Final Report to the
Commonwealth Department of Industry, Tourism and Resources

Review of Pharmaceutical Patent Extension and Springboarding Provisions in Various Jurisdictions

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Scope of Extension Provisions

The US extension provisions and the EU extension provisions apply to a broader class of patent claims than the corresponding Australian provisions. In particular, the US and EU extension provisions apply to patents which claim methods of *manufacturing* or *using* a 'product', in addition to claims to the 'product' itself. In contrast, the Australian extension provisions only apply to 'product' claims (claims to the pharmaceutical substance *per se*) and do not extend to 'process' or 'use' claims (methods of manufacturing claims and use claims, respectively), except to the extent that recombinant DNA processes may be subject to patent extensions. This distinction is significant because the nature of claims in respect of which an extension of term can be granted in Australia also determines the nature of patents in respect of which springboarding activities may be undertaken.

Length of Patent Extensions

All relevant jurisdictions only allow one extension of term per patent. The maximum length of an extension of the term of a patent is 5 years in the US, EU and Australia. There is a significant difference in maximum effective patent life across the relevant jurisdictions. A maximum effective life of 15 years is (implicitly) conferred by the Australian extension provisions and by SPCs in the EU, compared to a maximum effective life of 14 years (expressly conferred) in the US.

Different frames of reference are used to calculate extensions of patent term in the US, EU and Australia. In Australia and the EU, patent extensions are calculated by reference to the period commencing on the date of filing. In particular, the length of an extension is generally equal to the period between the date of filing and the first regulatory approval date, minus 5 years. In contrast, the patent extension period in the US is calculated by reference to the period commencing on the date an exemption to conduct human clinical trials is first granted **or** the date the patent is issued, *whichever is the later*.

The US extension provisions provide that the length of an extension will include 50% of time spent during the clinical testing phase *plus* 100% of time spent obtaining regulatory approval. In contrast, patent extensions in Australia and SPCs in the EU allow for 100% of the clinical testing period to be taken into consideration for the purpose of calculating the relevant extension.

2.Empirical Data on Patent Term

Patent Expiry Dates

There were very small differences between the data provided by the DITR on the patent expiry dates of 20 'blockbuster' and the verified data. The verified data showed that on average, 66% of the US and UK patents expired earlier than the equivalent Australian patents. Patents filed in the US expired earlier by an average of 16 months while patents filed in the UK expired earlier by an average of 17 months.

Length of Patent Extension

Empirical data shows that the length of the extension period for approximately 67% of patents is greater for patents filed in Australia than in the US by an average of 386 days. The extraction of pipeline drugs from the data resulted in the gap between the Australian and the US extension periods closing to 274 days. Empirical data also showed that the length of Australian patent extensions seems to be increasing over time, while the length of US patent extensions seems to be decreasing over time. Accordingly, the gap between the two jurisdictions seems to be widening.

Filing and Grant Dates

Empirical data on filing and grant dates show that the differences between the timing of filing the patent in Australia and in the UK were minimal. The average difference between the date of filing in Australia and the date of filing in the US is one month and in 58% of cases, the US patent is filed before the Australian patent is filed (by an average of 7 months). There are, however, significant differences between the date of filing in Australia and the date of grant in the US. In 92% of cases, the Australian patent is filed before the US patent is granted, by an average difference of 28 months.

Regulatory Approval

A comparative study of the regulatory approval times for new molecular entities shows that in the period of 1995 to 1999, the regulatory approval times are decreasing in the US, the EU and Australia.

Reasons for Differences in Patent Expiry Dates

Patents conferred in Australia may expire later than corresponding patents in the US and the EU due to structural, practical or transitional reasons.

There are no *structural reasons* for differences in expiry dates between the EU and Australia. There are, however, many structural reasons for the differences in expiry dates between the US on the one hand and the EU and Australia on the other hand. A different frame of reference is used to calculate extensions of patent term in the US, as

compared to the EU and Australia. The empirical data on filing and grant dates shows that the period of time which can be *taken into consideration* for the purposes of calculating US extensions of term is (on average) at least 2 years less than the corresponding period in Australia. Furthermore, the failure of the US extension provisions to allow the entire clinical testing phase to be taken into account represents an additional reason for relatively later patent expiry dates in Australia. The longer period of maximum effective life in Australia, relative to the US, may provide another reason for longer periods of patent extension in Australia and could account for a maximum of 1 years' difference in patent extension periods and thus patent expiry dates.

Patent expiry dates may differ across jurisdictions for *practical reasons* including: differences in regulatory approval periods, length of clinical trials and filing and grant dates. The differences in regulatory approval times could account for 6 months of the difference between patent expiry dates in the US and Australia. Another practical reason for the later expiry of total patent term is the later filing dates in Australia (relative to the US) for the same patents. In particular, later filing dates in Australia (relative to the US) will result in later expiry of the total patent term, even if the extended term in both jurisdictions is of equal length. The clinical trial period is generally the larger of the relevant time periods that is taken into account when calculating the length of patent extension. Relatively shorter periods of clinical trials in the US will result in shorter extension periods. There is some evidence that this period is decreasing in the US.

The *transitional reasons* for differences in expiry dates arise out of the *1994 Uruguay Round Agreements Act ("URAA")* and transitional provisions in the *Hatch-Waxman Act* in respect of pipeline drugs, both of which affect US patents. Provisions in the *URAA* provide a basis for extending the term of certain 'transitional patents' in the US beyond the 20 year period enjoyed in Australia because they automatically confer a term of 20 years from application or 17 years from grant (whichever is the longer). In the US, patented drugs that, as at the date of the enactment of the *Hatch-Waxman Act*, had commenced a process of clinical tests but were awaiting FDA approval (pipeline drugs) are granted a maximum extension period of 2 years, in contrast to the 5 year maximum applicable in relation to non-pipeline drugs.

Future Prospects for Closing the Gap between Patent Expiry Dates

The structural reasons for differences in expiry dates will not diminish in significance over time. However, practical reasons may change over time and close the gap between patent expiry dates. For example, if the length of the regulatory review period and clinical trial period decreases in Australia, relative to the US and the UK, the gap between patent expiry dates would be expected to close. The gap will also

close to the extent that patent filing dates in Australia and the US converge. The transitional issues will cease to affect the gap over time.

3. Other Methods for Extending Market Exclusivity

Pharmaceutical companies use methods, other than patents, to extend the market exclusivity of their drug products. A typical non-legislative means of extending market exclusivity is to obtain multiple patents relating to the same pharmaceutical. This "layering" of patents can be staggered over a long period of time and can have the effect of preventing generics manufacturers from entering the market.

In the US (and Canada), when a generics manufacturer files an abbreviated new drug application, and the applicant certifies that the patent is invalid or will not be infringed, then the patentee may bring an action against the generics applicant. The commencement of litigation results in an automatic stay of regulatory approval of the generic product. This stay lasts for 30 months in the US (24 months in Canada), until patent expiry or until the conclusion of the litigation, whichever comes first.

In the US, the *Hatch-Waxman Act* also provides that the first generic applicant to file an ANDA certifying that the patent is invalid or will not be infringed, will be *eligible* for a 180-day period of market exclusivity. The FDA cannot approve subsequently submitted ANDAs for the same drug until 180 days after the first commercial marketing of the drug under the previous application, or the court decision declaring the patent to be invalid or not infringed, whichever is earlier. A study released by the Federal Trade Commission in 2002, investigating whether the *Hatch-Waxman Act* has operated as intended, has sparked proposals for legislative change in the US.

The US, Canada and Australia all provide 'orphan drug' programs to encourage research and development of treatment for rare diseases. A product which is designated as an 'orphan drug' may be eligible for seven years of market exclusivity in the US, ten years of market exclusivity in the EU, and the benefit of a 'priority' evaluation pathway in Australia. In the US, six months market exclusivity can be granted for the studying drugs in children.

4. Review of Springboarding

Springboarding provides an exemption from infringement for uses of a patented invention that are reasonably related to seeking regulatory approval. Springboarding is allowed in the US, Canada and Australia. In the US and Canada, springboarding is allowed at *any time* during the patent term, and for any type of patent, as long as the use is reasonably related to seeking regulatory approval. In Australia, springboarding is limited to patents that the patent owner has chosen to extend, and is allowed from the date that an extension is granted. Springboarding in Australia can only occur on

patents for a pharmaceutical substance *per se*, or a pharmaceutical substance when produced by a process involving recombinant DNA. The European Union does not have springboarding provisions, but is currently debating a proposal by the European Commission to introduce such provisions.

Over the past five years, there has been strong lobbying of the Canadian government by generics manufacturers to allow manufacture for export during the patent term. The Canadian government has not adopted these proposals. In Israel, the springboarding provisions allow generics manufacturers to manufacture pharmaceuticals for export prior to patent expiration, but only for the purpose of obtaining regulatory approval in Israel or a foreign country.

5. Australian Proposal

The Australian government is currently considering proposals to revise the *Patents Act* to allow (1) manufacture for export during the extension period and (2) springboarding on *all* pharmaceutical patents for developmental and testing activities required to obtain regulatory approval.

It is *arguable* that the Australian *Patents Act* already allows manufacture for export during the extension period, by virtue of section 78(1)(a). A plausible interpretation of this section is that, due to the territorial limitations of patent rights to Australia, the only act of exploitation of a pharmaceutical substance that constitutes infringement during the extension period, is exploitation for the purpose of therapeutic use in Australia. We recognise that there are counterarguments to this construction, and we do not purport to resolve the issue of interpretation, but merely seek to identify a plausible interpretation

The proposed change in relation to springboarding should, in principle, facilitate generics manufacturers in obtaining regulatory approval, as it would reduce the time required for generics manufacturers to enter the market with their generic product.

1. REVIEW OF PATENT EXTENSIONS

1.1 Introduction

The US, the EU and Australia all provide for patent extensions of up to 5 years for certain patents. These laws and regulations are directed towards pharmaceuticals. The marketing approval process for new prescription drugs is lengthy and erodes the effective patent life for pharmaceutical products. Patent extensions are thus designed to reward innovation and compensate for the time taken in clinical trials and regulatory review.

1.2 United States

1.2.1 LAWS AND REGULATIONS

The standard term of a US patent is 20 years from the date of application. [1] The *1994 Uruguay Round Agreements Act* ("URAA") changed the term of US patents from 17 years from the date of grant to 20 years from the date of application, thus ensuring US compliance with the TRIPS Agreement. [2]

Amendments introduced by the *Drug Price Competition and Patent Term Restoration Act of 1984* ("the Hatch-Waxman Act") provided for extensions to the term of certain patents ("US extension provisions"). The US extension provisions are codified in 35 U.S.C. §156.

The *Hatch-Waxman Act* sought to balance the interests of innovator drug companies and generic manufacturers. First, the Act restored part of the patent term 'lost' during the process of obtaining regulatory approval, thereby creating new incentives for investing in research and development in relation to products which are subject to regulatory regimes.[3] In return, generic manufactures were granted expedited approval procedures (ANDA) and 'springboarding' provisions were enacted, as discussed in section 4 below.

(a) Scope of Extension Provisions

The US extension provisions apply to patents which claim methods of *manufacturing* or *using* a 'product', in addition to claims to the 'product' itself. [4]

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[1] 35 U.S.C. §154(a)(2).
[2] Agreement on Trade-Related Aspects of Intellectual Property Rights 1994.
[3] Shilpa Patel, 'Patent Fairness Act of 1999: The Implications of Extending Patents for Pipeline Drugs' (2000) 8 *Journal of Intellectual Property Law* 145, 147-8.
[4] 35 USC §156(a).

The US extension provisions only apply to patents which claim a 'product' or a method of using or manufacturing a 'product'. Therefore, the scope of the US extension provisions corresponds with the scope of the following definition of 'product':

- the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act); [5]

- the active ingredient of a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques; [6] or

- any medical device, food or colour additive subject to regulation under the Federal Food, Drug and Cosmetic Act.

(b) Requirements for an Extension of Term

The following conditions must be satisfied before an extension of term will be granted under the US extension provisions:

- an application for extension must be submitted by the owner of record of the patent or its agent [7] prior to the expiration of the original term of the patent; [8]

- the term of the patent must not have been extended previously; [9]

- the product must have been subject to a regulatory review period before its commercial marketing or use; [10] and

- permission for the commercial marketing or use of the product (after such regulatory review) must be the first such permission granted. [11]

In circumstances where a product is protected by more than one patent, only one of those patents may be the subject of an extension of term.[12]

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[5] 35 USC §156(f)(2)(A) (by virtue of the definition of 'drug product'.
[6] 35 USC §156(f)(2)(B) (by virtue of the definition of 'drug product'.
[7] 35 USC §156(a)(3).
[8] 35 USC §156(a)(1).
[9] 35 USC §156(a)(2).
[10] 35 USC §156(a)(4).
[11] 35 USC §156(a)(5).

(c) Length of Extension Period

The formula for calculating the length of an extension to the term of US patents is based on the length of the 'regulatory review period'. [13] In summary, the US extension provisions allow for an extension of term equal to 50% of the time devoted to the clinical testing phase *plus* 100% of the time spent obtaining approval under the *Federal Food, Drug and Cosmetic Act.* [14] We note that there may be a misunderstanding on page 5 of the DITR Discussion Paper on patent extensions and springboarding in relation to the method for calculating the length of an extension of term in the US.

Significantly, the formula for calculating the length of US patent extensions is subject to the following limitations:

- extensions of term under the *Hatch-Waxman Act* cannot exceed 5 years; [15]
- maximum effective patent life is expressly limited to 14 years; [16]
- periods during which the applicant for extension 'did not act with due diligence' are subtracted from the total term of extension; and [17]
- the length of extension cannot exceed 2 years in respect of patents for 'pipeline drugs'. [18] In summary, 'pipeline drugs' refer to patented drugs which, as at the date of the enactment of the *Hatch-Waxman Act*, had commenced a process of clinical tests but were awaiting FDA approval.

Figure 1 illustrates the method for calculating the length of US patent extensions. In particular, the emboldened black line represents the total length of the extension period, provided that such period does not exceed 5 years or result in an effective patent life of greater than 14 years. [19]

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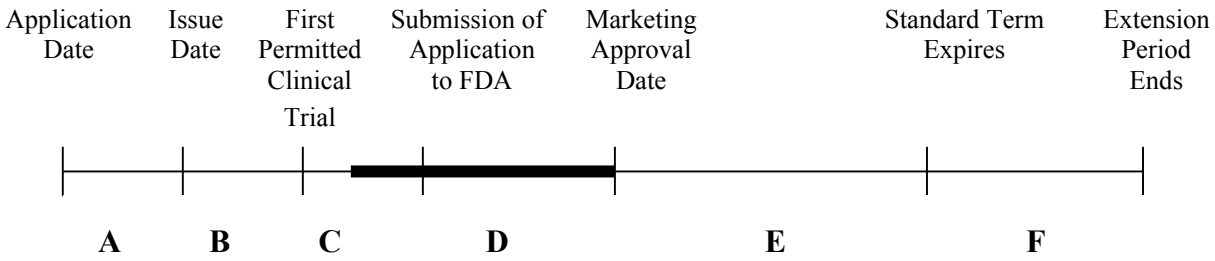
[12] 35 USC §156(c)(4) provides that 'in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product' Shilpa Patel, 'Patent Fairness Act of 1999: The Implications of Extending Patents for Pipeline Drugs' (2000) 8 *Journal of Intellectual Property Law* 145, 149.
[13] Edward Hore. 'A Comparison of United States and Canadian Laws as They Affect Generic Pharmaceutical Market Entry', 2000 (55) *Food Drug Law Journal* 373, 377-88.
[14] 35 USC §156(c) and (g)(B). Ibid.
[15] 35 USC §156(g)(6)(A).
[16] 35 USC §156(c)(3).
[17] 35 USC §156(c)(1).
[18] 35 USC 156§ (g)(6)(C).
[19] It is also assumed that the patentee acted with due diligence.

Figure 1.



Employing the symbols above, the length of US patent extensions (***F***) can be expressed in the following terms:

F = C/2 + D - periods where patentee did not act with due diligence.
Where:
$F \leq 5$
$E + F \leq 14$
A + B + C + D + E = 20 years

1.2.2 INTERPRETATION

The Court of Appeals for the Federal Circuit [20] has affirmed a decision of the District Court, [21] holding that extensions of term granted pursuant to 35 U.S.C. §156 ("*Hatch-Waxman* extensions") **can** be added to the extended patent term granted by the URAA.[22] In other words, *Hatch-Waxman* extensions can be added to a patent term of 17 years from grant **or** 20 years from application (whichever is the longer), provided that the standard patent was still "alive" as at 8 June 1995 independently of any *Hatch-Waxman* extensions.[23]

1.2.3 PROPOSALS FOR REFORM

(a) Pipeline drugs

The *Patent Fairness Act of 1999* was introduced into the House of Representatives on 28 April 1999 and the *Drug Patent Term Restoration Review Procedure Act of 1999* was introduced into the Senate on 27 May 1999. [24] These proposed Acts seek to extend the effective patent life of several pipeline drugs for a maximum period of 3

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[20] *Merck & Co v Kessler,* 80 F. 3d 1543, 1553 (Fed Cir. 1996), cert. denied, 117 S. Ct. 788 (1997).
[21] *Merck & Co v Kessler,* 903 F. Supp. 964 (E.D.Va 1995).
[22] Heidi Grygiel, 'Now They GATT Worry: The Impact of the GATT on the American Generic Pharmaceutical Industry' (1997) 6 *University of Baltimore Intellectual Property Law Journal*47, 60.
[23] *Merck & Co v Kessler,* 80 F. 3d 1543, 1553 (Fed Cir. 1996), cert. denied, 117 S. Ct. 788 (1997).
[24] Shilpa Patel, 'Patent Fairness Act of 1999: The Implications of Extending Patents for Pipeline Drugs' (2000) 8 *Journal of Intellectual Property Law* 145.

years. In summary, the Bills propose to compensate patentees for the reduction in effective patent life caused by the 2-year cap on extensions of term for pipeline drugs.

The progress of this legislation appears to have stalled. In particular, it appears that no Congressional action has occurred in relation to either Bill since August 1999. [25]

1.2.4 PATENT EXTENSIONS PURSUANT TO 35 USC § 154

Section 154(b) of USC 35 provides an independent basis for extending patent terms, whether in relation to pharmaceutical patents or otherwise. [26] In particular, section 154(b) of USC 35 allows for extensions of term in circumstances where the issue of an original patent is delayed due to interference proceedings, [27] secrecy orders [28] or appellate review by the Board of Patent Appeals and Interferences or by a Federal Court.[29]

Extensions of term granted pursuant to section 154(b) cannot exceed 5 years [30] and are subject to further qualifications if the extension arises out of a period of appellate review.[31]

Section 154(b) is not limited in application to patents of a particular kind, in contrast to the extension provisions codified in section 156 and discussed above. Therefore, section 154(b) appears to provide a basis for extending patent terms which is independent of (and additional to) the pharmaceutical extension provisions codified in section 156 and discussed above.

Section 154(b) was inserted into 35 USC by the *Patent Term Guarantee Act of 1999* and applies to patent applications filed on or after 29 May 2000.[32] Accordingly, these extension provisions do not affect any of the patents referred to in DITR Attachment A.

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[25] According to the Bill Status section of 'Thomas': http://thomas.loc.gov/
[26] With the exception of design patents. See Mandy Wilson, 'Pharmaceutical Patent Protection: More Generic Favoured Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation' (2001/2002) 90 *Kentucky Law Journal* 495, 512.
[27] 35 USC § 154(b)(1).
[28] 35 USC § 154(b)(1).
[29] 35 USC § 154(b)(2); provided that the patent is issued subsequent to that review, reversing an adverse determination of patentability.
[30] 35 USC § 154(b)(4).
[31] 35 USC § 154(b)(3).
[32] Mandy Wilson, 'Pharmaceutical Patent Protection: More Generic Favoured Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation' (2001/2002) 90 *Kentucky Law Journal* 495, 512.

1.3 Canada

1.3.1 LAWS AND REGULATIONS

Extensions to the standard term of patents are not currently available in Canadian law. Therefore, patents granted under Canadian law subsist for a maximum period of 20 years from the filing date of the application.[33]

1.3.2 PROPOSALS FOR REFORM

It does not appear that any patent extension reforms are currently being proposed in Canada.

1.4 European Union

1.4.1 LAWS AND REGULATION

The European Parliament enacted Supplementary Protection Certificate legislation in relation to 'medicinal products' on 2 July 1992. This legislation was adopted in Council Regulation (EEC) 1768/92 (***the SPC Regulation***) and became effective on 2 January 1993. [34] The SPC Regulation applies in Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and the United Kingdom.

The purpose of the SPC Regulation can be discerned from its recitals. The recitals expressly recognise that the period of effective patent life is 'insufficient' to compensate patentees for the research costs associated with the development of medicinal products. Accordingly, the (maximum) 15-year period of market exclusivity afforded by a Supplementary Protection Certificate (***SPC***) is intended to provide adequate compensation in respect of such costs.

(a) Scope of Extension Provisions

SPCs do not provide for a formal extension of the term of the relevant patent, namely, the patent which protects the medicinal product in question. Rather, a SPC achieves its objective of conferring an additional period of market exclusivity by conferring the same rights as a patent for a limited period commencing at the expiration of the original patent term. However, the practical effect of a SPC is not dissimilar to the

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[33] Section 44 of the Canadian *Patent Act* (1995): '… where an application for a patent is filed under this Act on or after October 1, 1989, the term limited for the duration of the patent is twenty years from the filing date.'

effect of an extension of patent term. In particular, the rights conferred by a SPC correspond with (and are subject to the same limitations and obligations as) the rights conferred by the relevant patent in relation to a claim for an authorised medicinal product. [35] Accordingly, the extension of protection provided by a SPC is hereafter referred to as an extension of term.

Article 4 of the SPC Regulation effectively restricts the nature of patent claims in respect of which a SPC may be granted. The protection conferred by a SPC is restricted to:

- the active ingredient of a medicinal product which has been subject to market authorisation, ie. claims to the *authorised compound* itself; and
- any *use* of the active ingredient as a medicinal product that has been subject to authorisation, ie. claims to *authorised uses* of the compound. [36]

In summary, the protection conferred by a SPC will be restricted to the particular active ingredient or use of active ingredient in respect of which market authorisation has been granted. [37] Therefore, active ingredients and uses of active ingredients (described or claimed in a patent) will not receive the protection conferred by a SPC unless those ingredients or uses have been granted authorisation. [38]

A SPC can only be granted in respect of the active ingredient (or combination of active ingredients) of a 'medicinal product'. [39]

In summary, 'medicinal product' is defined as any substance used for:

- the treatment or prevention of disease in human being or animals;
- medical diagnosis in humans or in animals; or
- modifying physiological functions in humans or in animals. [40]

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[34] Thomas Vinje, 'Symposium on U.S.-E.C. Legal Relations: Recent Developments In European Intellectual Property Law: How will they affect you and when?' (1994) 13 *The Journal of Law and Commerce* 301, at 312.
[35] SPC Regulation, Article 5: ' … the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations'.
[36] SPC Regulation, Article 4.
[37] Edward H Mazer, 'Supplementary Protection Certificates in the European Economic Community', (1993) 48 *Food & Drug Law Journal* 571, 574.
[38] Ibid.
[39] By virtue of Article 2 and 'the definition of 'product' in Article 1.
[40] Article 1 of the SPC Regulation defines 'medicinal product' as 'any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to

(b) Requirements for an Extension of Term

A SPC will only be granted if (as at the date of the application) the following conditions are fulfilled:

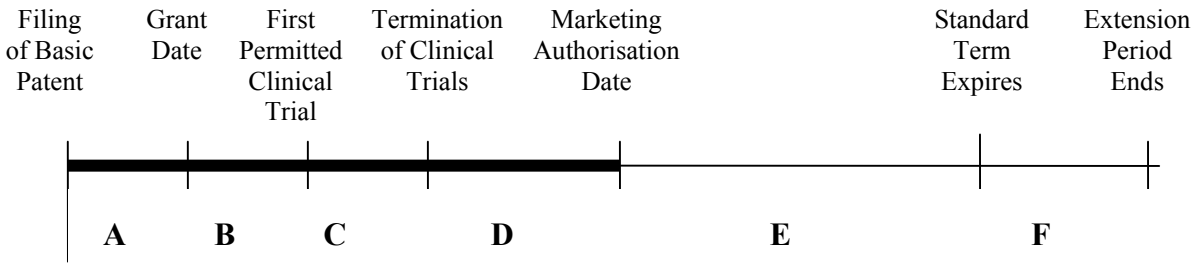
- The product is protected by a 'basic patent' in force in the EU member state in which the application for a certificate is made; [41]
- Market authorisation for the product has been granted in the aforementioned EU member state and this is the first such authorisation granted; [42] and
- The product has not previously received a SPC. [43]

(c) Length of Extension Period

SPCs take effect from the date of patent expiration (Article 13(1)) and subsist for a period equal to the period between the application date of the 'basic patent' and the first market authorisation date for the product, minus 5 years: Article 13(1). However, the duration of a SPC cannot exceed 5 years. (SPC Regulation, Article 13(1) and 13(2)). Therefore, SPCs provide for a maximum effective patent life of 15 years.

