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Australia's evolving scheme**

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Published

2013

Journal Title

Journal of Law and Medicine.

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How are pharmaceutical patent term extensions justified? Australia's evolving scheme

Charles Lawson*

This article examines the evolving patent term extension schemes under the Patents Act 1903 (Cth), the Patents Act 1952 (Cth) and the Patents Act 1990 (Cth). The analysis traces the change from "inadequate remuneration" to a scheme directed specifically at certain pharmaceuticals. An examination of the policy justification shows there are legitimate questions about the desirability of any extension. The article concludes that key information provisions in the Patents Act 1990 (Cth) that might assist a better policy analysis are presently not working and that any justification needs evidence demonstrating that the benefits of patent term extensions to the community as a whole outweigh the costs and that the objectives of extensions can only be achieved by restricting competition.

INTRODUCTION

The perennial problem faced by patent schemes all around the world is determining a proper patent term – too short and it is insufficient incentive (or reward) and too long and it is imposing an unnecessary restriction on competition (contrary to the public interest and involving high social costs). Finding the appropriate patent term has never been, and is unlikely to ever be, determined to the satisfaction of everyone. Global consensus according to the World Trade Organisation's *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS),¹ however, has settled on a patent term of 20 years from the date of lodging the patent application.² And the *Australia–United States Free Trade Agreement* (AUSFTA) now requires Australia to make a patent term extension available for pharmaceuticals.³ Despite this consensus, the question still remains whether a patent term extension is justified and how this might be assessed.

The Australian *Patents Act 1990* (Cth) should provide an excellent case study because there is an active patent term extension scheme⁴ together with provisions requiring applicants/recipients to lodge data and information about their patents that might inform patent extension policy discussions. The purpose of this article is to review the various patent term extension schemes that have applied in Australia from the *Patents Act 1903* (Cth), to the *Patents Act 1952* (Cth), to the current arrangements in the *Patents Act 1990* (Cth) and address the questions: (i) whether patent term extensions are justified; and (ii) how this might be assessed. The article is structured as follows. The next part examines the evolving statutory schemes under each statute and its amendments starting with the "inadequate remuneration" standard and progressing to the restricted scheme applying to just some pharmaceuticals. The following parts examine, in turn, litigation about "inadequate remuneration" in the *Patents Act 1903* (Cth), to the *Patents Act 1952* (Cth) until the abolition of this standard in the *Patents Amendment Act 1989* (Cth); the policy justification for the *Patents Amendment Act 1989* (Cth) and subsequent schemes in the *Patents Act 1990* (Cth); litigation about the pharmaceutical schemes under the post-1989 schemes; the information requirements included as amendments in the

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¹ [1995] *Australian Treaty Series* 8, Annex 1C (TRIPS).

² TRIPS, Art 33.

³ *Australia–United States Free Trade Agreement* [2005] *Australian Treaty Series* 1, Art 17.9(8).

⁴ Between 1991 and 2012 there were 721 patent term extension applications of which 621 (86%) were accepted and 100 (14%) were rejected: see IP Australia, *Pharmaceutical Patents Review, Background and Suggested Issues Paper* (IP Australia, 2012) p 9.

Intellectual Property Laws Amendment Act 1998 (Cth); and then the conclusion that critical questions about the justification for patent extensions remain unanswered and that this justification needs to be addressed according to the pro-competition methodology addressed in the Australian Government's commitments to the *Competition Principles Agreement* that regulation that restricts competition needs evidence demonstrating that the benefits of patent term extensions to the community as a whole outweigh the costs and that the objectives of extensions can only be achieved by restricting competition.

THE EVOLVING STATUTORY SCHEMES

The statutory schemes for patent term extension have evolved over time with various iterations in the *Patents Act 1903* (Cth), *Patents Act 1952* (Cth) and *Patents Act 1990* (Cth) and the amendments to these statutes. The following sets out the basic schemes in each statute.

Patents Act 1903 (Cth)

The *Patents Act 1903* (Cth) provided for a patent term of 14 years⁵ that was later increased to 16 years,⁶ and included an extension scheme covering all patents.⁷ This scheme required the patent holder to petition the court at least six months before the patent lapsed to extend the patent for a "further term".⁸ In deciding the matter the court considered "the nature and merits of the invention in relation to the public and to the profits made by the patentee as such and to all the circumstances of the case".⁹ The threshold requirement was that "if [the court] is of opinion that the patentee has been inadequately remunerated by his patent",¹⁰ then the court

... may order the extension of term of the patent or part of it for a further term not exceeding seven or in exceptional cases 14 years, or order the grant of a new patent for the term therein mentioned, and containing any restrictions conditions and provisions that the court may think fit.¹¹

The seven, or in exceptional cases 14, year terms were later modified to "five years or in exceptional cases 10 years".¹² Provision was made for extensions in cases of losses or damage suffered by war.¹³ These are not considered further in this article.

Patents Act 1952 (Cth)

The *Patents Act 1952* (Cth) repealed the *Patents Act 1903* (Cth) term extension provisions,¹⁴ provided for a patent term of 16 years,¹⁵ and included a similar extension scheme covering all patents.¹⁶ This scheme required the patent holder, "who considers that he has been inadequately remunerated", to petition the court at least six months before the patent lapsed to extend the patent for a "further term".¹⁷ In deciding the matter the court considered "the nature and merits of the invention in relation

⁵ *Patents Act 1903* (Cth), s 64(1).

⁶ *Patents Act 1921* (Cth), s 3(1).

⁷ *Patents Act 1903* (Cth), s 84. Note the amendments in *Patents Act 1921* (Cth), s 4.

⁸ *Patents Act 1903* (Cth), s 84(1).

⁹ *Patents Act 1903* (Cth), s 84(4).

¹⁰ *Patents Act 1903* (Cth), s 84(5).

¹¹ *Patents Act 1903* (Cth), s 84(5).

¹² *Patents Act 1921* (Cth), s 84(5).

¹³ *Patents Act 1921* (Cth), s 84(6).

¹⁴ *Patents Act 1952* (Cth), s 4(1) and Sch 1.

¹⁵ *Patents Act 1952* (Cth), s 68(1).

¹⁶ *Patents Act 1952* (Cth), ss 90-96. Note the minor amendments in *Patents Amendment Act 1979* (Cth), ss 43-46; *Patents Amendment Act 1976* (Cth), s 10 and Sch 1 (item 3).

¹⁷ *Patents Act 1952* (Cth), s 90(1).

to the public”, “the profits made by the patentee as such” and “all the circumstances of the case”.¹⁸ The threshold requirement was that “if [the court] is of opinion that the patentee has been inadequately remunerated by his patent”¹⁹ the court “may”

- (a) order the extension of the term of the patent, subject to such restrictions, conditions and provisions (if any) as the court thinks fit, for a further term not exceeding 5 years, or, in exceptional cases, 10 years; or
- (b) order the grant of a new standard patent for such term, not exceeding 5 years, or, in exceptional cases, 10 years, as the court thinks fit, and containing such restrictions, conditions and provisions (if any) as the court thinks fit.²⁰

Provision was also made for extensions in cases of losses or damage suffered by war.²¹ These are not considered further in this article, albeit this was a common ground up until the 1960s.²²

This entire scheme was then repealed by the *Patents Amendment Act 1989* (Cth) and a new scheme substituted.²³ The key element of the new scheme was to abolish patent term extensions except for patent dealing with “a pharmaceutical substance [which] is in substance disclosed in the complete specification of a standard patent and in substance falls within the scope of claim or claims of that complete specification”.²⁴ On an application falling within the statutory limitations of a “pharmaceutical substance” an automatic four-year term extension was granted.²⁵ The new scheme was then adopted in almost identical form in the *Patents Act 1990* (Cth).

Patents Act 1990 (Cth)

The *Patents Act 1990* (Cth) repealed the *Patents Act 1952* (Cth) term extension provisions,²⁶ provided for a patent term of 16 years²⁷ that was later changed to 20 years,²⁸ and included an extension scheme covering only some pharmaceutical patents.²⁹ This scheme required the patent holder of a patent of “a pharmaceutical substance [that] in substance is disclosed ... and in substance falls within the scope of the claim or claims” that had “requested the issue of a marketing approval certificate in respect of that substance”³⁰ to apply to the Commissioner of Patents at least one year before the patent term ended.³¹ In deciding the matter the Commissioner was required to grant an extension of four years if “the application for the extension, the marketing approval certificate and the proposed claim or claims are in accordance with the” statute, and “the proposed claim or claims do not claim matter other than the pharmaceutical substance or substances to which the application relates”.³²

This scheme was subsequently repealed by the *Patents (World Trade Organization Amendments) Act 1994* (Cth).³³ The current statutory scheme was then introduced as an amendment to the *Patents*

¹⁸ *Patents Act 1952* (Cth), s 93. Notably, these are the same requirements in the *Patents Act 1883* (UK) s 25(4) and the earlier *Patents Act 1903* (Cth), s 84(4).

¹⁹ *Patents Act 1952* (Cth), s 94(1).

²⁰ *Patents Act 1952* (Cth), s 94(1).

²¹ *Patents Act 1952* (Cth), s 95.

²² See Ricketson S, *The Law of Intellectual Property* (Law Book Co, Sydney, 1984) p 995.

²³ *Patents Amendment Act 1989* (Cth), s 6.

