and a method of inhibiting bone resorption by administering it in a particular manner. The patent was formulated slightly differently in each jurisdiction. It had been attacked and revoked in the UK but upheld in the US.<sup>130</sup> The relevant Australian patent claimed priority to 1989 and was directed to a specific alendronate monosodium trihydrate species, compositions containing it, and a process for preparing the acid or salts and methods for treating or preventing osteoporosis by administering these agents.<sup>131</sup> Merck sold a treatment under the brand name 'Fosamax', but then developed an alternative dosing regime, addressed in part to improving gastrointestinal side effects but also patient compliance with dosing and other marketing attractions. Gyles J's judgment contains an extensive discussion of the drug development process inside Merck, and the prominent influence of non-therapeutic issues in decision-making.<sup>132</sup> A paper prepared for a Merck technical review meeting in 1997 stated that:

Since much of the drive to develop these new approaches is based upon *Marketing needs*, the Marketing group will briefly present their perspectives on the potential value of the alternative formulations, tablet image and the *needs for increased dosing flexibility*.<sup>133</sup>

Of particular interest is a diagram and table entitled 'FOSAMAX Development Activities' prepared for Merck's Tactical Product Approval Committee.<sup>134</sup> This diagram illustrates, along a timeline, the key data findings, competitive product launches, possible filing dates for new use claims, and the expiry of the original use patent.

Gyles J described this internal Merck document at length and highlights some of the entries that suggest the filing was more concerned with the market and market protection issues than a genuine innovation directed at improved therapies. Indeed, in some of the later comments in the report for the Tactical Product Approval Committee in relation to Alternative Dosing Regimes, it seems that the supposed aim of addressing gastrointestinal side effects was more a rationale than a reality:

To overcome the perception of rigorous dosing and administration schedules, in addition to alternative formulations, alternative dosing of the tablet form should be considered. Once weekly oral dosing with the same total weekly dose could be offered as an alternative to daily dosing. This would probably have greater patient acceptance and *is unlikely to have a greater potential to induce upper gastrointestinal irritation*.

*Also, it may be possible to patent the weekly regimen, potentially with specific reference to the 35 and 70 mg doses. A patent would be more achievable if a rationale for considering possible improved safety could be put together based upon the dog esophageal model safety assessment testing. ... Human studies*

<sup>130</sup> Ibid 90 (Gyles J).

<sup>131</sup> Ibid 91 (Gyles J).

<sup>132</sup> Ibid 93–111.

<sup>133</sup> Ibid 101 (Gyles J) (emphasis in original).

<sup>134</sup> See *ibid* 102.

could show that alendronate daily or weekly are equally safe dosing regimens, but since esophageal adverse experiences are rare, it would require very large numbers to prove that weekly dosing is superior. *If weekly dosing is patentable, this regimen would allow for extension of the FOSAMAX patent to 2018.*<sup>135</sup>

Excerpts from later emails include the following:

*We are looking carefully (and quickly) at the patentability of weekly dosing. There are several intermittent [sic] regimens for bisphosphonates that have been included in patents, but Anastasia and I believe that we have at least some chance to get exclusive patent rights to use bisphosphonates weekly to lower the potential for esophageal ulceration (as well as enhance convenience) ...*

Marketing have expressed a strong interest in having a 35 or 70 mg tablet for once-a-week administration. It is believed that this approach may further realize a patent advantage.<sup>136</sup>

This documentation obviously had significance for Gyles J. His Honour later observed that '[t]he possibility of patent protection extending beyond the life of the existing patents was a most desirable side effect of the exercise and encouraged Merck to devote resources to the project'.<sup>137</sup>

Apart from the rather interesting internal documentation, Merck faced a substantial problem in the form of prior publication in *Lunar News* articles of April 1996, July 1996 and April 1997 about less frequent dosing of greater amounts of alendronate.<sup>138</sup> Notwithstanding the very limited circulation of these articles in Australia before the priority date, the prior publication of information regarding alternative dosing options was sufficient to pose difficulties for Merck in relation to novelty, as discussed further below.<sup>139</sup>

