THE EFFECTIVE PATENT LIFE OF PHARMACEUTICALS IN NEW ZEALAND — A SIMULATION

John Parker

This paper estimates effective patent life of pharmaceuticals in New Zealand (NZ EPL). A simulation technique is used based on the linking effect of the International Convention for the Protection of Industrial Property. The simulation procedure suggests that NZ EPL is declining and will yield no protection in the fairly near future, for drugs from the USA, UK and Switzerland. Two consequences for pharmaceuticals are suggested. One, the focus of the NZ patent term is likely to shift from the normal period of 16 years to the maximum available when extensions are included. Two, applications for extensions are likely to become routine. In these terms the recommendations by the Industrial Property Advisory Committee (IPAC), at least as they apply to pharmaceuticals, that the current patent life remain unchanged at 16 years and extensions have a maximum of 4 and not 10 years, are somewhat puzzling.

Keywords: Pharmaceuticals, patents, effective patent life, New Zealand, patent reform

INTRODUCTION

The New Zealand patent system is currently under review and change is likely soon.[1] This paper attempts to make a contribution to the reform debate by providing estimates of effective patent life of pharmaceuticals in New Zealand since the 1960s. A simulation technique is used based on the linking effect of the International Convention for the Protection of Industrial Property. The procedure allows the results of effective patent life (EPL) studies of drugs marketed in other countries, to be transposed to a New Zealand context. Practical reasons dictate the use of simulation. Individual drug data in consolidated form do not exist in New Zealand. Its compilation is expensive and requires specialist knowledge. Furthermore there is unlikely to be sufficient time for the process to be completed before reform is implemented.[2] EPL is the patent life left after a drug is cleared for sale to the public by the regulatory authorities. Specifically, in New Zealand it is the period between regulatory clearance by the Medicine Assessment Advisory Committee (MAAC) and patent expiry.

The simulation procedure is plausible for three main reasons:

- New Zealand does not develop a significant number of her own drugs.
- The other countries used in the linking procedure are the USA, UK and Switzerland. These nations are the major source of new drugs.
- The drugs concerned are probably not cleared for sale in New Zealand before they are registered in the countries named above.

IPAC

In September 1985 the Industrial Property Advisory Committee (IPAC) reported that the New Zealand patent term should stay at 16 years.[3] It also indicated that extensions should no longer be granted for war loss and inadequate remuneration, but that extensions should be introduced for delay due to regulatory clearance procedures. The Committee recommended that the maximum extension for regulatory delay should be 4 years. Thus under the proposed regime the present maximum patent life of 26 years (16 + 10 years extension), would become 20 years (16 + 4 years extension).

The Committee must therefore have been convinced that:

(a) The present patent term provides adequate protection for intellectual property, and

(b) The necessity for extensions is less now than it was in the past.

PURPOSE OF STUDY

The purpose of this study is to appraise (a) and (b) above by providing evidence on the effective patent life of pharmaceuticals in New Zealand. Pharmaceuticals are chosen for investigation because they are prone to regulatory delay, and it was their experience that prompted IPAC's recommendation that marketing constraint should be a grounds for extensions.

In a previous paper evidence was given of EPL values in New Zealand for 1978 USA originated drugs.[4] The present paper extends that study to:

(i) Exhibit the trend of effective patent life in New Zealand from the 1960s onwards, based on USA registered drugs.

(ii) Provide evidence from other major pharmaceutical nations, namely the UK and Switzerland.

SIMULATION BASED ON USA REGISTERED DRUGS

The 1985 Paper — a simulation

The 1985 paper shows that for the three years centred on 1978, the EPL

value in New Zealand for the American drugs concerned is 5.8 years or 36 per cent of the notional patent life (16 years).[5] These values are derived by simulation. Simulation is involved because NZ individual drug data to estimate EPL are not yet available. Simulation is also used because the exercise is in effect asking the question: What would the NZ EPL values have been if all the American drugs involved had been registered in New Zealand? One major precaution is taken. The EPL values are based on USA self-originated drugs only. This is an attempt to make sure that the drugs under consideration are not obtainable by New Zealand more quickly from elsewhere. An effort is made to exclude drugs originated outside America. This is important because these pharmaceuticals may have been available to New Zealand earlier than their USA registration date. To include them in their American guise may thus bias the NZ EPL downwards. Unfortunately in order to obtain a time series of observations, the 'American originiated only' precaution has had to be abandoned. The data are such that a run of information is only available for all US registered drugs.