²⁴ *Patents Act 1952* (Cth), s 90(1)(a) as amended.

²⁵ *Patents Act 1952* (Cth), s 95(2) as amended.

²⁶ *Patents Act 1990* (Cth), s 230.

²⁷ *Patents Act 1990* (Cth), s 67.

²⁸ *Patents (World Trade Organization Amendments) Act 1994* (Cth), s 4.

²⁹ *Patents Act 1990* (Cth), ss 70-79.

³⁰ Addressed further in *Patents Act 1990* (Cth), s 72.

³¹ *Patents Act 1990* (Cth), s 70(1).

³² *Patents Act 1990* (Cth), s 75(2).

³³ *Patents (World Trade Organization Amendments) Act 1994* (Cth), s 5(2).

Act 1990 (Cth) by the *Intellectual Property Laws Amendment Act 1998* (Cth).³⁴ There were no changes to the existing patent term extension provision to reflect Australia's commitment to the *Australia–United States Free Trade Agreement* as they were considered to comply already.³⁵ The scheme introduced by the *Intellectual Property Laws Amendment Act 1998* (Cth)³⁶ applies to a “standard patent”³⁷ over a limited class of “pharmaceutical substances *per se*”³⁸ and “pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology”,³⁹ granted on or after 27 January 1999 or granted before this date with a term that expires after 1 July 1995.⁴⁰

The term of extension is calculated as “the period beginning on the date of the patent and ending on the earliest first regulatory approval date” that is then “reduced (but not below zero) by ... [five] years”⁴¹ up to a maximum of five years.⁴² This essentially means that the extension is calculated as the amount of time that elapses between the patent grant and the earliest approval date to market the pharmaceutical substances less five years (above zero).⁴³ Put another way, this is the time taken to get regulatory approval from the Therapeutic Goods Administration after the patent is granted up to a maximum of five years.

The thresholds for a patent term extension are a completed application form⁴⁴ lodged with the Commissioner of Patents,⁴⁵ at the latest of within six months of either the patent grant or the commencement of inclusion on the Australian Register of Therapeutic Goods, or the commencement of the scheme (27 January 1999).⁴⁶ The application is then assessed and either accepted⁴⁷ or refused.⁴⁸ Notification of the application and acceptance/refusal is published in the *Official Journal*.⁴⁹ The threshold issues addressed in acceptance are that the patent has not previously been extended⁵⁰ and:

- (2) Either or both of the following conditions must be satisfied:
 - (a) 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;

³⁴ *Intellectual Property Laws Amendment Act 1998* (Cth), s 3 and Sch 1.

³⁵ *Australia–United States Free Trade Agreement*, Art 17.9(8); *Intellectual Property Laws Amendment Act 2006* (Cth).

³⁶ Notably there have been some minor amendments: see *Statute Law Revision Act 2011* (Cth), s 3 and Sch 7 (item 108); *Intellectual Property Laws Amendment Act 2006* (Cth), s 3 and Sch 7 (item 1); *Statute Law Revision Act 2005* (Cth), s 3 and Sch 1 (item 31); *Patents Amendment (Innovation Patents) Act 2000* (Cth), s 3 and Sch 1 (item 39).

³⁷ *Patents Act 1990* (Cth), s 3 and Sch 1 (“standard patent”).

³⁸ Where “pharmaceutical substance” means “a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves: (a) a chemical interaction, or physic-chemical interaction, with a human physiological system; or (b) action on an infectious agent, or on a toxin or other poison, in a human body; but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing” and “therapeutic use” means “use for the purpose of: (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or (b) influencing, inhibiting or modifying a physiological process in persons; or (c) testing the susceptibility of persons to a disease or ailment”: *Patents Act 1990* (Cth), s 3 and Sch 1 (“pharmaceutical substance” and “therapeutic use”).

³⁹ *Patents Act 1990* (Cth), s 70(2).

⁴⁰ *Intellectual Property Laws Amendment Act 1998* (Cth), s 3 and Sch 1 (item 8).

⁴¹ *Patents Act 1990* (Cth), s 77(1).

⁴² *Patents Act 1990* (Cth), s 77(2).

⁴³ See IP Australia, *Patent Manual of Practice & Procedure* (IP Australia, 2008) at [3.23.7].

⁴⁴ *Patents Act 1990* (Cth), s 71(1); *Patent Regulations 1991* (Cth), regs 6.8-6.11.

⁴⁵ *Patents Act 1990* (Cth), s 70(1).

⁴⁶ *Patents Act 1990* (Cth), s 71(2). An extension of time may be available: s 223. For a discussion of the nature of the Australian Register of Therapeutic Goods see *Merck & Co Inc v Arrow Pharmaceuticals Ltd* [2002] APO 13.

⁴⁷ *Patents Act 1990* (Cth), s 74(1), (2).

⁴⁸ *Patents Act 1990* (Cth), s 74(3), (4).

⁴⁹ *Patents Act 1990* (Cth), ss 72 and 74(2), (4).

⁵⁰ *Patents Act 1990* (Cth), s 70(1), (4).

- (b) one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology, 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.
- (3) Both of the following conditions must be satisfied in relation to at least one of those pharmaceutical substances:
 - (a) goods containing, or consisting of, the substance must be included in the Australian Register of Therapeutic Goods;
 - (b) the period beginning on the date of the patent and ending on the first regulatory approval date for the substance must be at least 5 years.⁵¹

The “first regulatory approval date” means the date of approval by the Therapeutic Goods Administration or the date of commencement of first inclusion on the Australian Register of Therapeutic Goods.⁵²

After accepting the application, there is an opposition period where the “Minister” or “any other person” can challenge the grant of the extension according to the statutory thresholds.⁵³ With no opposition, or where the Commissioner decides the extension should be accepted, then an extension is granted and notified in the *Official Journal*.⁵⁴ The extension is granted to the patent in its entirety, including those claims that are not to a pharmaceutical substance.⁵⁵ Further, during the term of the extension the patentee’s “exclusive rights”⁵⁶ are limited to pharmaceutical and therapeutic uses and dealings⁵⁷ and even these are subject to limits where the use is for gaining regulatory approval (spring-boarding).⁵⁸

“INADEQUATE REMUNERATION” IN THE PATENTS ACT 1903 (Cth) AND THE PATENTS ACT 1952 (Cth)

Both the *Patents Act 1903* (Cth) and the *Patents Act 1952* (Cth) up to the *Patents Amendment Act 1989* (Cth) required that there be “inadequate remuneration” as a threshold for considering a term extension⁵⁹ that was qualified by considering “the nature and merits of the invention in relation to the public”, “the profits made by the patentee as such” and “all the circumstances of the case”.⁶⁰ The various court decisions provided some guidance about this standard.

The first decision, *Re Robinson’s Patent* (1918) 25 CLR 116, concerned a patent for “[i]mprovements in and relating to shares for scarifiers, cultivators and like implements” (at 117, Isaacs J). Isaacs J’s approach in this case was to articulate principles: “[f]or future guidance ... I propose to state explicitly the principles which I find necessary to apply to the facts of the present case” (at 118). The foundation principle was the result of history and earlier dealings with term extensions (at 118-119):

For hundreds of years the law of England permitted no extension of a patent under any circumstances unless by a special personal Act of Parliament. In 1835 this was relaxed, and the Crown was permitted to grant extensions upon recommendation by the Judicial Committee of the Privy Council after careful inquiry. A practice has been established in England with very slight modifications from 1835 to 1883,

⁵¹ *Patents Act 1990* (Cth), s 70(2).

⁵² *Patents Act 1990* (Cth), s 70(5), (6).

⁵³ *Patents Act 1990* (Cth), s 75(1), (2); *Patent Regulations 1991* (Cth), regs 5.1-5.15.

⁵⁴ *Patents Act 1990* (Cth), s 76.

⁵⁵ *Patents Act 1990* (Cth), s 70(1).

⁵⁶ *Patents Act 1990* (Cth), s 13(1).

⁵⁷ *Patents Act 1990* (Cth), s 78(1).

⁵⁸ *Patents Act 1990* (Cth), s 78(2). “Spring-boarding”, which allows generic drug producers to undertake activities solely for the purposes of meeting pre-marketing regulatory requirements prior to patent expiry”: Minister for Industry, Science and Tourism, *Intellectual Property Laws Amendment Bill 1997*, Explanatory Memorandum, p 7. Notably, “spring-boarding” now applies to all pharmaceuticals: *Patents Act 1990* (Cth), s 119A.

⁵⁹ *Patents Act 1952* (Cth), s 94(1); *Patents Act 1903* (Cth), s 84(5).

⁶⁰ *Patents Act 1952* (Cth), s 93; *Patents Act 1903* (Cth), s 84(4).

when the Act of that year was passed, and thence to the present time; and that practice has fixed certain principles which must be observed in dealing with applications like the present ... Indeed, [ss 84(4) and (5) of the *Patents Act 1903* (Cth)], in following for all present purposes English legislation, are really modelled on prior decisions of the Privy Council. The rules and the practice of the Privy Council should, therefore, be followed wherever applicable and not contrary to statutory provision.

Isaacs J framed the patent as “somewhat in the nature of a contract with the public” (at 118),⁶¹ and stated (at 119):

[T]he State recognizes that special circumstances may deprive the patentee of the substantial benefit he is presumed and intended to get, namely, adequate remuneration during his term, in return for the benefit he has conferred upon the community by introducing his invention and presenting it to the public after his term has expired. The law permits him in that event to apply to vary his contract and obtain further consideration.

