INDUSTRIAL PROPERTY ADVISORY COMMITTEE

THE PATENT MONOPOLY
TERM AND EXTENSIONS
THEREOF

Report to The Minister of Justice

9 September 1985

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THE PATENT MONOPOLY TERM AND EXTENSIONS THEREOF

SUMMARY:

This report traverses the additional submissions received since our first report of 1 August 1983, and comments on recommendations made by the Australian Industrial Property Advisory Committee relating to this topic, and on legislation recently provided in U.S.A. to authorize patent term extensions to compensate for governmental marketing restraint.

It reviews the proposals and criticisms made in the submissions which the Committee has received, and it re-examines the tentative proposals advanced by the Committee in the earlier report.

Recommendations made as to the most desirable situation for New Zealand are prefaced by a call for discussion with Australia with the aim of reconciling our differing views to achieve harmonisation in the interests of C.E.R.

The report recommends the retention of the existing 16 year term with provision for prolongation up to four years to compensate for regulatory marketing constraint, the repeal of inadequate remuneration and war loss extensions (or alternatively an improved procedure for them), and the provision of a further ground for revocation of a patent where an extension of term is obtained on false representation.

INTRODUCTION

1.1 This report follows one made on this topic to the Minister of Justice on 1 August 1983. Based upon the information then before us we proposed tentatively in our preliminary report recommendations which would, if implemented,

(a) leave unaltered the present patent term of 16 years;

(b) repeal the existing provisions for prolongation of the initial patent term (a) due to a state of war, or (b) because of inadequate remuneration; and

(c) provide a simple procedure to extend the term by not more than four years where marketing had been delayed by regulatory clearance procedures, and which would promulgate the decision before the expiry of the original term, and so eliminate the uncertainty and inconvenience which now occurs in connection with some of the prolongations granted under the present legislative provisions.

1.2 We have continued the study of this matter as expeditiously as possible due to pressure to provide this report separate from a general review of patent law.

1.3 For background purposes this report should be read in conjunction with our earlier report on this subject. When we refer below by numbered paragraph to our earlier comments, the indicator, (P.R.) is a reference to our preliminary report.

1.4 We recommended that our preliminary report should be made available for public comment and we have now received 14 further submissions. Three of these came from new sources, the remainder being amplification or revision of submissions considered prior to that report.

1.5 In order to examine more effectively some of the issues raised, and particularly those which were asserted to be vital to the public interest, and yet conflicting, we invited representatives of some of the parties concerned to appear before the Committee.

THE SUBMISSION CONTENT

2.1 While the majority of submissions relate to the pharmaceutical area it should be remembered that the bulk of patents do not lie in that field. The material received prior to our earlier report is summarized in that document. As indicated therein it is not feasible to traverse in full every argument contained in every submission but we have attempted to update below the prevailing attitudes. The complete list of persons or organizations which have provided us with this helpful information is set out in Appendix A. In Appendix B we provide a summary of the additional submissions received since our first report.

PHARMACEUTICAL SECTOR

2.2 As stated in the earlier report the material contributed by the pharmaceutical manufacturing industry comes from two distinct groups whose interests cannot be reconciled. The major group consists of research based pharmaceutical companies most of which are subsidiaries of overseas companies. The other is composed of 2 New Zealand based companies engaged mainly in the local formulation and tableting of generic pharmaceuticals on which patent protection in New Zealand has expired.

CLAIMS BY THE RESEARCH BASED GROUP

2.3 Most of the views received from overseas pharmaceutical manufacturers' associations are also embraced by the voluminous submissions of the Pharmaceutical Manufacturers Association of New Zealand. The local association is identified in the following review as 'the P.M.A.' or 'the Association'.

This group initially urged -

(1) Better financial incentives to maintain expensive research, costly testing activities, and the introduction of expensive and low demand products into a small price controlled market;

(2) An enlargement of the present patent term from 16 to 20 years;

(3) Retention of the present term prolongation provisions for patents which have earned inadequate remuneration; and

(4) Special recognition of the regulatory constraint imposed on the marketing of pharmaceuticals while the patentee awaits permission to sell the patented medicine.