The Data Base

The data used in the 1985 paper are from Eisman and Wardell (1981) and Wardell and Sheck (1984). The same data are used in this study but Spivey and Trimble (1986) provided more up to date information, permitting the run of figures to be extended by five years from 1979 to 1984.[6]

Procedure

The first two studies above give three year moving average values for:

(A) Pendency, that is the time interval between patent application and patent grant;
(B) Total drug development time, that is the time from synthesis to registration; and
(C) Effective patent life, that is the interval between registration and patent expiry.

The Spivey and Trimble study gives three year moving average values for effective patent life of drugs in the USA for 1964 to 1983. Single year values are also given for 1963 to 1984. Unfortunately pendency and total development time figures are not given. These have to be assumed or derived. From the information in (A), (B) and (C), patent application dates and inoperative patent life (IPL) values for the USA are derived. In addition, using a method described in the 1985 paper,[7] New Zealand values for the following are calculated:

(D) Patent Application.
(E) Application to the Medicine Assessment Advisory Committee (MAAC).

(F) Regulatory Clearance.
(G) Patent Expiry.

By means of (D) through (G), inoperative patent life and effective patent life in New Zealand are derived.

Assumptions

The procedure relevant to New Zealand is dependent on six key assumptions:

(1) New Zealand is assumed not to obtain US originated and foreign originated US registered drugs, at an earlier date, from elsewhere.
(2) New Zealand patent appliction is assumed to occur precisely twelve months after application in the United States. This is the maximum grace period under the International Convention.
(3) Application to the MAAC is assumed to oc ur at precisely the same time as clearance by the Food and Drug Administration (FDA). It is presumed that the MAAC is not a 'first instance' regulatory authority.
(4) MAAC clearance is assumed to take 1.5 years and this interval is presumed to stay constant during the period under review.
(5) Effective patent life is defined from MAAC clearance to patent expiry. The time interval to acquire Pharmaceutical Benefit Scheme status (PBS) is not recognised as an element in the calculations.
(6) The derived EPL figures are not of course able to reflect any patent extensions that may have been secured within New Zealand. Therefore the procedure assumes that none have been acquired by the drugs concerned.

For 1980 onwards,[8] to derive NZ EPL values, it assumed that:

(7) Pendency in the USA stays at the 1979 level (3.7 years).
(8) The time interval between synthesis in America and patent application remains at the 1978 level (1.4 years). The 1979 figure is not used because it is markedly greater than any other year.

Assumption (1) warrants further comment. It may be broken down into alternatives: either USA registration of all drugs covered in the data base is assumed to occur at an earlier date than anywhere else in the world; or New Zealand is assumed not to begin MAAC registration procedures until FDA registration is complete for the individual drugs concerned. Both assumptions make it plain that the accuracy of the simulation procedure is dependent on the presumption that New Zealand does not acquire a significant number of these US registered drugs earlier from elsewhere. If there is a high proportion of New Zealand registered drugs, where the MAAC application date is not synchronised to FDA clearance, then the resulting figures for EPL will not accurately reflect the real situation.