The emboldened black line in Figure 2 represents the period of time which can be *taken into consideration* for the purposes of calculating the length of a SPC. In particular, the length of a SPC is equal to the period represented by the emboldened black line, *minus 5 years* (provided that the length of the SPC does not exceed 5 years).

Figure 2



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making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals'.

[41] SPC Regulation, Article 3(a).

[42] A valid authorisation to place the product on the market as a medicinal product has been granted: SPC Regulation, Article 3(b).

[43] SPC Regulation, Article 3(c).

Employing the symbols above, the length of EU patent extensions (***F***) can be expressed in the following terms:

F = A + B + C + D – 5
WHERE:
F ≤ 5

1.4.2 INTERPRETATION

The SPC Regulation was considered by the Court of Justice of the European Communities in *Biogen Inc v Smithkline Beecham Biolgicals SA*. [44] The Court of Justice held that, in circumstances where a medicinal product is protected by a number of basic patents (held by different patentees), the SPC Regulation does not preclude the grant of a SPC to each holder of a basic patent. [45]

1.4.3 PROPOSALS FOR REFORM

It does not appear that any patent extension reforms are currently being proposed in the European Union. However, proposed changes to the EU springboarding provisions are discussed further in section 4.4.2 below.

1.5 Australia

1.5.1 LAWS AND REGULATIONS

The term of a standard patent is 20 years from the date of filing the complete specification. [46] However, amendments introduced by the *Intellectual Property Laws Amendment Act 1998* (Cth) provide a basis for extending the term of certain standard patents for a maximum period of 5 years (***the Australian extension provisions***). [47] The Australian extension provisions are contained in sections 70 to 79A of the *Patents Act 1990* (Cth).

The purpose of the Australian extension provisions is to provide an 'effective patent life' in relation to pharmaceutical substances comparable to that enjoyed by inventions in other fields of technology (and comparable to that conferred by the

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[44] Case C-181/95, European Court Reports 1997, Page I-00357 (23 January 1997).
[45] Case C-181/95, European Court Reports 1997, Page I-00357 (23 January 1997).
[46] Unless the regulations prescribe another 'date of the patent': s. 67 of the *Patents Act 1990* (Cth), when read in light of s. 65 of the Act. The *Patents (World Trade Organization Amendments) Act 1994* (Cth) extended the term of certain standard patents from 16 years to 20 years, thus ensuring Australia's compliance with the Uruguay Round of GATT: James Lahore, *Patents, Trade Marks & Related Rights* [5930].
[47] *Patents Act 1990* (Cth), s. 77(2).

patent laws of other developed nations). [48] The provisions were enacted in recognition of the delays incurred by patentees during the regulatory approval process and the length of the drug development process. [49]

(a) Scope of Extension Provisions

The Australian extension provisions apply to a limited class of pharmaceutical patents. In particular, the Australian extension provisions only apply to patents which claim:

- pharmaceutical substances *per se;* [50] or
- pharmaceutical substances produced by a process that involves the use of recombinant DNA technology, [51]

provided that those substances fall within the scope of a claim of the complete patent specification.

The Australian extension provisions only apply in respect of claims to 'pharmaceutical substances'. Therefore, the definition of 'pharmaceutical substance', in part, determines the scope of the Australian extension provisions.

'Pharmaceutical substance' is defined in Schedule 1 of the *Patents Act* 1990 (Cth) as a substance (including a mixture or a compound of substances) for 'therapeutic use' whose application involves either:

- a chemical or physico-chemical interaction with a human physiological system; [52] or
- action on an infectious agent, toxin or other poison, in a human body.

The Schedule 1 definition of 'pharmaceutical substance' expressly excludes substances used solely for the purpose of *in vitro* diagnosis or *in vitro* testing.

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[48] Intellectual Property Laws Amendment Bill 1998, Revised Explanatory Memorandum
[49] Intellectual Property Laws Amendment Bill 1998, Revised Explanatory Memorandum
[50] *Patents Act 1990* (Cth), s. 70(2)(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'.
[51] *Patents Act 1990* (Cth), s. 70(2)(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'.
[52] The 'schedule 1' definition is '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 physico-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.'

A substance must be 'for therapeutic use' in order to fall within the definition of 'pharmaceutical substance'. In summary, 'therapeutic use' is defined in Schedule 1 of the *Patents Act 1990* (Cth) [53] as use for the purpose of:

- preventing, diagnosing, curing or ameliorating human disease, injury or ailment;
- influencing human physiological processes; or
- testing human susceptibility to disease or ailment.

(b) Requirements for an Extension of Term

In summary, an extension of the term of a pharmaceutical patent will only be granted if the following conditions are satisfied:

- A pharmaceutical substance *per se* must in substance fall within the scope of a claim of the complete specification (s. 70(2)(a)) or a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology must in substance fall within the scope of a claim of that specification [s.70(2)(b)];
- goods containing, or consisting of, the pharmaceutical substance must be included in the Australian Register of Therapeutic Goods (***ARTG***); [54] and
- a minimum period of 5 years has elapsed between the 'date of the patent' (generally the date of filing the complete specification) [55] and the 'first regulatory approval date' in relation to the pharmaceutical substance. [56] (The 'first regulatory approval date' is essentially the date of first inclusion in the ARTG of goods that contain, or consist of, the relevant pharmaceutical substance or (if pre-*Therapeutics Goods Act* marketing approval was given) the date of first marketing approval). [57]

Section 70(4) of the *Patents Act 1990* (Cth) confirms that extensions of term may only be granted once in respect of each patent. [58]

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[53] The Schedule 1 definition is '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.'
[54] *Patents Act* 1990 (Cth), s. 70(3)(a).
[55] Unless the regulations prescribe another date: *Patents Act* 1990 (Cth), s. 65.
[56] *Patents Act 1990* (Cth), s. 70(3)(b).
[57] *Patents Act 1990* (Cth), s. 70(5).
[58] (s. 70(4): The term of the patent must not have been previously extended under this Division.)

(c) Length of Extension of Term

Section 77 of the *Patents Act 1990* (Cth) sets out the method for calculating the length of an extension to the term of a standard patent. The term of an extension is equal to the period between the date of the patent[59] and the first regulatory approval date, minus 5 years. Accordingly, where 5 years (or less) elapse between the date of the patent and the first regulatory approval date, no extension of term will be available. This is consistent with section 70(3)(b) which requires a minimum period of 5 years between the date of the patent and the first regulatory approval date before an application for an extension can be made.[60]

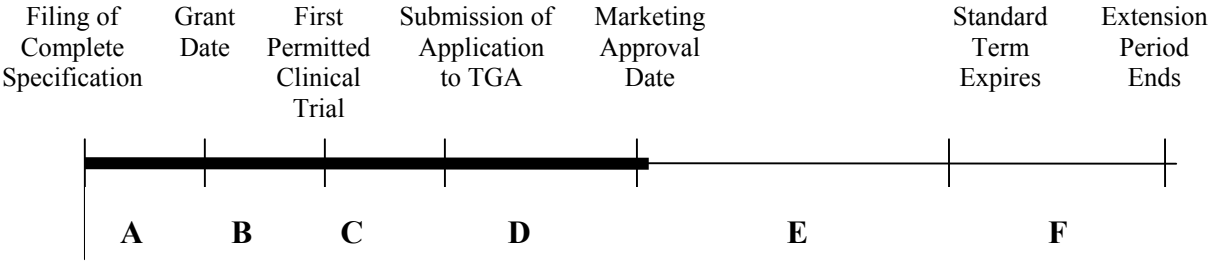
Section 77(2) confirms that extensions of term under the *Patents Act* 1990 (Cth) cannot exceed 5 years.

Where the period between the date of the patent and the first regulatory approval date falls between 5 to 10 years, the extension granted will result in an 'effective life' of 15 years.

However, where more than 10 years elapse between the date of the patent and the first regulatory approval date, the 'effective life' of the patent will be less than 15 years. This reduction in 'effective life' occurs because the maximum extension allowable cannot exceed 5 years (section 77(2)).

The emboldened black line in Figure 3 represents the period of time which can be *taken into consideration* for the purposes of calculating the length of an extension of term. In particular, the length of an extension of term is equal to the period represented by the emboldened black line, *minus 5 years* (provided that the length of the extension does not exceed 5 years).

Figure 3



[59] Generally the date of filing the complete specification unless the regulations provide otherwise: section 65, *Patents Act 1990* (Cth).
[60] 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: s. 70(3)(b).

Employing the symbols above, the length of Australian patent extensions (***F***) can be expressed in the following terms:

$F = A + B + C + D - 5$
WHERE:
$F \leq 5$

1.5.2 INTERPRETATION

(a) Meaning of 'Pharmaceutical Substance per se'

The Australian extension provisions only apply in respect of claims to 'pharmaceutical substances *per se*'. In *Boehringer Ingelheim International GmbH v Commissioner of Patents*, [61] Heerey J considered the meaning of 'pharmaceutical substance ***per se***' [62] and concluded that the Act draws a distinction between:

(i) a pharmaceutical substance that is the subject of a patent claim; and

(ii) a pharmaceutical substance that forms part of a method or process claim.

Heerey J held that the Australian extension provisions only apply to category (i) above, namely, patents which claim pharmaceutical substances *per se*. In particular, the Australian extension provisions do not apply to a pharmaceutical substance that forms part of a method or process claim, unless that pharmaceutical substance is produced by a process that involves the use of recombinant DNA technology (and thus falls within section 70(2)(b) of the *Patents Act 1990* (Cth)). Heerey J deduced a Parliamentary intention to foster primary research and development in inventive substances, rather than methods for their production (subject to the exception for recombinant DNA techniques) or the manner in which they are used. The Full Federal Court affirmed the reasoning of Heerey J on appeal in *Boehringer Ingelheim International GmbH v Commissioner of Patents.* [63]

In *Pre Jay Holdings Ltd and Woco Investments Ltd*, [64] a Delegate of the Commissioner of Patents applied the decision of Heerey J in *Boehringer Ingelheim International GmbH v Commissioner of Patents*. [65] On appeal to the Federal Court Heerey J affirmed the decision of the Delegate. In particular, in *Prejay Holdings Ltd v Commissioner of Patents* [66] Heerey J affirmed the Delegate's conclusion that section section 70(2)(a) is only available to extend the term of a patent in circumstances where there is at least one claim to a pharmaceutical substance (by itself), unqualified by process or method components.

(b) Meaning of "within the scope of the claim"

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[61] (2001) AIPC 91-670.
[62] In section 70(2) of the *Patents Act 1990*.
[63] (2001) 52 IPR 529.
[64] [2001] APO 18 (24 April 2001).
[65] (2001) AIPC 91-670.
[66] [2002] FCA 881, at para [13] ("Preejay Holdings").

In *Boehringer Ingelheim International GmbH v Commissioner of Patents,* [67] the Full Court of the Federal Court considered section 70(2)(a) of the *Patents Act* and, in particular, the meaning of the phrase 'one or more pharmaceutical substances *per se* must … in substance fall within the scope of the claim or claims of [the] specification'. [68] The Full Court rejected the appellant's contention that this phrase merely requires that the claims of the specification '*include* as an essential feature the pharmaceutical substance' per se. [69] In particular, the Full Court concluded that a pharmaceutical substance does not fall within the scope of a claim if it merely forms a necessary integer of that claim (notwithstanding the fact that 'in ordinary usage a necessary integer of a whole would be regarded as falling within the scope of that whole'). [70] Rather, the pharmaceutical substance (in itself) must be "included among the things claimed". [71] In other words, the pharmaceutical substance, in itself, must constitute a "thing claimed in the patent sense". [72]

In *Merck & Co., v Arrow Pharmaceuticals Limited,* [73] the Deputy Commissioner of Patents considered the test for determining whether a pharmaceutical substance in substance falls within the scope of a claim of a specification for the purposes of section 70(2). The Deputy Commissioner considered it 'appropriate' to assess compliance with 70(2) by reference to the test for determining the allowability of amendments under section 102 of the *Patents Act.* In particular, the Deputy Commissioner held that it was appropriate to determine whether a pharmaceutical substance falls 'within the scope of a claim' by employing the test for assessing the allowability of amendments adopted in *The Distillers Co. Ltd's Application* ("the *Distillers'* test"). [74] The *Distillers'* test asks whether the amendment would make anything an infringement which would not have been an infringement prior to the amendment. Accordingly, a pharmaceutical substance will only fall within the scope of a claim of a specification if it is possible to amend the patent to insert a new claim to that pharmaceutical substance *per se* without making something an infringement which would not otherwise have been an infringement.

(c) Inclusion in the ARTG

As noted above, an extension of term can only be granted if goods containing, or consisting of, the relevant pharmaceutical substance are included in the Australian

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[67] (2001) 52 IPR 529.
[68] (2001) 52 IPR 529, 538.
[69] (2001) 52 IPR 529, 535.
[70] (2001) 52 IPR 529, 538.
[71] (2001) 52 IPR 529, 538.
[72] (2001) 52 IPR 529, 538.
[73] [2002] APO 13 (17 April 2002).
[74] (1953) 70 RPC 221.

Register of Therapeutic Goods (***ARTG***). [75] This requirement was considered by the Deputy Commissioner of Patents in *Merck & Co., Inc v Arrow Pharmaceuticals Limited*. [76] The Deputy Commissioner concluded that the pharmaceutical substance 'forming the basis of the request for the extension of term must be included in that part of the ARTG that is publicly accessible' [77] and must 'also be included in the ARTG as an active ingredient' rather than a mere impurity.

1.6 Comparison of US, EU and Australian Extension Provisions

1.6.1 Scope of Extension Provisions

(a) Nature of Patent Claims Covered

The US extension provisions and the EU extension provisions apply to a broader class of patent claims than the corresponding Australian provisions. In particular, the US extension provisions apply to patents which claim methods of *manufacturing* or *using* a 'product', in addition to claims to the 'product' itself: 35 USC §156(a). Similarly, by virtue of the definition of 'basic patent' in Article1(c) of the SPC Regulation, applications for a SPC may be made by reference to patents which protect the active ingredient of a medicinal product, a method of producing the active ingredient of a medicinal product and an 'application' (ie. use) of a medicinal product.[78]

In contrast, the Australian extension provisions only apply to 'product claims' (claims to the pharmaceutical substance *per se*) and do not extend to 'process' or 'use' claims (methods of manufacturing and use claims respectively), except to the extent that recombinant DNA processes may be subject to patent extensions.

The significance of these differences relates to the relationship between the Australian extension provisions and the Australian springboarding provisions. In particular, the nature of claims in respect of which an extension of term can be granted also determines the nature of patents in respect of which springboarding activities may be undertaken.

(b) Nature of Substances Covered

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[75] *Patents Act* 1990 (Cth), s. 70(3) (a).
[76] [2002] APO 13 (17 April 2002).
[77] Namley, available under reg. 46(2) of the TGA Act.
[78] However, as discussed in section 1.4.1(a) above, only *authorised active ingredients* or *authorised uses* of the active ingredient receive the benefit of the protection conferred by a SPC.

In contrast to the Australian extension provisions, the US extension provisions extend to the active ingredient of new animal drugs and veterinary biological products. [79] Similarly, in the European Union, SPCs extend to substances used for treating and diagnosing disease in animals (Article 1(a) definition of 'medicinal product') and are also available in respect of patented 'plant protection products'.[80]

1.6.2 REQUIREMENTS FOR AN EXTENSION OF TERM

There are no significant differences across the relevant jurisdictions in relation to the requirements for an extension of term. For example, extensions of term across all relevant jurisdictions are contingent on the completion of a regulatory approval process. In the US, the product must have been subject to a regulatory review period before its commercial marketing or use. [81] In the EU, market authorisation for the product must have been granted. [82] Similarly, in Australia, goods containing, or consisting of, the pharmaceutical substance must be included in the Australian Register of Therapeutic Goods. [83]

Similarly, all relevant jurisdictions only allow one extension of term per patent.

1.6.3 LENGTH OF PATENT EXTENSIONS

(a) Maximum length of extension

The length of an extension of the term of a patent under the *Patents Act* 1990 (Cth) cannot exceed 5 years: section 77(2). Corresponding provisions in the US [84] and the EU (Article 13(2)) also limit the maximum length of a patent extension and market exclusivity, respectively, to 5 years.

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[79] 35 USC §156(f)(2)(B).
[80] Supplementary Protection Certificates (***SPCs***) are also available in respect of patented 'plant protection products' (as adopted in Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996). 'Plant protection products' include active substances intended to protect plants from harmful organisms, preserve plant products or destroy undesirable plants (Article 1 definition of 'plant protection products'; Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996). However, this section will focus on SPCs for 'medicinal products'.
[81] 35 USC §156(a)(4).
[82] A valid authorisation to place the product on the market as a medicinal product has been granted: SPC Regulation, Article 3(b).
[83] *Patents Act* 1990 (Cth), s. 70(3)(a).
[84] 35 USC §156(g)(6)(A).

However, the uniformity in *maximum* length of an extension does not necessarily result in uniform lengths of extension across the relevant jurisdictions, for the reasons discussed below.

(b) Different frames of reference for calculating length of extension

Different frames of reference are used to calculate extensions of patent term in the US, EU and Australia. In Australia, the patent extension period is calculated by reference to the period commencing on the '*date of the patent.'* [85] The 'date of the patent' is the date of filing the complete specification unless the regulations provide otherwise. [86] Therefore, the length of an extension is generally equal to the period between the date of filing the complete specification and the first regulatory approval date, minus 5 years.

In the European Union, the length of a SPC is calculated by reference to the period commencing on the date of *patent application*. In particular, the length of a SPC is equal to the period between the date on which the application for a 'basic patent was lodged' and the date of first market authorisation, minus 5 years. (Article 13(1), SPC Regulation). The concepts of the 'date of the patent' and date of patent lodgement, employed in Australian and EU law respectively, will hereafter be referred to as 'the filing date' of the patent.

In contrast, the patent extension period in the US is calculated by reference to the ***'regulatory review period'***. In summary, this period generally commences on the date an exemption to conduct human clinical trials is first granted under section 355 of the *Federal Food, Drug, and Cosmetic Act*. However, only that part of the 'regulatory review period' which commences after the date of patent issue can be taken into consideration in calculating the length of the extension. Therefore, US extensions of term are calculated by reference to the period commencing on the date an exemption to conduct human clinical trials is first granted **or** the date the patent is issued, *whichever is the later*.

(c) Different methods of calculating length of extension

The US extension provisions provide that the length of an extension will include 50% of time spent during clinical testing phase *plus* 100% of time spent obtaining approval under the *Federal Food, Drug and Cosmetic Act.*[87] In contrast, patent extensions in Australia and SPCs in the EU allow for 100% of the clinical testing period to be taken into consideration for the purpose of calculating the relevant extension.

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[85] *Patents Act 1990* (Cth), section 77.
[86] *Patents Act 1990* (Cth), section 65.
[87] 35 USC §156(c) and (g).

Furthermore, only that part of the 'regulatory review period' which commences after the date the patent is issued can be taken into consideration in calculating the length of the extension.

Periods during which the applicant for extension 'did not act with due diligence' are subtracted from the total term of extension in the US, [88] whereas no such corresponding provision exists in Australia or the EU.

1.6.4 MAXIMUM EFFECTIVE PATENT LIFE

The concept of 'effective patent life' refers to the period commencing on the date of first regulatory approval for a pharmaceutical product and ending on the termination date of the patent which protects that product.

There is a significant difference in maximum effective patent life across the relevant jurisdictions. A maximum effective life of 15 years is conferred by the Australian extension provisions and by SPCs in the EU, compared to a maximum effective life of 14 years in the US.

[88] 35 USC §156(c)(1).

1.7 Summary

1.7.1 TABULAR SUMMARY

Jurisdiction	Nature of Claims Covered	Natures of Substances Covered	Maximum Length of Extension	Maximum Effective Life
US	Product, process and use claims	Extends to drugs for humans and animals	5 years	14 years
Canada	N/A	N/A	0 years	N/A
European Union	Product, process and use claims	Extends to drugs for humans and animals and to 'plant protection products'	5 years	15 years
Australia	Product claims only (unless recombinant DNA process used)	Extends to drugs for humans only	5 years	15 years

2. EMPIRICAL DATA ON PATENT TERM

2.1 Introduction

This section focuses on the patent expiry dates of extended patents in the US, the EU and Australia. Firstly, this section verifies, on the basis of data provided by DITR on 20 'blockbuster drugs', whether there are any differences in patent expiry dates between jurisdictions. Secondly, empirical data is provided on patent extension lengths and filing and grant dates, both, which are potential reasons for differences in patent expiry dates. Thirdly, empirical data is provided on patent extension lengths for patents that expire in the period of 2009 and 2010 to determine if there is a change in extension length over time and whether this will effect the differences in patent expiry. Fourthly, regulatory review periods in the US, the EU and Australia are compared to determine whether the differences between jurisdictions are significant and how this effects the date of patent expiry. Finally, there is a discussion and evaluation of this empirical evidence and a discussion of the structural, practical and transitional reasons behind these differences and a prediction of the possible future trends.

2.2 Data on Patent Expiry

The empirical data to be verified is contained in DITR Attachment A to the DITR Discussion Paper of September 2002, relating to the patent expiry dates in US, UK and Australia of 20 pharmaceuticals. These substances are classified as 'blockbuster drugs', according to gross world sales in 2000. The SPC system in the EU applies to national patents and thus data on the United Kingdom is used to illustrate the situation in the EU.

DITR Attachment A provides a comparison of the date of expiry of the patent in Australia with the date of expiry of the equivalent patent in overseas jurisdictions. The concern is that if pharmaceutical patents are expiring later in Australia, Australian generics manufacturers are unable to compete in overseas markets against generics manufacturers located in jurisdictions where the patent has already expired.

The columns in DITR Attachment A specify the generic drug name, brand name, gross world sales in 2000, patent owner, Australian patent expiry date, US patent expiry date, UK patent expiry date, and the difference (in months) between the Australian patent expiry date and the US and UK expiry dates.

To assist in the verification of the data in DITR Attachment A, DITR provided a confidential list of data, ("DITR list") with information linking the generic drug name with patent numbers in the US, UK and Australia.

Table 1 (see below) contains a summary of the verification results and notes the data that is confirmed and the data that was found to be invalid.

2.2.1 METHODOLOGY

(a) Overview

The general methodology used to verify the expiry dates in DITR Attachment A was to locate the patent number in the DITR list (by reference to the generic drug name) and use that patent number to search the relevant patent office data base. The patent expiry date was then compared with the data provided in DITR Attachment A. If the date was the same as the date in DITR Attachment A, the data was confirmed (and noted in Table 1 as "confirmed"). If the date differed from the date in DITR Attachment A, this was noted in Table 1 as "invalid" and the correct figure was noted.

The number of months that the US and UK patents expire before the Australian patent was calculated using the confirmed data (and the new data) in order to verify the comparative columns in DITR Attachment A. The brand names and patent owners in DITR Attachment A were not verified.