2.4 The P.M.A. has responded to our preliminary report with a further submission and supporting documents exceeding 40 pages. In it there is -

(1) a continued claim for a basic term of 20 years;

(2) approval of the proposed regulatory constraint extension provision, but argument for a period of up to 10 years, and not 4 years as we have suggested;

(3) an enlargement of the proposed qualifying restraint period to include delays arising from activities overseas necessary to provide information which must be provided to the Drug Assessment Committee;

(4) a call for the retention of the provision for an extension on the ground of inadequate remuneration with a potential extension of 10 years; and

(5) a proposal to increase Patent Office staff to accelerate the disposal of term prolongation applications.

2.5 By invitation from the P.M.A. a submission has been provided by Professor J.E.S. PARKER who is the Associate Professor in Economics at Otago University. The content of an independent submission from Professor J.D.K. NORTH may also be coupled with the views of this group, and both of these submissions are summarized in Appendix B.

2.6 Glaxo New Zealand Limited applauds recognition of the marketing restraint problems but considers that a 20 year term would be a better solution.

GENERIC PHARMACEUTICAL MANUFACTURERS

2.7 There is a continued claim for a term not greater than 16 years with no extensions, but if they are to be allowed then it is asserted that licences should be available to New Zealand owned companies at a royalty of not more than 5%. To avoid retrospective prolongation extensions it is suggested that applications should be required earlier and that orders protecting interim users should be made in every case to induce speedy processing of such applications by applicants. The regulatory

constraint extension proposals are opposed because it is believed that applicants would be able to compel, by their conduct, a 20 year term in every case. It is further suggested that if any extensions are granted they should not be valid beyond the termination of any similar prolongation granted in Australia.

DEPARTMENT OF HEALTH

2.8 The Department's initial attitude is summarized in paragraph 3.14(P.R). It stated that experience has shown that medicine prices will only reduce where there is a cheaper competitor, and that where it has become possible to buy generic drugs there has been a substantial saving. It was submitted that an enlargement or prolongation of the patent term is against the public interest because it would inhibit savings in pharmaceutical benefit costs and be damaging to part of the developing local pharmaceutical manufacturing and distributing industry.

2.9 The Department's first reaction to our suggestion that there should be compensation for regulatory constraint loss was that it believed that quantification by the Commissioner of Patents of the delay would be time consuming and involve it in additional investigations beyond its administrative capacity. While it conceded that promulgation of prolongation decisions up to three years after the expiry of the original term is discouraging for generic marketing companies, and it did not support that practice, it regarded the present provisions as preferable to the proposal of the Committee since the current procedure allows all parties to be aware of the existence of the prolongation application.

2.10 Since then however several new factors have arisen, and the Department has also had an opportunity to consult the new Minister of Health. The Department states that it has learned of further cases where generic manufacturers have opted not to introduce medicines because patentees have applied for term prolongations upon which decisions have not been given. It is asserted that this is costly to the taxpayer. The Department also states that it has become aware of medicines which have been patented for over 16 years but are still under patent protection because of the grant of subsequent 'process patents' which prevent advantage being taken of the cheaper product. It also observes that since the issue of our first report the number of applications for prolongations has increased and that any recommendation by the Committee on patent extensions will essentially be one on the pricing of pharmaceuticals.

2.11 As a consequence the Department of Health does not support extensions based on regulatory constraint, it sees advantage in a finite period of patent protection with no provision for extension, and would accept a prolongation of two years on all pharmaceutical patents.

AGRICULTURAL SECTOR

2.12 The earlier submissions in this area are traversed in paragraphs 4.1 to 4.4(P.R) of our first report. The Agricultural Chemical and Animal Remedies Manufacturers' Association of N.Z. now complain that the Committee's proposals mean a reduction of the possible patent term from 26 to 20 years against a background of the erosion of the effective term during the last 20 years from 14 to 6-8 years. The Association urges a maximum regulatory constraint extension of 10 years which should include the time spent in overseas toxicological and enviromental studies to satisfy New Zealand registration authorities.