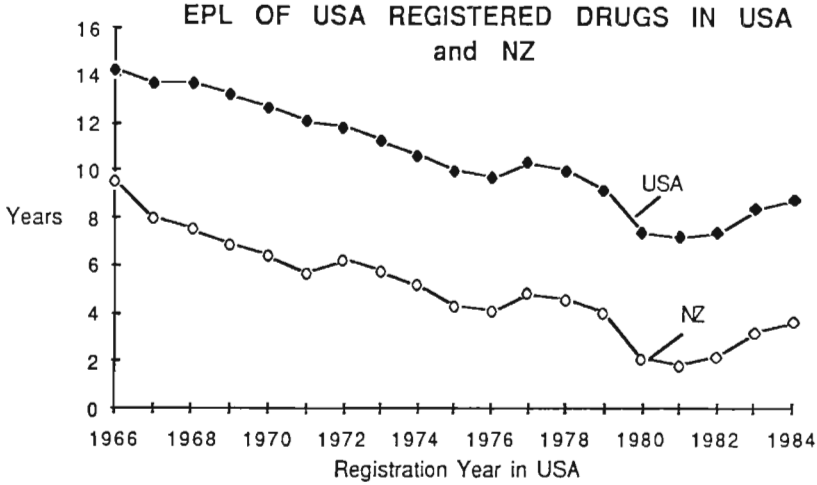
Nationality

An additional problem has to be faced. The expression, USA self-originated, refers to the nationality of the originating company, not to the country of synthesis or country of first registration. Hence a drug that is discovered in the UK subsidiary of an American multinational corporation will be classed as US self-originated, even though synthesis and first registration may have occurred in Britain. Consequently the precaution in the original paper, where the data are confined to USA self-originated drugs, may only be partially successful. It is hoped however that in the current exercise, the inclusion of information from two other nations, namely the UK and Switzerland, will alleviate the problem.

The Results

Graph 1 below shows the EPL of USA registered drugs in America and New Zealand.

GRAPH 1



Two major conclusions may be drawn:

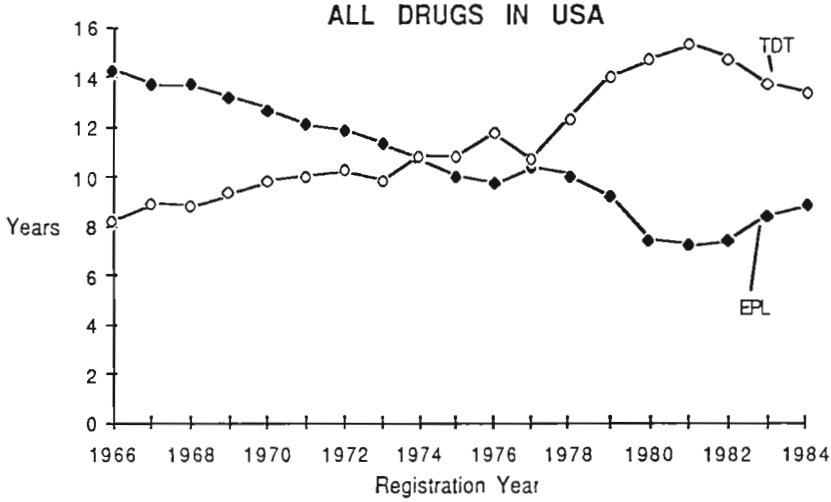
(1) There has been a decline in EPL over the time period 1966-1984 for both countries.
(2) The New Zealand values for EPL are consistently less than their American equivalents.

To illustrate, the EPL in America has declined from 14.3 years for 1966 registered drugs to 9.2 years for 1979 drugs, and to 8.8 years for 1984 drugs.[9] The corresponding figures for New Zealand are 9.6 years, 4.0 years and 3.6 years respectively. The typical difference in EPL between

American and New Zealand is such that drugs on average have 4.1 years less commercially useful patent life in New Zealand.

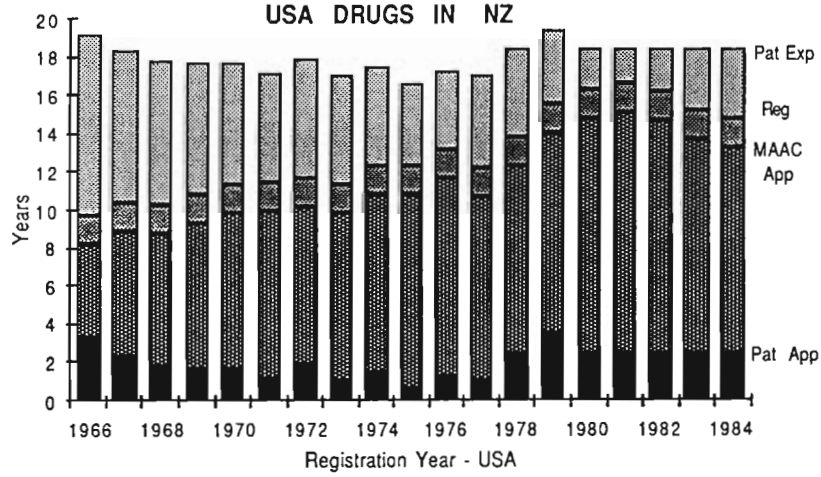
The reasons for the decline in EPL in both countries are clear. The decline in America is due to the rise in total drug development time (TDT). The decline in New Zealand is due to the rise in TDT in the USA, and the predetermination of NZ patent application dates by the grace period provisions of the International Convention.