However, Gyles J's primary attack on the patents related to the basic lack of patentable subject matter. First, his Honour dispensed fairly ruthlessly with the four claims expressed in the form of composition claims: 'It is tolerably plain on the face of the patent that the so-called composition claims lack subject matter.'<sup>140</sup> His Honour pointed to standard formulation techniques and a complete lack of specific adaptation to a weekly regimen as opposed to some other dosing system, concluding that:

These are not composition claims as that concept would normally be understood, that is, claims to a new and unique compound. They are not combination claims whereby the whole is something different from the sum of the parts. When properly analysed the composition claims are devoid of practical content. They are not 'inventions' and are not a manner of manufacture.<sup>141</sup>

<sup>135</sup> Ibid 103–4 (emphasis in original).

<sup>136</sup> Ibid 106–8 (emphasis in original), citing: Email from John A Yates to Elizabeth Stoner and Edward M Scolnick, 9 June 1997; Email from Askok V Katdare to Michelle W Kloss et al, 13 June 1997.

<sup>137</sup> *Arrow v Merck* (2004) 63 IPR 85, 113.

<sup>138</sup> Ibid 95, 96, 100 (Gyles J).

<sup>139</sup> See below nn 158–9 and accompanying text.

<sup>140</sup> *Arrow v Merck* (2004) 63 IPR 85, 114.

<sup>141</sup> Ibid.

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In relation to the remaining method claims, his Honour observed that they each 'relate[d] to the use of a known substance with known properties for a known purpose in a known manner.'<sup>142</sup> Gyles J could discern no new process, method of administration or disclosure of any new compound properties. After discussing relevant authorities further, his Honour concluded on an interim basis:

each of the so-called method claims was one way of utilising alendronate and its known qualities for the known purpose of preventing or treating osteoporosis by a known method of oral administration. They are in the nature of directions for use. That does not constitute an invention or a manner of manufacture.<sup>143</sup>

Gyles J went on to discuss the practical and commercial impact of situations such as the present case, where a pharmaceutical company has base patent rights around chemical compositions and therapeutic applications, which may then operate to stop or hinder any clinical trials which are required as part of the regulatory process but are not authorised by the patent owner. As Gyles J commented,

[t]he regulatory regime is such that clinical trials are essential before there can be commercial exploitation. The opportunity for refining and improving the application of the base patent is, in a practical sense, limited to the patentee or those authorised by it. Once Merck obtained the base patent, it could control that field. As it controls use of the compound, it acquires the most widespread knowledge of the application of the compound. The patentee will thus have a virtual monopoly of the commercial development of it. ... a practical monopoly of the opportunity of further refining the use of that invention.<sup>144</sup>

As a sidenote, putting to one side the commercial issues, this type of situation raises the question of the existence of, or need for, a research exemption in relation to patent infringement. The Advisory Council on Intellectual Property's *Patents and Experimental Use: Options Paper* concluded that there 'appears to be no strong empirical evidence in Australia of any form of patent "thicket" affecting cumulative innovation', but did acknowledge the risk that it could evolve.<sup>145</sup> It is interesting to note the position of Medicines Australia, in its response to the Options Paper, where it stated: 'that experimental use should be encompassed within the exclusive rights of the patent owner still remains as our overall preferred position'.<sup>146</sup> As a result, the scope of any defence in relation to research use, whether legislated or introduced by case law,<sup>147</sup> is of considerable

<sup>142</sup> Ibid.

<sup>143</sup> Ibid 115.

<sup>144</sup> Ibid 115–16.

<sup>145</sup> Advisory Council on Intellectual Property, *Patents and Experimental Use: Options Paper* (2004) 38 <<http://www.acip.gov.au/library/Experimental%20Use%20Options%20Paper%20A.pdf>>.

<sup>146</sup> Submission to Advisory Council on Intellectual Property, Consideration of Patents and Experimental Use, 14 March 2005, Submission No 13, 1 (Medicines Australia) <<http://www.acip.gov.au/expuseoptsubs/Medicines%20Australia.pdf>>. The submission briefly continued, 'however, given ACIP's desire for respondents to stay within the options proposed our members [sic] position would be to favour option B — No Change.': at 1.