As a consequence, the patentee might receive an extension as a “concession and not a right” after satisfying two obligations: establishing inadequate remuneration, and then “candour and good faith” in all the circumstances that are material to assessing the extension recognising that even without adequate remuneration circumstances might justify an extension (at 119-120). The leading principle relevant to establishing inadequate remuneration was (at 120):

[T]hat the concession to the patentee of an extension of his patent, based on the disproportion between the benefit he has given and the reward he has received, is always subject to the paramount consideration of the public interest.

As a consequence of meeting this “public interest”, the extension might be denied or granted subject to conditions, such as public uses, price limits, licensing terms, and so on (at 120-121). The *Patents Act 1903* (Cth) (and the *Patents Act 1952* (Cth)) then identified four qualifying factors for the court to consider before making the final assessment about “inadequate remuneration”:⁶²

- “*the nature ... of the invention in relation to the public*”: This involved an inquiry into the art concerned, the steps taken, and the public adoption of the invention (at 121). Essentially, this was an inquiry into the quality of inventiveness displayed by the invention.
- “*the ... merits of the invention in relation to the public*”: This involved the “value or advantage or benefit” of the disclosed invention and involved an inquiry into the “actual substantial benefit to the public for which the petitioner claims he has not been fully or equitably paid” (at 122); put differently, “considerable practical merit for the public, deserving of some substantial remuneration” (at 122). Essentially, this was an inquiry into the utility of the invention’s contribution.
- “*the profits made by the patentee as such*”: This involved showing that the “profits are disproportionately small in comparison with the merits of [the] invention in relation to the public” (at 123). While no rules for the necessary evidence were established (at 124-125), patentees (the “as such” confining the profits to the patentee as a consequence of the patent alone (such as royalties and not other factors, such as manufacturing profits)) were required to show they had attempted to profitably place their invention on the market (or a reasonable excuse) (at 127-128), and were expected to maintain proper accounts providing an intelligible complete account, that might include expenses such as the patentee’s own time, advertising, travelling, attending shows, legal advice, and so on, set out in an affidavit (at 125-127). Essentially, this was an inquiry into how much profit flowed from the invention to the patentee as a consequence of the patent (such as royalties).
- “*all the circumstances of the case*”: While these circumstances are “necessarily not susceptible of enumeration or definition” (at 128), this involved having regard to the “personal ingenuity and efforts and expenses of the inventor in arriving at his invention” (at 128). Essentially, this is an inquiry into any of the circumstances that have affected the patentee and invention in gaining the deserving benefit of the patent’s exclusivity.

⁶¹ Citing *Re Herbert’s Patent* (1867) LR 1 PC 399 at 402 (Sir William Earle).

⁶² See *Patents Act 1952* (Cth), s 93; *Patents Act 1903* (Cth), s 84(4).

Applying these principles to the facts, Isaacs J considered that the invention of corrugating or compressing the metal on the share end instead of cutting away part of the tool was more effective in operation and cheaper to manufacture than the unimproved shares (at 129). As such, the merits of the invention were not “conspicuously great”, albeit they were “sufficiently great”, and there was sufficient utility as the invention was adopted, a rival manufacturer was keen to exploit the invention on expiry (and vigorously opposed the extension), and the invention had proved valuable in agriculture (at 129-130). Further, the profits were found to be inadequate *if* the invention’s “merits had been properly pressed upon the public” (at 133). The broader negative circumstances, however, being the failure to exploit the invention outside South Australia, was only mitigated by the disruption of the then current war and “overcoming the passive resistance of manufacturers and farmers and convincing them of the advantages of his invention” (at 134). The end result was that there was “inadequate remuneration” and an extension was granted, subject to a number of provisions, restrictions and conditions directed to balancing the extension and the broader public interest (at 139-140).

In subsequent decisions under both the *Patents Act 1903* (Cth) and the *Patents Act 1952* (Cth) the courts have essentially applied this approach providing further guidance about the particular factors that may or may not be taken into consideration in determining “inadequate remuneration”. The problem has always been that the qualifying factors are essentially subjective and necessarily speculative. As a consequence, the basic principles are easily stated, but applying them in practice was arguable, complex, expensive and unpredictable.

TABLE 1 Some of the patent term applications under the Patents Act 1903 (Cth), s 84(5) and Patents Act 1952 (Cth), 94(1) up to the Patents Amendment Act 1989 (Cth) amendments

Case name and citation	Extension	
	Granted	Refused
<i>Re Robinson's Patent</i> (1918) 25 CLR 116	✓	
<i>Re Trufood of Australia Ltd</i> (1920) 28 CLR 294		✓
<i>Re Dunlop's Patent</i> (1922) 31 CLR 579		✓
<i>Ex parte Celotex Corp; Re Shaw's Patents</i> (1937) 57 CLR 19	✓	
<i>Re Johnson's Patent</i> (1938) 61 CLR 50		✓
<i>Gillette Industries Ltd v Commissioner of Patents</i> (1943) 67 CLR 529	✓	
<i>Re Ryall's Patent</i> (1949) 78 CLR 170	✓	
<i>Re Electric & Musical Industries Ltd's Patent</i> (1949) 79 CLR 643	✓	
<i>Re Northern Rotary Engines Ltd's Patent</i> (1950) 81 CLR 332		✓
<i>Re Courtaulds Ltd's Patent</i> (1952) 86 CLR 153	✓	
<i>Re Usines De Melle's Patent</i> (1954) 91 CLR 42	✓	
<i>Re Bendix Aviation Corp's Patent Application</i> (1961) 107 CLR 349	✓	
<i>Re NV Philips Gloeilampenfabrieken's Patent (No 1)</i> (1966) 121 CLR 70		✓
<i>Re NV Philips Gloeilampenfabrieken's Patent (No 2)</i> (1967) 121 CLR 83		✓
<i>Re General Tire & Rubber Co's Patent Application</i> (1968) 117 CLR 613		✓
<i>Re HV McKay Massey Ferguson (Aust) Pty Ltd's Patent</i> (1976) 50 ALJR 684; 9 ALR 646		✓

TABLE 1 *continued*

Case name and citation	Extension	
	Granted	Refused
<i>Re Eli Lilly & Co's Application</i> [1982] 1 NSWLR 526; (1982) 42 ALR 101	✓	
<i>Re Ciba-Geigy AG's Application</i> (1983) 68 FLR 26; 1 IPR 171	✓	
<i>Re Application of Merck & Co Inc</i> (1983) 1 IPR 583	✓	
<i>Re Imperial Chemical Industries Ltd's Australian Patent Extensions</i> [1983] 1 VR 1	✓	
<i>Re Vidal's Patent</i> [1983] 1 VR 16	✓	
<i>Re Sanofi's Patent Extension Petition</i> [1983] 1 VR 25	✓	
<i>Re Application of Pfizer Inc</i> (1986) 4 NSWLR 566; 6 IPR 527	✓	
<i>EI Du Pont de Nemours & Co v Commissioner of Patents</i> (1987) 9 NSWLR 206; 8 IPR 293		✓
<i>GD Searle & Co v Commissioner of Patents</i> (1987) 8 IPR 225	✓	
<i>Re Union Carbide Agricultural Products Co Inc</i> (1986) 8 IPR 376	✓	
<i>EI Du Pont de Nemours & Co v Cadbury Schweppes Pty Ltd</i> (1987) 16 FCR 437; 10 IPR 641	✓	
<i>Smith Kline & French Laboratories v Commissioner of Patents</i> (1988) 12 IPR 21	✓	
<i>Re Tanabe Seiyaku Co Ltd</i> (1988) 13 IPR 177	✓	
<i>Bayer AG v Blewett</i> (1988) 96 FLR 50; 13 IPR 225	✓	
<i>Re Application by Parke Davis & Co</i> (1988) 14 IPR 310	✓	
<i>Re Application of Sandoz Ltd</i> (1989) 14 IPR 541	✓	
<i>Aktiebolaget Hassle v Commissioner of Patents (No 1)</i> (1989) 96 FLR 154; 14 IPR 585	✓	
<i>EI Du Pont de Nemours & Co v Commissioner of Patents (No 3)</i> (1989) 15 IPR 296	✓	
<i>American Home Products Corp v Commissioner of Patents</i> (1989) 16 IPR 252	✓	
<i>Smith Kline & French Laboratories (Aust) Ltd v Commissioner of Patents</i> (1990) 18 IPR 513		✓
<i>Re Merrell Dow Pharmaceuticals Petition</i> (1991) 20 IPR 347		✓
<i>Re Imperial Chemical Industries Ltd</i> (1992) 24 IPR 597	✓	

The range of decisions set out in Table 1 attests to the potential to make arguments for an extension rather than the expectation that workable principles would have evolved over these decades. A good example of the kinds of problems in making this assessment was illustrated in the decision in *Re Imperial Chemical Industries Ltd* (1992) 24 IPR 597 (Ashley J). In this case the patent was for an injectable pharmaceutical for anaesthetics (called “diprivan”) and an extension was sought by way of a new grant on the basis of “inadequate remuneration” (at 599-600). Ashley J articulated the statutory requirements of “inadequate remuneration” (at 601-602),⁶³ and “the nature and merits of the invention