2.13 Federated Farmers of New Zealand (Inc.) has indicated, that having regard for the competing and conflicting factors, the Committee's report has achieved a reasonable balance, and it supports the findings on the adequacy of the 16 year term and the other recommendations.

GENERAL MANUFACTURING SECTOR

2.14 The earlier submissions of this group are outlined in paragraphs 5.1 to 5.4(P.R). There is now added thereto the reaction of the New Zealand Manufacturers' Federation (Inc.). The Federation accepts the recommendations on maintaining the existing term, and the substitution of a regulatory constraint extension provision for the existing term extension provisions.

FURTHER FACTORS REVIEWED BY THE COMMITTEE

3.1 It is necessary to examine the new factors which have arisen, and to comment on some aspects of the additional submissions. Although inter-related to some extent, this can best be done under the separate headings of Term, and Term Extensions.

TERM

3.2 We have been urged to recommend that the basic patent term be -

(1) kept at 16 years without extension opportunities;

(2) prolonged to 18 years for all pharmaceuticals with no extensions;

(3) increased to 20 years with opportunity for both regulatory constraint and inadequate remuneration extensions.

3.3 Although we have mentioned the need to have regard for the C.E.R. objectives of harmonisation of laws which bear upon the trade between Australia and New Zealand, we were concerned to reach a conclusion in our first report upon what is in the best interests overall for New Zealand. We concluded that there is not sufficient justification for an increase in the present term of 16 years. We are now aware of the recommendation of the Australian Industrial Property Advisory Committee. The majority has stated that their present term of 16 years should not be altered, either generally or in the case of particular industries. A minority of two members urged consideration of a reduction to 10 years. A minority of three members agreed with our preliminary views that there should be an extension for regulatory delay with a maximum extension of four years. This minority also said that in the light of the CER Agreement the term should be the same length in both countries. A majority of the Australian Committee however rejects these arguments.

3.4 The proposal to allow term prolongations to 18 years for pharmaceutical inventions (with no extension) comes from the Department of Health. We feel this has been provoked by the Department's desire to achieve certainty on the point of cessation of the term, and also to avoid the regulatory constraint extension procedures which our last report mooted. We believe that the second concern is excessive and not well-founded as we explain later.

3.5 We do not favour a special term for patents in any selected sectors of technology.

3.6 The problem of marketing constraints is not confined to pharmaceutical products, and the various areas involved are affected in different ways. For example while pharmaceutical and agricultural chemicals require

prior marketing approval, electrical devices are permitted entry to the market on the assumption that they meet the requirements dictated by industry standards, and if they do not the marketing may be interrupted. A different approach applies to the approval of timber preservation processes. This of course raises the question whether a patentee should be expected to anticipate some form of marketing control, and if so, to what extent. Furthermore it is it not possible to predict what additional products will come under restraint. Special rules for selected sectors of technology introduce administrative difficulties and uncertainty about the validity of their application. The existence of areas for special treatment in determining the extent of the initial patent term can lead to excessive claims about the purpose of the invention in order to cross what must be at best imprecise lines of demarcation.

3.7 An examination of the attitude of more than 120 overseas patent administrations reveals that very few countries have varied the term for any technical area. In those cases of variation the area concerned is food or medicine manufacture where the term has been reduced to half the normal length. We felt that if there is a need to recognize erosion of the patent term by regulatory constraint in some areas of technology, it is more feasible to deal with it as a subsequent alteration of the original term in the light of the evidence advanced in any particular case.

3.8 It will have been noted from our reference above to the Australian Advisory Committee's recommendation that the majority view is that there should be no variation of term for particular industries.

3.9 It was conceded by parties appearing before us that it is not the function of our Committee to assess the desirable patent term on the basis of the price which the State decides it will pay for particular pharmaceuticals, and it would appear to us that the Department of Health alone must perform the function of advising the Minister of Health on the correct balance between what will be paid for medicine covered by patent rights and the health of the community.

3.10 The Australian report referred to above states: 'Arguments that Australia should join the international trend towards a 20 year term are unconvincing. The supposed trend is only among Western industrialised countries, mostly having economies with which Australia's economy has little in common'. We have set out in

paragraph 7.18(P.R) our views on the call for an increase in the patent term to 20 years and, other than a compromise in respect of a complete elimination of any term extensions, we have not seen any new factors to change that attitude.