GRAPH 2



Graph 3 adds extra detail, with the full run of years, presented in stacked bar form.

GRAPH 3



USA Senate Hearings

In mid 1983, USA Senate Hearings were held on Patents, Copyrights and Trademarks. These concerned "a bill to amend the patent law to restore the term of the patent grant for the period of the time that non patent regulatory requirements prevent the marketing of a patented product."[10] The most substantive evidence presented to the relevant Sub Committee was from Grabowski and Vernon.[11] In this evidence the impact on the drug innovation process is examined with the emphasis on patent protection, product substitution, and the regulatory process.

The case for extending patents to compensate for non-patent regulatory requirements was eventually accepted and finally became American law in the form of the Drug Price Competition and Patent Term Restoration Act of 1984. This provides for the extension of the patent term for new drugs, based on the length of the regulatory review interval. Mechanisms are put in place to restore effective patent life and to provide 'exclusivity' periods.[12] It should be noted however that restoration will not have an impact on New Zealand EPL values. The NZ patent time clock on US drugs will still be linked to the date of application in America, thus effective patent life in New Zealand will be unaffected.

Conclusions

The effective patent life of USA registered drugs has been on a decreasing trend since 1966. The most recent figures show that for the single year 1984, a value of 8.8 years or 52 per cent of notional patent life (17 years) has been reached. The 8.8 years EPL in America implies a figure of 3.6 years in New Zealand, if pendency stays at 3.7 years, and if the time interval between synthesis and patent application in the USA stays at 1.4 years. In effect a situation has now been reached where 77.5 per cent of the 16 year notional patent life in NZ has been lost. This loss has been as high as 88.75 per cent for the three year moving average centred on 1981.

SIMULATION BASED ON UK REGISTERED DRUGS

The Data Base

New Zealand values for effective patent life are also calculated from a UK data base. Studies conducted at the Centre for Medicines Research yield enough information to allow a rerun of the methods used above.[13]

Procedure

Walker and Prentis give annual average values for 1960 to 1982 for UK marketed drugs of:

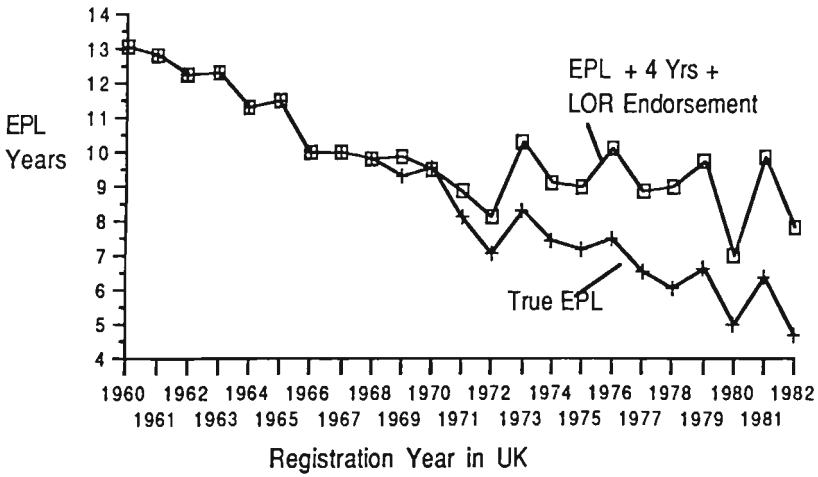
- Drug development time; that is the time from patent application to registration.
- Effective patent life; that is the time interval between registration and patent expiry.

