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Pharmaceutical Patent Term Restoration in New Zealand

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ABSTRACT *This paper draws attention to the 1998 legislation in Australia which introduced a drug-specific patent term restoration procedure called a supplementary protection certificate. After investigating effective patent life data the results suggest that there is a case for such a measure in New Zealand.*

Keywords: pharmaceuticals, patents, effective patent life, patent reform and multinationals.

Introduction

Under the *Intellectual Property Laws Amendment Act 1998* the Australian Parliament introduced a supplementary protection certificate (SPC) to extend the life of qualifying pharmaceutical patents by up to five years. The SPC is a drug-specific extension procedure, designed to reduce the impact on effective patent life of the time absorbed by the drug development process.[1] Effective patent life (EPL) is the patent term remaining after the development process is complete and the drug concerned has been authorised for sale. This is the period before generic imitation becomes legitimate, during which the patent owner is the sole seller. The purpose of this article is to explain the nature of the SPC, set out the detail of its operation, and address the question of whether New Zealand should adopt a similar procedure. The answer will involve an appraisal of recent patent law changes and a review of the EPL evidence.

Logic of the SPC

For nations with a sizeable innovative pharmaceutical industry like Australia, the justification for a drug-specific enhancement procedure is based on equity and innovation arguments. The equity argument focuses on the impact of extended development time relative to other activities. Most industries do not suffer such routine patent erosion. With the possible exception of agricultural chemicals, veterinary products, aircraft, and nuclear irradiation, the development process does not absorb a significant amount of the patent term. For most inventions nominal and effective patent life are approximately the same. However, with pharmaceuticals not only is innovation very patent dependent but it is also subject to a high level of patent erosion. A 10–12-year period between first patenting and final regulatory approval is not unusual. Relative to most other activities there is a case for special procedures to compensate for the particular circumstances of the

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industry. The innovation argument acknowledges the reasons for extended development time, namely safety and efficacy, but points out that the associated patent loss is an impost. EPL erosion is not an aberration but an inevitable feature of the drug-development process during which new entities pass through a state-mandated regulatory process in order to prove they are fit to be marketed. In this sense patent time absorption is a tax on innovation. A disincentive is generated that may well be harmful to the flow of new pharmaceuticals.

For nations that do not have a significant pioneering drug industry like New Zealand, supplementary considerations apply. They turn on influences like:

- An appreciation that wide-ranging and effective laws to protect intellectual property are required to foster technological change and growth.[2]
- An understanding that foreign direct investment both inward and outward is an important means to receive and exploit technology.
- An awareness that a country's reputation is crucial to its rating as a destination for foreign investment.
- An acceptance that the international community is not indifferent to behaviour that is at variance with accepted standards.[3]

Thus, there may be risks in adopting standards of intellectual property protection that do not comply with global norms.[4] In addition there are practicalities like the arrival time lags of new pharmaceuticals and their prices. These may be adversely influenced if the multinational drug companies are not impressed by the quality of the local intellectual property environment.

The SPC Details and Examples

An SPC is defined as the difference between the date of first market authorisation for a new pharmaceutical and the patent-filing date less five years. If the date of first market authorisation within Australia is X and the patent filing date is Y and if no maximum SPC applies then enhanced effective patent life will always equal 15 years:

$$\text{Basic EPL} = 20 - (X - Y)$$
$$\text{SPC} = (X - Y) - 5$$

Then enhanced EPL equals basic EPL + SPC which equals 15 years, i.e.

$$20 - (X - Y) + (X - Y) - 5 = 15.$$

However, the maximum permitted SPC is five years, which means that enhanced EPL will only equal 15 years if the development interval is 10 years or less. For every year above 10 years, enhanced EPL is correspondingly reduced.[5] In effect a maximum SPC of five years provides an incentive to curtail development time to 10 years.