⁶³ *Patents Act 1952* (Cth), s 94(1).

in relation to the public”, “the profits made by the patentee as such” and “all the circumstances of the case” (at 600-601).⁶⁴ The criteria for “inadequate remuneration” were then framed as the petitioner proving (at 602):

- “[i]s the invention one of more than ordinary utility?”;
- “[h]as it been adequately remunerated?”; and
- “[i]s any absence of remuneration due to no fault of the patentee?”⁶⁵

The petitioner also argued this was an “exceptional case” and so deserved a longer term of extension (at 602-604).⁶⁶ Ashley J articulated these requirements as a need to satisfy one or more of the following “main classes” (at 602):

- (1) Where the invention, being useful to the public, is itself of an exceptional character, as being of exceptional inventive ingenuity.
- (2) Where the invention, being of sufficient merit to warrant some extension, is of exceptional benefit to the public.
- (3) Where the invention is inherently of such a character that it must take longer than usual to get it on the market.⁶⁷

The complexity of the circumstances then illustrates the difficulty in making a decision that properly balances the interests of the patent holder and the broader public interest without explicit data about the kinds of incentives that encourage invention (and also release of invented products and processes). This demonstrates the essentially subjective and necessarily speculative nature of determining “inadequate remuneration”. Here the pharmaceutical was researched from 1965 with a patent application being lodged in 1974 and a convention application made in Australia in 1975 (at 605). Human trials of the pharmaceutical were started in 1977, commercial formulation was made in 1983, marketing approval was granted in 1985, and commercial release was in 1987 in Australia (at 605). The patent was granted and the term was from 28 March 1974 to 28 March 1991, with a period of available exploitation from November 1987 (commercial release) to March 1991 (patent expiry) – “about 3-1/3 years out of the 16 year life of the patent” (at 605). The patentee contended (at 605):

[T]he profit made from the patent in the term of the grant was quite inadequate; and that a 10 year extension is necessary to produce an adequate profit in all the circumstances. It is said that to grant a 10 year extension would, in effect, do no more than give the patentee something close to the ordinary 16 years of a patent term to exploit its invention.

Ashley J reviewed the considerable history of the invention in the context of anaesthesia and the desirability of an injectable pharmaceutical (at 605-612). This was because the Commissioner of Patents had objected that the discovery of the anaesthetic chemical was “fortuitous” and its formulation into a pharmaceutical relied on existing know how and no inventiveness (at 607). Ashley J concluded that the petitioner’s patented chemical was fortuitously discovered as part of a “very expensive process of trial and error” (at 612-613) so that “fortuitous” as “a description belittles the breadth and intensity of the petitioner’s research” (at 613). Ashley J found the patented invention was an “exceptional case” being an invention of “exceptional inventive ingenuity” (at 613). Ashley J also considered, although not as “a feature of significance” (at 614), that the Commissioner of Patents’ objection that the formulation into a pharmaceutical relied on existing know how and no inventiveness was correct (at 614). The Commissioner of Patents also objected that the petitioner had delayed getting the pharmaceutical to market (at 614). This was rejected because, during the period from March 1975 (convention application in Australia) and May 1987 (commercial release in Australia), the petitioner was actively involved in getting the pharmaceutical to market and any delays were a result of “a reasonable commercial decision” (at 614-617).

Ashley J accepted the “large body of medical evidence” (including at least two medical witnesses presenting oral evidence) that the invention as commercially formulated “has conferred and will in the

⁶⁴ *Patents Act 1952* (Cth), s 93.

⁶⁵ Citing *Re Fleming’s Patent* (1919) 36 RPC 55 at 70 (Sargant J).

⁶⁶ *Patents Act 1952* (Cth), s 94(1).

⁶⁷ Citing *Re Perry and Brown’s Patents* (1931) 48 RPC 200 at 214 (Luxmoore J).

future confer very great benefits upon the Australian public” (at 617). The judgment then detailed at some length the various criticisms about the benefits to the Australian public, including uses, price, safety, apnoea, and so on (at 621-624 and 627-628). In conclusion, Ashley stated J (at 633):

[I]t appears to me that diprivan will assume a significant role as a sedative in cases of regional anaesthesia. It is likely to have a role in intensive care management, but the extent of that role is a little uncertain. Its use in paediatrics seems likely to be restricted to particular areas of surgery. Its use in obstetrics will be limited ... The evidence has satisfied me that diprivan has merit from the standpoint of the public in each of these potential areas of usage. The merit appears likely to be most evident in the settings of sedation associated with regional anaesthesia and intensive care use.

Ashley J’s judgment then addressed further argument about public benefit and remuneration as a consequence of the asserted added costs of the pharmaceutical (at 633-647). The detail is not important other than to demonstrate the complexity and detail in assessing the elements of “inadequate remuneration” and that it is essentially a qualitative judgment about whether the invention is deserving of an extension. What is particularly evident from this judgment is the extraordinary lengths to which the petitioner went to present evidence about the public benefits of the invention, the length of the hearing, and the detail of the judgment in attempting to justify the 10-year extension.⁶⁸ In essence, this demonstrates the essentially subjective and necessarily speculative nature of this statutory scheme.

This scheme under the *Patents Act 1952* (Cth) (and *Patents Act 1903* (Cth)) was then abandoned with the *Patents Amendment Act 1989* (Cth) that substituted a scheme directed specifically to certain pharmaceuticals that allowed an automatic extension if the procedural requirements of a granted patent for a “pharmaceutical substance” and a marketing approval certificate were satisfied.⁶⁹ The justification for abandoning the scheme was:

Extensions under the existing procedures must be based on the grounds of inadequate remuneration or, rarely in practice, of war loss. Those procedures require complicated evidence and argument to be presented in lengthy court proceedings which are costly to industry and government, and the eventual outcome remains uncertain for years. The new procedures will be simpler, less costly to use and offer greater certainty to patent holders and others.⁷⁰

The substituted scheme is considered next.

THE POLICY JUSTIFICATION FOR THE POST-PATENTS AMENDMENT ACT 1989 (CTH) SCHEMES

Recall that term extension in the *Patents Act 1952* (Cth) (and *Patents Act 1903* (Cth)) was abandoned with the *Patents Amendment Act 1989* (Cth) that substituted an alternative scheme.⁷¹ This scheme was essentially the one adopted by the *Patents Act 1990* (Cth)⁷² until it was also abandoned by the *Patents (World Trade Organization Amendments) Act 1994* (Cth)⁷³ and then a new (similar) scheme inserted by the *Intellectual Property Laws Amendment Act 1998* (Cth).⁷⁴ The various policy justifications for these schemes are insightful.

The Industrial Property Advisory Committee reviewed the patent system in Australia in 1984 from “a predominately economic perspective”.⁷⁵ In dealing with patent term extensions, the majority

⁶⁸ The hearing continued over 10 days and the judgment runs to approximately 50 pages: see *Re Imperial Chemical Industries Ltd* (1992) 24 IPR 597 at 597 (Ashley J).

⁶⁹ *Patents Act 1952* (Cth), s 95(2) following the amendments by the *Patents Amendment Act 1989* (Cth), s 6.

⁷⁰ Commonwealth, House of Representatives, *Parliamentary Debates* (3 June 1988) p 3255 (Barry Jones, Minister for Science, Customs and Small Business).

⁷¹ See *Patents Amendment Act 1989* (Cth), s 6.

⁷² See *Patents Act 1990* (Cth), ss 70-79.

⁷³ See *Patents (World Trade Organization Amendments) Act 1994* (Cth), s 5.

⁷⁴ See *Intellectual Property Laws Amendment Act 1998* (Cth), s 3 and Sch 1.

⁷⁵ Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (AGPS, 1984) p 3.

of the committee's recommendation was clear: "that the procedures for granting of extensions of the terms of standard patents be eliminated in toto".⁷⁶ The minority similarly rejected extension.⁷⁷ The majority's reasoning was also very clear:

In the view of the majority, in the absence of contrary empirical evidence, it strains credulity to contemplate that research or innovation investment decisions, made early in the life of the innovation, could ever be materially influenced by the prospective availability of an extension after expiration of the initial 16 year term to compensate for inadequate remuneration, particularly when allowance is made for discounting. On the other hand, such extensions would increase social costs. It should be noted that regulatory delay affects many innovations in many industries in many different ways. For example, automotive emissions, building and sanitary systems, telecommunications, human medicines and agrochemicals are all subject to regulation which may significantly delay the marketing of new products. Delays in marketing may be caused by a variety of factors other than government regulations and which, irrespective of their source or nature, affect patentees' financial returns. In this context, price control might be added to delay as a further factor affecting returns. To single out regulatory delays caused by federal legislation as the only ground for extension of term would be illogical in the view of the majority of the Committee. For these reasons the majority rejects the proposal for extensions for regulatory delay.⁷⁸

The Australian Government at the time responded by approving the committee's recommendation "in principle" and committed to "consider this aspect further".⁷⁹ Shortly after this the Australian Government announced that it would provide an extension for pharmaceuticals and agricultural and veterinary chemicals for which the effective patent life was eroded by regulatory delays.⁸⁰ This was then implemented in the *Patents Amendment Act 1989* (Cth) where the extension was justified:

The arrangements acknowledge that the effective patent life for pharmaceuticals for human use is reduced by the stringent and time-consuming evaluation procedures that the Department of Community Services and Health is required to conduct to ensure both the safety of patients and the efficacy of drugs. An extension of four years will be available for a patent so far as it claims a pharmaceutical substance which is subject for the first time to importation and general marketing approval by that Department. This provision recognises that subsequent marketing approvals for different forms, formulations or strengths of a pharmaceutical substance, or for the substance made by a different process, are invariably granted more rapidly than the original approval. During the final two years of an extension, a competing company will be allowed to gear up to be in a position to enter the market immediately on expiry of the extension.⁸¹

The *Patents Amendment Act 1989* (Cth) also followed after the Australian Government had announced a series of measures, including "to provide for extensions to patent life on pharmaceuticals for human use",⁸² as part of the Pharmaceutical Industry Development Plan to address the Australian pharmaceutical industry's perception of Australia as a "hostile environment" in which to operate.⁸³ In effect, the Australian Government accepted that the effective patent life for pharmaceuticals required special treatment.