PATENT TERM EXTENSIONS

3.11 To examine fully the criticisms levelled at our regulatory constraint extension proposal it is necessary to reiterate and amplify the factors on which it is based.

3.12 It is important to have regard for the public interest in the avoidance of unduly long monopolies, to provide during the currency of the initial term a clear statement of the date when the patent will finally expire, and to avoid serious inconvenience to interested parties by ensuring that there is confidence in the statutory basis for the extension of a patent term. It is now also necessary to bear in mind the recommendation of the Australian Industrial Property Advisory Committee which has recommended that the procedures for granting of extensions of the terms of standard patents be eliminated in toto.

3.13 The present provisions in the Patents Act for extensions of term on the ground of inadequate remuneration suggest that a patentee is expected to derive a certain "adequate" remuneration from the invention he has made and disclosed. The Banks Committee in the United Kingdom in its report on the British Patent System (CMND 4407, 1970) did not accept this as a philosophy of the patent system and we agree. The system is based upon the bargain between the inventor and the State in which a limited monopoly is granted in return for public disclosure and availability of the invention. The limited monopoly cannot be a guarantee that a patentee will derive remuneration to a certain level and must be rather the opportunity to take his chance in the market sheltered by a period of exclusivity. For this reason we do not see the right to a prolongation of the patent term on the ground of inadequate remuneration as fundamental to the system. However we do see a certain inequity where exploitation is precluded by regulatory constraints resulting in the State derogating from its grant.

3.14 One suggestion made to us in support of the retention of the present extension provisions proposes enlargement of the Patent Office staff to accelerate the processing of these applications. We adhere to our original view that the failure to promulgate extension decisions before the expiry of the original term is caused by factors other than the speed of Patent Office processing. It is due to the time scale dictated by the Act and regulations and the time taken by applicants to present the massive volume of supporting evidence. An examination of an adequate sample of these applications reveals that on average the time taken to provide this evidence is over 20 months as opposed to the three months which the applicant has as an unquestioned right under the regulations. Bearing in mind the onus on the applicant to prove the extent of the income from the patent as compared with the expenditure incurred to derive it, and the international character of the operation of pharmaceutical and allied companies, it is not surprising that numerous declarations are involved frequently embracing several thousand pages. On the other hand we believe that those applications which really stem from marketing constraint could be decided on very few pages under the procedure we envisaged in our earlier report.

3.15 Another suggestion, received from the sector antagonistic to such extensions, proposes that the filing of prolongation applications should be required at an earlier point in time. This would have the disadvantage of diminishing the period over which income from the invention is examined and would neglect the enlarged and most significant period at the end of the patent term. The Committee's tentative proposal confined to marketing restraint erosions of term would allow the filing of such applications much earlier than at present since the examination of the derived income would not be involved.

3.16 Other restrictive submissions seek (1) the grant of a 5% royalty licence to all local manufacturers when prolongations are granted, (2) the issue of an Order protecting all interim users of the patent subject matter where the prolongation procedure is not completed prior to the expiry of the original term, and (3) the restriction of prolongations in New Zealand to coincide with the expiry of similar extensions in Australia.

3.17 We feel it would be anomalous to declare that a patentee deserved a prolongation of term due to inadequate remuneration from the initial term or regulatory delay, and then contemporaneously and automatically to award licences to all comers.