(b) DITR List

There were a number of inconsistencies with the data in the DITR list and DITR Attachment A. The DITR list did not contain some of the drugs, or contained a drug with a very similar (but not identical) spelling, or contained 2 versions of the drug in question. Thus, there are 10 patent expiry dates (out of a total of 44 patent expiry dates) that could not be confirmed. Inconsistencies and problems in obtaining data are noted briefly in Table 1 and explained fully in Appendix 1.

(c) United States

To validate the data on the patent expiry dates in the United States, the Patents Assistance Centre on the USPTO website was used.[89] This service provides a list of US patents that have been extended (by reference to their brand names), and their expiry dates.

There are two drugs from DITR Attachment A that are not on the US Patents Assistance Centre list of extended US patents.[90] Consequently, their patent expiry dates could not be confirmed.

(d) United Kingdom

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[89] United States Patent and Trademark Office, Patent Terms Extended Under 35 USC § 156 http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.html.

To validate the data on the patent expiry dates in the United Kingdom, the search engines of the Supplementary Protection Certificate Service were used.[91] A prefix of either EP or GB was required before the patent number.

The generic drug "fosinopril" elicited 2 matches in the Supplementary Protection Certificate Service for the same patent number. The patent expiry dates for one of the claims correlated with the data in DITR Attachment A and thus this version was used to verify the data.

No records were found in the Supplementary Protection Certificate Service for the patent number for the drug "olanzopine". The patent expiry date in the UK for this drug has not been confirmed.

(e) Australia

To validate the data on the Australian patent expiry dates, the patent administration system in the patent mainframe database provided by IP Australia was searched using the Australian patent number.[92] This search generates detailed information on the patent, including the patent expiry date.

All the Australian patent expiry dates in DITR Attachment A were confirmed using this methodology.

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[90] These drugs are disodium pamidronate and olanzapine.
[91] United Kingdom Patent Office, Supplementary Protection Certification Search, http://webdb2.patent.gov.uk/rspc/Search.asp.
[92] IP Australia, Patent Administration System, http://www.ipaustralia.gov.au/patents/P_data.htm.

2.2.2 EMPIRICAL DATA ON PATENT EXPIRY DATES - TABLE 1

	Generic Drug Name	Brand Name	Australian Patent Expiry	US Patent Expiry	UK Patent Expiry	Months US expires before Australia	Months UK expires before Australia
1	**simvastatin**	Zocor	Jul-05 ***Confirmed***	Dec-05 ***Confirmed***	May-03 ***Confirmed***	- 5 ***Confirmed***	26 ***Confirmed***
2	**atorvastatin** *(DITR list: atovasatin x 2)*	Lipitor	May-12 **Confirmed** *(for patent number 601981)*	Sept-09 ***Confirmed*** *(for patent number 4681893)*	Nov-11 ***Confirmed*** *(for patent number 247633)*	32 ***Confirmed***	6 ***Confirmed***
3	**amlodipine**	Norvasc	Feb-08 ***Confirmed***	July-06 ***Confirmed***	Mar-04 ***Confirmed***	19 ***Confirmed***	36 ***Invalid * 47***
4	**lansoprazole**	Prevacid/ Zoton	Sept-09 ***Confirmed***	May-09 ***Confirmed***	Dec-05 ***Confirmed***	4 ***Confirmed***	45 ***Confirmed***
5	**loratadine**	Claritin/ Claratyne	Jun-06 ***Confirmed***	Jun-02 ***Confirmed***	Nov-02 ***Confirmed***	48 ***Confirmed***	43 ***Confirmed***
6	**olanzapine**	Zyprexa	Mar-12 ***Confirmed***	Apr-11	Sept-11	11	13
7	**sertraline**	Zoloft	Oct-05 ***Confirmed***	Dec-05 ***Confirmed***	Oct-05 ***Confirmed***	-2 ***Confirmed***	0 ***Confirmed***
8	**pravastatin**	Pravachol	Jun-06 ***Confirmed***	Oct-05 ***Confirmed***	Aug-04 ***Confirmed***	8 ***Confirmed***	22 ***Confirmed***
9	**amoxicillin + potassium clavulanate** *(not found in DITR list)*	Augmentin		Dec-02			
			No patent numbers available in DITR list – patent expiry date unconfirmed				
10	**ciprofloxacin**	Ciproxin	Dec-02 ***Confirmed***	Dec-06 ***Confirmed***	Jul-02 ***Invalid Jan-02***	- 48 ***Confirmed***	- 5 ***Invalid 11***

	Generic Drug Name	Brand Name	Australian Patent Expiry	US Patent Expiry	UK Patent Expiry	Months US expires before Australia	Months UK expires before Australia
11	**enalapril** *(DITR list: enalapril (plus) and enalapril maleate?)*	Renitec	Apr-01 **Confirmed** *(for enalapril maleate)*	Dec-01 ***Confirmed*** *(for enalapril maleate)*	Dec-02 ***Confirmed*** *(for enalapril maleate)*	- 8 ***Confirmed***	- 20 ***Confirmed***
12	**fluticasone** *(DITR list: fluticasone propionate)*	Flovent/ Flixotide	Feb-06 ***Confirmed***	Nov-03 ***Confirmed***	Mar-05 ***Confirmed***	27 ***Confirmed***	11 ***Confirmed***
13	**cetirizine** *(DITR list: cetrizine)*	Zyrtec	Feb-07 ***Confirmed***	Jun-07 ***Confirmed***	Feb-02 ***Invalid Feb-07***	- 4 ***Confirmed***	60 ***Invalid * 0***
14	**lisinopril** *(not found in DITR list)*	Prinivil	Dec-04	Dec-01	Oct-02	36	26
			No patent numbers available in DITR list – patent expiry dates unconfirmed				
15	**famotidine**	Pepcid	Jul-03 ***Confirmed***	Oct-00 ***Confirmed***	Jul-00 ***Confirmed***	36 ***Invalid*33***	36 ***Confirmed***
16	**disodium pamidronate** *(DITR list: pamidronate)*	Aredia	Aug-10 ***Confirmed***	Jul-05		61	
17	**quinapril**	Accupril	Sept-06 ***Confirmed***	Oct-02 ***Confirmed***	Apr-04 ***Confirmed***	47 ***Confirmed***	29 ***Confirmed***
18	**lovastatin** *(not found in DITR list)*	Mevacor	Jun-05	Jun-01		48	
			No patent numbers available in DITR list – patent expiry dates unconfirmed				
19	**fosinopril**	Monopril	Nov-06 ***Confirmed***	Dec-02 ***Confirmed***	Nov-06 ***Confirmed*** *(2 matches)*	47 ***Confirmed***	0 ***Confirmed***
20	**nefazodone**	Serzone	Mar-07 ***Confirmed***	Mar-03 ***Confirmed***	Mar-07 ***Confirmed***	48 ***Confirmed***	0 ***Confirmed***
DITR Attachment A Data		**Percentage of patents expiring in the US/UK *before* AU**				***74%***	***71%***
Verified Data		**Percentage of patents expiring in the US/UK *before* AU**				***66%***	***66%***
DITR Attachment A Data		**Average months expiry *earlier* in the US/UK than AU**				***19 months***	***19 months***
Verified Data		**Average months expiry *earlier* in the US/UK than AU**				***16 months***	***17 months***

2.2.3 DIFFERENCE IN EXPIRY DATES

The verification of data is complete on 34 out of the total of 44 patent expiry dates. There are 10 patent expiry dates that could not be confirmed.

(a) United States v. Australia

On average, 74% of the US patents expired earlier than the equivalent Australian patents according to the data in DITR Attachment A.[93] In relation to the data that was able to be verified (see Table 1), 66% of the US patents expired earlier than the equivalent Australian patents.[94] Thus, there was only a small difference between the verified data and the data contained in DITR Attachment A in relation to the proportion of US patents that expired earlier than their Australian equivalents.

The average number of months that US patents expire before Australian patents was 19 months according to the data in DITR Attachment A. In relation to the verified data, the average number of months that US patents expire before the equivalent Australian patent is 16 months. Thus, there is a difference of 3 months between the verified data and the data contained in DITR Attachment A in relation to average period of earlier expiry in the United States.

(b) United Kingdom v. Australia

On average, 71% of UK patents expired earlier than the equivalent Australian patents according to the data in DITR Attachment A.[95] In relation to the data that was able to be verified (see Table 1), 66% of UK patents expired earlier than the equivalent Australian patents.[96] Thus, there was a only a small difference between the verified data and the data contained in DITR Attachment A in relation to the proportion of UK patents that expire earlier than their Australian equivalents.

The average number of months that UK patents expire before Australian patents was 19 months according to the data in DITR Attachment A. In relation to the verified data, the average number of months that UK patents expire before Australian patents is 17 months. Thus, there is a difference of 2 months between the verified data and the data contained in DITR Attachment A in relation to average period of earlier expiry in the UK.

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[93] According to the data in Attachment A, out of 19 patents, 14 of these patents expired earlier in the US than Australia.
[94] According to the verified data, out of the 15 patents verified, 10 of these patents expired earlier in the US than Australia.
[95] According to the data in Attachment A, out of 17 patents, 12 of these patents expired earlier in the UK than Australia.
[96] According to the verified data, out of the 15 patents verified, 10 of these patents expired earlier in the UK than Australia.

2.2.4 CONCLUSIONS

Although the data verification could not be completed, the differences between the data in DITR Attachment A and the correct data are not particularly large. Thus, it is not expected that that the true values of the data that could not be verified would differ significantly from the values given in DITR Attachment A.

The confirmed data shows that *Australian patents expire later* than both the US and UK patents in approximately two-thirds of cases, for an average of approximately a year and a half.

2.3 Data on Patent Extension

A possible reason for patents in Australia expiring later than in the US and the UK, is the length of patent extension. Thus, it is interesting to examine empirical data on the average length of patent extensions in the US, the UK and Australia for equivalent patents.

2.3.1 METHODOLOGY

The data on the average length of extension periods in Australia, the UK and the US was generated in different ways for each jurisdiction. The drugs olanzopine and pamidronate were excluded from the table as only the extension length in Australia could be found.[97]

(a) United States

In the United States, the Patents Assistance Centre (on the USPTO website) provides a list of US patents that have been extended.[98] This service provides the length of the extension period for each drug.

(b) United Kingdom

In the UK, the Supplementary Protection Certificate Service provides data on the length of the extension term for some patents. The extension length of the other UK patents was generated using the search engines of the Patents Status Enquiry system on the UK Patent Office website.[99]

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[97] The length of the extension period for olanzapine in Australia was 318 days and for pamidronate it was 1,826 days.
[98] United States Patent and Trademark Office, Patent Terms Extended Under 35 USC § 156, http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.html.
[99] UK Patents Office, Patents Status Enquiry http://webdb4.patent.gov.uk/patents/index.html.

(c)Australia

In Australia, the Patent Enquiry System provides data on the complete filing date and the final expiry date of a patent. The term of protection under Australian patent law is 20 years (from the date of complete filing), thus the period of extension can be determined by calculating the difference between the filing date and the expiry date, and subtracting 20 years.[100]

Table 2 sets out empirical data on the length of patent extension in the three jurisdictions.

[100] A date calculator was used to calculate the differences between dates. See http://dan.drydog.com/datecalculator.html.

2.3.2 EMPIRICAL DATA ON LENGTH OF PATENT EXTENSION - TABLE 2

	Generic Drug Name	Brand Name	Australian Patent Extension Length	US Patent Extension Length	UK Patent Extension Length	Difference Between Australia and US	Difference Between Australia and UK
1	**simvastatin**	Zocor	1,638 days	1, 704 days	822 days	-66 days (US)	+816 (AU)
2	**atorvastatin** *(DITR list: atovasatin x 2)*	Lipitor	1, 827 days	1, 213 days	1, 622 days	+614 days (AU)	+205 (AU)
3	**amlodipine**	Norvasc	1, 814 days	1, 252 days	365 days	+562 days (AU)	+1449 (AU)
4	**lansoprazole**	Prevacid/ Zoton	1, 505 days	1, 381 days	132 days	+124 days (AU)	+1373 (AU)
5	**loratadine**	Claritin/ Claratyne	1, 826 days	730 days	537 days	+1096 days (AU)	+1289 (AU)
7	**sertraline**	Zoloft	1, 826 days	1, 228 days	1, 825 days	+598 days (AU)	+1 (AU)
8	**pravastatin**	Pravachol	1, 826 days	1, 598 days	1, 158 days	+228 days (AU)	+668 days (AU)
9	**amoxicillin + potassium clavulanate** *(not found in DITR list)*	Augmentin	***No patent numbers available in DITR list – Patent extension length unconfirmed***				
10	**ciprofloxacin**	Ciproxin	478 days	3 years (1096 days)	161 days	- 618 days (US)	+317 (AU)

	Generic Drug Name	Brand Name	Australian Patent Extension Length	US Patent Extension Length	UK Patent Extension Length	Difference Between Australia and US	Difference Between Australia and UK
11	**enalapril** *(DITR list: enalapril (plus) and enalapril maleate?)*	Renitec	499 days	676 days	1, 114 days	- 177 days (US)	+ 615 (AU)
12	**fluticasone** *(DITR list: fluticasone propionate)*	Flovent/ Flixotide	1, 826 days	1, 004 days	1, 483 days	+822 days (AU)	+ 343 days (AU)
13	**cetirizine** *(DITR list: cetrizine)*	Zyrtec	1, 826 days	1, 826 days	1, 826 days	0	0
14	**lisinopril** *(not found in DITR list)*	Prinivil	***No patent numbers available in DITR list – Patent extension length unconfirmed***				
15	**famotidine**	Pepcid	1, 219 days	293 days	202 days	+926 days (AU)	+1,017 days (AU)
17	**quinapril**	Accupril	225 days	2 years (730 days)	924 days	-505 days (US)	- 699 days (UK)
18	**lovastatin** *(not found in DITR list)*	Mevacor	***No patent numbers available in DITR list – Patent extension length unconfirmed***				
19	**fosinopril**	Monopril	1, 826 days	2 years (730 days)	1, 825 days	+1096 days (AU)	+1 day (AU)
20	**nefazodone**	Serzone	1, 826 days	2 years (730 days)	1,824 days	+1096 days (AU)	+ 2 days (AU)
Average			**1, 465 days**	**1, 079 days**	**1, 055 days**	**+386 days (AU)**	**+ 493 days (AU)**
Average (without Pipeline Drugs)			**1, 480 days**	**1, 206 days**	**974 days**	**+274 days (AU)**	**+618 days (AU)**

2.3.3 CONCLUSIONS

Although it was not possible to verify all the data on the length of patent extension periods, it seems that the *extension periods granted in Australia are longer* than those granted in the US. In particular, approximately 67% of patents have a length of extension period that is greater in Australia than in the US. The average extension length in Australia was 1,465 days compared to 1, 079 days in the US and 1, 055 days in the UK. For all the verified patents, the average number of days by which the Australian extension period exceeded the US extension period was 386 days (approximately 1 year).

The data was reanalysed by taking out the pipeline drugs, to see the effect on the extension length across the three jurisdictions.[101] This did not dramatically decrease the *percentage of patents* with an extension period greater in Australia than in the US (reduction from 67% to 64%). However, the extraction of the pipeline drugs increased the average length of the US extension period from 1, 079 to 1, 206 days. This resulted in the gap between Australia and the US extension periods closing (from 386 days to 274 days). The gap between Australia and the UK extension periods widened (from 493 days to 618 days).

2.4 Data on the Change in the Extension Length Over Time

It is possible that the length of extension periods is changing over time. To analyse this hypothesis, empirical data was collected on the length of extension periods for eight patents that expire in the US in the period 2009 to 2010.

2.4.1 METHODOLOGY

Eight drugs were chosen from the US Patents Assistance Centre list of extended patents. These drugs were chosen by locating the latest expiring drugs on the US list and checking whether these drugs were also on the DITR list (and thus the Australian patent number would be known). The eight drugs that expired the latest and for which Australian patent numbers could be found had expiry dates ranging from May 2009 to November 2010. Because the choice of drugs was by expiry date, the type of pharmaceutical product and the success of the drug (in terms of world sales) was random.

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[101] See section 1.2.1(c) for a discussion of pipeline drugs. The pipeline drugs were assumed to be loratadine, quinapril, fosinopril and nefazodone.

The length of extension in the US is provided on the US Patents Assistance Centre list of extended patents.[102]

The corresponding Australian patent number was obtained from the DITR list using the US patent number. The Patent Administration System was used to determine the length of the extension period.[103]

Table 3 sets out empirical data on the length of patent extension in the three jurisdictions, where the patents will expire in the US in 2009/2010.

2.4.2 DATA ON THE CHANGE IN PATENT EXTENSION LENGTH OVER TIME - TABLE 3

No.	Generic Name	US Expiry	AU Expiry	US Extension Length	AU Extension Length	Difference between US and AU
1	Cidofovir	Jun-10	Jul-12	305 days	1, 827 days	1, 522 days (AU)
2	Docetaxol	Dec-09	Feb-11	903 days	1, 302 days	399 days (AU)
3	Donapezil	Nov-10	Mar-13	888 days	1, 742 days	854 days (AU)
4	Mycophenolate	May-09	Jan-12	824 days	1, 524 days	700 days (AU)
5	Ranitidine Bismuth	Aug-10	Feb-12	387 days	956 days	569 days (AU)
6	Ropivacaine	Sep-10	Jan-11	1, 400 days	1, 510 days	110 days (AU)
7	Topotecan	May-10	Mar-12	786 days	1, 198 days	412 days (AU)
8	Zafirlukast	Sep-10	Apr-11	1, 496 days	1, 826 days	330 days (AU)

[102] United States Patent and Trademark Office, Patent Terms Extended Under 35 USC § 156 http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.html.
[103] IP Australia, Patent Administration System, http://www.ipaustralia.gov.au/patents/P_data.htm.

	Average			**874 days**	**1, 486 days**	**612 days**

The length of patent extensions in Table 2 can be compared with a selection of eight drugs[104] from Table 1 that had US expiry dates ranging from 2000 to 2006 (excluding pipeline drugs). These eight drugs have an average extension length in Australia of 1309 days and in the US of 1106 days, resulting in an average difference in extension length in Australia compared to the US of 203 days.

2.4.3 CONCLUSIONS

Table 3 shows that the length of Australian patent extensions seems to be slightly *increasing* over time (from 1, 309 days to 1, 486 days) while that the length of the US patent extensions seems to be *decreasing* over time (from 1106 days to 874 days). Accordingly, the gap between the two jurisdictions seems to be *widening* (from 203 to 612 days), largely due to a decrease in the length of extension period in the US.

2.5 Filing and Grant Dates

The *Paris Convention* provides that any person, who has filed a patent application in one of the member countries has a 'right of priority' to file an application in any other member countries within 12 months from the date of first filing. [105] According to this principle, a patent applicant may claim as a priority date the filing date of an earlier patent application. Thus, after the initial filing in one country, an innovative manufacturer has a one year "window" in which to file in other countries where they wish to obtain patent protection whilst still claiming the priority date of the first application. Since the company does not have to file in every country at the same time, filing dates can differ between jurisdictions.

In the United States, the date that signifies the start of the calculation of the period of extension is either (1) the date that the applicant is granted an exemption to conduct the first clinical trial ('exemption date') or (2) the grant date, whichever is later. Thus, if the grant date occurs after the exemption date, then the extension period is calculated by reference to the regulatory review period after the grant date. In the United Kingdom and Australia, however, the date of *filing* is significant as it designates the start of the calculation of the period of extension.

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[104] These drugs were simvastatin, amlodipine, sertraline, pravastatin, ciprofloxacin, enalapril maleate, fluticasone propionate and famotidine.
[105] The Paris Convention for the Protection of Industrial Property, Art. 4.

2.5.1 METHODOLOGY

Different methodologies were used to determine the filing and grant dates of patents in the US, the UK and Australia.

(a) United States

To determine the patent filing and grant dates in the US, the patent database (on the USPTO website) was searched via patent number.

(b) United Kingdom

In the UK, the Supplementary Protection Certificate Service and search engines of the Patents Status Enquiry system on the UK Patent Office website were used to determine the patent filing dates.[106]

(c) Australia

To determine the patent filing dates in Australia, the patent mainframe database provided by IP Australia was searched using the patent numbers.[107] This search generates detailed information on the patent, including the filing date of the patent.

(d) Table 4

Table 4 sets out examine empirical data on the filing dates in the US, the UK and Australia, and the grant dates in the US, in order to determine how this variable effects the patent expiry dates in these three countries. Data on the date of exemption for clinical trials (as well as data on the grant date) in the US would be useful as both dates interact to designate the start of the calculation of the period of extension. However, we were unable to obtain evidence of the date of exemption of these drugs in the US, thus Table 3 only includes US grant dates for the patents.

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[106] See UK Patents Office, Patents Status Enquiry http://webdb4.patent.gov.uk/patents/index.html.
[107] IP Australia, Patent Administration System, http://www.ipaustralia.gov.au/patents/P_data.htm.

2.5.2 EMPIRICAL DATA ON FILING AND GRANT DATES - TABLE 4

	Generic Drug Name	Brand Name	AU Filing Date	US Filing Date	US Grant Date	UK Filing Date	Months AU files before US files	Months AU files before US grants	Months AU files before UK files
1	**simvastatin**	Zocor	Jan-81	Dec-80	Apr-84	Feb-81	- 1 (US)	39 (AU)	1 (AU)
2	**atorvastatin**	Lipitor	May-87			May-87			0
3	**amlodipine**	Norvasc	Mar-83	Feb-84	Feb-86	Mar-83	11 (AU)	35 (AU)	0
4	**lansoprazole**	Prevacid/	Aug-85	Jul-85	Dec-86	Jul-85	-1 (US)	- 16 (US)	- 1 (UK)
5	**loratadine**	Claritin/Claratyne	Jun-81	Jun-80	Aug-81	Jun-81	- 12 (US)	2 (AU)	0
6	**olanzapine**	Zyprexa	Apr-91						
7	**sertraline**	Zoloft	Oct-80	Nov-79	Aug-85	Oct-80	- 11 (US)	58 (AU)	0
8	**pravastatin**	Pravachol	Jun-81			Jun-81			0
9	**amoxicillin + potassium clavulanate**	Augmentin							
10	**Ciprofloxacin**	Ciproxin	Aug-81	May-84	Jun-87	Aug-81	33 (AU)	58 (AU)	0

	Generic Drug Name	Brand Name	AU Filing Date	US Filing Date	US Grant Date	UK Filing Date	Months AU files before US files	Months AU files before US grants	Months AU files before UK files
11	**enalapril maleate**	Renitec	Dec-79			Dec-79			0
12	**fluticasone propionate**	Flovent/Flixotide	Feb-81	Feb-81	Jun-82	Feb-81	0	16 (AU)	0
13	**cetrizine**	Zyrtec	Feb-82	May-83	Jun-85	Feb-82	15 (AU)	40 (AU)	0
14	**lisinopril**	Prinivil		Feb-81	Feb-83				
15	**famotidine**	Pepcid	Feb-80	Dec-79	Aug-81	Dec-79	- 2 (US)	18 (AU)	- 2 (UK)
16	**disodium pamidronate**	Aredia	Aug-85	Sept-86	Dec-87		12 (AU)	28 (AU)	
17	**quinapril**	Accupril	Feb-86			Oct-81			- 52 (UK)
18	**lovastatin**	Mevacor		Jun-79	Nov 1980				
19	**fosinopril**	Monopril	Nov-81	Dec-80	Jun-82	Nov-81	- 11 (US)	7 (AU)	0
20	**nefazodone**	Serzone	Mar-82	Mar-81	Jul-82	Mar-82	- 12 (US)	4 (AU)	0
			Average Difference of Months				**2 (AU)**	**24 (AU)**	**- 4 (UK)**

2.5.3 SUMMARY OF DIFFERENCES IN FILING AND GRANT DATES - TABLE 5

	US Filing	US Grant	UK Filing
AU Files Before			
% of Time	**33%**	**92%**	**6%**
Average number of months	**18 months**	**28 months**	**1 month**
AU Files at Same Time as			
% of Time	**8%**	**0%**	**74%**
AU Files Later than			
% of Time	**58%**	**8%**	**20%**
Average number of months	**7 months**	**16 months**	**18 months**

2.5.4 CONCLUSIONS

Across the blockbuster drugs surveyed, although there were variations for individual drugs, Table 4 shows that there were not significant differences in the *average filing dates* between the US, UK and Australia. Table 4 shows that the average difference between Australia and the US filing dates was 2 months, and that the average difference between Australia and the UK filing dates was 4 months.