⁷⁶ Industrial Property Advisory Committee, n 75, p 39.

⁷⁷ Industrial Property Advisory Committee, n 75, p 80.

⁷⁸ Industrial Property Advisory Committee, n 75, p 39.

⁷⁹ Commonwealth, House of Representatives, *Parliamentary Debates* (28 November 1986) p 3986 (Barry Jones, Minister for Science, Customs and Small Business).

⁸⁰ Commonwealth, House of Representatives, *Parliamentary Debates* (3 June 1988) p 3255 (Barry Jones, Minister for Science, Customs and Small Business).

⁸¹ Commonwealth, House of Representatives, *Parliamentary Debates* (3 June 1988) p 3255 (Barry Jones, Minister for Science, Customs and Small Business).

⁸² Industry Commission, *The Pharmaceutical Industry, Report No 51*, Vol 1 (AGPS, 1996) p 96, citing Button J and Blewitt N, "Joint Media Statement: Policies for the Development of the Pharmaceutical Industry", *Media Release 115/81* (13 September 1987).

⁸³ See Industry Commission, n 82, pp 96 and 437.

This *Patents Amendment Act 1989* (Cth) scheme was essentially carried over to the *Patents Act 1990* (Cth).⁸⁴ The *Patents (World Trade Organization Amendments) Act 1994* (Cth) then abandoned this extension scheme and extended the term of all patents from 16 to 20 years for all existing patents:

This change will subsume the special provisions for extending the term of pharmaceutical patents to 20 years. The government nevertheless remains committed to providing an effective 15-year term for those patents and is working closely with industry to that end.⁸⁵

This work with industry was developing an extension scheme in line with United States, Japan and European standards,⁸⁶ albeit the scheme favoured by the Australian Government overcompensated for the regulatory delay by calculating the extension term as the period between the patent grant and marketing approval and included the time taken developing the pharmaceutical before marketing approval was sought.⁸⁷ The proposed scheme was consistent with European standards and more generous than United States standards.⁸⁸ The Australian Government's preferred model for the 15-year effective life patent protection for pharmaceuticals with up to five years extension (with "spring-boarding")⁸⁹ was finally adopted in the *Intellectual Property Laws Amendment Act 1998* (Cth).⁹⁰

The broad policy justification for the *Intellectual Property Laws Amendment Act 1998* (Cth) term extensions was to allow patent holders a better opportunity to exploit their patent with an adequate "effective patent life", a signal for positive investment in an innovative pharmaceutical industry in Australia, and a patent regime comparable with Australia's competitors.⁹¹ The need for specific action for the pharmaceutical industry was articulated as follows:

The development of a new drug is a long process. A new chemical entity, from which a pharmaceutical is derived, is patented early in the process. However, considerable research and testing is still required before the product can enter the market. This long development time, combined with the considerable regulatory process to register and market a new product, means that companies usually have considerably fewer years under patent in which to gain a return on their investment. This becomes significant to the industry as companies rely heavily on patents to generate the substantial cash flows necessary to finance the development of new drugs.⁹²

The Intellectual Property and Competition Review Committee was tasked in 2000 with reviewing the patent scheme, among other intellectual property schemes, according to the *Competition Principles Agreement's* "guiding principle" that "legislation ... should not restrict competition unless it can be

⁸⁴ See *Patents Act 1990* (Cth), ss 70-79.

⁸⁵ Commonwealth, House of Representatives, *Parliamentary Debates* (18 October 1994) p 2189 (Gordon Bilney, Minister for Development Cooperation and Pacific Island Affairs). See also Gruen N, Bruce I and Prior G, *Extending Patent Life: Is It in Australia's Economic Interests?* (Industry Commission, Staff Information Paper, 1996).

⁸⁶ See Industry Commission, n 82, pp 440-443. A contemporaneous government document demonstrates the policy development: Department of Industry, Science and Technology, *Effective Patent Life for Pharmaceuticals: An Option Paper* (Department of Industry, Science and Technology, 1995) p 3, stating "the Government is committed to providing a 15 year effective life patent protection for pharmaceuticals ... This means extending the term of a patent up to 25 years depending on when the new drug was authorized for marketing in Australia. In detail, this equates to extending the term of the patent ... and the day on which registration of the new drug in the Australian Register of Therapeutic Goods (ARTG) commenced."

⁸⁷ Industry Commission, n 82, pp 443-444.

⁸⁸ Industry Commission, n 82, p 444.

⁸⁹ See *Patents Act 1990* (Cth), s 119A.

⁹⁰ See Minister for Industry, Science and Tourism, *Intellectual Property Laws Amendment Bill 1998*, Revised Explanatory Memorandum, p 2.

⁹¹ Commonwealth, Senate, *Parliamentary Debates* (26 March 1998) p 1375 (Ian Campbell, Senator for Western Australia); Commonwealth, House of Representatives, *Parliamentary Debates* (26 November 1997) p 11274 (Warren Truss, Minister for Customs and Consumer Affairs).

⁹² Commonwealth, Senate, *Parliamentary Debates* (26 March 1998) p 1375 (Ian Campbell, Senator for Western Australia); Commonwealth, House of *Parliamentary Debates* (26 November 1997) p 11274 (Warren Truss, Minister for Customs and Consumer Affairs).

demonstrated⁹³ that: (a) the benefits of the restriction to the community as a whole outweigh the costs; and (b) the objectives of the legislation can only be achieved by restricting competition".⁹⁴ The committee examined the terms of patents and mercurially concluded:

TRIPS sets the term of the standard patent at no less than 20 years. The committee does not believe that a case can be made for further extending the maximum patent term, and therefore takes it as given.⁹⁵

Perhaps surprisingly, the committee's only recommendation about patent terms was to increase the renewal fees to exclude "less innovative" (or rather less profitable) patents.⁹⁶ The committee's conclusion is at best ambivalent about whether patent terms for some pharmaceuticals up to 25 years were justified.

The preparation of the *Intellectual Property Laws Amendment Act 1998* (Cth) complied with the Australian Government's commitments to the *Competition Principles Agreement* and assessed the likely competition effects of the proposed legislation and recorded this in the Bill's Regulatory Impact Statement.⁹⁷ The justification for the term extension set out in the Regulatory Impact Statement was:

The development of a new drug is a long process, estimated to average around 12 years, which requires a new chemical entity to be patented early in the process in order to secure its intellectual property rights. However, considerable research and testing is still required before the product can enter the market. As a consequence, patentees of new drugs usually have considerably fewer years under patent in which to maximise their return.

It is expensive to bring a drug to market, around US\$380 million, and involves considerable risk. As such, research based pharmaceutical companies rely heavily on patents to generate the substantial cash flows needed to finance the development of new drugs from the discovery stage, through the pre-clinical and clinical development phases, to eventual marketing.

A country's patent system is also an important factor in contributing to a company's decision on whether to invest or not. If Australia has a weak patent system, relative to its competitors, there is a risk that investment in research and development will be lost to those offering stronger patent protection.⁹⁸

The concerns about not extending the patent term also appear to have involved the sending of a "negative signal" about Australian as a place for investment in pharmaceutical research and development,⁹⁹ a reduction in the capacity of firms to invest in and develop new drugs,¹⁰⁰ and the dissipation of the long-term investment by the government in education and research by firms moving

⁹³ The construction of the *Competition Principles Agreement*, cl 5(1), relies on the term "demonstrated" in setting out the standard to be achieved in applying the "guiding principle" in reviewing existing legislation and proposed legislation that restricts competition, while the *Competition Principles Agreement*, cl 5(5), expressly requires "evidence" that proposed legislation restricting competition is consistent with the "guiding principle". While this might be construed as a lower standard for reviewing existing legislation, the preferable construction is evidence demonstrating that the guiding principle has been satisfied. That is, "legislation that restricts competition must be accompanied by evidence that the benefits of the restriction to the community as a whole outweigh the costs, and that the objectives can only be achieved by restricting competition": Productivity Commission, *Regulation and Its Review 2002-03, Annual Report Series* (Productivity Commission, 2003) p 7.

⁹⁴ *Competition Principles Agreement*, cl 5(1). This reflected a key outcome of the Hilmer Committee report that "[t]here should be no regulatory restrictions on competition unless clearly demonstrated to be in the public interest": Independent Committee of Inquiry into Competition Policy in Australia, *National Competition Policy* (AGPS, 1993) p 212 (also called the Hilmer Committee report).

⁹⁵ Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (IP Australia, 2000) p 156.