<sup>147</sup> Cf the US position in *Merck KGaA v Integra LifeSciences I Ltd*, 125 S Ct 2372 (2005). In this case, the US Supreme Court effectively broadened the 'safe harbour' use of patented inventions

significance. If Parliament does make statutory changes, the scope of any such exception is unclear, especially in relation to whether it would permit clinical trials as equivalent laws in a few other territories do.<sup>148</sup>

Following his Honour's comments about the negative impacts upon downstream innovation, Gyles J struggled with the notion that the base patent life could effectively be extended through simple refinement of previous instructions for use — a new 'best method' of practice:

There is something anomalous about a patent being obtained for all pharmaceutical uses of a chemical compound without disclosing any particular dosage regime for any particular use but with the patentee later claiming a new, stand-alone, patent for a particular dosage regime for a particular purpose that was contemplated at the time of the base patent, with no new properties of the compound having been discovered in an inventive fashion in the meantime.<sup>149</sup>

Perhaps a comparison may be drawn with certain selection patents over compound claims, where an initial patent claims a whole class of compounds and a subsequent patent claims a particular compound within that class. In any event, Gyles J's obvious distaste for evergreening situations is apparent in his Honour's brief discussion of the potential application of *Patents Act 1990* (Cth) Chapter 7, dealing with patents of addition:

the legislature obviously intended that, even if what is proposed is a true improvement in or modification of the main invention, and not merely instructions as to use of it, a consequent patent of addition should not extend beyond the life of the base patent.<sup>150</sup>

Under *Patents Act 1990* (Cth) s 81(1), if there has been an application for, or a grant of, protection on one patent ('the main invention'), and the patentee, applicant or an authorised person applies for a further patent for an improvement or modification of the main patent, the Commissioner may grant a patent of addition for that improvement or modification. A critical factor is that, failing an extension of term under the provisions of Chapter 6 Part 6<sup>151</sup> the term of a patent of addition is generally only coincident with the term of the patent for the main invention.<sup>152</sup> However, s 81(1)(c) requires that an application for the further patent be 'made in accordance with the regulations'. It is conceivable that this might be read generally to require that an application be made in accordance with the regulations applicable to any patent, but the Australian Patent Office's *Manual of Practice and Procedure* indicates that the application must specify

for any reasonable purpose connected to the generation of data for submission for regulatory approval, including but not limited to clinical trials.

<sup>148</sup> In particular Germany and Japan: see, eg, Advisory Council on Intellectual Property, above n 145, 40–1.

<sup>149</sup> *Arrow v Merck* (2004) 63 IPR 85, 116.

<sup>150</sup> *Ibid* (citations omitted).

<sup>151</sup> Note that under these provisions, the patent of addition may be extended independently of the patent for the main invention: *Patents Act 1990* (Cth) s 83(2).

<sup>152</sup> See *Arrow v Merck* (2004) 63 IPR 85, 116 (Gyles J) commenting that '[e]ven if it could qualify as a patent of addition pursuant to Ch 7 of the Act it would have been limited to the term of the salt patent.'

that it is for a patent of addition.<sup>153</sup> It is hard to envisage that a pharmaceutical company attempting evergreening-type tactics would want to characterise a patent designed to effectively extend the protection given to a family of related innovations as a patent of addition, since even a successful application would not extend the term of protection for it or the main invention. However, because of the apparent requirement that an applicant actually ask for a patent of addition, Chapter 7 does not provide a mechanism for the Commissioner to characterise a subsequent application as being for a patent of addition at their initiative and discretion.