There are two important differences in the information available compared to the USA data. These are the definition of drug development time and the absence of pendency values. The UK publication defines the beginning of development as the date of patent filing rather than the date of synthesis. In addition no information is provided on pendency, that is the time interval between patent application and patent grant. Fortunately, this is not too important as both the UK and New Zealand define the beginning of patent life from the date of application and not the date of grant. The absence of a full definition of drug development time is however more serious. Assumptions have to be made about the interval between synthesis and patent filing, in order to derive values for total drug development time.

The procedure relevant to New Zealand is dependent on seven key assumptions. These are analgous to those used with the USA data except that UK application for a patent is assumed to take place one year after synthesis and this application is assumed to become 'substantive' in a further year. In effect filing, which relates to substantive applications, is assumed to take place two years after synthesis. This means that in both the UK and New Zealand filing is assumed to occur two years after synthesis.[14]

GRAPH 4

EPL of UK Registered Drugs in UK

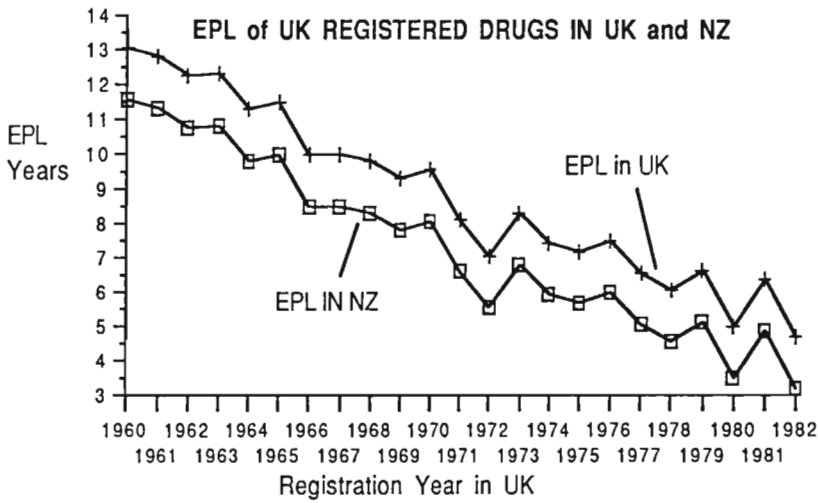


The Results

Graph 4 shows UK effective patent lives and their New Zealand equivalents. The UK figures have a break point and for drugs introduced after 1968 there are two versions of EPL values. This is a result of the 1977 Patents Act. The Act raised the UK patent term from 16 to 20 years, as part of the harmonisation instituted amongst some EEC members. However the extension did not apply to all current patents. Only those issued after June 1967 had their term increased to twenty years and furthermore a license of right (LOR) endorsement was applied to these 'new' existing patents. New patents, that is, those applied for after the Act came into force (in mid 1978), have the full 20 year term with LOR endorsement.

The upper line on Graph 4 shows UK values for EPL including the four year extension plus LOR endorsement. The lower UK line on the graph shows the EPL values, without the 'new' existing patent extension provided by the 1977 Patents Act. The term 'true' effective patent life has been applied to this line to stress that the four year increase in patent life plus LOR endorsement, is in fact a much encumbered extension. The LOR endorsement means that any company may, as of right, obtain a licence under the patent to manufacture and sell the product concerned. Because there is a considerable delay in registering drugs, it will take a number of years before full unencumbered 20 year patents are operative on marketed drugs. Walker and Prentis estimate that the earliest that such unencumbered patents will make an impact on the 'true' effective life series is introduction year 1983.[15] Only after then will the two UK EPL series begin to merge.

GRAPH 5



Graph 5 shows that when the UK 'true' effective patent life is compared with the New Zealand EPL, the difference is always 1.5 years. On reflection this is not surprising. The two countries have the same patent term (16 years), NZ filing under the International Convention and UK patent filing occur at the same time, and both countries define patent life from filing of the complete or substantive specification. Hence the only difference is the 1.5 year appraisal time assumed for the MAAC.