⁹⁶ Intellectual Property and Competition Review Committee, n 95, pp 156-157.

⁹⁷ The relevant standards at the time were articulated by the Office of Regulation Review (now the Office of Best Practice Regulation) according to an analytical process model: see Office of Regulation Review, *A Guide to Regulation* (Office of Regulation Review, 1998). A similar analytic process is now promulgated by the Office of Best Practice Regulation: see Office of Best Practice Regulation, *Best Practice Regulation Handbook* (Department of Finance and Deregulation, 2010).

⁹⁸ Revised Explanatory Memorandum, n 90, p 3.

⁹⁹ Revised Explanatory Memorandum, n 90, p 4.

¹⁰⁰ Revised Explanatory Memorandum, n 90, p 5.

their activities to other places.¹⁰¹ These concerns appears to have been based on the finding that:

A strong patent system is an important contributor to the competitiveness of Australia's investment climate. This was confirmed by the Industry Commission, which agreed that, in most circumstances, it would be undesirable for Australia to be out of step with the periods of protection offered to most other developed countries. To do otherwise would send a highly visible and particularly strong negative signal about the Australian climate for innovation and research and development.¹⁰²

The Regulatory Impact Statement for the *Intellectual Property Laws Amendment Act 1998* (Cth) merely asserted that patents would deliver competitiveness to the investment climate. No evidence was cited for this conclusion, and the confirming authority of the Industry Commission cited in justification of the scheme (quote immediately above) relied on the same assertion that patents would deliver benefits. The Industry Commission had accepted that the Australian Government was already committed to extending the effective patent life for pharmaceuticals¹⁰³ and stated its belief that “[a]dequate patent protection is a critical factor for success in the pharmaceutical industry and so has an important influence on company perceptions of Australia as an investment location”.¹⁰⁴ Interestingly, the Industry Commission did cite earlier views questioning the benefits of adopting intellectual property measures in addition to those minimum standards required by Australia's commitments to international agreements, and made no further analysis of these views¹⁰⁵ even though patent term extensions were not a requirement of Australia's then international commitments (in TRIPS or the yet to be concluded AUSFTA). Further, the Industry Commission also appears only to have considered the existing patent scheme, or its complete removal, rather than its modification to maximise competitiveness and community benefit, given that TRIPS precludes its entire abolition.¹⁰⁶ In short, the Industry Commission does not appear to have been a necessarily strong supporter of the scheme favoured by the Australian Government.

LITIGATION UNDER THE POST-1989 ACT SCHEMES

Table 2 lists most of the reported decision about disputes involving patent term extensions under the various schemes applying under the *Patents Act 1990* (Cth): (i) before the *Patents (World Trade Organization Amendments) Act 1994* (Cth) amendments; and (ii) after the *Intellectual Property Laws Amendment Act 1998* (Cth) amendments. These schemes were directed specifically to a limited number of pharmaceutical substances that were included in goods listed on the Australian Register of Therapeutic Goods. In contrast to the litigation under the earlier “inadequate remuneration” provisions that involved considerable evidence and qualitative judgments about the worth of a patent (addressed above), this litigation is predominantly directed to procedural technicalities about eligibility under the statute¹⁰⁷ and the meaning of “pharmaceutical substance”.¹⁰⁸ Of particular concern and evidence in

¹⁰¹ Revised Explanatory Memorandum, n 90, p 5.

¹⁰² Revised Explanatory Memorandum, n 90, p 8.

¹⁰³ Industry Commission, n 82, pp 66-67.

¹⁰⁴ Industry Commission, n 82, p 444 (emphasis added).

¹⁰⁵ Industry Commission, n 82, pp 438-439; see also Bureau of Industry Economics, *The Economics of Patents, Occasional Paper No 18* (AGPS, 1994) pp 46-50.

¹⁰⁶ Industry Commission, n 82, pp 439-440. See also Industry Commission, *Research and Development, Report No 44* (AGPS, 1996) p 186.

¹⁰⁷ See *Alphapharm Pty Ltd v H Lundbeck A/S* (2011) 92 IPR 628 (K Ayers); *Re LTS Lohmann Therapie-Systeme AG* (2009) 82 IPR 640 (G Jenkins); *Re GD Searle LLC* (2008) 80 IPR 210; [2008] APO 31 (S Barker); *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618 (Lindgren J); *Pfizer Corp v Commissioner of Patents* (2006) 155 FCR 578; 70 IPR 559 (Emmett, Allsop and Greenwood JJ); *Alphapharm Pty Ltd v H Lundbeck A/S* (2006) 69 IPR 629 (S Barker); *Pfizer Corp v Commissioner of Patents (No 2)* (2006) 69 IPR 525 (Bennett J); *Re Pfizer Corp* (2005) 67 IPR 201 (P Spann); *Pfizer Inc v Commissioner of Patents* (2005) 141 FCR 413; 64 IPR 547 (Bennett J); *Re Pfizer Inc* (2004) 62 IPR 627 (D Herald); *Merck & Co Inc v Arrow Pharmaceuticals Ltd* (2003) 59 IPR 226 (Wilcox J); *Re Applications by Hassle AB* (1999) 45 IPR 291 (J Werner); *Beecham Group plc v Lek DD Ljubljana Pharmaceutical Co* (1996) 36 IPR 461 (V Thom); *Prejay Holdings Ltd v Commissioner of Patents* (2003) 57 IPR 424 (Wilcox, Cooper and Allsop JJ); *Re Astra Lakenedel Aktiebolag* (1994) 29 IPR 183 (D Herald); *Beecham Group plc v Department of Community Services & Health* (1993) 42 FCR 82; 25 IPR 537 (Northrop J).

this litigation is the uncertainty about the proper meaning of the term “pharmaceutical substance *per se*” with the prospect of further litigation still necessary to establish a settled meaning.¹⁰⁹ In *Boehringer Ingelheim International GmbH v Commissioner of Patents (No 2)* (2001) 112 FCR 595; 52 IPR 529 at 537-538 Wilcox, Whitlam and Gyles JJ upheld the decision of Heerey J that the meaning of the term “pharmaceutical substance *per se*” was that the pharmaceutical substance form some element of the patent claims, and for the purposes of the statute, must fall within the scope of the patent claims. Problems arise, however, in how closely associated the pharmaceutical substance must be with the claimed invention to fall within the term “pharmaceutical substance *per se*”. Various decisions demonstrate that this is not necessarily easily (or consistently) determined.¹¹⁰ Significantly, the early litigation appears to have resolved many of the uncertainties in the statute.

TABLE 2 Some of the patent term applications under the Patents Act 1952 (Cth), 94(1) (after the Patents Amendment Act 1989 (Cth)) and the Patents Act 1990 (Cth), s 76(1)

Case name and citation	Extension	
	Granted	Refused
Before the Patents (World Trade Organization Amendments) Act 1994 (Cth)		
<i>Beecham Group plc v Department of Community Services & Health</i> (1993) 42 FCR 82; 25 IPR 537	✓	
<i>Merck Patent GmbH v Virbac (Aust) Pty Ltd</i> (1992) 26 IPR 70	✓	
<i>Re Astra Lakenedel Aktiebolag</i> (1994) 29 IPR 183		✓
<i>Virbac (Aust) Pty Ltd v Merck Patent GmbH</i> (1994) 29 IPR 548		✓
<i>Beecham Group plc v Lek DD Ljubljana Pharmaceutical Co</i> (1996) 36 IPR 461		✓
After the Intellectual Property Laws Amendment Act 1998 (Cth)		
<i>Re Application by Hassle AB</i> (1999) 45 IPR 291		✓
<i>Boehringer Ingelheim International GmbH v Commissioner of Patents (No 2)</i> (2001) 112 FCR 595; 52 IPR 529		✓
<i>Re Zentaris Aktiengesellschaft</i> [2002] APO 41	✓	
<i>Prejay Holdings Ltd v Commissioner of Patents</i> (2003) 57 IPR 424		✓
<i>Merck & Co Inc v Arrow Pharmaceuticals Ltd</i> (2003) 59 IPR 226	✓	
<i>Re Pfizer Inc</i> (2004) 62 IPR 627		✓

¹⁰⁸ See *Re Children's Medical Center Corp* (2011) 95 IPR 385 (L McCaffery); *LTS Lohmann Therapie Systeme AG & Schwarz Pharma Ltd v Commissioner of Patents* (2010) 118 ALD 425 (Downes J and Member Schafer); *Re NV Organon* [2009] APO 8 (P Spann); *Sanofi-Aventis* [2007] APO 35 (G Jenkins); *Euro-Celtique, SA* [2007] APO 13 (R Finzi); *Pharmacia Italia SpA v Mayne Pharma Pty Ltd* (2006) 69 IPR 1 (Weinberg J); *Prejay Holdings Ltd v Commissioner of Patents* (2003) 57 IPR 424 (Wilcox, Cooper and Allsop JJ); *Re Application by LTS Lohmann Therapie-System GmbH & Co KG* (2002) 57 IPR 104 (D Herald); *Re Zentaris Aktiengesellschaft* [2002] APO 41 (D Herald); *Boehringer Ingelheim International GmbH v Commissioner of Patents (No 2)* (2001) 112 FCR 595; 52 IPR 529 (Wilcox, Whitlam and Gyles JJ); *Virbac (Aust) Pty Ltd v Merck Patent GmbH* (1994) 52 FCR 534; 29 IPR 548 (Burchett J); *Re Astra Lakenedel Aktiebolag* (1994) 29 IPR 183 (Lee J); *Merck Patent GmbH v Virbac (Aust) Pty Ltd* (1992) 26 IPR 70 (D Herald).