Table 5 is useful as it breaks down the data to show how often the Australian patent is filed before the US and the UK patents are filed; how often the Australian patent is filed before the US patent is granted; and by how many months in each case, on average. Table 5 shows that the differences between timing of filing in Australia and the UK are minimal; patents are filed in Australia and the UK at the same time in the majority of cases (74%). The UK files before Australia in 20% of cases (by an average of 18 months) and Australia files before the UK in 6% of cases (by an average of one month).

While Table 4 showed that the average difference between Australia and the US filing dates is 1 month, Table 5 shows that in 58% of cases, the US patent is filed before the Australian patent is filed (by an average of 7 months). This is significant as it shifts the frame of reference by which the standard 20 year patent term is calculated.

On average, there were significant differences between the date of filing in Australia and the date of grant in the US. Table 5 shows that it is a common occurrence (92% of cases) for the Australian patent to be filed before the US patent is granted. The average difference between the Australian filing and the US granting of a patent was 28 months. Since these dates mark the outer limits of the calculation of patent extension length, this is a significant difference and may account for 1 to 2 years of the differences in patent expiry dates.

2.6 Data on the Period of Regulatory Review

The period of regulatory review is important as it cuts into the maximum effective life of the patent and is relevant for determining the length of patent extension. In the US, the EU and Australia, all of the regulatory review period is used in the calculation of the extension period. A comparison of the target goals set by the regulatory bodies in these jurisdictions and data on the actual time taken for regulatory review is useful for the discussion of the reasons for differences in patent expiry dates.

2.6.1 UNITED STATES

The *Prescription Drug User Fee Act of 1992 (PDUFA)* as reauthorised and amended by the *Food and Drug Administration Modernization Act of 1997* was intended to streamline the FDA approval process and decrease drug application review time. The Act set performance indicators in order reduce the time to marketing authorisation. The performance goal for the FDA review of a standard new drug application (NDA) is *10-12 months*.

The average regulatory review period for "new molecular entities"[108] is slowly increasing; in 2001 it was 18.8 months, [109] compared with 15.6 months in 2000,[110] and 12 months in 1999.[111] This average time includes FDA review time for the first NDA submission, plus any subsequent time during which the pharmaceutical company addresses deficiencies in the NDA and resubmits the application, plus subsequent FDA review time. The Centre for Drug Evaluation and Research states that the reason why the average length of regulatory review has increased is due to a smaller percentage of priority applications[112] and the high number of applications with prolonged regulatory histories, rather than the features of the FDA procedure itself.[113]

Clinical Trials

The FDA also assists industry to design effective clinical trials, and since 1992 the total drug development time for new molecular entities has dropped 18%, from 7.2

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[108] A medication containing an active substance that has never before been approved for marketing in any form in the United States.
[109]American Association of Pharmaceutical Scientists http://www.aaps.org/news/articles/2002/031502pharmreport.asp.
[110] Centre for Drug Evaluation and Research, 'FDA's Drug Review and Approval Times', http://www.fda.gov/cder/reports/reviewtimes/default.htm
[111] Centre for Drug Evaluation and Research, 'Report to the Nation: 1999' (1999) http://www.fda.gov/cder/reports/rtn99-1.htm#NewDrugReview.
[112] Priority New Drug Applications cover products which are determined to provide a significant therapeutic or public health advance and have a 6 month FDA review performance goal.
[113] Centre for Drug Evaluation and Research, 'FDA's Drug Review and Approval Times', http://www.fda.gov/cder/reports/reviewtimes/default.htm.

years (in 1993-1995) to 5.9 years (in 1996-1998).[114] In 1997, the average time between the exemption date and submission of the NDA to the FDA was five years.[115]

2.6.2 EUROPEAN UNION

In the European Union, there are two ways of approving new drugs; (1) a decentralised procedure and (2) a centralised procedure. The decentralised procedure is based on the principle of reciprocity such that if a new drug is approved in one member state, then it is taken to be approved in all member states. The centralised procedure is provided by the European Agency for the Evaluation of Medicinal Products (EMEA). The EMEA allocates 210-days for scientific evaluation and 90 days for consideration of the opinion by the European Commission. The effect is a single-market authorization that applies to the whole European Union. The standard target regulatory review time is *300 days*. [116]

2.6.3 AUSTRALIA

Statutory timeframes exist for the processing of prescription medicines applications for entry on the Australian Register of Therapeutic Goods. The Therapeutic Goods Regulations allow *255 working days* to complete an approval for a new chemical entity.[117]

The average time taken by the TGA to evaluate medicines for inclusion on the Register of Therapeutic Drugs has reduced from 702 working days for evaluations completed in 1990 to 106 working days (equivalent to 258 calendar days) for evaluations completed in 1995.[118]

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[114] Tufts Centre for the Study of Drug Development, 'Clinical Development Times for New Drugs Drop 18%, Reversing 12 T ear Trend' (July 1999) http://csdd.tufts.edu/InfoServices/ImpactReportPDFs/impactReportJuly1999.pdf.

[115] Centre for Drug Evaluation and Research, 'FDA's Drug Review and Approval Times', http://www.fda.gov/cder/reports/reviewtimes/default.htm.

[116] Australian National Audit Office 1996, Drug Evaluation by the Therapeutic Goods Administration: Department of Health and Family Services, Audit Report No. 8 of 1996-97, AGPS, Canberra.

[117] This consists of a maximum of 135 days for evaluation by clinical, toxicology and pharmaceutical staff; 80 days for Australian Drug Evaluation Committee; and
40 days for the TGA delegate's decision. The count of elapsed days stops whenever TGA requires additional information from a pharmaceutical company. Australian National Audit Office 1996, Drug Evaluation by the Therapeutic Goods Administration: Department of Health and Family Services, Audit Report No. 8 of 1996-97, AGPS, Canberra.

[118] Australian National Audit Office 1996, Drug Evaluation by the Therapeutic Goods Administration: Department of Health and Family Services, Audit Report No. 8 of 1996-97, AGPS, Canberra. There was a follow-up audit in 2000 to review the extent to which TGA had implemented recommendations made by the ANAO in 1996 on the efficiency, effectiveness and accountability of TGA's evaluation and approval of prescription drugs for public use. See Drug Evaluation by the Therapeutic Goods at http://www.anao.gov.au/WebSite.nsf/Publications/4A256AE90015F69B4A25695400115A70.

In Australia, pharmacoeconomic data (costs, outcomes and cost-outcome ratios) are required for purposes of regulatory review in addition to those of efficacy, safety and quality. This has been described by one commentator as a "fourth hurdle". [119] The requirement of pharmacoeconomics may increase the regulatory time before a new drug reaches the market and thus decrease the maximum effective patent life of such drugs.

2.6.4 COMPARISON

The Centre for Medicines Research has conducted a comparative study of the regulatory approval times for new molecular entities in major markets.[120] The Centre has identified the key factors influencing the approval periods as being the quality of the dossier, the ability of the company to respond quickly to deficiencies, and the regulatory authority's ability to manage the review effectively. The study showed that in the period of 1995 to 1999, the regulatory approval times in major world markets (including the US, EU and Australia) are decreasing.

In 1999, the median regulatory approval time in the US was approximately 1 year, in the EU Centralised Procedure it was about 1.3 years, in the European Mutual Recognition Procedure it was 1.8 years,[121] and in Australia was approximately 1.5 years.[122] The study found that while regulatory review periods in the US and the EU were similar, the majority of applications were not submitted simultaneously to both markets.

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[119] InPharm, 'Regulatory Affairs; Paths to Approval', (Reuters: February 1999) http://www.inpharm.com/intelligence/rbi030299.html.
[120] Centre for Medicines Research, 'R & D Briefing: Profile of Performance (3) Review Times – Is There Still Room for Improvement?' 2001, http://www.cmr.org/pdfs/rd31.pdf.
[121] The centralised body, EMEA is in direct competition with the regulation provided by national agencies, which may contribute to its efficiency in comparison to the Mutual Recognition Procedure. See H. Miller 'Challenging the FDA' (Financial Times, July 7, 1998) see http://www-hoover.stanford.edu/publications/digest/991/miller.html.
[122] Centre for Medicines Research, 'R & D Briefing: Profile of Performance (3) Review Times – Is There Still Room for Improvement?' 2001, http://www.cmr.org/pdfs/rd31.pdf.

2.7 Reasons for Differences in Expiry Dates between AU and US Patents

2.7.1 INTRODUCTION

Patents conferred in Australia may expire later than corresponding patents in the US and EU for reasons including: differences in the structure of the extension provisions across the relevant jurisdictions (***structural reasons***); practical differences in the length of regulatory approval periods and clinical testing phases (***practical reasons***) and reasons arising out of transitional provisions in the relevant Acts (***transitional reasons***).

2.7.2 STRUCTURAL REASONS FOR CURRENT DIFFERENCES IN EXPIRY DATES

This section compares structural reasons for current differences in expiry dates between the US and Australia. (As between the EU and Australia, there are no structural reasons for differences in expiry dates.)

(i) Different Frames of Reference for calculating length of extension

Different frames of reference are used to calculate extensions of patent term in the US, EU and Australia.

In Australia, the patent extension period is calculated by reference to the period commencing on the 'date of the patent' (section 77 of the *Patents Act 1990* (Cth). The 'date of the patent' is generally the date of filing the complete specification. In the European Union, the length of a SPC is calculated by reference to the period commencing on the date on which the application for a 'basic patent was lodged' (Article 13(1), SPC Regulation).

In contrast, the patent extension period in the US is calculated by reference to the 'regulatory review period'. This period generally commences on the date an exemption to conduct human clinical trials is first granted under section 355 of the *Federal Food, Drug, and Cosmetic Act*. However, only that part of the 'regulatory review period' which commences after the date of patent grant can be taken into consideration in calculating the length of the extension. Therefore, US extensions of term are calculated by reference to the period commencing on the date an exemption to conduct human clinical trials is first granted **or** the date the patent is granted, *whichever is the later*.

The significance of these different 'commencement dates' can be discerned from Table 3 in section 2.4.2 above. The data in Table 3 confirms that US patents are generally granted after the complete specification is filed in Australia. In particular,

the US patents in DITR Attachment A were granted (on average) 24 months after the date of filing of the complete specification in Australia. Therefore, according to the data in Table 3 in section 2.4.2 above, the period of time which can be taken into consideration for the purposes of calculating US extensions of term is (on average) at least 2 years less than the corresponding period in Australia.

(ii) Extension of Term Formulae

Figure 4 below provides a chronological illustration of the process of regulatory approval for pharmaceutical products. Periods 'C' and 'D' refer to relevant stages in the regulatory approval process. Periods 'A', 'B', 'E' and 'F' are relevant to the process of calculating the length of extensions of term.

Figure 4

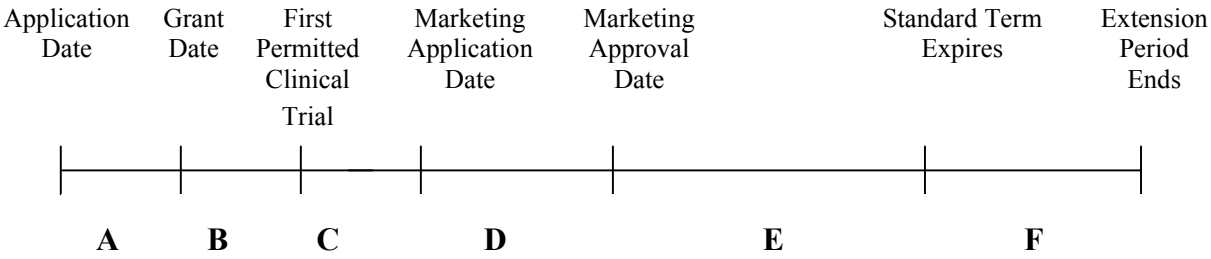


Table 6 below summarises the formulae for calculating the length of extension periods across the relevant jurisdictions, employing the symbols referred to in Figure 4 above. The formulae below reflect the fact the US extension provisions do not allow A, B and C/2 to be taken into consideration when calculating the length of extension, whereas the Australian provisions allow such periods to be taken into account but then subtract 5 years from the resulting total.

Table 6: Extension Formulae

Jurisdiction	**Extension Formula** 'F' refers to the length of the extension period	**Maximum Length of Extension**	**Maximum Effective Life**
US	F = C/2 + D - periods where patentee did not act with due diligence	F ≤ 5	E + F ≤ 14
EU	F = A + B + C + D – 5	F ≤ 5	E + F ≤ 15
AU	F = A + B + C + D – 5	F ≤ 5	E + F ≤ 15

(iii) Periods which can be taken into consideration for the purposes of calculating extensions of term

The emboldened black line in Figures 5, 6 and 7 below represent the period of time which can be *taken into consideration* for the purposes of calculating the length of the extension period in each jurisdiction. The emboldened black line is **not** synonymous with the length of the relevant extension period; rather it illustrates the periods of time which can be *taken into consideration* for the purpose of calculating such periods.

Figure 5: United States

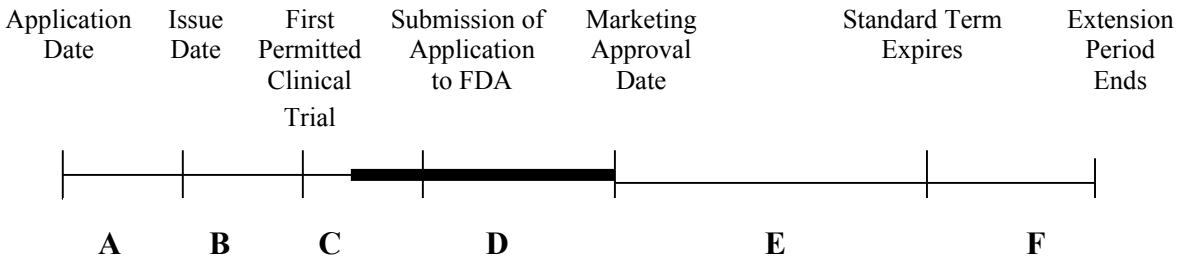


Figure 6: Australia

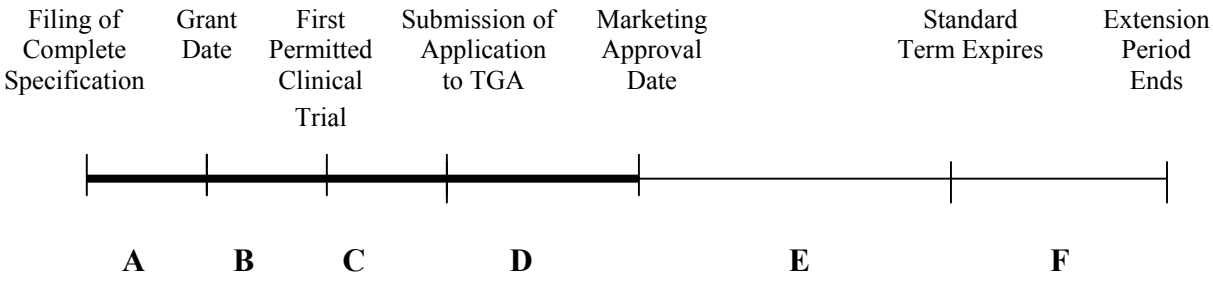
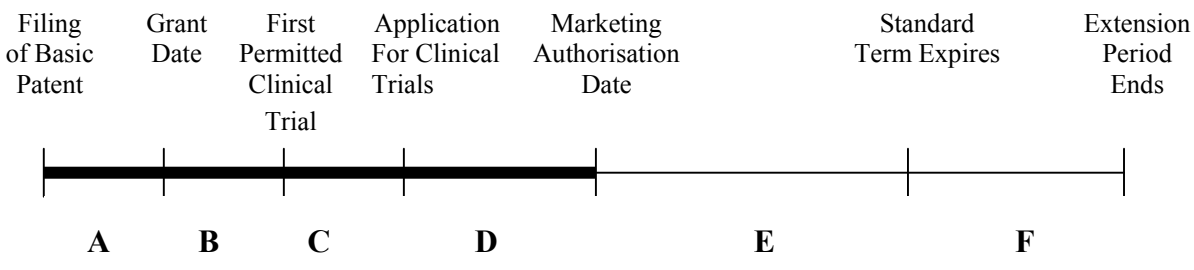


Figure 7: European Union



(iv) Formula for calculating the difference between US and AU extension periods

The formula for calculating the difference between US and Australian extension periods (excluding from consideration the 'due diligence' exception) is A + B + C + D – 5 (the Australian extension formula) *minus* C/2 + D (the US extension formula). It follows that:

(A + B + C + D – 5) – (C/2 + D) = A + B + C/2 – 5 = difference between the length of US and AU extension periods

On the basis of the confirmed data in Table 1 above (in relation to the drugs in Attachment A), one would expect that A + B + C + D – 5 (the Australian extension formula) would be greater than C/2 + D (the US extension formula). This equation translates to:

A + B + C + D – 5 > C/2 + D
→ A + B + C/2 – 5 > 0
→ A + B + C/2 > 5

Therefore, the Australian extension provisions will generate a longer period of extension (relative to the US extension provisions) to the extent that A + B + C/2 is greater than 5. In other words, the Australian extension provisions will generate a longer period of extension (relative to the US extension provisions) if the period commencing on the application date and ending at the half-way mark of clinical trials exceeds 5 years. Conversely, the Australian extension provisions will generate a shorter period of extension (relative to the US extension provisions) if the period commencing on the application date and ending at the half-way mark of clinical trials is less than 5 years.

More particularly, on the basis of the confirmed data in Table 2 (in relation to the drugs in Attachment A), one would expect that A + B + C + D – 5 (the Australian extension formula) would be greater than C/2 + D (the US extension formula) by an average of approximately 386 days (or 1.05 years).

This equation translates to:

A + B + C + D – 5 = C/2 + D + 1.05
→ A + B + C/2 – 6.05 = 0
→ A + B + C/2 = 6.05

Therefore, on the basis of the confirmed data in Table 2, the reason that the length of patent extensions in Australia exceed the length of patent extensions in the US is that A + B + C/2 is 1.05 years greater than the 5-year period required to generate

extensions of equal length. In other words, on the basis of the confirmed data in Table 2 (and assuming that the periods A, B, C and D are of equal length in both the US and Australia), patent extensions are relatively longer in Australia than in the US because the period commencing on the application date and ending at the half-way mark of clinical trials exceeds 5 years by approximately 1.05 years.

Significantly, the discussion above is based on the assumption that periods A, B, C and D are of equal duration in both jurisdictions. Furthermore, the significance of capping is not taken into consideration. In particular, on the assumption that periods A, B, C and D are of equal length in Australia and the US (and subject to capping), the length of the Australian extension period will exceed the length of the US extension period if the half-way mark of clinical trials occurs more than 5 years after filing the relevant patent application. Adopting the aforementioned assumption demonstrates the way in which the structure of the relevant provisions requires US patentees to reach the half-way mark of clinical trials within 5 years of the application date in order to gain a period of extension that is relatively longer than their Australian counterparts.

(c) Different methods of calculating length of extension

The US extension provisions provide that the length of an extension includes 50% of time spent during the clinical testing phase[123] *plus* 100% of time spent obtaining approval under the *Federal Food, Drug and Cosmetic Act.*[124] In contrast, patent extensions in Australia and SPCs in the EU allow for 100% of the clinical testing phase to be taken into consideration for the purpose of calculating the relevant extension. Therefore, (all other things being equal and subject to capping) the failure of the US extension provisions to allow the entire clinical testing phase to be taken into account for the purpose of calculating the length of the extension period represents a further reason for longer patent extension periods in Australia and, therefore, relatively later patent expiry dates in Australia.

Furthermore, only that part of the 'regulatory review period' which commences after the date the patent is granted can be taken into consideration in calculating the length of the extension in the US. Therefore, in circumstances where US patents are granted *after* the commencement of first clinical trials, the period of time which can be taken into consideration for the purposes of calculating the period of patent extension is eroded further. In summary, period 'C' (and hence period C/2) in the diagram above

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[123] The 'clinical testing phase' refers to the period commencing on the date an exemption to conduct human clinical trials was first granted under section 355 of the *Federal Food, Drug, and Cosmetic Act* and ending on the date an application for FDA approval was made.
[124] 35 USC §156(c) and (g).

is effectively reduced by reference to the period of time the grant date 'encroaches' into period C.

Periods during which the applicant for extension 'did not act with due diligence' are subtracted from the total term of extension in the US, [125] whereas no such corresponding provision exists in Australia or the EU. This may provide an additional reason for shorter extension periods in the US.

In summary, the reasons discussed above may account for the fact that the length of the extension periods for the Australian patents included in DITR Attachment A exceeded the corresponding US periods by an average period of 386 days (see Table 2 of section 2.3.2).

[125] 35 USC §156(c)(1).

(d) Differences in Maximum Effective Life

A maximum effective life of 15 years is (implicitly) conferred by the Australian extension provisions and by SPCs in the EU, compared to a maximum effective life of 14 years expressly conferred in the US.

Employing the symbols above, maximum effective life in the US is: $E + F \leq 14$. In contrast, maximum effective life in the EU and Australia is: $E + F \leq 15$.

The longer period of maximum effective life in Australia, relative to the US, represents a further possible reason for longer periods of patent extension in Australia. This difference in maximum effective life could account for a maximum of 1 years' difference in patent extension periods and thus patent expiry dates. In particular, all other things being equal, the potential to enjoy one extra year of effective life in Australia (compared to the US) gives rise to the possibility of receiving one additional year of extended patent term in Australia.

2.7.3 Practical Reasons for Current Differences in Expiry Dates

(i) Regulatory Review Periods

Relatively shorter periods of regulatory review in the US will result in shorter extension periods. For example, if the FDA takes comparatively less time than the Therapeutic Goods Administration in Australia to grant approval for pharmaceuticals, a smaller proportion of period 'D' can be taken into consideration for the purposes of calculating the length of extensions in the US (relative to Australia).

The regulatory bodies in the US, EU and Australia have set similar targets for regulatory review (see Section 2.6). In practice, it seems that the median regulatory approval time differ between jurisdictions: in 1999 the median US regulatory approval time was 1 year, while in Australia it was 6 months longer. In the EU, the median regulatory approval time for the centralised procedures was 1.3 years compared to 1.8 years for the decentralised procedure. Thus, the differences in regulatory approval times could account for 6 months of the difference between patent expiry dates in the US and Australia.

(ii) Clinical Trial Periods

c Relatively shorter periods of clinical trials in the US will result in shorter extension periods. For example, if comparatively less time is required to conduct US clinical trials than Australian clinical trials, a smaller proportion of period 'C/2' can be taken into consideration for the purposes of calculating the length of extensions in the US (relative to Australia). There is some evidence that this period is decreasing in the US. We have been unable to obtain data on clinical trial periods in Australia.

(iii) Different Filing Dates

Later filing dates in Australia (relative to the US) result in later expiry of the standard term, thus providing a further possible reason for later expiry of 'total patent term' (ie. standard term plus extended term). In particular, later filing dates in Australia (relative to the US) will result in later expiry of the total patent term, even if the extended term in both jurisdictions is of equal length.

On the basis of the drugs considered in Table 4 of section 2.5.2, Australian applications are filed (on average) 2 months *prior to* the corresponding US application. On the basis of this statistic *alone* (and assuming equal periods of extension), one would expect earlier patent expiry in Australia (relative to the US). In particular, the average filing difference of 2 months between Australia and the US appears to be inconsistent with the fact of earlier patent expiry in the US (relative to Australia) in 64% of Attachment A cases. However, when the relevant drugs are considered in greater detail, a slightly different picture emerges.

In relation to the drugs considered in Table 4 of section 2.5.2, the relevant Australian patent application was filed *later than* the corresponding US application in 58% (7 out of 12) of cases (see Table 5 of section 2.4.3). In those cases, the Australian application was filed 7 months (on average) later than the corresponding US application. Five of those 7 cases in which the Australian patent application was filed later than the corresponding US application were associated with later patent expiry in Australia (being 700 days on average). [126] This is consistent with the general hypothesis that later filing in Australia is a contributing cause of later patent expiry in Australia. However, later filing in Australia (relative to the US) does not *necessarily* result in later patent expiry because the length of the extension period is also an important determinant of total patent term.