Gyles J then spent some time grappling with the decision of the Full Federal Court in *Faulding*.<sup>154</sup> At one point, his Honour conceded that '[i]t does seem to follow that it was held that a mere dosage regime of a known chemical compound for a known therapeutic use based upon known properties and involving no new method of administration was patentable'.<sup>155</sup> His Honour expressed obvious dissatisfaction with this position, preferring the approach taken by the English Court of Appeal in *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc.*<sup>156</sup> Ultimately, however, Gyles J distinguished *Faulding* on its facts, finding that in the present case there was no new technical effect or utility.<sup>157</sup>

Obviously mindful of the potential susceptibility of revocation based purely on arguments related to manner of manufacture, Gyles J went on to demolish the Merck patent on novelty grounds as well. His Honour first found that the *Lunar News* publications (which included a website reference as well as physical copies of the publication) had anticipated a number of the claims, but not all of them.<sup>158</sup> A number of the other claims were found to have been anticipated by Merck's own marketing activities predating the priority date.<sup>159</sup> However, Gyles J rejected attacks by Arrow on the grounds of entitlement (it had been alleged that a true inventor had not been included),<sup>160</sup> false suggestion,<sup>161</sup> and fair basis.<sup>162</sup>

Finally, Gyles J dealt only partly with issues in relation to inventive step, though his Honour had already made his views apparent in his discussion about manner of manufacture, finding a complete lack of patentable subject matter.<sup>163</sup> Gyles J expressly rejected inventive step in relation to the so-called composition claims. In relation to the method claims, his Honour observed that '[i]ngenuity might be exercised, but not invention.'<sup>164</sup>

<sup>153</sup> See Australian Patent Office, above n 22, [18.1.3].

<sup>154</sup> (2000) 97 FCR 524. See *Arrow v Merck* (2004) 63 IPR 85, 116–20.

<sup>155</sup> *Arrow v Merck* (2004) 63 IPR 85, 119.

<sup>156</sup> [2001] RPC 1. See *ibid* 119–20.

<sup>157</sup> *Arrow v Merck* (2004) 63 IPR 85, 120.

<sup>158</sup> *Ibid* 123.

<sup>159</sup> *Ibid* 124 (Gyles J).

<sup>160</sup> *Ibid*.

<sup>161</sup> *Ibid*. See also *Patents Act 1990* (Cth) s 138(3)(d), which prescribes a two-limbed test: one arm linked to the entitlement argument and one arm linked to an allegation of false representation of some prior art.

<sup>162</sup> *Arrow v Merck* (2004) 63 IPR 85, 125.

<sup>163</sup> *Ibid* 114–20.

<sup>164</sup> *Ibid* 125.

In conclusion, on the various grounds discussed above, all the claims that Arrow had attacked were indeed invalid. On the basis of the material set out in the judgment — in particular the extensive use of internal Merck documentation related to the process and motivations for patent filing<sup>165</sup> — it is hard not to feel strong sympathy toward Gyles J's findings on manner of new manufacture, inventiveness and novelty, even if the first two in particular may be open to question on appeal.

It is interesting also to compare this outcome to the UK decision in *Merck & Co Inc's Patents*,<sup>166</sup> which also related to alendronate. Although the case ultimately turned on differing UK laws relating to methods of medical treatment, the court found that the second patent lacked novelty and was obvious in the light of the prior art. Merck's appeal against Jacob J's decision in that case was unsuccessful.<sup>167</sup>

The decision in *Arrow v Merck* has since been appealed and was heard before Heerey, Dowsett and Hely JJ in May 2005, and again before Heerey, Dowsett and Kiefel JJ in December 2005. The outcome of that appeal is awaited with interest.<sup>168</sup> Earlier in *Merck & Co Inc v Arrow Pharmaceuticals Ltd*,<sup>169</sup> Heerey J ruled on a procedural matter connected to Arrow's attempt to uphold the original findings on grounds of inventive step in relation to which Gyles J had not made findings of primary fact.<sup>170</sup> Heerey J decided that the issue should not be argued at the appellate level as it would be unfair to Merck and would not enable efficient processing of the appeal by the Full Federal Court.<sup>171</sup>

In contrast, consider the earlier office-level decision in relation to an opposition brought by Lek Pharmaceutical against Smithkline Beecham.<sup>172</sup> The Delegate of the Commissioner held that, despite problems in relation to novelty, inventive step and fair basis in relation to a few claims, the majority of the application was acceptable.<sup>173</sup> The invention related to a new ratio for a common antibiotic composition for paediatric use — interestingly, again with the aim of reducing the problem of gastric irritancy.