Comment on the Results

New Zealand EPL drops from a 1960 value of 11.58 years to a 1982 value of 3.18 years. The corresponding UK figures are 13.08 and 4.68 years respectively. In percentage terms these represent a 72.5 per cent drop for NZ and 64.2 per cent for the UK. The UK figures are based on the 'true' effective patent life series. They do not include the licence of right addition provided by the 1977 Patents Act. In effect therefore the actual difference between the two countries is larger than the figures suggest. Furthermore in the future, as unencumbered patents with a notional patent life of 20 years become available in the UK, the gap will widen. New Zealand effective patent lives will not benefit from the UK extension because, under the International Convention, the UK filing date will still be operative in determining the beginning of patent life for these NZ imported drugs.

SIMULATION BASED ON SWISS REGISTERED DRUGS

The Swiss Data Base and Procedure

New Zealand values for effective patent life may also be calculated from a Swiss data base.[16] Mattison *et al.* give three year moving average values for Swiss self-originated new chemical entities (NCEs) over the time period 1961 to 1979 for Total Development Time (TDT). TDT is defined as the time interval from synthesis to registration. No information is given relating to effective patent life. This has to be inferred by the now familiar chain linking procedure.

The procedure relevant to New Zealand is dependent on the usual assumptions. The distinctive ones are:

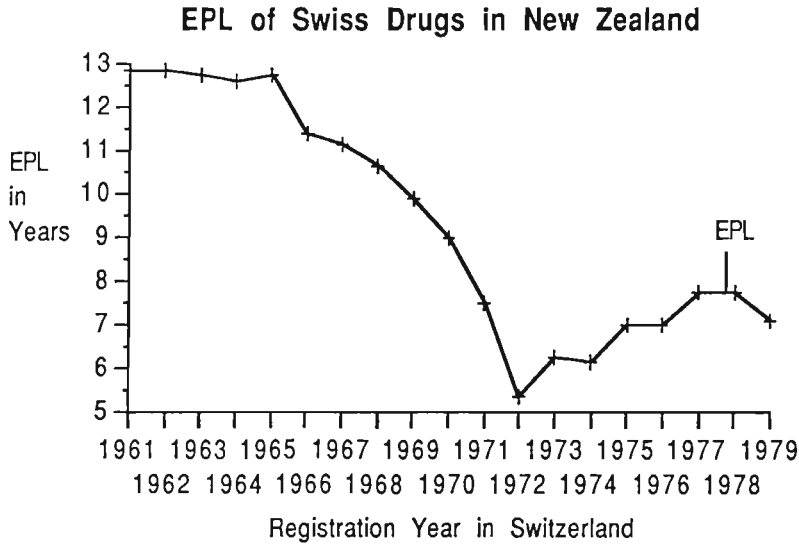
- All Swiss drugs in the sample are assumed to be patented. In fact until 1978, under Swiss law only processes and not products were patentable. In 1978 patents were extended to cover substances and processes.
- Swiss patent application is assumed to occur 1.5 years after synthesis.[17]

In the case of the Swiss data the origination assumption is probably valid. One of the weaknesses of the simulation procedure is the

assumption that registration occurs first in the country under consideration. Fortunately in the Swiss case the assumption can be made with confidence. The sample composition is such that it is highly likely that all of the drugs were developed and first marketed in Switzerland.

Graph 6 shows New Zealand EPL values derived via the Swiss TDT figures.