2.7.4 TRANSITIONAL REASONS FOR CURRENT DIFFERENCES IN EXPIRY DATES

(i) Uruguay Round

As noted above, the *1994 Uruguay Round Agreements Act* ("URAA") ensured that US patents filed after 8 June 1995 were granted a term of 20 years from the date of application, rather than 17 years from the date of grant. Transitional provisions were also enacted which applied to patents in force on (or that resulted from an application filed before) the date that is 6 months after enactment of the *Uruguay Round Agreements Act.* In respect of these 'transitional' patents, section 154(c)(1) of 35

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[126] The drugs that expired later in Australia than the US were lansoprazole, loratadine, famotidine, fosinopril and nefazodone. The drugs that expired earlier in Australia than the US were simvastatin and sertraline. We note that loratadine, fosinopril and nefazodone are likely to be pipeline drugs.

U.S.C. automatically conferred a term of 20 years from the date of application or 17 years from the date of grant, whichever is the longer. [127] Therefore, in circumstances where the patent is granted more than 3 years after the application date, the transitional provisions generate an 'extended term', ie. a term which is longer than the standard term of 20 years from filing.

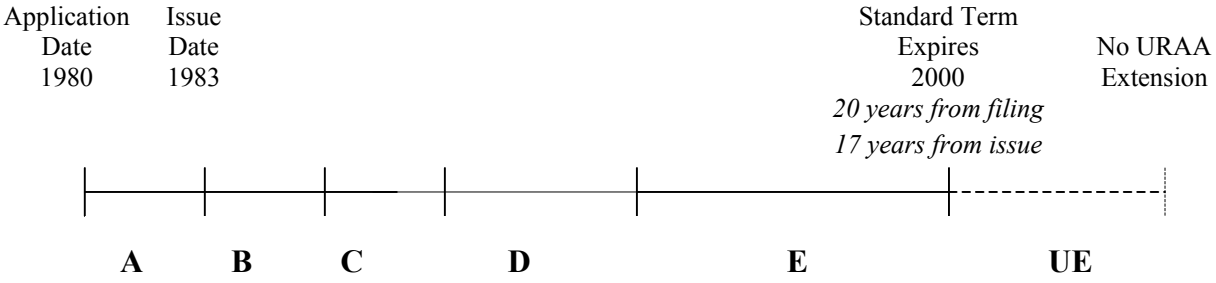
The length of the period of extension conferred by virtue of the transitional provisions (a "Uruguay extension" - and denoted 'UE' in the diagram below) can be expressed as follows:

UE = A – 3
(Where UE cannot be less than zero).

Accordingly, where 3 years or less elapse between the date of application and grant, the transitional provisions do not generate a Uruguay extension. This scenario is illustrated in Figure 8 below.

As noted in section 1.2.2. above, *Hatch-Waxman* extensions can be added to the extended patent term granted by the URAA. [128] Therefore, *Hatch-Waxman* extensions can be added to the period 'UE'.

Figure 8: **United States and Uruguay Extensions**

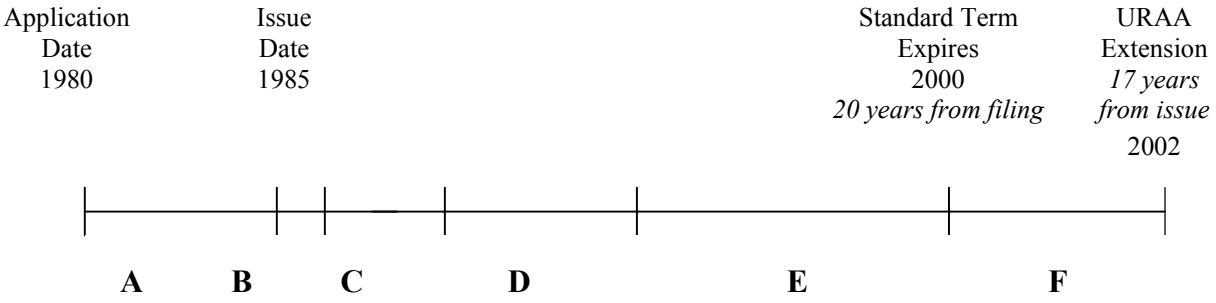


Alternatively, where a period greater than 3 years elapses between the date of application and grant, the transitional provisions result in a Uruguay extension. As noted above, the precise period of the Uruguay extension (period 'F') can be calculated by reference to the formula: F = A – 3. For example, where 5 years elapse

[127] Section 154(c)(1), 35 USC provides: 'The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.'
[128] Heidi Grygiel, 'Now They GATT Worry: The Impact of the GATT on the American Generic Pharmaceutical Industry' (1997) 6 *University of Baltimore Intellectual Property Law Journal*47, 60.

between the date of application and grant, a 2-year Uruguay extension will result. This scenario is illustrated in Figure 9 below.

Figure 9: **United States and Uruguay Extensions**



The *Patents (World Trade Organization Amendments) Act 1994* (Cth) (PWTOAA) is the Australian equivalent of the URAA. In particular, the PWTOAA extended the term of Australian patents from 16 years to 20 years, thus conferring a maximum term of 20 years from the date of patent application. Therefore, in contrast to their US counterparts, Australian patentees do not enjoy the benefit of Uruguay extensions. Accordingly, the transitional provisions of the URAA provide a basis for extending US patent terms beyond the period enjoyed in Australia. The average length of a Uruguay extension is one year.[129] The existence of Uruguay extensions militates against earlier patent expiry in the US (relative to Australia).

(ii) Pipeline Drugs

As noted in Section 1.2.1(c), the length of extensions of term cannot exceed 2 years in respect of patents for pipeline drugs.[130] This 2-year cap in respect of pipeline drugs contrasts with the 5-year maximum term of extension applicable in relation to patents in Australia. Therefore, the 2-year maximum extension period which applies in respect of pipeline drugs has the potential to account for a maximum of 3 years' difference between the length of patent extensions in Australia and the US. For example, loratadine, fosinopril and nefazodone were subject to extensions of 2 years and 5 years in the US and Australia respectively, presumably by virtue of the 2-year maximum period of extension which applies in relation to pipeline drugs in the US and the 5-year maximum which applies in Australia.

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[129] S. Schondelmeyer, 'Economic Impact of GATT Patent Extension on Currently Marketed Drugs (PRIME Institute, College of Pharmacy, University of Minnesota; Minneapolis, March 1995).
[130] 35 USC 156§ (g)(6)(C).

On the basis of the verified data in Table 2 (in relation to the drugs in DITR Attachment A) the average length of patent extensions in Australia is 386 days longer than the average length of patent extensions in the US . When the four pipeline drugs (loratadine, quinapril, fosinopril and nefazodone) in DITR Attachment A are removed from consideration, the average length of patent extensions in Australia is 274 days longer than the average length of patent extensions in the US. The inclusion of pipeline drugs in DITR Attachment A thus accounts for 112 out of 386 days of the average difference between the length of patent extensions in the US and Australia. Accordingly, assuming that the proportion of pipeline drugs in DITR Attachment A (ie. 25%) is representative, the existence of pipeline drugs may account for approximately 29% of the average difference between the current extension periods in Australia and the US.

2.7.5 FUTURE PROSPECTS FOR CLOSING THE GAP BETWEEN PATENT EXPIRY DATES

This section considers the variables which need to change to close the "gap" between patent expiry dates in the US and Australia.

(i) Structural Factors

The structural reasons for differences in expiry dates, discussed above, will not diminish in significance over time.

Section 154(b) of USC 35, which applies in relation to patent applications filed on or after 29 May 2000,[131] allows for extensions of term in circumstances where the issue of an original patent is delayed due to interference proceedings, [132] secrecy orders [133] or appellate review by the Board of Patent Appeals and Interferences or by a Federal Court. [134] These extension provisions, to the extent that they allow for extensions of term in addition to those granted by the pharmaceutical extension provisions in section 156 of USC 35, will provide an additional basis for extending US patent terms. Therefore, these provisions will tend to lengthen the period of US extensions and thus delay US patent expiry, thereby assisting to close the gap between US and Australian patent expiry.

(ii) Practical Factors

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[131] Mandy Wilson, 'Pharmaceutical Patent Protection: More Generic Favoured Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation' (2001/2002) 90 *Kentucky Law Journal* 495, 512.
[132] 35 USC § 154(b)(1).
[133] 35 USC § 154(b)(1).
[134] 35 USC § 154(b)(2); provided that the patent is issued subsequent to that review, reversing an adverse determination of patentability.

Length of regulatory review periods

Absolute changes in regulatory review periods in the US and Australia that do not result in relative changes between the two jurisdictions are not relevant to the size of the gap, because both jurisdictions allow 100% of this period to be taken into consideration for the purpose of calculating the length of the extension period. For example, (subject to capping and all other things being equal) if period 'D' increases or decreases by the same amount in Australia and the US, no change in the size of the gap will occur.

There is evidence to show that the regulatory approval times in the US, EU and Australia are decreasing (see Section 2.6).

However, relative changes in period 'D' may assist in closing the gap. In particular, (subject to capping and all other things being equal) the gap will close if period 'D' increases in the US (relative to Australia).

Length of clinical trials

Both relative and absolute changes in the length of period 'C' are relevant to the size of the gap. A uniform absolute decrease in the length of period 'C' across both jurisdictions will result in a reduction of the gap. In other words, if period 'C' decreases by the same amount in Australia and the US, the gap will nevertheless reduce in size. This reduction of the gap arises because only 50% of period 'C' is taken into consideration for the purpose of calculating the length of the extension period in the US, whereas the entire period is taken into account in Australia.

Relative increases or decreases in the length of clinical trials will also be relevant in closing or broadening the gap.

Recent figures in the US show that the length of clinical trials is decreasing. We were unable to find any evidence about whether the length of clinical trials in Australia is changing.

Filing dates

The "gap" between patent expiry dates in the US and Australia will widen to the extent that Australian filing dates occur later in time. Conversely, the gap will close to the extent that patent filing dates in Australia and the US converge.

US issue date

The date on which a patent is granted is not relevant to the calculation of extension periods in Australia, in contrast to the position in the US. In particular, if patents are issued later in the US such that 'issue date' increasingly encroaches into period 'C', the length of patent extensions in the US is likely to decrease relative to Australia, with the result that the gap in expiry dates will increase.

(iii) Transitional Issues

The transitional issues discussed above in section 2.7.4 above will cease to be relevant in the future. However, such transitional issues may continue to affect patent expiry dates until approximately 2025 (when the transitional provisions of the URAA should cease to confer Uruguay extensions).

3. OTHER METHODS FOR EXTENDING MARKET EXCLUSIVITY

3.1 Introduction

Although patents (and patent extensions) are the main form of gaining a monopoly over the market for pharmaceuticals, companies use other means in order to attain market exclusivity after the patent expires. This section canvasses the non legislative and legislative methods that pharmaceutical companies use to extend the market exclusivity of their drugs.

3.2 Non-Legislative Methods

(a) Multiple Patents on the Same Drug

A key method of extending market exclusivity of a pharmaceutical substance is to obtain multiple patents relating to the same pharmaceutical. Innovative manufacturers may apply for a new patent on different features of the same drug, such as:[135]

- Process of manufacturing the raw material;
- Combination of compounds already approved; [136]
- Use (medical indications to which the drug can be applied);
- Administration of the drug (ie. dose, method of treatment);
- Metabolites resulting from the enzymatic degradation of the parent drug by the body;[137]
- Non-essential feature of the drug such as the colour or shape of a pill or packaging.

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[135] *EU v. Canada – Patent Protection of Pharmaceutical Products,* WT/DS/114 (March 17, 2000).
[136] Nearly 50% of the drugs approved by the FDA in the 1990's were "new formulations" or "new combinations" of compounds already approved. U.S. Food and Drug Administration, "NDAs Approved in Calendar Years 1990-1999 by Therapeutic Potentials and Chemical Types" (February 15, 2000).
[137] S. Hall, 'Prescription for Profit', *N.Y. Times Mag. 42* (Mar. 11, 2001). See (*Mylan v. Thompson, Civ.* No. 00-2876 (RMV) (D.C. D.C.) (Mar. 13, 2001); *Watson (Watson v. Henney,* Civ. No. S00-3516 (D.C. MD) (Jan. 8, 2001), Patent protection of Bristol Myers' anti-anxiety drug BuSpar was due to expire on November 2000. The day before its exclusivity was set to expire, the U.S. Patent and Trademark Office issued Bristol-Myers a metabolite patent for the chemical (or metabolite) produced inside the human body when a person ingests BuSpar. Bristol Myers then submitted this new patent for inclusion in FDA's Orange Book. The generic company, Mylan, could not be granted approval for the generic version of BuSpar due to Bristol Myers' Orange Book Listing. On March 2001, a federal judge held that Bristol-Myers Squibb had acted improperly and ordered the FDA to approve the generic version of BuSpar.

This "layering" of patents[138] can be staggered over a long period of time so that when an old patent on the pharmaceutical substance is nearing expiry, a new patent can be granted to extend the market exclusivity of their drug.

Layering of patents can have the effect of preventing generic manufacturers from actually entering the market. For example, if the patent on the pharmaceutical substance has expired, but the innovative manufacturer still has a patent on the administration of the drug (via injection), the generics manufacturer can enter the market with a generic version only so long as the generic drug has a different method of administration. If there were only one way that the drug could be administered, then the generics manufacturer would effectively be prevented from entering the market, as they could not produce a generic version without infringing the patent on the administration of the drug.

The layering of patents can also have the effect of creating (and capturing) a new market before the generic version enters the old market. Innovative manufacturers could patent a new formulation of the pharmaceutical and encourage doctors to prescribe the newer version to the current users. When the generic version of the old drug enters, the current users have already swapped to the newer formulation and the innovative manufacturer still holds the majority of the market.[139]

3.3 Legislative Methods

3.3.1 US

(a) Patent Infringement Suits and Stays of Regulatory Approval

In the US, a subsequent ANDA applicant the *Hatch-Waxman Act* streamlines the regulatory approval process by eliminating requirements of the *Food, Drug and Cosmetics Act* for generics manufacturers. A pharmaceutical company that wants to market a generic form of a pioneer drug may file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA), certifying that the generic drug is a bioequivalent of the pioneer drug and relying on the FDA's previous determination that the drug is safe and effective.

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[138] "Layering" is also called "evergreening" by the generics manufacturers and "ongoing innovation" by the innovative manufacturers. See Canada's Research Based Pharmaceutical Companies, 'Ongoing Innovation', http://www.canadapharma.org/Media_Centre/Special_Reports/S-17InnovApril01_e.html; L. Glasgow, 'Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?' (2001) 41 *IDEA* 227.

[139] For example, Eli Lilly & Co introduced a once-a-week Prozac treatment and marketed it to the users of the daily Prozac drug. The patent on the daily Prozac expired in August 2001 but the weekly drug patent is still in force. See J. Benassi, Not Without a Fight, (Brobeck, Phleger & Harrison LLP).

The Orange Book lists all FDA approved prescription drugs, including new and generic drugs. In both the US and Canada, when a generics manufacturer files an ANDA, the applicant must certify (by reference to the Orange Book) either: (1) that there is no patent for the drug, (2) that the patented has expired, (3) that the patent will expire, (4) that the patent is invalid, or (5) that the patent will not be infringed.[140] If the generics manufacturer certifies that the patent is invalid or will not be infringed (this is called a paragraph IV certification) a notice is served on the patentee,[141] who has forty-five days to bring an action against the generic applicant. The commencement of litigation results in an *automatic stay of regulatory approval* of the generic product. This stay lasts for 30 months in the US,[142] until patent expiry, or until the conclusion of the litigation, whichever comes first.

Instituting patent litigation can entitle the innovative manufacturer to more than two years market exclusivity and thus has led to *frivolous suits* by innovative manufacturers in an attempt to retain exclusivity over a drug beyond their patent term.[143] Often the patent that is subject to litigation is the result of the innovative manufacturer's "layering" strategy of applying for new patents on alternative uses and formulations of old patents.

Likewise, the opportunity to extend market exclusivity by listing a patent in the Orange Book has been an incentive for companies to list a variety of patents pertaining to the same drug product.[144] The current policy of the FDA is that patents presented for listing in the Orange Book are not reviewed, to determine whether they actually claim the drug product described in the application. Thus, a company could act in bad faith and successfully list patents that do not satisfy the listing criteria, but would have the same power to trigger the 30 month stay as would any validly listed patent. Such conduct can lead to intervention by the Federal Trade Commission, which may issue a consent order prohibiting the innovative company from taking any

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[140] 21 U.S.C. § 355(j)(2)(A)(vii); PM(NOC) Regulations at s5(1)(a) and s5(1)(b).
[141] The notice is known as a "paragraph IV certification" in the US and a "notice of allegation" in Canada.
[142] The 30-month day period approximates the time necessary for FDA review and approval of an ANDA. Federal Trade Commission, "Generic Entry Prior to Patent Expiration" July 2002, http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.
[143] See Eli *Lilly & Company v. Barr Laboratories, Inc* 100 F.Supp.2d 917, rev'd in part, aff'd in part, 222 F.3d 973 (Fed. Cir. 2000) where the court declared that Eli Lilly had two patents on substantially the same claim (for Prozac), the second of which was invalid and thus their patent on Prozac expired in 2001 rather than 2003.See *Fla. Breckenridge Inc. v. Solvay Pharm*. 174 F.3d 1227, 1236 (11th Cir. 1999).
[144] A. Engelberg, 'Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?' (1999) 39 *IDEA* 389, 415.

action that would trigger additional stays or from wrongfully listing patents in the Orange Book for a product for which the company already has an NDA.[145]

There have also been rare cases where innovative manufacturers are eligible for multiple 30-month delays. Multiple stays can occur where the innovative manufacturer lists an *additional patent* in the Orange Book (generally a formulation patent) *after* the generics manufacturer has already filed its ANDA with a paragraph IV certification. The generics manufacturer must recertify that its ANDA does not infringe the latter granted patent. If the innovative manufacturer challenges the re-certification, then a second 30 month stay will commence. If the court finds that the patent is invalid or that the generics manufacturer does not infringe the patent, the regulatory approval of the ANDA becomes valid from the day of the ruling.[146]

In May 2001, legislation entitled '*Greater Access to Affordable Pharmaceuticals Act' (GAAP)* was introduced by the US Senate to amend the *Hatch-Waxman Act.*[147] The main relevant features of the proposal are: (1) eliminate the automatic 30 month stay so that innovative companies would instead have to apply for the courts for a preliminary injunction and show the court how the generic version would infringe their patent, and (2) give generics companies the ability to go to court to seek delisting of patents that are inappropriately listed with the FDA. *GAAP* was passed by the US Senate on July 31 2002 and is waiting approval by the House of Representatives.[148]

On July 30 2002, the FTC released an industry wide study (which started in April 2001) on generic drug competition, which included an investigation into whether the *Hatch-Waxman Act* has operated as intended or whether it has unintentionally allowed anticompetitive practices to occur which deter the entry of generic drugs onto the market.[149] The FTC study found that for nearly 70% of the drug products covered by the survey, the innovative manufacturers instituted proceedings against the first generics manufacturer in relation to the certification regarding patent validity or non-infringement.[150] The patents that were most often the subject of paragraph IV certifications, and consequent patent infringement litigation, were formulation and method of use patents. In 73% of patent infringement cases, the generics

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[145] Federal Trade Commission, Wrongful "Orange Book" Listing Raises Red Flag with FTC; Leads to Consent Order with Biovail Corp. Concerning its Drug Tiazac, http://www.ftc.gov/opa/2002/04/biovailtiazac.htm.
[146] 21 U.S.C. § 355 (j).
[147] *Greater Access to Affordable Pharmaceuticals Act* (GAAP, S.812), House of Representatives (Brown-Emerson – H.R. 1862).
[148] Note that two companion bills have also been introduced in the House, one by Reps. John Thune (R-S.D) and Jo Emerson (R-Mo), H.R. 5311, the other by Reps. Sherrod Brown (D-Ohio) and Henry Waxman (D-Calif), H.R. 5272.
[149] Federal Trade Commission, "Generic Entry Prior to Patent Expiration" July 2002, http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.
[150] Ibid 13.

manufacturer succeeded.[151] The study also showed that multiple 30 month stays have prevented FDA approval of generic applicants for 4 to 40 months beyond the initial 30 month period.[152] The 4 courts that have ruled on these cases have each found the relevant patent to be invalid or not infringed.[153] The study recommended that only one automatic 30 month stay per drug product per ANDA should be permitted to resolve infringement disputes is order to mitigate the possibility of abuse of this provision.

On October 21 2002, US President Bush publicly announced that the Food and Drug Administration is issuing proposed new regulations that allow a maximum of one automatic 30-month stay in patent infringement litigation against a generic competitor.[154] The proposal also included a prohibition on the listing of non-essential patents with the FDA; permitted listing will include patents on active ingredients, drug formulations and uses of a drug. Therefore patents on packaging or on metabolites produced by the body in response to the drug, cannot be listed with the FDA. Patent submissions must be filed in conjunction with a more detailed (and signed) attestation and false attestations will lead to criminal charges. These changes are designed to minimise the listing of inappropriate patents and minimise the automatic triggering of delay for frivolous reasons. The new FDA regulations put forward by President Bush are weaker than the *GAAP* with respect to 30 month stays as *GAAP* proposes that an innovative manufacturer must apply to the court for a stay of the generic drug application. Democrats have commented that the plan is not strong enough, and that more comprehensive reform is required. However, the new regulations are stronger in some areas than *GAAP*, such as the prohibition on the listing of non-essential patents in the Orange Book.

(b) Agreements Between Innovators and Generics

In the US, the *Hatch-Waxman Act* provides that if an ANDA contains a paragraph IV certification and relates to a drug for which an ANDA has already been submitted by another generics manufacturer (with a paragraph IV certification), then the application by the subsequent generics manufacturer shall only be effective 180 days after the first commercial marketing of the drug under the previous application, or the court decision declaring the patent to be invalid or not infringed, whichever is earlier.[155] Put another way, the first generic applicant to file an ANDA containing a paragraph IV certification will be *eligible* for a 180-day period of market exclusivity. The start

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[151] Ibid.
[152] Ibid 44.
[153] Ibid 39.
[154] White House, President Takes Action to Lower Prescription Drug Prices By Improving Access to Generic Drugs (October 22, 2002) http://www.whitehouse.gov/news/releases/2002/10/print/20021021-4.html.
[155] USC §355)j)(5)(B)(iv).

of the exclusivity period is 'triggered' either by the first commercial marketing or the court decision is earlier. Until an eligible ANDA applicant's 180-day exclusivity period has *expired*, FDA cannot approve subsequently submitted ANDAs for the same drug. The aim of this provision is to provide an economic incentive for generics manufacturers to certify that a listed patent is valid and find alternative, non infringing forms of patented drugs.[156]

There have been cases where innovative manufacturers have colluded with the first generic applicant to keep the generic version off the market in exchange for large amounts of money.[157] These agreements have the effect of 'parking' the 180-day exclusivity, as it will not be triggered until the first commercial marketing or a court decision favourable to the generics manufacturer. Because the 180-day exclusivity period of the first generic applicant to file has not expired (nor, indeed, even been triggered), the FDA are unable to approve any subsequent ANDA's for the same product. Therefore, an ANDA applicant who is 'eligible' for exclusivity is able to delay other generic competition for entering the market for an indefinite period of time if they fail to trigger the 180-day exclusivity[158]

This can be a lucrative investment for innovative manufacturers. In the first year of a patent on a new drug expiring, the generic form of the drug takes approximately 35% of the market; a figure that rises to 50% after two years.[159] As well as taking a significant proportion of the market share, the entry of the generic version of the drug into the market drives down the price of the brand name drug; average drug prices decrease an average of 20% within 2 years of generic drug entry.[160] Thus such agreements have been subject to complaints by the Federal Trade Commission (FTC) based on the innovator manufacturer's attempts to restrain competition. The two leading cases were both resolved by consent order, prohibiting the innovative companies from entering into arrangements with the first ANDA filer where the

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[156] Federal Trade Commission, "Generic Entry Prior to Patent Expiration" July 2002, http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.
[157] *In re Cardizem CD Antitrust Litig.,* 105 F. Supp. 2d 618 (E.D. Mich. 2000); *In re Cardizem CD Antitrust Litig.,* 105 F. Supp. 2d 682 (E.D. Mich. 2000); *Andrx Pharm. Inc. v. Friedman*, 83 F. Supp. 2d 179 (D.D.C. 2000), 256 F.3d 799 (D.C.Cir. 2001); *Biovail Corp. Int'l v. Hoechst Aktiengesellschaft,* 49 F. Supp. 2d 750 (D.N.J. 1999).
[158] US Food and Drug Administration, '180-Day Generic Drug Exclusivity' (Centre for Drug Evaluation and Research, 2001), http://www.fda.gov/cder/about/smallbiz/generic_exclusivity.htm.
[159] Data from the Pharmaceutical Manufacturers Association in M. Davies, 'Monopolistic Tendencies of Brand-Name Drug Companies in the Pharmaceutical Industry' (1995) 15 *J.L. & Com.* 357, 365; cf. J. Wheaton, 'Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984' (1986) 35 *Cath. U.L. Rev.* 433, 468-469, stating that a brand name manufacturer's market is not greatly affected by the entry of a generic manufacturer.
[160] H. Grabowski, J. Vernon, 'Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act' (1992) 35 J. of Law & Econ. 331.

generics company agrees not to enter the market with a non-infringing product or to transfer the 180-day exclusivity period.[161]

The FTC study included recommendations for changes to the *Hatch-Waxman Act* to seek to stop collusion between innovative and generics manufacturers. The FTC recommends an amendment in order to ensure that where the first generic applicant to file fails to market its drug within 90 days of approval, delays marketing its drug due to an agreement with an innovative manufacturer, fails to challenge a new patent on the drug within 60 days, or withdraws its application to market the drug, then the generic applicant would lose their 180-day market exclusivity. That 180-day period would transfer to the next generic applicant to file. The FTC study also recommended that Congress pass the *Drug Competition Act*[162] to require first generics applicants and innovative manufacturers to provide copies of certain agreements to the FTC and the Department of Justice in order to prevent abuses of the *Hatch-Waxman* 180-day market exclusivity provision.