¹⁰⁹ See Sands P and Iles E, “Patent Term Extensions in Australia” (2010) 24 *Australian Intellectual Property Law Bulletin* 35 at 36-38.

¹¹⁰ See eg *Re NV Organon* [2009] APO 8 (P Spann); *Merck & Co Inc v Arrow Pharmaceuticals Ltd* (2003) 59 IPR 226 (Wilcox J); *Prejay Holdings Ltd v Commissioner of Patents* (2003) 57 IPR 424 (Wilcox, Cooper and Allsop JJ); *Re Zentaris Aktiengesellschaft* [2002] APO 41 (D Herald), and so on.

TABLE 2 *continued*

Case name and citation	Extension	
	Granted	Refused
<i>Pfizer Inc v Commissioner of Patents</i> (2005) 141 FCR 413; 64 IPR 547	✓	
<i>Re Pfizer Corp</i> (2005) 67 IPR 201	✓	
<i>Pharmacia Italia SpA v Mayne Pharma Pty Ltd</i> (2006) 69 IPR 1	✓	
<i>Alphapharm Pty Ltd v H Lundbeck A/S</i> (2006) 69 IPR 629	✓	
<i>Pfizer Corp v Commissioner of Patents (No 2)</i> (2006) 69 IPR 525	✓	
<i>Pfizer Corp v Commissioner of Patents</i> (2006) 155 FCR 578; 70 IPR 559	✓	
<i>Euro-Celtique, SA</i> [2007] APO 13		✓
<i>Sanofi-Aventis</i> [2007] APO 35	✓	
<i>Alphapharm Pty Ltd v H Lundbeck A/S</i> (2008) 76 IPR 618		✓
<i>Re GD Searle LLC</i> (2008) 80 IPR 210		✓
<i>Re LTS Lohmann Therapie-Systeme AG</i> (2009) 82 IPR 640		✓
<i>Re NV Organon</i> [2009] APO 8	✓	
<i>LTS Lohmann Therapie Systeme AG v Commissioner of Patents</i> (2010) 118 ALD 425		✓
<i>Alphapharm Pty Ltd v H Lundbeck A/S</i> (2011) 92 IPR 628	✓	
<i>Re Celgene Corp</i> (2011) 93 IPR 309		✓
<i>Re Children's Medical Center Corp</i> (2011) 95 IPR 385		✓

INFORMATION PROVISION

At the time the current patent term extension was being introduced in the *Intellectual Property Laws Amendment Act 1998* (Cth) there was unanimous support for the provisions in the Senate¹¹¹ and House of Representatives.¹¹² A key amendment introduced in the Senate was to attempt to address in the longer term the justification for patent term extensions, balancing incentives to invest in research and development, and the increased price consequences of further exclusivity.¹¹³ The mover stated:

This amendment requires that those who are applying for the additional patent time provide some information to the government. The aim of this is to basically assess whether what the government is trying to do is actually working and whether the money that we are spending – as I said before, we are looking at over \$800 million in a period of 10 years – is being put to best use. I think the wording is self-explanatory: the total amount spent on each type of research and development, including pre-clinical research and clinical trials, in respect of the drug which was the subject of the application.¹¹⁴

¹¹¹ See Commonwealth, Senate, *Parliamentary Debates* (26 March 1998) p 1375 (Ian Campbell, Senator for Western Australia); (9 July 1998) p 5322 (Kate Lundy, Senator for the ACT); p 5323 (Meg Lees, Senator for South Australia); p 5324 (Bob Brown, Senator for Tasmania).

¹¹² See Commonwealth, House of Representatives, *Parliamentary Debates* (26 November 1997) p 11274 (Warren Truss, Minister for Customs and Consumer Affairs); (11 March 1998) p 1049 (Stephen Martin, Member for Cunningham); p 1051 (Jackie Kelly, Member for Lindsay); p 1053 (Martyn Evans, Member for Bonython); p 1058 (Allan Rocher, Member for Curtin).

¹¹³ Commonwealth, Senate, *Parliamentary Debates* (9 July 1998) p 5323 (Meg Lees, Senator for South Australia).

¹¹⁴ Commonwealth, Senate, *Parliamentary Debates* (9 July 1998) p 5330 (Meg Lees, Senator for South Australia).

The amendment requires that, after a patent extension has been granted, the patent holder submit information to the "Secretary of the Department" before the end of each following "financial year" being:

- (a) details of the amount and origin of any Commonwealth funds spent in the research and development of the drug which was the subject of the application; and
- (b) the name of any body:
 - (i) with which the applicant has a contractual agreement; and
 - (ii) which is in receipt of Commonwealth funds; and
- (c) the total amount spent on each type of research and development, including pre-clinical research and clinical trials, in respect of the drug which was the subject of the application.¹¹⁵

This provision has been implemented through a process that requires the information to be lodged with the Secretary of Health and Family Services:

As at 18 December 1998, [the] Dep[artment] of Health have advised their requirements as:

- the details of the amount and origin of any Commonwealth funds spent in the research and development of the drug which is the subject of the application (s 76A(a)) and the names of any body with which the applicant has a contractual agreement and which is in receipt of Commonwealth funds (s 76A(b)) as well as the total amount spent on each type of research and development (s 76A(c)) relate to activities occurring in Australia concerning the specific drug registered on the [Australian Register of Therapeutic Goods], on which the application for extension of term is based.
- the total amount spent on the drug (s 76A(c)) needs to cover the period from initial research up until the granting of the extension of term. The Health Department would then require a supplementary return which provides the amount of research and development funds spent on the particular drug for the period from granting the extension of term up until the expiry of the patent.
- access to the information in the notification would be governed by the [*Freedom of Information Act 1982* (Cth)]. However, collective information would be publicly available.¹¹⁶

This information is provided to and maintained by the Pricing Section, Pharmaceutical Evaluation Branch of the Department of Health and Ageing.¹¹⁷ Despite the commitment that "collective information would be publicly available", this information is not presently publicly available.

CONCLUSIONS

The analysis of patent term extensions under the *Patents Act 1903* (Cth), the *Patents Act 1952* (Cth) and the *Patents Act 1990* (Cth) demonstrates the dramatic changes from a broad scheme directed to all patents to a narrowly focused scheme directed to a particular subset of pharmaceutical patents. The analysis also shows that the "inadequate remuneration" under the *Patents Act 1903* (Cth) and the *Patents Act 1952* (Cth) up to the *Patents Amendment Act 1989* (Cth) was essentially subjective and necessarily speculative – essentially requiring qualitative decisions from judges based on their perspectives about whether a patent was deserving of an extension. The analysis then demonstrates that the schemes under the *Patents Amendment Act 1989* (Cth), *Patents Act 1990* (Cth) up to the *Patents (World Trade Organization Amendments) Act 1994* (Cth), and the *Patents Act 1990* (Cth) after the *Intellectual Property Laws Amendment Act 1998* (Cth) provided a more direct assessment standard, albeit there remain some contentions about procedural technicalities and the meaning of key terms. The questions for this article, however, are: (i) whether patent term extensions are justified; and (ii) how this might be assessed. While there is unlikely to be a direct answer to the first question, there is certainly a methodology mandated by the Australian Government's commitment to the *Competition Principles Agreement* that addresses the second question and will make any conclusions more easily justified.

¹¹⁵ *Patents Act 1990* (Cth), s 76A.

¹¹⁶ IP Australia, *Patent Manual of Practice & Procedure* (IP Australia, 2008) at [3.23.13].

¹¹⁷ IP Australia, n 116 at [3.23.13].

The starting point in any justification for regulation is determining whether regulation is necessary presuming that unnecessary regulation is a restriction on competition.¹¹⁸ The *Competition Principles Agreement* expressly recognises that in some circumstances the benefits of restrictions on competition will outweigh the costs, and that legislation restricting competition may be necessary. In applying the *Competition Principles Agreement's* “guiding principle”¹¹⁹ (that “legislation that restricts competition must be accompanied by evidence that the benefits of the restriction to the community as a whole outweigh the costs, and that the objectives can only be achieved by restricting competition”)¹²⁰ to reviewing existing legislation¹²¹ and proposed legislation which restricts competition,¹²² the *Competition Principles Agreement* identifies some of the relevant elements of the “public interest” that may be relevant in determining the threshold or standard necessary for the benefit to outweigh the costs:¹²³

Without limiting the matters that may be taken into account ... the following matters shall, where relevant, be taken into account:

- (d) government legislation and policies relating to ecologically sustainable development;
- (e) social welfare and equity considerations, including community service obligations;
- (f) government legislation and policies relating to matters such as occupational health and safety, industrial relations and access and equity;
- (g) economic and regional development, including employment and investment growth;
- (h) the interests of consumers generally or of a class of consumers;
- (i) the competitiveness of Australian businesses; and
- (j) the efficient allocation of resources.¹²⁴

The words of the *Competition Principles Agreement* provide little guidance about the methodology for assessing the “public interest”. The Commonwealth, States and Territories have very different views about the appropriate methodology¹²⁵ and how the “public interest” test should be applied.¹²⁶ To overcome this problem, and take advantage of evolving experience and concerns,¹²⁷ the Australian Government’s Office of Best Practice Regulation provides guidelines in the *Best Practice Regulation Handbook* articulating the relevant methodology¹²⁸ that is consistent with international standards of high-quality and performing regulation,¹²⁹ and consistent with the *Competition Principles Agreement* commitments.¹³⁰ Essentially, the methodology requires the conduct of a Regulatory Impact

¹¹⁸ This was a fundamental part of the National Competition Policy: see Independent Committee of Inquiry into Competition Policy in Australia, n 94, pp 211-212.