Table 1 illustrates the effect of the SPC. The table also shows the contrast between effective patent life in Australia with SPC enhancement and New Zealand where there is no such procedure. For example, if the development time is assumed to be 10 years in both countries, then EPL is 50% higher in Australia. The detailed evidence rehearsed below suggests that such a difference may well be germane.

Table 1. The SPC and effective patent life in Australia and New Zealand

Development time in years	6	8	9	10	11	12	13	15
EPL in years in Australia with SPC	15	15	15	15	14	13	12	10
EPL in years in New Zealand with no SPC	14	12	11	10	9	8	7	5

Notes: The development time is the time, in years, between first patent application and registration in Australia. This interval is assumed to be the same in New Zealand. EPL is effective patent life which is the balance of the patent term post registration. EPL in Australia with SPC is the basic EPL with a 20-year patent term plus the SPC with a five-year maximum. EPL in New Zealand is the EPL with a 20-year patent term but no SPC enhancement.

New Zealand EPL Evidence

The Qualifying Criteria

Effective patent life data have been collected for New Zealand pharmaceuticals. To qualify for inclusion in the sample each drug must be a new chemical entity or a patentable entity, with a Gazette listing or registration date and must have been marketed in New Zealand. Where there is more than one registration date per drug, the earliest is selected. Only one patent is counted per chemical entity and the earliest is selected. Second indication patents are not included.[6] Combination drugs are included only if they are of sufficient novelty to be patented. AIDS drugs are excluded because their regulatory procedures are so unusual. Also excluded are process patents because they are rarely specific to particular drugs.

Source of Sample Data

The identity and licensing dates of new drugs are determined via the New Zealand Gazette. This is the official weekly newspaper of the government. It promulgates notices that include new drug registrations, company and partnership matters, insolvency, and land transfers. Gazette notification signifies that a drug has been through the registration process and is now licensed for sale. The ministerial signing date is included with each entry. This is assumed to be the marketing date of the drugs concerned. In effect any lag between ministerial authorisation and launch is deemed to be a management failure which should not be included in the data.

Patent information is collected either by direct enquiries to companies or by searches undertaken by intellectual property lawyers. These determine which drugs are protected and identify the relevant patents. The associated register sheets obtained from the Patent Office provide detail of filing and expiry dates.[7]

Sample Size and Definitions

The final sample is 212 marketed drugs, all of which have a reliable matching of patents with products. For each of these, effective patent life (EPL) is derived. EPL is defined as the interval between the Gazette ministerial signing date and patent expiry. Negative values for effective patent life are counted. These signify a situation where patents expire before market authorisation. The time lost (TL) is also calculated. This is defined as the interval between patent filing in New Zealand and the drug registration date. TL is of course equivalent to the development time after patent application.

Table 2. Mean effective patent life and time lost values

Interval	EPL (20)	EPL (20) + Ext	16 All	Time Lost	*N*
Mean 66–69	12.45	15.07	12.45	3.55	4
Mean 70–74	9.27	9.75	9.28	6.72	24
Mean 75–79	6.80	9.50	6.81	9.19	30
Mean 80–84	4.50	6.47	4.25	11.75	47
Mean 85–89	7.23	9.48	5.96	10.04	41
Mean 90–94	9.25	10.32	6.02	9.98	26
Mean 95–99	7.44	7.69	3.85	12.15	40
Mean 1960s	12.45	15.07	12.45	3.55	4
Mean 1970s	7.90	9.61	7.91	8.09	54
Mean 1980s	5.77	7.88	5.05	10.95	88
Mean 1990s	8.15	8.73	4.71	11.29	66
Overall	7.18	8.72	5.81	10.19	212

Notes: Interval is the time of registration. EPL (20) is a mixture of 20- and 16-year patent terms with no extensions. EPL (20) + Ext is a mixture of 20- and 16-year patent terms, including extensions. 16 All assumes all patents have 16-year patent terms. Time Lost is the interval between patent filing in New Zealand and the associated drug registration date. *N* is the number of observations. There are three drugs registered in the interval 1995–1999 whose patents have expired prior to 1 January 1995 and thus do not qualify for the new 20-year term. Hence the 1995–1999 mean EPL (20) plus mean Time Lost will not sum to 20 years. Extensions have been granted to 44 drug patents with a mean addition of 7.4 years and a mode of 8 years.