Even more recently in *Hexal Australia Pty Ltd v Roche Therapeutics Inc*,<sup>174</sup> Roche Therapeutics Inc tried to obtain interlocutory relief in respect of alleged infringement of its 'beta-blocker' Australian patent, entitled 'Use of Carbazole

<sup>165</sup> See above nn 134–5 and accompanying text.

<sup>166</sup> [2003] FSR 29 ('*Merck & Co Inc's Patents First Instance*').

<sup>167</sup> *Merck & Co Inc's Patents* [2004] FSR 16 ('*Merck & Co Inc's Patents Appeal*'). See also the decision in relation to related regulatory approval matters in *R (On the Application of Merck Sharp & Dohme Ltd) v Licensing Authority* [2005] EWHC 710 (Admin) (Unreported, Moses J, 28 April 2005).

<sup>168</sup> At the time of writing, judgment in the appeal was still pending. Note also that cost orders were made in *Arrow Pharmaceuticals Ltd v Merck & Co Inc* [2005] FCA 188 (Unreported, Gyles J, 9 March 2005).

<sup>169</sup> [2005] FCA 425 (Unreported, Heerey J, 13 April 2005).

<sup>170</sup> *Arrow v Merck* (2004) 63 IPR 85, 125.

<sup>171</sup> *Merck & Co Inc v Arrow Pharmaceuticals Ltd* [2005] FCA 425 (Unreported, Heerey J, 13 April 2005) [3].

<sup>172</sup> *Smithkline Beecham plc v Lek Pharmaceutical & Chemical Co DD* (2004) 61 IPR 626.

<sup>173</sup> *Ibid* 644 (Delegate Jenkins).

<sup>174</sup> (2005) 66 IPR 325.

Compounds for the Treatment of Congestive Heart Failure'.<sup>175</sup> In this case, no actual application for market approval had been granted — the application was made on the basis of intention only. Hexal Australia Pty Ltd ('Hexal') and Alphapharm contended validity (novelty and inventiveness), infringement and fair basis. Stone J decided there were serious issues to be tried on both infringement and invalidity, with a preliminary leaning towards invalidity.<sup>176</sup> Ultimately Stone J refused the application for interlocutory relief on the balance of convenience, deciding damages could be clearly quantified and were an adequate remedy.<sup>177</sup> Interestingly — though it was not a point discussed much in the judgment — in relation to the issue of balance of convenience, counsel for Hexal and Alphapharm argued that the public interest (in having access to cheaper medicines and against the assertion of invalid patent rights) was a relevant consideration.<sup>178</sup>

## VI CONCLUSION

In the field of pharmaceuticals there is obviously a large financial incentive for originator drug companies to push the boundaries of protection systems. For these companies, a patent is another business tool to be exploited as part of their duty to maximise shareholder returns. Whether through innovation in technology, innovation in the use of legal mechanisms, or both, we can expect to see the originator sector<sup>179</sup> working hard to expand protection of its intellectual property assets in the most effective way it can. Efforts to 'evergreen', 'bootstrap' and 'double up' patent portfolios — which might alternatively be viewed simply as an astute use of legal rules — will continue.

These are not fundamentally new problems but some of the changes introduced by the *AUSFTA* further promote extended protection. Most of the obvious changes are those that expand the protection offered by peripheral mechanisms — through regulatory data exclusivity and tightened controls over marketing approval for generics companies — rather than making any fundamental changes to patent law. It is interesting to observe another example of indirect measures being used to support intellectual property protection, here in the form of the 'patent-friendly' certification required of those seeking marketing approval for drugs.<sup>180</sup> There is an implicit presumption of infringement pending (self-) declaration of innocence — a declaration that is made under threat of penalties if improper. Further, it seems that these provisions have had some adverse side effects for the over-the-counter and complementary medicine sectors of the broader drug industry, raising compliance costs for little net benefit. The

<sup>175</sup> Ibid 326 (Stone J).

<sup>176</sup> Ibid 330–7, 340.