As discussed above in relation to stays of regulatory approval, in July 2002, legislation entitled '*Greater Access to Affordable Pharmaceuticals Act' (GAAP)* was passed by the US Senate to amend the *Hatch-Waxman Act. GAAP* proposes to reform the "180-day rule" by closing the loophole that enables an innovative company to pay a generics manufacturer to stay off the market. Under the proposed amendments, a generics drug company that does not vigorously attempt to bring its product to market or is considered by the Secretary of Health and Human Services (in consultation with the FTC) to have engaged in illegal, anticompetitive or collusive practices would lose their right to exclusivity. Thus, under the proposed reform, if a generics drug manufacturer has entered into an agreement with an innovative manufacturer to keep the generic version off the market, this agreement would no longer prevent other generics manufacturers from entering the market.

(c) Orphan drugs and Pediatric testing

In the US, innovative manufacturers are given incentives of market exclusivity for research and development of drugs to treat rare conditions and children. Under the *Orphan Drug Act*[163], market exclusivity is granted to certain drugs that treat rare conditions.[164] To qualify for protection, the condition must affect less than 200,000 people in the US, or proof is required that there is no reasonable prospect of profit

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[161] Federal Trade Commission, 'Consent Agreement Resolves Complaint Against Pharmaceutical Companies Hoechst Marion Roussel, Inc. and Andrx Corp' (2001) http://www.ftc.gov/opa/2001/04/hoechst.htm.

[162] *The Drug Competition Act* S.574, introduced by Senator Patrick Leahy (D-VT).

[163] § 360aa-340ee (FDCA 525-528).

[164] E. Hore, 'A Comparison of United States and Canadian Laws as they Affect Generic Pharmaceutical Market Entry' (2000) 55 *Food Drug L.J.* 373.

from the drug. A drug that the FDA designates as an "orphan" product and approves for marketing may be eligible for seven years of market exclusivity. This would prevent the grant of regulatory approval for generic drugs (via ANDA) and New Drug Applications (from independent clinical studies).

In the US, six months market exclusivity can be granted for studying drugs in children.[165] This term is added to the drug's existing patent term or the term of any other market exclusivity; whichever expires last. In order to qualify, the FDA must request pediatric studies of the drug and then accept the reports of the studies submitted by the manufacturer.

(d) Data Exclusivity

The *Hatch-Waxman Act* prohibits competing manufacturers from relying on clinical data from an innovative manufacturer to gain FDA approval for a certain amount of time.[166] This period of data exclusivity lasts for five years for new compounds and three years for new uses of an existing compound. This is more significant for new uses as the effective patent life of a new compound is often longer than five years. This period does not extend the actual patent period but is an added period of protection which can extend the market exclusivity of the drug if the term of the patent expires before the exclusivity period.[167] The reason is that while generics companies can conduct their own clinical trials, it is an expensive process and thus data exclusivity effectively creates a barrier for generics company entry into the market.

3.3.2 CANADA

(a) Patent Infringement Suits and Stays of Regulatory Approval

In Canada, the *Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations))* creates a scheme very similar to the US *Hatch-Waxman Act*.[168] Under these regulations, generics manufacturers can seek regulatory approval by lodging an

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[165] This provision was introduced by the *Food and Drug Administration Modernization Act* (1997) § 111. 21 USC § 355a (FDCA 505A); FDA, Guidance for Industry Qualifying for Pediatric Exclusivity under Section 505A of the Federal Food, Drug and Cosmetic Act (Sept. 1999) <http://www.fda.gov/cder/guidance/clin1.pdf>. Up until 2000, pediatric exclusivity had only been granted for 17 drugs. Tufts Center for the Study of Drug Development, "Clinical development times for new drugs drop 18%, reversing 12-yr trend," *Tufts CSDD Impact Report*, Volume 1 (July 1999): 1-3/

[166] 21 USC § 355 (J0(4)(D)(ii),(iii).

[167] NIHCM Foundation, 'A Primer: Generic Drugs, Patents and the Pharmaceutical Marketplace' (New York, June 2002).

[168] The Canadian regulations were modelled on the 1984 *Hatch-Waxman Act* in the United States.

Abbreviated New Drug Submission (ANDS) and can establish bioequivalence by reference to an approved drug.[169]

In Canada, (as in the US) when a generics manufacturer files an abbreviated new drug application, the applicant must accept that they will not be granted regulatory approval until the patent has expired or certify that the patent is invalid or that it will not be infringed by their product.[170] If the generics manufacturer certifies that the patent is invalid or not infringed, a notice is served on the patentee,[171] who may then commence litigation. The litigation in response to the certification is a judicial review application (while in the US it is an action for patent infringement).[172] The commencement of litigation results in an automatic stay of regulatory approval of the generic product for 24 months in Canada, until patent expiry or until the conclusion of the litigation, whichever comes first. Thus the generic product cannot enter the market during this period.

In 1998, the Supreme Court of Canada held that these Regulations constituted a "draconian regime" because the generics company is kept out of the market "automatically… without any consideration of the merits".[173] The Canadian government may review these provisions soon: in June 2002, the House of Commons Standing Committee on Industry, Science and Technology committee voted 10-1 to revisit the automatic injunction clause in Canadian drug regulations.[174]

(b) Provincial Drug Plan Coverage

The province of Quebec in Canada has a unique reimbursement plan which provides that all drug products on the provincial formulary will be reimbursed for the first 15 years that they appear on the formulary, regardless of their cost. After 15 years, consumers will only be reimbursed for the lowest priced drug. In every other

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[169] *Patented Medicines (Notice of Compliance) Regulations,* SOR 93-133, 5(1) (2001) (Can.).
[170] 21 U.S.C. § 355(j)(2)(A)(vii); PM(NOC) Regulations at s5(1)(a) and s5(1)(b).
[171] The notice is known as a "paragraph IV certification" in the US and a "notice of allegation" in Canada.
[172] *Eli Lilly & Co. v. Apotex Inc (1997)* 76 C.P.R. (3d) 1 at 5-6 (F.C.A). Thus, either party may commence a parallel patent action. Different results can be reached in the judicial review process and the patent action for the same drug and the same patent. For example, in *Apotex v. Hoffmann-La Roche (1999) 1 C.P.R (3d)* at 22, the generics manufacturer, Apotex was prohibited from receiving a NOC for naproxen under the PM(NOC) Regulations. Apotex commenced an action for a declaration that the patent on naproxen was invalid and was successful. The prohibition on the NOC was thus overturned in *Hoffman-La Roche Ltd. v. Apotex Inc.* File No. T-1898-93, April 30, 1999,
[173] *Eli Lilly & Co. v. Novopharm Ltd.*, [1998] 2 S.C.R. 129.
[174]G. McGregor, 'Parliamentary Committee to Probe "Draconian" Drug Patent Law' (Ottawa Citizen, June 12, 2002) http://www.cdma-acfpp.org/en/inthenews/2002_july_15_01.html. In October 2002, the CGPA submitted a proposal to the Commission on the Future of Health Care in Canada, recommending the repealing of the automatic 24 month injunction. See Canadian Generic Pharmaceutical Association, http://www.cdma-acfpp.org/en/news_releases/index.shtml

Canadian province, the public drug insurance program only covers the lowest price drugs.

The effect of the policy is to extend market exclusivity for brand name drugs, since there is no incentive to buy a generic alternative. The "15 year rule" was introduced to encourage multi-national innovator pharmaceutical manufacturers to base their production in Quebec. This rule has been criticised by the Canadian Generic Pharmaceutical Association. [175]

3.3.3 EUROPEAN UNION

(a) Orphan Drugs

The *Orphan Drug Regulations* entered into force in January 2000 and provide ten years marketing exclusivity for designated products.[176] The European Commission will designate a product as an "orphan product" if the condition treated by the disease will affect no more than five per ten thousand persons in the EC or if it would be infeasible economically to develop the drug without orphan drug incentives. While orphan drugs are entitled to 10 years of marketing exclusivity, after five years any member state can initiate proceedings limiting the exclusivity period to six years if the designation of orphan product no longer applies (ie. if the product is earning large profits or the prevalence of the condition has increased).

(b) Data Exclusivity

The European Union does not have a uniform data protection period for all medicinal products – products are protected for six to ten years depending on the particular member state.[177] The regulations allow member states to offer no data protection period beyond patent expiration.[178]

3.3.4 AUSTRALIA

(a) Orphan Drugs

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[175] Canadian Generic Pharmaceutical Manufacturers, http://www.cdma-acfpp.org/en/news_releases/may_16_02.shtml
[176] Regulation (EC) No. 141/2000 of the European Parliament and of the Council on Orphan Medicinal Prdoucts, 2000 O.J (L 18) 1.
[177] European Commission, *The Rules Governing Medicinal Products in the European Union, Notice to Applicants – Medicinal Products for Human use, Procedures for Marketing Authorization*, Vol 2A (Office for Official Publications of the European Communities 1998).
[178] Art. 4.8.a(iii).

Australia has adopted an orphan drug program to ensure the availability of a greater range of treatments for rare diseases.[179] The program waives up to 100% of the TGA evaluation fee for an orphan drug and provides a distinct 'priority' evaluation pathway for processing such products.[180] Market exclusivity is not currently part of the program. A recent report by the Department of Health and Aged Care held that careful study would be required before such an option is implemented.[181]

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[179]Regulations to the Therapeutic Goods Act 1989. A drug will be designated as an "orphan drug" if the condition that it treats affects less than 2000 patients or the drug is not commercially viable. See TGA, *Orphan Drug Program*, (January 1998).

[180] The Therapeutic Goods Administration can use information from the US FDA *Orphan Drugs Program* as part of the Australian evaluation process.

[181] Department of Health and Aged Care, 'The Orphan Drug Program and Improving Community Access to Effective Drugs for Rare Diseases' (December 2001), http://www.health.gov.au/tga/docs/pdf/orphrev.pdf . The consultation period for this report closed July 2002.

4. REVIEW OF SPRINGBOARDING

4.1. Introduction

A patent confers on a patentee the right to exclude others from using the patented invention during the patent term. Ordinarily, a patent will be infringed by another person making, using or selling the invention, without authority. Springboarding provides an exemption from infringement, for uses of a patented invention that are reasonably related to seeking regulatory approval. The rationale of the springboarding exemption is to allow generics manufacturers to work on a pharmaceutical product before the patent is expired, in order to allow faster regulatory approval and entry into the market of generic drugs as soon as possible after patent expiration.

These type of provisions are commonly known as "Bolar exceptions" or "clinical trial exceptions" in the US and Canada.[182] In 2000, the World Trade Organisation Dispute Panel upheld the right to allow the use of a patented invention for the purposes of gaining regulatory approval.[183]

4.2. United States

4.2.1 LAWS AND REGULATIONS

Under US law, it is an infringement to make, use, offer to sell or sell any patented invention within the United States without authority.[184] The key springboarding provision in US law is section 271(e)(1) of the United States Code which provides that it is not an act of infringement to "make, use, offer to sell, or sell within the US (or import into the US) a patented invention *solely for uses reasonably related"* to the development and submission of information for regulatory approval. [185] This exception was introduced by the *Hatch-Waxman Act* with the dual objective to ensure adequate incentives for generics manufacturers and to make lower price pharmaceuticals more readily available to the public.[186]

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[182] The *Drug Price Competition and Patent Term Restoration Act 1984* Pub.L.No. 98-417, 98 Stat. 1585 was introduced in the US after the Court of Appeals for the Federal Circuit asserted the narrow limits of the common law experimental use doctrine: *Roche Products, Inc. v. Bolar Pharmaceutical Co.* 733 F.2d 858 (Fed. Cir.) cert. Denied, 469 U.S. 856 (1984).
[183] *EU v. Canada – Patent Protection of Pharmaceutical Products,* WT/DS/114 (March 17, 2000). The panel also decided that Canada's stockpiling practices were not consistent with TRIPs.
[184] Patent Act of 1952, *United States Code,* Title 35, § 271(a).
[185] Patent Act of 1952, *United States Code,* Title 35, § 271(e)(1).
[186] A. Engleberg, 'Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?' (1999) 39 *Idea* 389, 389.

In the US, springboarding is not limited to the extension period but is allowed at any time during the patent term. Springboarding is allowed for all patented inventions, except certain new animal drugs or veterinary biological products.[187]

4.2.2 INTERPRETATION

There has been a large amount of litigation in US courts surrounding what types of activities are "solely for uses reasonably related to" developing information in order to seek regulatory approval.

In *Scripps Clinic & Research Foundation v. Genentech Inc*.,[188] the court took a literal interpretation of the statute and held that an infringing use that was not solely for the purpose of gaining FDA approval did not fall within the springboarding provision. The court ruled that the provision was intended to be narrow. Where the infringing use served *multiple* purposes (ie. in order to file a patent in a foreign country), the springboarding exemption did not apply. In *Intermedics, Inc. v. Ventritex Inc*.,[189] the court took a broader view and found that the intention of the statute was to allow potential competitors to ready themselves, during the life of the patent, to enter into the market as soon as possible after patent expiry. The court ruled that the use of clinical data for the purpose of raising capital was a non-infringing use. The reasoning in *Intermedics* has been followed by subsequent courts.[190]

4.2.3 PROPOSALS FOR REFORM

There is no evidence of any proposals to reform the US law on springboarding.

4.3. Canada

4.3.1 LAWS AND REGULATIONS

In 1993, in anticipation of the signing of NAFTA, Canada introduced the *Patented Medicines (Notice of Compliance) Regulations* as part of amendments to the *Patent Act*.[191] In order to comply with NAFTA,[192] the amendments abolished the compulsory

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[187] *Ibid*. Springboarding applies to a patented invention, other than a new animal drug or veterinary biological product (as those terms are used in the *Federal Food, Drug, and Cosmetic Act* and the Act of March 4, 1913) that is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques.
[188] 666 F. Supp. 1379 (N.D. Cal. 1987).
[189] 755 F. Supp. 1269 (N.D. Cal. 1991).
[190] *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.,* 982 F.2d 1520, 25 U.S.P.Q.2d (BNA)1196 (1992); *NeoRx Corp v. Immunomedics, Inc*. 877 F. Supp. 202 (D.N.J. 1994).
[191] *Patented Medicines (Notice of Compliance) Regulations,* SOR 93-133, 5(1) (2001) (Can.). See P. Carter, 'Federal Regulation of Pharmaceuticals in the United States and Canada' (1999) *21 Loy. L.A. Int'l & Comp.* L.J. 215, 243.
[192] *North American Free Trade Agreement*, Dec. 17, 1992, 32 I.L.M. 289 (1993) art. 1709, § 7, at 673.

licensing scheme, which had allowed generics manufacturers to apply to the Commissioner of Patents for a license to manufacture and market a patented drug after the first seven years of patent protection had expired, upon payment of a royalty fee to the patentee.[193]

The amendments also introduced a springboarding exception allowing a generics manufacturer to make a patented drug solely for Health Canada's regulatory approval, in order to aid generics manufacturers in entering the market. The key springboarding provision is found in section 55.2(1) of the Canadian Patent Act,[194] and provides that it is not an infringement of a patent for any person to "make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information" for regulatory approval. Springboarding can occur at any time during the patent term. As discussed in chapter 1, patent extensions are not allowed.

The validity of the springboarding exception to infringement was upheld by the WTO Dispute Panel in 2000.[195] Canada's "stockpiling" exception,[196] which allowed the manufacture of pharmaceuticals for six months prior to the expiry of a patent, was ruled to be contrary to TRIPs by the WTO Dispute Panel[197] and consequently repealed in 2001.[198]

4.3.2 INTERPRETATION

Although the Canadian statute uses language nearly identical to the US statute, in contrast with the US there has been little litigation in Canada about what type activities are included in the springboarding provision.[199]

Instead, most of the litigation in Canada has focussed upon the issuance of the notice of compliance. Under the Canadian regulations, a party applying for a notice of compliance must state that the existing patent is not valid, or that the making or selling of the drug for which the submission is filed would not infringe the claim for the drug or the use of the drug.[200] Litigation has centred around whether the

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[193] P. Carter, 'Federal Regulation of Pharmaceuticals in the United States and Canada' (1999) *21 Loy. L.A. Int'l & Comp.* L.J. 215, 242.
[194] *Patent Act 1985* S55.2(1).
[195] EU v. Canada – Patent Protection of Pharmaceutical Products, WT/DS/114 (March 17, 2000). The WTO Panel agreed with Canada that the springboarding provision falls within the "limited exceptions" of Article 30.
[196] *Patent Act 1985* S55.2(2).
[197] EU v. Canada – Patent Protection of Pharmaceutical Products, WT/DS/114 (March 17, 2000).
[198] Repealed, 2001, c. 10, s. 2.
[199] M. Atkinson, 'Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada' (2002) 11 *Pac. Rim L. & Pol'y J.* 181, 194.
[200] *Patented Medicines (Notice of Compliance) Regulations*, SOR 93-133, § 5(1) (2001)(Can.).

application for an injunctive order starts an action for infringement,[201] which party bears the onus of proof in establishing infringement (or lack thereof),[202] and the amount of detail required in the statement of the legal and factual basis of the allegation.[203]

4.3.3 PROPOSALS FOR REFORM

In 1997, before the WTO Dispute Panel case was decided, the Canadian Pharmacists Association (CPhA) and the Canadian Generic Pharmaceutical Association (CGPA; an organisation representing Canadian generics manufacturers) [204] made a submission to the Standing Committee of Industry, recommending changes to the Patent Act.[205] The proposed amendments included allowing generics companies to manufacture, for export purposes only, before the 6 month early working period,[206] any drug which patent expires more than 6 months prior to patent expiration in Canada.[207] The Committee held that there was not "sufficient evidence to suggest that [an exemption to export where the relevant patent has expired] would be within the context of our international trade obligations."[208] The Committee also noted that such an amendment would be unprecedented internationally. The Committee did not recommend such a change. However the Committee cautioned the government that anecdotal evidence suggests that generics companies have relocated their manufacturing facilities outside Canada in order to make drug products for foreign markets.

In 1999, the CGPA made a similar submission to the House of Commons Standing Committee on Foreign Affairs and International Trade, proposing an amendment to the Patent Act to permit the exportation of generic drugs to countries where there was no patent protection.[209] CGPA argued that the changes to the *Patent Act* in 1993 to remove compulsory licensing (and hence preclude manufacture for export) meant that

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[201] *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.,* [1995] 1 F.C. 588, 599.
[202] *Syntex (U.S.A.) Inc. v. Novopharm Ltd.*, [1996] 65 C.P.R. (3d) 499, 505.
[203] *Ibid*. at 504.
[204] Formerly known as Canadian Drug Manufacturer's Association.
[205] Standing Committee of Industry regarding the Review of the *Patent Act Amendment Act*, *1992* http://www.parl.gc.ca/committees352/indu/reports/05_1997-04/chap3-e.html
[206] This provision was subject to the WTO Dispute Panel ruling and was found to be invalid. EU v. Canada – Patent Protection of Pharmaceutical Products, WT/DS/114 (March 17, 2000).
[207] Canadian Pharmacists Association, http://www.pharmacists.ca/content/about_cpha/whats_happening/government_affairs/government_briefs_040197.cfm.
[208] Standing Committee of Industry regarding the Review of the *Patent Act Amendment Act*, *1992*, http://www.parl.gc.ca/committees352/indu/reports/05_1997-04/rec-e.html.
[209] House of Commons Standing Committee on Foreign Affairs and International Trade, Canada and the Future of the World Trade Organisation, (June 1999) http://www.parl.gc.ca/InfoComDoc/36/1/FAIT/Studies/Reports/faitrp09-e.htmnumbertoc. CGPA argued that such an exemption to infringement would be compliant with the three step test in Article 30 in TRIPs.

Canadian companies were forced to relocate their manufacturing facilities in order to compete in overseas markets. The Committee did not adopt the CGPA proposal in their recommendations to the Canadian government. The Committee concluded that there should be a "national consensus" before discussing the issue of drug patents in the then forthcoming new round of WTO negotiations.[210]

In October 2002, the CGPA submitted a proposal to the Commission on the Future of Health Care in Canada, outlining recommended changes to reduce health care expenditures in Canada. The proposed changes include allowing generics companies to manufacture drugs for export for use in developing countries.[211] The Canadian government has not adopted these recommendations.

4.4. European Union

4.4.1 LAWS AND REGULATIONS

There is currently no treaty, regulation or directive in the EU that addresses the issue of springboarding. The European Patent Convention provides that infringement of a European patent shall be dealt with by national laws.[212] This area of law has not been harmonised.

At present, the nature of experimental work that a generics manufacturer can undertake on a patented invention is left to the discretion of EU countries, none of which have expressly provided for springboarding in their national law.[213] The issue has been addressed in the case law of the EU member states. In the United Kingdom and the Netherlands,[214] the provision of samples is not permitted during the patent term. In Germany, springboarding is allowed as part of general investigation of research. In Italy, testing is possible during an extended patent term.[215]

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[210] House of Commons Standing Committee on Foreign Affairs and International Trade, Canada and the Future of the World Trade Organisation, (June 1999) http://www.parl.gc.ca/InfoComDoc/36/1/FAIT/Studies/Reports/faitrp09/22.htm

[211] Canadian Generic Pharmaceutical Association, http://www.cdma-acfpp.org/en/news_releases/index.shtml.

[212] Convention on the Grant of European Patents (European Patent Convention), October 1973, s64(3).

[213] European Generic Medicines Association, Pharmaceutical Intellectual Property Issues and Enlargement, <www.egagenerics.com/facts_figures/eu_enlargement/bolar_enlargement.htm>.

[214] In 1997, the European Court of Justice ruled a judicial interpretation of the law in the Netherlands which held that the use of a patented drug by a generics manufacturer for the purpose of gaining regulatory approval, is an act of patent infringement, was not contrary to the EC treaty. See Case C-316/95, *Generics BV v. Smith Kline & French Lab. Ltd.,* 1997 CEC (CCH) 1029 (1997).