Mean Values and Law Changes

Table 2 presents the derived values over the sample period 1966–1999 with a variety of intervals. Three versions of EPL are presented in an attempt to allow for the 1995 law changes in New Zealand. Until that year the standard patent term was 16 years with extensions of up to 10 years available for war loss and inadequate remuneration. On 1 January 1995 the standard term was raised to 20 years and extensions were abolished. All non-expired patents qualified for the new term but those with extensions pending could either abandon their claim and qualify for the new 20-year term, or persevere and be heard under the old plus 10-year maximum rules.[8] The table also shows the values for time lost (TL). This measure is useful for two reasons: first, it is more likely to reveal the underlying time trends because the derived values are not affected by the 1995 patent-term changes; in addition the somewhat paradoxical concept of negative patent life is avoided.

Table 2 shows that the overall mean EPL on all measures is under nine years and that the mean time lost is approximately 10 years. There is also a suggestion that over the sample period the commercially useful patent life in New Zealand has been declining.

Figure 1 reinforces the impression that effective patent life is declining. Only the EPL (20) + extensions series is presented. This saves space and is also a useful reminder that the current situation involves a mixture of patent terms. Observations include 16- and 20-year terms and also whatever extension may have been secured under the pre-1995 regime. While Figure 1 suggests that there is a declining trend in mean EPL values, caution is appropriate before accepting such a conclusion. Greater detail is required for verification. Table 3 exhibits this by presenting the results of regression procedures.

Regressions—Whole Period

Mixed messages emerge from Table 3. When measures are used where there are varying patent terms as in EPL (20) and EPL (20) + Ext, there is no support for the proposition

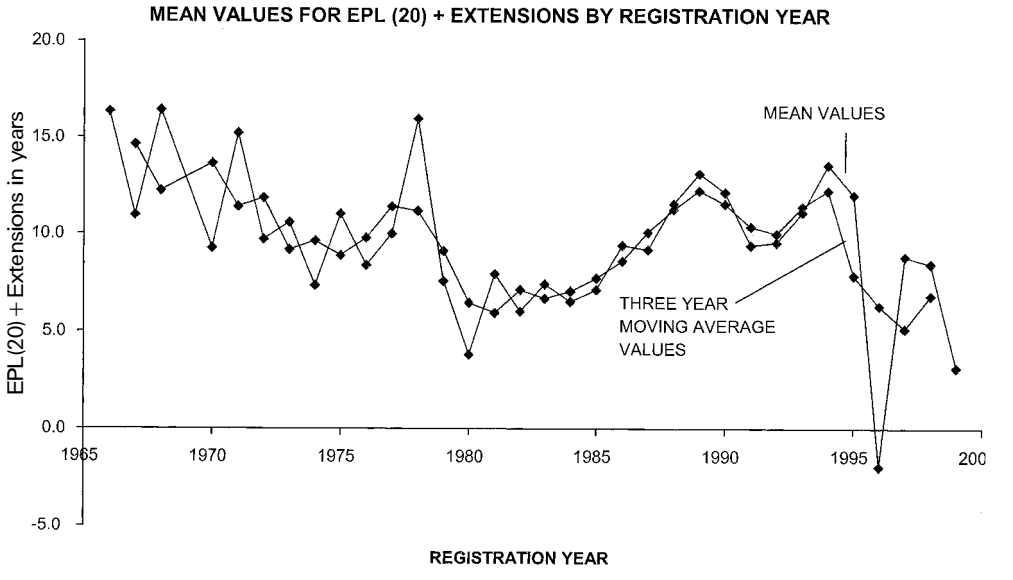

Figure 1. Mean values for EPL (20) plus extensions by registration year.

that effective patent life continues to be eroded through time. However, when measures are used that are independent of the 1995 law changes, there is a statistically significant time trend. Thus the TL and '16 All' indicators support the proposition that time lost is rising and hence effective patent life is falling.