GRAPH 6



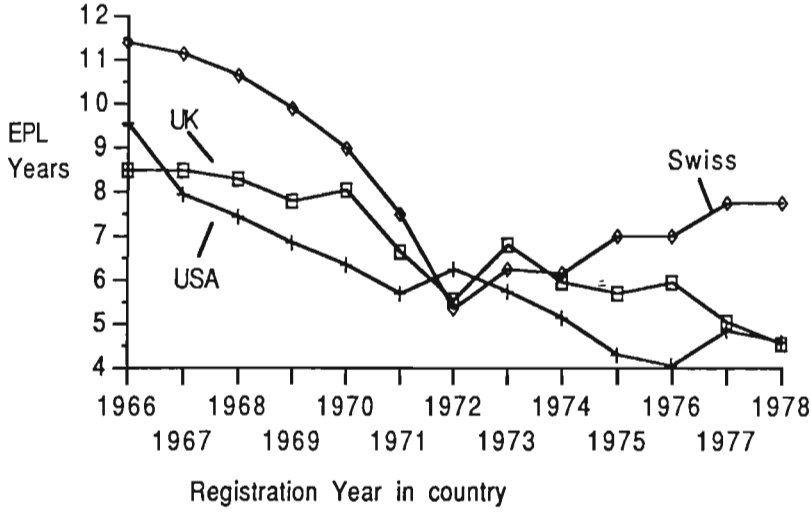
THREE COUNTRIES COMPARISON

The trend of effective patent life in New Zealand is downwards for all of the three countries with the possible exception of Switzerland. Graph 7 illustrates the trend over the drug registration period 1966 to 1978. This is the period for which all three countries have a complete set of observations.

Graph 8 shows the trend in EPL in New Zealand for the USA and the UK, over the drug registration period 1966 to 1982. Information for this more extended period of time is not available for Switzerland. The graph shows that there has been a fall in EPL in nearly every year and that the terminal value for USA registered drugs, is 2.2 years and for the UK equivalents, 4.89 years. The reason for the decline in EPL is clear. Total development time has been rising in nearly every registration year in both the USA and UK.

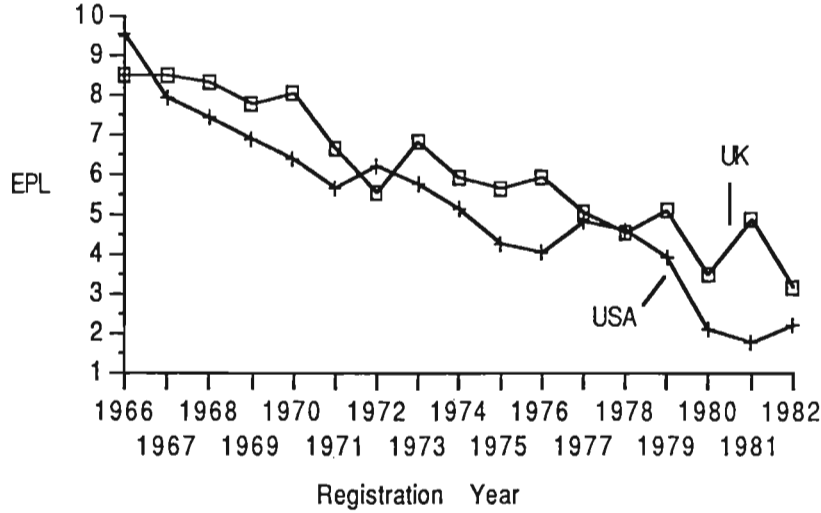
GRAPH 7

EFFECTIVE PATENT LIFE IN NZ



GRAPH 8

EFFECTIVE PATENT LIFE IN NZ



The individual country results can be used to predict when EPL values will become zero in New Zealand. Using standard linear 'line of best' fit procedures the following predictions emerge:

Country of Registration	Registration year overseas when NZ EPL is predicted to be zero
USA	1991
UK	1991
SW	1994

OVERALL CONCLUSIONS

The simulation procedure suggests that NZ EPL is declining and will yield no protection in the fairly near future, for pharmaceuticals from the three drug countries studied. Applications for extensions are likely to become routine for NZ patented drugs, as their protection becomes more and more eroded. The focus of the patent term is likely to shift from the normal period of 16 years to the maximum available when extensions are included. The recommendation by IPAC that the 16 year term should remain unchanged but 4 years and not 10 should be the maximum extension, is thus likely to be perceived as a reduction in the period of patent protection.

The presumption by IPAC in (a) and (b) above, that the current patent life is satisfactory and that extensions are less necessary now than they used to be, does not appear to be valid for the NZ pharmaceutical industry. The recommendations that the current patent life remain unchanged and extensions have a maximum of 4 years are therefore somewhat puzzling. To quote IPAC: "our basic approach is that so long as there are proper safeguards against abuse we favour a strong patent system supportive of innovation and technology transfer".[18] The recommendations of the Committee, at least as they apply to pharmaceuticals, do not appear consistent with this approach. The same may be said of the Department of Trade and Industry when they say ". . . . it is not clear that on balance, a reduction in the patent term would be in the best interests of New Zealand."[19] The Department appears to support IPAC's recommendations without appreciating that they amount to a reduction in patent term.