[215] European Generic Medicines Association, Pharmaceutical Intellectual Property Issues and Enlargement, <www.egagenerics.com/facts_figures/eu_enlargement/bolar_enlargement.htm>.

4.4.2 PROPOSALS FOR REFORM

Amendments to introduce springboarding provisions are currently being debated.[216] In July 2000, the European Generic Medicines Association (EGMA) proposed amendments to national and EU laws in order to allow development, testing and experimental work during the patent period for the purposes of regulatory approval.[217] In November 2001, the European Commission proposed major modifications to the existing pharmaceutical legislation in the European Union. These changes include an exemption from infringement for testing conducted for purposes of regulatory approval for generic medicinal products.[218] The aim of the proposed introduction of a springboarding provision is to support the generics industry and promote competition in the pharmaceutical field. European Commission estimates that EU generics only hold 10% of market share, whereas American generics hold 35% of market share.[219] The Commission estimates that the springboarding provision might save European generics manufacturers up to two years.[220]

Other proposed changes include a "fast-track" registration procedure for products of significant therapeutic interest, conditional marketing authorisation where there is a significant patient need, a one year extension for additional innovative indications which bring important clinical benefit for patients and a harmonisation of administrative data protection periods between member states of 10 years.[221]

4.5. Australia

4.5.1 LAWS AND REGULATIONS

In Australia, the patentee has the exclusive right during the term of the patent, to exploit the invention and to authorise another person to exploit the invention.[222] Where the invention is a product, the definition of "exploit" is to "make, hire, sell or

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[216] Proposals for Pharmaceutical Regulatory Reform in the European Union: Part 1, The Audit of the European Medicines Evaluation Agency and the Pharmaceutical Review (2001).
[217] The European Generic Medicines Association proposed the insertion of the following provision into EU law: "Any experimental work, testing or provision of samples required for the purpose of a registration cannot regarded as a breach of the intellectual property protection of the original medicine." European Generic Medicines Association, EGA Position Paper, 'A Proposal to Include a Development and Testing Provision for Generic Medicines in National and EU Laws' (July 2000).
[218] Proposals to Modify European Parliament and Council Directive 2001/83/EC on the Community Code relating to medicinal products for human use, Article 10(4).
<http://pharmacos.eudra.org/F2/review/doc/twoc/codehumain_11-2001_en.pdf>.
[219] E. Liikanen, Commission's Proposal to Review EU Pharmaceutical Legislation, (Press Conference, July 2001, Brussels).
[220] Ibid.
[221] Ibid.
[222] *Patents Act 1990*, section 13.

otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it or keep it for the purpose of doing any of these things."[223]

Where an extension is granted, the springboarding provisions provide that the exclusive rights of the patentee are deemed *not* to be infringed by: [224]

- A person exploiting the **pharmaceutical substance *per se*** (or a pharmaceutical substance when produced by a process involving recombinant DNA technology) **solely for purposes in connection with having the goods included in the Australian Register of Therapeutic Goods** or obtaining similar regulatory approval under the law of a foreign country;[225]

Thus, after an extension is granted, a person may exploit the pharmaceutical substance[226] for the purpose of acquiring regulatory approval.

The *Patents Act 1990* also provides that *during the term of the extension*, the exclusive rights of the patentee are deemed *not* to be infringed by: [227]

- A person exploiting the **pharmaceutical substance *per se*** (or a pharmaceutical substance when produced by a process involving recombinant DNA technology) **for a purpose other than therapeutic use**;[228]
- A person **exploiting any form of the invention other than the pharmaceutical substance *per se*** (or a pharmaceutical substance when produced by a process involving recombinant DNA technology) (for any purpose).[229]

Although this provision is not a springboarding provision (because it does not specifically address activities for the purposes of gaining regulatory approval), it does limit the exclusive rights of a patentee during the extension term. In effect, this section provides that the patentee's rights only extend to the exploitation of a pharmaceutical substance per se, or to the exploitation of claims to a pharmaceutical substance when produced by a process involving recombinant DNA technology, *for therapeutic use*.[230] Thus, the exclusive rights of the patentee do not attach to other

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[223] *Patents Act 1990*, Schedule 1.
[224] *Patents Act 1990*, Schedule 78. The *Intellectual Property Laws Amendment Act 199*8 amended the Patents Act to allow this springboarding activity.
[225] *Patents Act 1990*, section 78(2).
[226] See Section 1.5.1(a) for a discussion of the definition of a "pharmaceutical substance."
[227] *Patents Act 1990*, Schedule 78. The *Intellectual Property Laws Amendment Act 199*8 amended the Patents Act to allow this springboarding activity.
[228] *Patents Act 1990*, section 78(1)(a).
[229] *Patents Act 1990*, section 78(1)(b).
[230] Explanatory Memorandum, Intellectual Property Laws Amendment Bill 1998, Parliament of the Commonwealth of Australia, Senate, 12.

types of exploitation, because under this section such exploitation will be deemed not to be infringement.

4.5.2 INTERPRETATION

The aim of the springboarding provisions in Australia is to balance, on one hand, the rights of pharmaceutical companies who are granted a patent extension due to regulatory delay and, on the other hand, the interests of the manufacturers who may wish to develop a generic version of the product. In Australia, springboarding is limited to patents that the patent owner has chosen to extend and is allowed from the date an extension is granted.[231] Under the *Patents Act 1990*, only patents for a pharmaceutical substance *per se*,[232] or the pharmaceutical substance when produced by a process involving recombinant DNA technology, are eligible for extension.[233] Thus, springboarding is only allowed on these types of claims in Australia and thus cannot be used in relation to any other patents such as patents covering the process of manufacture of the invention or the use of the invention. Such other patents may be necessary in seeking regulatory approval and thus the Australian legislation in practice may adversely impact upon generics manufacturers.

4.5.3 PROPOSALS FOR REFORM

Various options are being considered by the Australian government in relation to changing the springboarding provisions to focus upon the *purpose* of the activity (ie. to seek regulatory approval) rather than the *type* of patent.

Refer to Chapter 5 for a discussion of the Australian proposal.

4.6. Other Jurisdictions

4.6.1 ISRAEL

In February 1998, the Israeli government amended the patent law to provide that exploitation of a patented invention, solely and exclusively for the purpose of obtaining regulatory approval for the sale and/or use of the subject matter of the patent, whether in Israel or in any other country, shall not constitute infringement of the patent. Thus, under the new laws, generic companies are allowed to manufacture limited quantities of pharmaceuticals for export prior to the expiration of the patent,

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[231] *Patents Act 1990*, subsection 70(2).
[232] See Section 1.5.1(a) for a discussion of the definition of a "pharmaceutical substance."
[233] *Patents Act 1990*, subsection 70(2).

but only for the purpose of submitting data to foreign health authorities for marketing approval.[234]

The law has been subject to massive lobbying by Israeli generics manufacturers and intense opposition by the United States and the European Union.[235] The United States has mounted strenuous objections to this amendment, and has placed Israel on the "Special 301 Priority Watch List" for failing to observe intellectual property rights.[236] The "Special 301" provisions of the *Trade Act of 1974* require the United States Trade Representative to determine whether the "acts, policies and practices of foreign countries deny adequate and effective intellectual property rights or fair and equitable market access for US persons that rely on intellectual property protection." Israel has been designated as a country noted on the priority watch list due to their failure to provide adequate copyright protection and their amended laws on patents that allow manufacture in order to export for regulatory purposes.[237] Innovative manufacturers have predicted that the provision will be misused for large scale manufacturing of pharmaceutical products for export and have criticised the Israeli government for failing to implement any effective enforcement mechanisms to prevent abuse of this provision and.[238]

4.6.2 INDIA

In May 2002, India amended their patent law, to change the scope of patentable inventions, to raise the term of patents to 20 years, to narrow the framework on compulsory licensing, and to removes license of right. The reform was undertaken in order to conform to the TRIPs agreement.[239] One commentator has criticised the new legislation as not supporting the domestic industry by failing to incorporate a provision to allow an exception for infringement for manufacture for export.[240]

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[234] United States Trade Representative, 1999 National Trade Estimate (NTE) Report, http://www.ustr.gov/reports/nte/1999/contents.html. The law also contains a provision allowing patent extension.

[235] I. Shachter, 'Amendment of the Israel Patent Law in order to Provide for Non-Infringing Pre-expiry Exploitation of Patents and Their Expiry of Term' Reinhold Cohn & Partners, http://www.patents.co.il/artsum21.html.

[236] USTR Announces Results of Special 301 Annual Review, Office of the United States Trade Representative, May 1998, http://www.ustr.gov/releases/1998/05/98-44.pdf. If a country is designated as a Priority Foreign Country, the USTR must decide within 30 days whether to initiate an investigation of the acts or policies that were the basis of the designation.

[237] USTR Announces Results of Special 301 Annual Review, Office of the United States Trade Representative, May 1998, http://www.ustr.gov/releases/1998/05/98-44.pdf

[238] Pharmaceutical Manufacturers Association (PhRM), Issues & Policy: International: NTE: Israel, http://www.cptech.org/ip/health/phrma/nte-99/israel.htm.

[239] The Patents (Second Amendment) Bill, 2002 amended the Indian Patent Act (19700> The law was awaiting the assent of the President in June 2002.

[240] D. Abrol, 'Over-riding the Indian Interest', India Together (June 2002) http://indiatogetehr.org/legislation/bills/patentsamend.htm.

4.6.3 OTHER JURISDICTIONS

There does not seem to be any other jurisdictions that permit manufacture for export during the patent term.

4.7. Comparison of Springboarding Provisions Across Jurisdictions

The US, Canada and Australia all include provisions in their patent Acts to allow the use of a patented invention for reasons related to seeking regulatory approval. The EU does not have springboarding provisions but is currently debating a proposal by the European Commission to introduce springboarding provisions.

In the US and Canada, springboarding is allowed at any time during the patent term for any type of patent. In Australia, springboarding can only occur once the patent extension has been granted, and only upon patents that are eligible for extension (namely, a pharmaceutical substance *per se* and a pharmaceutical substance when produced by a process involving recombinant DNA). Thus, in Australia, springboarding can only occur on certain types of patents.

4.7.1 TABULAR SUMMARY

Jurisdiction	Spring boarding?	When?	Type of Patent?	Purpose of Use?
US	Yes	At any time during the patent term	Any patent	Solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use of sale of drugs or veterinary biological products
Canada	Yes	At any time during the patent term	Any patent	Solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product
Europe	No	N/A	N/A	N/A
Australia	Yes	During the period in which a patent term has been extended	Pharmaceutical substance *per se* or a pharmaceutical substance when produced by a process involving recombinant DNA	Solely for purposes in connection with having the goods included in the Australian Register of Therapeutic Goods or obtaining similar regulatory approval under the law of a foreign country

5 AUSTRALIAN PROPOSAL

5.1 Introduction

The Australian government is currently considering a proposal to revise the *Patents Act* to allow (1) manufacture for export during the extension period and (2) springboarding for developmental and testing activities required to obtain regulatory approval on *all* pharmaceutical patents.

5.2 Manufacture for Export

The proposal to allow, during the period of an extension of patent term, the manufacture of pharmaceuticals for export, is aimed at stimulating growth of the generics industry, tapping into the export potential, and promoting Australia as an investment location for generics manufacturers.[241]

It is *arguable* that the Australian *Patents Act* already allows manufacture for export during the extension period, by virtue of section 78(1)(a). This argument is explained below.

Limitation of rights under Section 78(1)(a)

Section 78(1) defines the scope of the patentee's exclusive rights during the extension period, by setting out the activities that do not constitute an infringement. Section 78(1)(a) provides that exploitation of the pharmaceutical substance *per se* or of the pharmaceutical substance when produced by a process involving recombinant DNA technology (both hereafter simplified to "pharmaceutical substance"), for a purpose *other than* "therapeutic use",[242] is not an infringement of the patent. That is to say, under section 78(1)(a) the *only* act of exploitation of a pharmaceutical substance that constitutes an infringement during the extension period is exploitation for the purpose of therapeutic use.

Exploitation and infringement

The *Patents Act* provides that the grant of a patent bestows on the patentee the exclusive rights to exploit the invention and to authorise another person to exploit the invention.[243] The word "exploitation", in relation to a product, is defined in Schedule 1 to mean essentially make, hire, sell or otherwise dispose of the product. Thus, the

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[241] DITR Discussion Paper of September 2002.
[242] The phrase "therapeutic use" is defined in Schedule 1 to mean essentially use for the purpose of preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons (hereafter "treating disease").
[243] *Patents Act 1990*, Section 13(1).

manufacture in Australia of a patented pharmaceutical substance constitutes an "exploitation" of that substance.

Whether or not that manufacture constitutes an infringement of the patent during the extension period depends on the *purpose* of the exploitation. Under section 78(1)(a), the exploitation during the extension period will *not* be an infringement unless the purpose of the exploitation is for "therapeutic use".

Territorial limitation of patent rights

The *Patents Act* expressly states that a patent "has effect throughout the patent area".[244] The patent area is Australia.[245] Thus, the exclusive rights of the patentee under the *Patents Act* are the right to exploit, and the right to authorise another person to exploit, the patent *in Australia*.

Because an Australian patent only has effect in Australia, it would seem to follow that the reduced exclusive rights of the patentee during the extension period are territorially limited. That is to say, it seems a plausible reading of section 78(1)(a) that the only act of exploitation of a pharmaceutical substance that constitutes an infringement during the extension period is exploitation for the purpose of therapeutic use *in Australia*.

Manufacture for export

In the usual case of manufacture for sale in Australia, the manufacture is an exploitation for the purpose of therapeutic use in Australia, because the manufacture is for the purpose of producing and selling the pharmaceutical substance to treat disease in Australia. In the case of manufacture *solely for export*, however, it may be argued that the manufacture is an exploitation for a purpose *other than* therapeutic use in Australia, because the pharmaceutical substance is not being manufactured for the purpose of treating disease *in Australia*.

We recognise that there are counterarguments to this construction, as well as other arguments to support this construction. We do not purport to resolve the issue of interpretation, but merely seek to identify a plausible interpretation: namely, that manufacture for export purposes is already allowed in the *Patents Act* under s78(1)(a).

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[244] *Patents Act 1990*, Section 13(3).
[245] *Patents Act 1990*, Schedule 1 definition of "patent area".

5.3 Springboarding

The Australian government is currently considering a proposal to revise the springboarding provisions in the *Patents Act* to align that Act with legislation in comparable jurisdictions. The proposed change, as outlined in the DITR discussion paper, is to allow springboarding for developmental and testing activities required to obtain regulatory approval on *all* pharmaceutical patents. By this we understand that springboarding would by allowed on all patents pertaining to pharmaceuticals, such as 'use', 'method' and 'process' patents. Thus, springboarding would depend on the *purpose* of the activity rather than the *type* of patent.

5.3.1 Effect of Springboarding Proposal on Generics Manufacturers

The Therapeutic Goods Administration (TGA), through the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations*, is responsible for the quality, safety and efficacy of drugs and medical devices in Australia. In assessing a pharmaceutical product, the TGA must consider factors such as the "strength of a product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used."[246]

The regulatory approval process for pharmaceuticals is particularly rigorous and time consuming.[247] Springboarding is currently allowed on pharmaceutical substances *per se* and pharmaceutical substances when produced by a process involving recombinant DNA technology. The proposed changes to allow springboarding on *all* patents pertaining to pharmaceuticals, would enable generics manufacturers to exploit not only patented inventions for "pharmaceutical substances *per se*" but also patents on methods of manufacture of pharmaceuticals and on uses of pharmaceuticals.

The ability to exploit such patented inventions should, in principle, facilitate regulatory approval, as it would reduce the time required for generics manufacturers to enter the market with their generic product.

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[246] Therapeutic Goods Administration, Medicines Regulation and the TGA (December 1999) http://www.health.gov.au/tga/docs/pdf/medregs.pdf.

[247] See Australia's submission to the WTO Dispute Panel, *EU v. Canada – Patent Protection of Pharmaceutical Products,* WT/DS/114 (March 17, 2000). See *Australian Guidelines for the Registration of Drugs, Vols 1 & 2* and *the Australian Guidelines for the Listing of Drugs, http://www.health.gov.au/tga/pubs/pubs.htm#medlist*.

Under the *Therapeutic Goods Act 1989,* the generics manufacturer must submit the following information to the TGA:[248]

- Details of the facilities, method of manufacture and controls to be used in the manufacture, preparation and packaging of the drug
- Details of the tests applied to control the purity, stability and safety of the drug
- Evidence that all test batches of the drug used in the studies in the submission were manufactured and controlled in a manner that is representative of market production
- Evidence of clinical safety and effectiveness (established by comparative studies with another patent product)

As discussed in Section 3.2, innovative manufacturers often use a "layering" strategy of patenting different features of the same drug.

For example, an innovative manufacturer can patent the following features of a drug:

- Process of manufacturing the raw material;
- Compound of substances;
- Use (medical indications to which the drug can be applied);
- Administration of the drug (ie. dose, method of treatment);
- Metabolites resulting from the enzymatic degradation of the parent drug by the body;
- Non-essential feature of the drug such as the colour or shape of a pill or packaging.

It is interesting to examine which of the above patents fall within the scope of the current springboarding provisions and the effect on generics manufacturers of allowing springboarding on *all* types of patents (as per the proposal).

(a) Process of manufacturing the raw material

Process patents do not fall within the scope of the current springboarding provisions so generics manufacturers could not springboard off a patent on the process of manufacturing the pharmaceutical. Thus, currently generics manufacturers would be unable to exploit the patented process in order to manufacture the pharmaceutical

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[248] *EU v. Canada – Patent Protection of Pharmaceutical Products*, WT/DS/114 (March 17, 2000), 4. The EU Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) has been adopted in Australia with TGA annotations, http://www.health.gov.au/tga/docs/html/euguidead.htm#application.

substance. The generics manufacturer would have to find another way to manufacture the substance or wait until the patent on the process expired.

Under the proposal, springboarding would be allowed on process patents. Thus, a generics manufacturer would be able to exploit the patented process to manufacture the pharmaceutical substance. Since details on the method of manufacture are required by the TGA for regulatory approval, allowing springboarding on the process should, in principle, facilitate regulatory approval for the generic version of the drug.

(b) Compounds of Substances

Currently, compounds of substances are subject to springboarding due to the definition of 'pharmaceutical substance' in Schedule 1 of the *Patents Act,* which includes a 'mixture or a compound of substances' (see Section 1.5.1(a)). Thus generics manufacturers could springboard off a patent for the compounds of substances.

The proposal would not change the current state of affairs and would thus have no effect on facilitating generics manufacturers in obtaining regulatory approval.

(c) Use (medical indications to which the drug can be applied)

Currently, 'use' patents are not subject to springboarding so generics manufacturers could not springboard off a patent for the use of the pharmaceutical substance. Presumably, clinical trials to demonstrate safety and effectiveness (as required by the TGA) would require the drug to be 'used' or applied in the relevant medical fashion. Obviously, if the generics manufacturer had an alternative use (which wasn't under patent) then they could seek regulatory approval for such a use without infringing a patent. However, the generics manufacturer would not be allowed to 'use' the drug in clinical trials (in order to gain regulatory approval) if the 'use' was protected by a patent.

Under the proposal, springboarding would be allowed on patents for the 'use' of a pharmaceutical substance. Thus, a generics manufacturer would be able to exploit the patented use in order to conduct clinical trials. Since evidence of clinical safety and effectiveness are required by the TGA for regulatory approval, allowing springboarding on the use of a pharmaceutical should, in principle, facilitate regulatory approval for the generic version of the drug.

(d) Administration of the drug (ie. dose, method of treatment)

Currently, patents for the administration of a drug are not subject to springboarding so generics manufacturers could not springboard off such a patent. Presumably, clinical trials to demonstrate safety and effectiveness (as required by the TGA) would require the drug to be administered in the relevant medical fashion. As noted above in relation to 'use' of a drug, the generics manufacturer would not be allowed to administer the drug in clinical trials (in order to gain regulatory approval) if the particular way of administering the drug was under patent.

Under the proposal, springboarding would be allowed on patents for the 'administration' of a pharmaceutical substance. Thus, a generics manufacturer would be able to administer the drug, even if the administration was patented, in order to conduct clinical trials. Since evidence of clinical safety and effectiveness are required by the TGA for regulatory approval, allowing springboarding on the administration of a pharmaceutical would facilitate regulatory approval for the generic version of the drug.

(e) Metabolites resulting from the enzymatic degradation of the parent drug by the body

Metabolites resulting from the enzymatic degradation of the parent drug by the body would probably not fall under the definition of 'pharmaceutical substance' in Schedule 1 of the Patents Act and thus are not subject to springboarding. If a generics manufacturers sought to conduct clinical trials, the patented metabolite would be produced in the body of the patients and thus the patent would arguably be infringed.

The proposal would mean that patents protecting metabolites would be subject to springboarding. Thus regulatory approval would be facilitated.

(f) Non-essential feature of the drug such as the colour or shape of a pill or packaging

Currently, patents for non-essential features of a drug such as the colour or shape of a pill or packaging are not subject to springboarding. Generics manufacturers are required to submit information about packaging of the drug to the TGA and thus would need to design their own packaging, colour or shape in order not to infringe the patent.

Under the proposal, springboarding would be allowed on all patents, and thus generics manufacturers could exploit patented inventions for the colour or shape of a pill or the packaging in order to seek regulatory approval. This would facilitate the regulatory review process.

Conclusion

In conclusion, the effect of the proposal on generics manufacturers should, in principle, facilitate regulatory approval as generics manufacturers would be able to conduct clinical trials and submit data to the TGA in relation to the process and manufacture of drugs without (potentially) infringing a patent. This should, in principle, result in earlier market entry for the generic version of the drug.

APPENDIX 1: PROBLEMS WITH CONFIRMING EXPIRY DATES

Problems with Data

There were three generic drugs that were not found in the DITR list.[249] The patent numbers for these drugs are not yet known and thus the data concerning their patent expiry dates is yet to be confirmed.

There were two entries in the DITR list for the drug "atovastatin".[250] The first entry (with the Australian patent number 601981[251]) correlated with the information in DITR Attachment A (ie the patent expiry dates were all confirmed for that version of the drug). Thus the data for the first entry of "atovastatin" was used.

The patent number on the DITR list for 'ciprofloxacin' was found on the list of extended US patents but the brand name was marked as 'baytril' while DITR Attachment A stated that the brand name was 'ciproxin'. A search of the USPTO patents database using the patent number yielded the specification which confirmed the same chemical constituents as the Australian patent and the same inventor as marked on DITR Attachment A. The expiry date for 'baytril' was Dec-06, which was the same as DITR Attachment A and thus the data was confirmed.

There was no entry for "enalapril" in the DITR list – there was an entry for "enalapril (plus)" and "enalapril maleate". The patent expiry dates for "enalapril (plus)" correlated with the patent expiry dates for "enalapril" in DITR Attachment A. Thus, the "enalapril (plus)" data was used.

There were three drugs for which there were no entries on the DITR list that matched the generic drug name exactly ("fluticasone", "cetirizine" and "disodium pamidronate"). However, there were entries in the DITR list which were very similar ("fluticasone propionate", "cetrizine", "pamidronate"). The patent expiry dates for these similar drugs correlated with the patent expiry dates in DITR Attachment A. Thus it is assumed that the difference was due to spelling errors or inconsistencies in abbreviations. The data for fluticasone propionate, cetrizine and pamidronate were used. These changes are noted in Table 1.

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[249] Amoxicillin + potassium clavulanate, lisinopril and lovastatin.
[250] Note that in the DITR Attachment A, the spelling was atorvastatin. This is assumed to be a spelling mistake, the drug name should be spelt atovastatin.
[251] US patent number 4681893 and UK patent number 247633.