¹¹⁹ *Competition Principles Agreement*, cl 5(1). See also Independent Committee of Inquiry into Competition Policy in Australia, n 94, p 212.

¹²⁰ Productivity Commission, Annual Report Series, n 93, p 7.

¹²¹ *Competition Principles Agreement*, cl 5(3).

¹²² *Competition Principles Agreement*, cl 5(5).

¹²³ The *Competition Principles Agreement* also sets out a number of matters that legislation reviews “should” consider: see *Competition Principles Agreement*, cl 5(9).

¹²⁴ *Competition Principles Agreement*, cl 1(3).

¹²⁵ See generally House of Representatives Standing Committee on Financial Institutions and Public Administration, *Inquiry into Aspects of the National Competition Policy Reform Package* (AGPS, 2002); Senate Select Committee on Socio-economic Consequences of the National Competition Policy, *Riding the Waves of Change* (Senate Printing Unit, 2000); Senate Select Committee on Socio-economic Consequences of the National Competition Policy, *Competition Policy: Friend or Foe?* (Senate Printing Unit, 1999).

¹²⁶ This was a commonly expressed view in submissions to the Senate Select Committee on Socio-economic Consequences of the National Competition Policy, *Competition Policy: Friend or Foe?* (Senate Printing Unit, 1999) p 101.

¹²⁷ See eg Borthwick D and Milliner R, *Independent Review of the Australian Government's Regulatory Impact Analysis Process* (Department of Finance and Deregulation, 2011).

¹²⁸ Office of Best Practice Regulation, n 97, pp 7-45.

¹²⁹ Office of Best Practice Regulation, n 97, p 5. See also Organisation for Economic Co-operation and Development, *Guiding Principles on Regulatory Quality and Performance* (OECD, 2005).

¹³⁰ See Productivity Commission, Annual Report Series, n 93, pp xv-xvi.

Analysis and the preparation of a Regulatory Impact Statement. The Regulatory Impact Analysis is “the process of examining the likely impacts of a proposed regulation and a range of alternative options which could meet the government’s policy objectives”.¹³¹ The Regulatory Impact Statement “formalises and provides evidence of the key steps taken during the development of the proposal, and includes an assessment of the costs and benefits of each [considered] option”.¹³²

While there is no set format for a [Regulatory Impact Statement], it should generally contain seven elements, setting out:

1. the problem or issues that give rise to the need for action;
2. the desired objectives;
3. a range of options (regulatory and non-regulatory, as applicable) that may constitute feasible means for achieving the desired objectives;
4. an assessment of the impact (costs, benefits and, where relevant, levels of risk) of a range of feasible options for consumers, business, government and the community;
5. a consultation statement;
6. a conclusion and recommended option; and
7. a strategy to implement and review the preferred option.¹³³

Further:

- where a regulatory proposal restricts competition, agencies must demonstrate in the RIS that the preferred option generates a net benefit to the community as a whole and that the only way of achieving the government’s objective is to restrict competition;
- agencies may be given direction regarding which options to analyse in a RIS for the Cabinet or a committee of the Cabinet. This would require the sponsoring minister to write to the Prime Minister or the Cabinet Secretary, copied to the Treasurer and the Minister for Finance and Deregulation;
- where a regulatory proposal implements a specific election commitment, the RIS should focus on the commitment and the manner in which the commitment should be implemented, not on the initial regulatory decision; and
- new or amended cost recovery arrangements must comply with the Australian Government’s Cost Recovery Guidelines and relevant Finance Circulars.¹³⁴

While the *Intellectual Property Laws Amendment Act 1998* (Cth) was subject to a similar methodology, the outcome was not a convincing justification for patent term extensions, relying primarily on assertions of benefit.¹³⁵ The outcome of the analysis in this article has also been to demonstrate that patent term extensions for certain pharmaceuticals have been adopted despite there being credible opposition and acquiescence. The 1984 Industrial Property Advisory Committee majority recommended “that the procedures for granting of extensions of the terms of standard patents be eliminated in toto”,¹³⁶ and the 2000 Intellectual Property and Competition Review Committee concluded: “[t]he committee does not believe that a case can be made for further extending the maximum patent term, and therefore takes it as given” without expressly endorsing the existing patent extension scheme.¹³⁷ More recently, in 2002-2003, the Department of Industry, Tourism and Resources and the Productivity Commission concluded that Australian generic pharmaceutical manufacturers were being disadvantaged because, under the patent extension, patent holders with extensions were able to maintain exclusivity while the same patents had expired in other

¹³¹ Office of Best Practice Regulation, n 97, p 7.

¹³² Office of Best Practice Regulation, n 97, p 7.

¹³³ Office of Best Practice Regulation, n 97, p 14.

¹³⁴ Office of Best Practice Regulation, n 97, p 15.

¹³⁵ For a comprehensive analysis of this proposition see Lawson C, “Patent Privileges and the National Competition Policy – Patent Scope and Allocation?” (2005) 33 ABLR 7 at 23-25.

¹³⁶ Industrial Property Advisory Committee, n 75, p 39.

¹³⁷ Intellectual Property and Competition Review Committee, n 95, p 156.

jurisdictions.¹³⁸ This is supported by contemporaneous empirical analysis of patent extensions in Australia compared to the United States (and the United Kingdom) that confirmed that 67% of extended patents in Australia had a longer extension than in the United States and, on average, Australian patent extensions exceeded United States extensions by 368 days.¹³⁹ Perhaps the most significant finding has been the 1984 Industrial Property Advisory Committee majority finding “that regulatory delay affects many innovations in many industries in many different ways ... To single out regulatory delays caused by federal legislation as the only ground for extension of term would be illogical in the view of the majority of the Committee.”¹⁴⁰

Despite the credible opposition and acquiescence to embracing patent term extensions, there is a scheme in the *Patents Act 1990* (Cth) and the analysis in the article identifies its justification as a “negative signal” about Australia as a place to invest in pharmaceutical research and development,¹⁴¹ a reduced capacity for firms to invest in and develop new drugs,¹⁴² the dissipation of the long-term investment by the government in education and research by firms moving their activities to other places,¹⁴³ and a desire to match the patent schemes of other developed countries.¹⁴⁴ These assertions reflect the oft-stated complaint that a longer “effective” patent term is required for pharmaceuticals because of the substantial investments necessary and the long regulatory delays in getting to market.¹⁴⁵ The significant advance in the *Intellectual Property Laws Amendment Act 1998* (Cth) amendments, however, was to introduce information requirements¹⁴⁶ that start to address these assertions. The analysis in the article demonstrates that these information requirements have effectively become regulatory impediments (so-called “red tape”) and that the valuable information about the funds expended on research and development, and amounts spent on research and development during the patent term extension, are not publicly available. While this information is not necessarily sufficient to address the justifications for patent extensions, it does represent a means by which valuable information can be collected that is relevant to policy development in this area. In particular, this information is likely to address key questions about the Australian Government’s commitment to research and development relied on by patent holders, the kinds of costs imposed by regulatory compliance and an indication of the quantum of costs associated with getting pharmaceuticals to market (and perhaps an indication of the return on investment). While the existing scheme in the *Patents Act 1990* (Cth) is entrenched through commitments to the AUSFTA, further analysis is necessary to test the special pleadings that pharmaceuticals (as opposed to other technology sectors) necessarily require special attention.

POSTSCRIPT

On 15 October 2012 the then Parliamentary Secretary for Innovation announced a review of pharmaceutical patents, including patent term extensions. The Review Panel’s draft report, *Pharmaceutical Patents Review*, was released in 2 April 2013. The final report was provided to the Australian Government in May 2013.

¹³⁸ Department of Industry, Tourism and Resources, *Discussion Paper on Patent Extensions and Springboarding, and the Effect on Generic Pharmaceuticals Manufacturers in Australia* (Department of Industry, Tourism and Resources, 2002) p 1; Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program, Research Report* (AusInfo, 2003) p 8.8.

¹³⁹ Christie A, Elkman S and Howlett M, *Review of Pharmaceutical Patent Extension and Springboarding Provisions in Various Jurisdictions* (Intellectual Property Research Institute of Australia, 2002) pp 36-40.

¹⁴⁰ Industrial Property Advisory Committee, n 75, p 39.

¹⁴¹ Revised Explanatory Memorandum, n 90, p 4.

¹⁴² Revised Explanatory Memorandum, n 90, p 5.

¹⁴³ Revised Explanatory Memorandum, n 90, p 5.

¹⁴⁴ Revised Explanatory Memorandum, n 90, p 8.

¹⁴⁵ For a good example see Finzi R and Boyce T, *Pharmaceutical Extensions in Australia: A Reference Guide* (Pizzey’s, 2009) p 1.

¹⁴⁶ *Patents Act 1990* (Cth), s 76A.