NOTES AND REFERENCES

1. Industrial Property Advisory Committee, *The Patent Monopoly Term and Extensions Thereof.* Report to the Minister of Justice, September 1985. In June 1987, the Department of Trade and Industry produced a discussion paper called *Intellectual Property Protection — A Business Perspective.*
2. Work is in progress by the present author, to collect individual drug EPL information. It will be some time before the results are available.
3. Industrial Property Advisory Committee, 1985, *op. cit.*

4. J.E.S. Parker, 'The effective patent life of American originated drugs in New Zealand', *New Zealand Economic Papers,* 19, 1985. Strictly the year 1978 refers to a three year moving average of drugs for the years 1977 to 1979.
5. Parker, *op. cit.* Notional patent life in New Zealand extends for 16 years from the filing date of the complete specification. Notional patent life in the USA extends for 17 years from the date of grant.
6. See Martin M. Eisman and William M. Wardell, 'The decline in effective patent life', *Research Management,* 21, 1, 1981, pp. 18-21; Wiliam M. Wardell and Lorraine E. Sheck, 'Is pharmaceutical innovation declining?', in Bjorn Lindgren (ed.), *Pharmaceutical Economics,* IHE, 1984; and Richard N. Spivey and Gene A. Trimble, 'Effect of the Drug Price Competition Act on market exclusivity of new drugs: a similation', *Drug Information Journal,* 20, 1986, pp. 27-35.
7. Parker, *op. cit.* The procedure relies on the linking effect of the 'grace period'. Under the International Patent Convention a patent holder has 12 months in which to apply to other Member countries. During this time 'prior publication' does not apply. Hence the grace period procedure defines the maximum time interval between application in the first and subsequent countries.
8. The 1984 NZ figures are derived from single year EPL values because the three year moving average values do not extend to 1984.
9. The USA EPL figures used are 'base line' in the sense that no adjustment is made to reflect the extensions available under the Drug Price Competition and Patent Term Restoration Act of 1984. See Spivey and Trimble, *op. cit.*
10. Frontispiece of the Hearings on S 1306, The Patent Term Restoration Act, 1983, Serial no. J-98-46.
11. See Sub Committee's Hearings, pp. 129-81, including an interim report of work by H.G. Grabowski and J.M. Vernon: 'A sensitivity analysis of expected profitability of pharmaceutical research and development', *Managerial and Decision Economics,* 3, 1, 1982.
12. The minimum period of exclusivity is 5 years. The maximum period of effective patent life is not permitted to go beyond 14 years. See Spivey and Trimble, *op. cit.*
13. See Stuart A. Walker and Roger A. Prentis, 'Drug research and pharmaceutical patents', *Pharmaceutical Journal,* 5 January 1985.
14. In the UK prior to the 1977 Patents Act, there was a 12 months period during which a provisional application became a complete application. Under the 1977 Patents Act there is, in practice, a similar type of arrangement. Up to 12 months is available for an application to become 'substantive'. In both instances, the patent term runs from the filing date of the complete or substantive application. A Convention application in New Zealand is classed as 'complete' and patent life runs from that date. Thus an original UK application supporting a drug developed and first patented in the UK, will begin its patent life at the same time as its Convention equivalent in New Zealand. The first (UK) application triggers the Convention grace period, hence the NZ application occurs twelve months after the UK original.
15. Walker and Prentis, *op. cit.*
16. See Nancy Mattison, Eileen Thomas, Gene A. Trimble and William M. Wardell, 'The development of self-originated drugs by Swiss pharmaceutical firms, 1960-1980', *Regulatory Toxicology and Pharmacology,* 4, 1984, pp. 157-73.
17. 1.5 years is chosen guided by advice from Pharma Information of Basle. In response to the question: 'What is the typical time interval between synthesis and patent appliction?', the answer between 1 and 3 years, was given.
18. IPAC Report to the Minister of Justice, September 1985, *op. cit.,* p. 17.
19. Department of Trade and Industry, 1987, *op. cit.,* p. 24.