Regressions—Sub-periods

Understanding the regressions in Table 3 is enhanced when detailed procedures are applied to sub-periods within the sample. Regressions are calculated from 1966 with single registration years added progressively. Comment is restricted to the time-lost series alone for two reasons: the 16 All regression results mirror their TL equivalents and the trends in the other EPL results are obscured by the 1995 law changes and/or extensions granted.

The first significant regression at the 5% level occurs for the interval 1966–1974. From 1966 to 1976 a 1% significance level is established. This continues right through

Table 3. Regression of effective patent life and patent time lost on registration year

Sample	Constant	Registration Year	R^2	Significance Level
16 All	333.88	−0.1653	0.0868	1%
EPL (20)	2.27	0.0025	0.0005	NS
EPL (20) + Ext	107.43	−0.0497	0.0054	NS
TL	−317.88	0.1653	0.0868	1%

Notes: The dependent variable is the value for EPL or TL. The Significance Level is determined by a two-tailed *t*-test on the coefficient on Registration Year. NS denotes 'not significant'. Direct inspection of the plots of residuals, and the Durbin Watson and serial autocorrelation statistics, show that there is no tendency for the residuals to be correlated.

to 1999. The regressions reach a maximum value for R^2 of 0.335 in the period 1966–1980. From then on the regression coefficients weaken to a final level of 0.087.

When yet another approach is used that involves a six-year moving average type of procedure, starting with the interval 1966–1971 and finishing with 1994–1999, the following emerges:

- Increasing TL is indicated by one interval at the 1% level of significance. This is for the period 1975–1980.
- The same message is conveyed by five intervals with significance levels at 5%. These are 1968–1974, 1971–1976, 1974–1979, 1975–1980 and 1991–1996.[9]

There are just two intervals that indicate a decline in time lost with a significance level of 5%. These are 1984–1989 and 1985–1990.

When the above two are combined to cover the interval 1984–1990 the R^2 does not strengthen and the significance level remains at 5%.

Summary

The principal finding is for time lost to rise and thus effective patent life to fall over the 1966–1999 period. While there is little doubt about the predominant effect, there are weak indications that during 1984–1990 there is a reversal of trend. For the two six-year intervals 1984–1989 and 1985–1990, the registration year coefficients are negative and significant at the 5% level. Time lost shows a tendency to decrease. However, this situation does not persist for long. None of the succeeding six-year intervals have statistically significant observations indicating a rise in EPL. In fact there is a suggestion of a return to the usual downward trend for the remainder of the period. Thus in the nine succeeding post-1990 six-year intervals, seven have a positive sign for the registration year coefficient with one for 1991–1996 significant at 5%. There are only two intervals with a negative sign, neither of which is anywhere near significant. When the interval 1987–1999 is used to summarise the recent trend, the registration year coefficient is positive but not significant at 5%, but would qualify at 7%.

Comment

In terms of the policy implications for New Zealand perhaps the most relevant figures are the mean values for time lost and EPL (20) + Ext for the period 1995–1999 and their trends. These capture what has occurred since the 1995 law change to a 20-year patent term. The time lost is 12.15 years and the EPL (20) + Ext is 7.69 years. There is no statistically significant time trend within these intervals, but the differences between 1990 and 1994 mean values and their 1995–1999 equivalent are relevant. Thus the extra 2.2 years for time lost and 2.6 years' reduction in EPL (20) + Ext are both significant at the 5% level. If the mean time lost figure of 12.15 years is assumed to apply in Australia then the SPC-enhanced EPL would be 12.85 years. In New Zealand where there is no such procedure, the equivalent figure would be 7.85 years, or 61% lower. Put another way, an extra five years on the New Zealand EPL figure would be an increase of 64%.