Table 6 Drugs with Unconfirmed Patent Expiry

Number	Generic Drug Name	Jurisdictions where Expiry Date is Unconfirmed
6	Olanzapine	US
9	Amoxicillin + potassium clavulanate	US
12	Flucitasone Propionate	US
14	Lisinopril	AU, US, UK
16	Pamidronate	US
18	Lovastatin	AU

Summary of Attempted Searches

6. Olanzapine

The US Patent number on DITR List not found on extended US patent list

- "Quick search" on USPTO website yielded a patent for a method for modifying a fault-tolerant processing system (not a pharmaceutical drug product)
- Incorrect US patent number

The UK Patent number on DITR List not found on UKPTO patent database

- Searched under 'olanzapine' as title
    - 130 matching documents, US patent on 2-methyl theino benzodiazepine, feb-95 assignee Eli Lilly
- Could not find AU patent number in the list of matching documents
- Incorrect UK patent number

9. Amoxicillin + potassium clavulanate

DITR list had no listing of Amoxicillin + potassium clavulanate

- Searched on USPTO database under Amoxicillin + potassium clavulanate and found no patents
- Searched on USPTO database under Amoxicillin and augmentin and found 47 hits
- Google search found press release that court had invalidated remaining 3 GlaxoSmithKline patents on Augmentin (May 2002) which would otherwise be due to expire December 2002 (same date as Att A) GSK is appealing the decision

- Printed product description for Augmentin from GSK website

10. Ciprofloxacin

Patent number on DITR List was found on the list of extended US patents but the brand name was Baytril rather than Ciproxin

- Expiry date for Baytril was Dec-06, same as Att A
- Quick search using patent number found patent with patent owner Bayer (same as Att A) and specification seemed to be same as AU (ie. 7-amino-1-cyclopropyl-4oxo-1)
- This looks like the same drug and thus has been included in Tables 1 and 2

12. Flucitasone Propionate

Patent number on DITR list corresponds to US extended patent list but brand name is listed as 'cutivate ointment' (ie topical application) rather than 'flovent' (inhalent/spray)

- Expiry date in Nov-03 on US list
- Expiry date in Nov-03 on Att A list

14. Lisinopril

DITR list had no listing of Lisinopril

Searched under brand name of Prinivil on US extended patent list

- Found extended US patent, expiry date Dec-01, same as Att A
- Searched on USPTO website via patent number
- Found patent for Aminoacid derivatives as antihypertensives (inventor was Merck same as Att A)
- Not included in Att A

Searched on UKPTO under lisinopril

- 40 entries, none with US patent number
- None which looked like "aminoacid derivatives as antihypertensives"

16. Pamidronate

US patent number on DITR list not found on extended US patent list

- Found using patent number search (seems to be same chemical constituents as Australian patent)
- Filed in Sep-86 (thus should expire Sep-06 if std 20 year term without extension)
- Att A expiry is Jul 05

18. Lovastatin

Patent no. not found on DITR List

Mevacor (brand name) found on list of extended US patents

- Expiry date on US list is Jun-01 (same as Att A figures)

- NEW data from DITR says US expiry date Dec –01
- Not added to Table 1

Searched on the UKPTO under Lovastatin

- 177 entries
- No entries with same US patent number as Mevacor on extended US patents list
- Found PCT application for method of production of lovastatin (filing date Oct-96), not same inventor

Searched on the UKPTO under Merck Sharp Dohme (as applicant)

- 3000 entries

Searched by Merck Sharp Dohme and title/abstract/application no./International Class

- No results

Searched on PCT under Merck Sharp Dohme

- No entries

APPENDIX 2: 35 UNITED STATES CODE

Sec. 154. - Contents and term of patent

(a) In General. -

(1) Contents. -

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

(2) Term. -

Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

(3) Priority. -

Priority under section 119, 365(a), or 365(b) of this title shall not be taken into account in determining the term of a patent.

(4) Specification and drawing. -

A copy of the specification and drawing shall be annexed to the patent and be a part of such patent.

(b) Term Extension. -

(1) Interference delay or secrecy orders. -

If the issue of an original patent is delayed due to a proceeding under section 135(a) of this title, or because the application for patent is placed under an order pursuant to section 181 of this title, the term of the patent shall be extended for the period of delay, but in no case more than 5 years.

(2) Extension for appellate review. -

If the issue of a patent is delayed due to appellate review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended for a period of time but in no case more than 5 years. A patent shall not be eligible for extension under this paragraph if it is subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review.

(3) Limitations. -

The period of extension referred to in paragraph (2) -

(A)

shall include any period beginning on the date on which an appeal is filed under section 134 or 141 of this title, or on which an action is commenced under section 145 of this title, and ending on the date of a final decision in favor of the applicant;

(B)

shall be reduced by any time attributable to appellate review before the expiration of 3 years from the filing date of the application for patent; and

(C)

shall be reduced for the period of time during which the applicant for patent did not act with due diligence, as determined by the Commissioner.

(4) Length of extension. -

The total duration of all extensions of a patent under this subsection shall not exceed 5 years.

(c) Continuation. -

(1) Determination. -

The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) Remedies. -

The remedies of sections 283, 284, and 285 of this title shall not apply to acts which -

(A)

were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B)

became infringing by reason of paragraph (1).

(3) Remuneration. -

The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

Title 35 Sec. 156. - Extension of Patent Term

(a)

The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if -

(1)

the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2)

the term of the patent has never been extended under subsection (e)(1) of this section;

(3)

an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4)

the product has been subject to a regulatory review period before its commercial marketing or use;

(5)

(A)

except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B)

in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C)

for purposes of subparagraph (A), in the case of a patent which -

(i)

claims a new animal drug or a veterinary biological product which

(I)

is not covered by the claims in any other patent which has been extended, and

(II)

has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii)

was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the "approved product".

(b)

Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended -

(1)

in the case of a patent which claims a product, be limited to any use approved for the product -

(A)

before the expiration of the term of the patent -

(i)

under the provision of law under which the applicable regulatory review occurred, or

(ii)

under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B)

on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2)

in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product -

(A)

before the expiration of the term of the patent -

(i)

under any provision of law under which an applicable regulatory review occurred, and

(ii)

under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B)

on or after the expiration of the regulatory review period upon which the extension of the patent was based; and

(3)

in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make -

(A)

the approved product, or

(B)

the product if it has been subject to a regulatory review period described in paragraphs [1] (1), (4), or (5) of subsection (g). approved product.

(c)

The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that -

(1)

each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2)

after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3)

if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

(4)

in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

(d)

(1)

To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain -

(A)

the identity of the approved product and the Federal statute under which regulatory review occurred;

(B)

the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C)

information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

(D)

a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(E)

such patent or other information as the Commissioner may require.

(2)

(A)

Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify -

(i)

the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and

(ii)

the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Commissioner, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

(B)

(i)

If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than 180 days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in

accordance with regulations promulgated by such Secretary, determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making the determination shall make such determination not later than 90 days after the receipt of such a petition. For a drug product, device, or additive subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the Secretary may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Commissioner of Food and Drugs. For a product subject to the Virus-Serum-Toxin Act, the Secretary of Agriculture may not delegate the authority to make the determination prescribed by this clause to an office below the office [2] of the Assistant Secretary for Marketing and Inspection Services.

(ii)

The Secretary making a determination under clause (i) shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and shall notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

(3)

For the purposes of paragraph (2)(B), the term "due diligence" means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(4)

An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.

(5)

(A)

If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Commissioner for an interim extension

during the period beginning 6 months, and ending 15 days, before such term is due to expire. The application shall contain -

(i)

the identity of the product subject to regulatory review and the Federal statute under which such review is occurring;

(ii)

the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii)

information to enable the Commissioner to determine under subsection (a)(1), (2), and (3) the eligibility of a patent for extension;

(iv)

a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v)

such patent or other information as the Commissioner may require.

(B)

If the Commissioner determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Commissioner shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C)

The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D)

Each certificate of interim extension under this paragraph shall be recorded in the official file of the patent and shall be considered part of the original patent.

(E)

Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the date on which the

product involved receives permission for commercial marketing or use, except that, if within that 60-day period the applicant notifies the Commissioner of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section -

(i)

for not to exceed 5 years from the date of expiration of the original patent term; or

(ii)

if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F)

The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension -

(i)

in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii)

in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii)

in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

(e)

(1)

A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2)

If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(f)

For purposes of this section:

(1)

The term "product" means:

(A)

A drug product.

(B)

Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2)

The term "drug product" means the active ingredient of -

(A)

a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B)

a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(3)

The term "major health or environmental effects test" means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4)

(A)

Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B)

Any reference to section 503, 505, 512, or 515 is a reference to section 503, 505, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

(C)

Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151-158).

(5)

The term "informal hearing" has the meaning prescribed for such term by section 201(y) [3] of the Federal Food, Drug, and Cosmetic Act.

(6)

The term "patent" means a patent issued by the United States Patent and Trademark Office.

(7)

The term "date of enactment" as used in this section means September 24, 1984, for a human drug product, a medical device, food additive, or color additive.

(8)

The term "date of enactment" as used in this section means the date of enactment of the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.

(g)

For purposes of this section, the term "regulatory review period" has the following meanings:

(1)

(A)

In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B)

The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of -

(i)

the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 [3] became effective for the approved product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, (FOOTNOTE 3) and

(ii)

the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507 [3] and ending on the date such application was approved under such section.

(2)

(A)

In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B)

The regulatory review period for a food or color additive is the sum of -

(i)

the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a

petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii)

the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(3)

(A)

In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B)

The regulatory review period for a medical device is the sum of -

(i)

the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii)

the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(4)

(A)

In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B)

The regulatory review period for a new animal drug product is the sum of -

(i)

the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective

for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and

(ii)

the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

(5)

(A)

In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B)

The regulatory period for a veterinary biological product is the sum of -

(i)

the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

(ii)

the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(6)

A period determined under any of the preceding paragraphs is subject to the following limitations:

(A)

If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B)

If the patent involved was issued before the date of the enactment of this section and -

(i)

no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted,

(ii)

no major health or environmental effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

(iii)

no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submittted, [4] before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C)

If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

(h)

The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section

APPENDIX 3: 25 UNITED STATES CODE

Sec. 271. - Infringement of patent

(a)

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b)

Whoever actively induces infringement of a patent shall be liable as an infringer.

(c)

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d)

No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

(1)

derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent;

(2)

licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent;

(3)

sought to enforce his patent rights against infringement or contributory infringement;

(4)

refused to license or use any rights to the patent; or

(5)

conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)

(1)

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2)

It shall be an act of infringement to submit -

(A)

an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B)

an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3)

In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4)

For an act of infringement described in paragraph (2) -

(A)

the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B)

injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C)

damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to

sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(f)

(1)

Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2)

Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g)

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after -

(1)

it is materially changed by subsequent processes; or

(2)

it becomes a trivial and nonessential component of another product.

(h)

As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i)

As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent

APPENDIX 4: CANADA *PATENT ACT 1985*

Contents of patent

42. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.

FORM AND TERM OF PATENTS

Term of patents based on applications filed on or after October 1, 1989

44. Subject to section 46, where an application for a patent is filed under this Act on or after October 1, 1989, the term limited for the duration of the patent is twenty years from the filing date.

R.S., 1985, c. P-4, s. 44; R.S., 1985, c. 33 (3rd Supp.), s. 16; 1993, c. 15, s. 42.

Term of patents based on applications filed before October 1, 1989

45. (1) Subject to section 46, where an application for a patent is filed under this Act before October 1, 1989, the term limited for the duration of the patent is seventeen years from the date on which the patent is issued.

Term from date of issue or filing

(2) Where the term limited for the duration of a patent referred to in subsection (1) had not expired before the day on which this section came into force, the term is seventeen years from the date on which the patent is issued or twenty years from the filing date, whichever term expires later.

R.S., 1985, c. P-4, s. 45; R.S., 1985, c. 33 (3rd Supp.), s. 16; 1993, c. 15, s. 42; 2001, c. 10, s. 1.

Liability for patent infringement

55. (1) A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damage sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement.

Liability damage before patent is granted

(2) A person is liable to pay reasonable compensation to a patentee and to all persons claiming under the patentee for any damage sustained by the patentee or by any of those persons by reason of any act on the part of that person, after the application for the patent became open to public inspection under section 10 and before the grant of the patent, that would have constituted an infringement of the patent if the patent had been granted on the day the application became open to public inspection under that section.

Patentee to be a

(3) Unless otherwise expressly provided, the patentee shall be or be

party — made a party to any proceeding under subsection (1) or (2).

Deemed action for infringement — (4) For the purposes of this section and sections 54 and 55.01 to 59, any proceeding under subsection (2) is deemed to be an action for the infringement of a patent and the act on which that proceeding is based is deemed to be an act of infringement of the patent.

Exception — **55.2** (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

(2) and (3) [Repealed, 2001, c. 10, s. 2]

Regulations — (4) The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1), including, without limiting the generality of the foregoing, regulations

(*a*) respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any product to which a patent may relate may be issued to a patentee or other person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act;

(*b*) respecting the earliest date on which a notice, certificate, permit or other document referred to in paragraph (*a*) that is issued or to be issued to a person other than the patentee may take effect and respecting the manner in which that date is to be determined;

(*c*) governing the resolution of disputes between a patentee or former patentee and any person who applies for a notice, certificate, permit or other document referred to in paragraph (*a*) as to the date on which that notice, certificate, permit or other document may be issued or take effect;

(*d*) conferring rights of action in any court of competent jurisdiction with respect to any disputes referred to in paragraph (*c*) and respecting the remedies that may be sought in the court, the procedure of the court in the matter and the decisions and orders it may make; and

(*e*) generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (*a*) in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.

Inconsistency or conflict — (5) In the event of any inconsistency or conflict between

(*a*) this section or any regulations made under this section, and

(*b*) any Act of Parliament or any regulations made thereunder,

this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.

For greater certainty

(6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.

APPENDIX 5: EUROPEAN COUNCIL REGULATION (EEC)

No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products

Official Journal L 182 , 02/07/1992 P. 0001 - 0005

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,
Having regard to the proposal from the Commission (1),
In cooperation with the European Parliament (2),
Having regard to the opinion of the Economic and Social Committee (3),
Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;
Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection top encourage such research;
Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;
Whereas this situation leads to a lack of protection which penalizes pharmaceutical research;
Whereas the current situation is creating the risk of research centres situated in the Member States relocating to countries that already offer greater protection;
Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market;
Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;
Whereas the duration of the protection granted by the certificate should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusively from the time the medicinal product in question first obtains authorization to be placed on the market in the Community;
Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product;
Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and Community level;
Whereas the transitional arrangements applicable to applications for certificates filed and to certificates granted under national legislation prior to the entry into force of this Regulation

should be defined;
Whereas special arrangements should be allowed in Member States whose laws introduced the patentability of pharmaceutical products only very recently;
Whereas provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law,
HAS ADOPTED THIS REGULATION:

Article 1

Definitions For the purposes of this Regulation:
(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;
(c) 'basic patent' means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
(d) 'certificate' means the supplementary protection certificate.

Article 2

Scope Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure as laid down in Council Directive 65/65/EEC (4) or Directive 81/851/EEC (5) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

Article 3

Conditions for obtaining a certificate A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
(a) the product is protected by a basic patent in force;
(b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;
(c) the product has not already been the subject of a certificate;
(d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.

Article 4

Subject-matter of protection Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.

Article 5

Effects of the certificate Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

Article 6

Entitlement to the certificate The certificate shall be granted to the holder of the basic patent or his successor in title.

Article 7

Application for a certificate 1. The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3 (b) to place the product on the market as a medicinal product was granted.
2. Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

Article 8

Content of the application for a certificate 1. The application for a certificate shall contain:
(a) a request for the grant of a certificate, stating in particular:
(i) the name and address of the applicant;
(ii) if he has appointed a representative, the name and address of the representative;
(iii) the number of the basic patent and the title of the invention;
(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3 (b) and, if this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization;
(b) a copy of the authorization to place the product on the market, as referred to in Article 3 (b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;
(c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.
2. Member States may provide that a fee is to be payable upon application for a certificate.
Article 9
Lodging of an application for a certificate
1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3 (b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.
2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:
(a) the name and address of the applicant;
(b) the number of the basic patent;
(c) the title of the invention;
(d) the number and date of the authorization to place the product on the market, referred to in Article 3 (b), and the product identified in that authorization;
(e) where relevant, the number and date of the first authorization to place the product on the market in the Community.

Article 10

Grant of the certificate or rejection of the application 1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9 (1) shall grant the certificate.

2. The authority referred to in Article 9 (1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.
3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9 (1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.
4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.
5. Member States may provide that the authority referred to in Article 9 (1) is to grant certificates without verifying that the conditions laid down in Article 3 (c) and (d) are met.

Article 11

Publication 1. Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9 (1). The notification shall contain at least the following information:
(a) the name and address of the holder of the certificate;
(b) the number of the basic patent;
(c) the title of the invention;
(d) the number and date of the authorization to place the product on the market referred to in Article 3 (b) and the product identified in that authorization;
(e) where relevant, the number and date of the first authorization to place the product on the market in the Community;
(f) the duration of the certificate.
2. Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9 (1). The notification shall contain at least the information listed in Article 9 (2).

Article 12

Annual fees Member States may require that the certificate be subject to the payment of annual fees.

Article 13

Duration of the certificate 1. The certificate shall take effect at the end of the lawful term of the basic patent for a perid equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years.
2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

Article 14

Expiry of the certificate The certificate shall lapse:
(a) at the end of the period provided for in Article 13;
(b) if the certificate-holder surrenders it;
(c) if the annual fee laid down in accordance with Article 12 is not paid in time;
(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place on the market in accordance with Directive 65/65/EEC or Directive 81/851/EEC. The authority referred to in Article 9 (1) may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 15

Invalidity of the certificate 1. The certificate shall be invalid if:
(a) it was granted contrary to the provisions of Article 3;
(b) the basic patent has lapsed before its lawful term expires;
(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.
2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the renovation of the corresponding basic patent.

Article 16

Notification of lapse or invalidity If the certificate lapses in accordance with Article 14 (b), (c) or (d) or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9 (1).

Article 17

Appeals The decisions of the authority referred to in Article 9 (1) or of the body referred to in Article 15 (2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

Article 18

Procedure 1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless that law lays down special procedural provisions for certificates.
2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

Article 19

Transitional provisions 1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.
In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.
In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.
2. An application for a certificate as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force.

Article 20

This Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before the date on which this Regulation enters into force or to applications for a certificate filed in accordance with that legislation before the date of publication of this Regulation in the Official Journal of the European Communities.

Article 21

In those Member States whose national law did not on 1 January 1990 provide for the patentability of pharmaceutical products, this Regulation shall apply five years after the entry into force of this Regulation.

Article 19
shall not apply in those Member States.

Article 22

Where a certificate is granted for a product protected by a patent which, before the date on which this Regulation enters into force, has had its term extended or for which such extension was applied for, under national patent law, the term of protection to be afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years.

FINAL PROVISION

Article 23

Entry into force This Regulation shall enter into force six months after its publication in the Official Journal of the European Communities. This Regulation shall be binding in its entirety and directly applicable in all Member States.
Done at Luxembourg, 18 June 1992. For the Council

APPENDIX 6: AUSTRALIA *PATENTS ACT 1990*

13 Exclusive rights given by patent

(1)
Subject to this Act, a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention.
(2)
The exclusive rights are personal property and are capable of assignment and of devolution by law.
(3)
A patent has effect throughout the patent area.

65 Date of patent

The date of a patent is:

(a)
the date of filing of the relevant complete specification; or

(b)
where the regulations provide for the determination of a different date as the date of a patent—the date determined under the regulations.

67 Term of standard patent

The term of a standard patent is 20 years from the date of the patent.

70 Applications for extension of patent

(1)
The patentee of a standard patent may apply to the Commissioner for an extension of the term of the patent if the requirements set out in subsections (2), (3) and (4) are satisfied.

(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;

(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.

(4)
The term of the patent must not have been previously extended under this 70

71 Application for extension to lapse in certain circumstances

An application for an extension of the term of a patent lapses if the applicant does not, within the prescribed period, give the Commissioner:

(a) a marketing approval certificate in respect of the pharmaceutical substance to which the application relates; and

(b) a proposed claim or claims.

72 Issue of marketing approval certificate

Where:

(a) a patentee asks the Secretary to the Department of Community Services and Health, in writing, for the issue of a marketing approval certificate in respect of a pharmaceutical substance; and

(b) the Secretary to the Department of Community Services and Health has approved the marketing of that substance, or a product containing that substance, in Australia; the Secretary must immediately give a marketing approval certificate in the approved form to the patentee in respect of that substance.

73 Advertisement of application for extension

Where:

(a) a patentee applies for an extension of the term of a patent; and

(b) the patentee gives the Commissioner the documents referred to in section 71; the Commissioner must publish in the Official Journal a notice to the effect that the Commissioner proposes to consider the application.

74 Opposition to extension

The Minister, the Secretary to the Department of Community Services and Health or a person interested may, within the prescribed period and in accordance with the regulations, oppose the grant of an extension of the term of a patent on either one or both of the following grounds, but on no other ground:

(a) that the application for the extension, the marketing approval certificate, or the proposed claim or claims, is or are not in accordance with this Act;

(b) that the proposed claim or claims claim matter other than the pharmaceutical substance or substances to which the application relates.

75 Determination of application for extension

(1) The Commissioner may determine an application for an extension of the term of a patent even though the term of the patent has expired.

(2) Where the time for opposing the grant of an extension of the term of a patent has expired, the Commissioner must, if satisfied that:

(a) the application for the extension, the marketing approval certificate and the proposed claim or claims are in accordance with this Act; and

(b) the proposed claim or claims do not claim matter other than the pharmaceutical substance or substances to which the application relates; grant an extension of the term of the patent for a period of 4 years in relation to the proposed claim or claims, but if not so satisfied, the Commissioner must, subject to subsection (3), refuse to grant an extension of the term of the patent.

(3) The patentee may, within such period as the Commissioner allows, amend the proposed claim or claims.

(4) If, after amendments are made under subsection (3), the Commissioner is satisfied as to the matters referred to in subsection (2), the Commissioner must grant an extension of the term of the patent for a period of 4 years in relation to the proposed claim or claims, but if the Commissioner is not so satisfied the Commissioner must refuse to grant an extension of the term of the patent.

(5) Where the Commissioner grants, or refuses to grant, an extension of the term of a patent, the Commissioner must publish in the Official Journal a notice setting out the terms of the decision.

(6) The Commissioner must not grant, or refuse to grant, an extension of the term of a patent unless the Commissioner has given the applicant, and any person who opposed the grant of the extension under section 74, a reasonable opportunity of being heard.

(7) Where relevant proceedings in relation to a patent are pending, the Commissioner must not determine an application for an extension of the term of the patent without the leave of the court.

79 Delegation

The Secretary to the Department of Community Services and Health may, by signed instrument, delegate to an officer of that Department all or any of the powers and functions of the Secretary under this Division.

76 Grant of extension

(1)

The Commissioner must grant an extension of the term of a standard patent if:

(a)

there is no opposition to the grant; or

(b)

in spite of opposition, the Commissioner's decision, or the decision on appeal, is that the extension should be granted.

(2)

If the Commissioner grants an extension, the Commissioner must notify the applicant in writing of the grant and publish a notice of the grant in the *Official Journal* .

77 Calculation of term of extension

(1)

If the Commissioner grants an extension of the term of a standard patent, the term of the extension is equal to:

(a)

the period beginning on the date of the patent and ending on the earliest first regulatory approval date (as defined by section 70) in relation to any of the pharmaceutical substances referred to in subsection 70(2);

reduced (but not below zero) by:

(b)

5 years.

(2)

However, the term of the extension cannot be longer than 5 years.

78 Exclusive rights of patentee are limited if extension granted

(1)

If the Commissioner grants an extension of the term of a standard patent , the exclusive rights of the patentee during the term of the extension are not infringed:

(a)

by a person exploiting:

(i)

a pharmaceutical substance *per se* that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

(ii)

a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification;

for a purpose other than therapeutic use; or

(b)

by a person exploiting any form of the invention other than:

(i)

a pharmaceutical substance *per se* that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

(ii)

a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance

disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification.

(2) If the Commissioner grants an extension of the term of a standard patent, the exclusive rights of the patentee after the grant of the extension are not infringed by a person exploiting:

(a) a pharmaceutical substance *per se* that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

(b) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification;

solely for purposes in connection with:

(c) having goods included in the Australian Register of Therapeutic Goods, where the goods are intended for therapeutic use; or

(d) obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.

Schedule 1 Dictionary

"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 physico-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;

“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