<sup>177</sup> Ibid 340.

<sup>178</sup> Ibid 338, 340 (Stone J).

<sup>179</sup> See IFAC-3, above n 68, which was discussed above as the 'pioneer' part of the sector, connoting in part visions of pioneers of a bygone age forging a new life in their trek across the American landscape.

<sup>180</sup> Cf *AUSFTA*, opened for signature 18 May 2004, [2005] ATS 1, ch 17 (entered into force 1 January 2005), describing the additional protection for technical protection measures and electronic rights management information in a copyright context.



government's new and improved formulation, to be implemented by the Therapeutic Goods Amendment Bill [No 2] 2005 (Cth), should diminish this side effect, but of course it implicitly acknowledges the unintended breadth of the original provisions.

Perhaps the most significant direct impact will come from the side effects of the interaction between *AUSFTA* art 17.9.9 and the grace period provisions, if indeed that bizarre loophole is not dismissed or shut down — as it should be — but is instead successfully exploited. It is unlikely that the 'anti-evergreening' changes will rein in patent prosecutions; at face value, they simply strengthen the ability of pharmaceutical companies to enforce patents. If, however, these provisions do emerge as constraining patent enforcement, then the US is likely to challenge them. As discussed above, these provisions may already be in breach of the *AUSFTA* and *TRIPS* by introducing discrimination as to enjoyment of rights in a particular technological field. Indeed, there were reports earlier this year that the federal government was considering abandoning the 'anti-evergreening' amendments in response to heavy lobbying by the US pharmaceutical industry and the US Trade Representative.<sup>181</sup> A formal review of the *AUSFTA* was imminent at the time of writing.

Ultimately, the core checks and balances on evergreening practices are those provided by IP Australia and the courts. However, this oversight can only be brought to bear upon matters taken before those institutions, and of course many issues will not make it that far. The disparity in resources and expertise between IP Australia and private patent attorneys funded by the pharmaceutical industry is obvious, and the potential implications of the lack of resources at the assessment stage have been mentioned elsewhere.<sup>182</sup> This is a universal issue that applies well beyond pharmaceutical patents and it does not admit any easy resolution. Sometimes, so-called 'dodgy' patents will be brought to heel, but in other instances they will be granted and may exert an unwarranted dissuasive effect.

Granting secondary patents of the method of use or administration type also brings up once more the thorny issue of whether methods of medical treatment should be patentable. It seems clear that there is at least some level of underlying judicial discomfort in relation to patents of this character, especially those with no apparent substantive merit. However, given the majority authority on the patentability of such claims, the safest primary mode of attack on such patents will presumably remain on the grounds of novelty, inventiveness, and other core requirements of patentability beyond the threshold question of 'manner of new manufacture', which by and large continues to be whittled down on many fronts to its 'core residuum'.<sup>183</sup> Even attacks on inventiveness are likely to prove problematic, especially if the more robust approaches of lower courts are overturned on appeal.

<sup>181</sup> Steve Lewis, 'FTA Drug Safeguard at Risk', *The Australian* (Sydney), 3 January 2006, 1.

<sup>182</sup> See, eg, Arup, above n 84, 226.

<sup>183</sup> See Warwick A Rothnie, *The New Law of Patents* (17 August 2005) IPwar's Patents <<http://homepage.mac.com/wrothnie/iblog/C149316833/E883935307/index.html>>, which refers to the position taken by Finkelstein J on the proviso to s 6 of the *Statute of Monopolies 1623*, 23 Jac 1, c 3, in *Faulding* (2000) 97 FCR 524.

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Given the limited term of patent duration, the patent system is, at least theoretically, of a fundamentally deciduous character. However, in practice, a constantly replanted patent thicket can appear the biological equivalent of an evergreen. Over time we should expect to see the shade provided by such cover deepen rather than lessen. The ever-increasing reach of the proprietary trend in intellectual property seems set to continue, with evergreening practices in relation to drug patents being merely one example. In terms of end results, not all such instances of extended protection will be inimical to downstream innovation and health costs, but it is hard to envisage a future without instances of abuse.