Does such a five-year difference matter? The answer turns on the importance of the length of the effective patent term to innovating pharmaceutical companies. Evidence to demonstrate the effect of the supplementary influences listed above is obviously difficult to assemble. Thus for example the assertion that drugs may arrive later and cost more because of an adverse intellectual property environment is extremely hard to validate. However, there are broad indications that the innovating drug companies are reacting

adversely to the current situation. Anecdotal evidence suggests that a capital flight from New Zealand is under way. From a situation where there used to be 13 drug-manufacturing plants there are now four and these concentrate on producing generics rather than originals.[10] Many firms including the Glaxo Group, which started corporate life as a New Zealand producer of powdered milk, have diverted their efforts to Australia and elsewhere. They have reduced their investment leaving a token presence of sales and warehousing. Of course there are many reasons for this apparent capital diversion besides patent term erosion. The small size of the New Zealand market, the effectiveness of the state buying agency Pharmac in forcing down drug prices, the delays and frustrations involved in registration and subsidy listing, all are among a host of factors likely to be relevant. Nevertheless it is reasonable to assume that a comparatively low EPL is an adverse influence. A situation where there is a five-year gap relative to Australia, is almost certainly a negative component in the drug multinationals' perception of the New Zealand market.

Conclusion

There is little doubt that over the sample period EPL has declined. Relative to Australia, New Zealand appears to be at an EPL disadvantage. The question for New Zealand policy-makers is whether this justifies a law change to rectify the situation. The SPC is a specific for this malady. It is the author's contention that such a reform should be adopted.[11]

Notes and References

1. The SPC was first applied in the European Union in January 1993 and spread to all members by January 1998.
2. For example, the strength of patent protection is relevant to the growth of economies. See D. M. Gould and W. Gruben, 'The role of intellectual property rights in economic growth', *Journal of Development Economics*, 48, 1996, pp. 323–350.
3. A New Zealand example is the reaction of the multinational pharmaceutical industry to the 1989 Budget amendments to the 1981 *Medicines Act*, where the New Zealand government assigned to itself the power to import generic drugs before the expiry of the associated pioneer patents. Pressure was so great that the offending amendments were promptly revoked. See 'The government backs down over drug patents', *National Business Review*, 15 September, 1989.
4. For example, in America the *Omnibus Trade and Competitiveness Act* of 1998 establishes 'watch list' categories and associated trade sanctions, for countries with sub-standard protection of intellectual property.
5. There is one strange clause in the Act which states that no application for an SPC will be accepted where the development interval is less than five years. Such an application would of course be illogical. For example, a pharmaceutical with a development time of three years would have a basic EPL of 17 years. If the SPC procedure were applied then this would have the effect of reducing EPL from 17 to 15 years.
6. These have only just been granted patentable status in New Zealand. Pharmaceutical Management Agency Ltd v. The Commissioner of Patents and others (CA 56/99, 17 December 1999).
7. Support for this project has come from the Researched Medicines Industry Association of New Zealand Inc. and the University of Otago. A. J. Park and Son, intellectual property lawyers, have also been of major assistance. I am grateful to all for their help.
8. The relevant legislation is the 1994 *Patents Amendment Act*. As of 1 February 2000 there is one pharmaceutical extension claim outstanding.
9. There are no observations for registration year 1969, hence the apparent seven-year interval for 1968–1974.

10. L. Thomson, 'Multi million dollar manufacturing plant for Douglas Pharmaceuticals', *New Zealand Pharmacy*, April 1996.
11. See also J. Parker, 'Pharmaceutical patent reform in New Zealand', *New Zealand Economic Papers*, 31, 1, 1997, pp. 85–91.