3.18 The call for the issue of an order to protect interim users in the case of every prolongation decision promulgated after the expiry of the normal term has, as an objective, an incentive to prolongation applicants to conduct their applications with expedition. While the objective is laudable such a practice would not be equitable. Quite apart from the massive evidence which applicants are forced to assemble in support of their applications, the procedure to be followed is not within the total control of patentees, and in fact, unless restrained, an opponent could, under this proposal, ensure by his own conduct an Order to his own advantage. Those who intend to deal with matter which has been subject to a patent monopoly must expect to be cognizant with the relevant provisions, and the procedure, of the Patents Act. Although as indicated earlier, the time frame dictated by the Act for this procedure frustrates the issue of decisions before the expiry of the original term, ample notice of the existence of these proceedings is given. Firstly, all such applications are advertised in the Patent Office Journal twice, followed subsequently by notification of the decision. Additionally the relevant sheet in the Patent Register is endorsed with a warning of the currency of such an application, and a special register records all prolongation applications, and their result in due course. As earlier mentioned where circumstances occasionally prevent Patent Office Journal notification before the expiry of the original term, notwithstanding the endorsement of the Patent Register before the cessation of the original term, orders protecting interim users are issued. Consequently it would appear to be unreasonable to allow, by means of an Order in every case, access to an invention for which a continuing monopoly is warranted, by those who have contributed nothing to the state of the art, simply because notification of the extension has been delayed. That view seems even more appropriate where the extension has been necessary due to the intervention of the State in the patentee's marketing efforts.

3.19 In regard to the third matter we are concerned about the importance of not placing our manufacturers at a disadvantage as compared with those of other nations, in taking up the manufacture of goods for which patents have lapsed, but we cannot see that it is feasible to award patent term extensions on the condition that they are coterminous with any similar extensions which may be granted in Australia. It is not likely that the grounds advanced for the extension will be precisely the same, or have the same merit, in both countries, and the matter is complicated by the fact that in Australia prolongations are decided by the Court. The delay in ascertaining

whether a similar application exists in Australia (if that is possible), the delay in awaiting a decision there, or the need for a subsequent revision of an extension already granted here, would introduce even greater uncertainty than that which now exists.

3.20 It has been put to us that our regulatory constraint extension proposal would enable pharmaceutical company patentees, by their conduct, to ensure the grant of a 20 year term for each patent. It is said that the more inadequate the information provided to support an application for marketing clearance the greater would be the likelihood of a prolongation of the patent. While a premature application, or slow response to requisitions for information, cannot be discounted, it must be remembered that it will be for the patentee to establish by evidence that the prolongation is justified. The potential problem will be minimised if opposition to prolongation applications is retained. In any event a substantial portion of the maximum period of extension envisaged, i.e. 4 years, would be validly attributable to real regulatory constraint erosion in the case of pharmaceutical inventions. A review of a sample of medicines for which distribution approval has been sought, and which are covered by patents, indicates that some delay does occur between the filing of a patent application and the distribution application. On the one hand one might expect some pressure to exist in the matter of marketing due to competition, or the need to secure financial yield before the advent of some superior medicines, and on the other it would be most unusual for an invention to be capable of manufacture immediately after filing a patent application. The pharmaceutical inventor undoubtedly has to contend with additional constraints and it is a matter for conjecture how much of the total should be deducted for that delay which is encountered in the exploitations of inventions generally. The majority considers that a restriction of the maximum possible extension to four years would meet all those factors and discourage abuse.

3.21 Although we cannot determine the final procedure adopted in respect of any of our recommendations which are approved, it seemed to us that a marketing constraint extension application could be reduced to relatively simple documentary verification by the patentee of the time involved in clearance procedures, and that only in rare cases would it be necessary for the Health Department to be involved. That department's activities would not be brought into question by the Commissioner of Patents to any greater degree than they now are under the inadequate remuneration extension procedures.

3.22 Concerning the complaint of the Department of Health that it has been denied medicines at reduced cost at the end of a patent term because 'process patents' had been granted in the interval: in the absence of more specific information we remain to be convinced of the injustice suggested. When a patent expires the subject matter covered becomes available to the public. Where a patent of addition is granted the term expires at the same time as that of the parent patent. Where a further ordinary patent is granted, to be valid, it must be based on a new inventive step, and the public cannot expect to take free advantage of the further step along with the material of the first patent which has expired.

3.23 Some submissions have been critical of our proposal that regulatory constraint of marketing should be deemed to have terminated when the regulatory body grants permission to distribute the product on a national basis, and in the case of pharmaceuticals, through retail chemists.

3.24 Professor North said that this proposal was not sufficiently precise since in his opinion effective marketing only commences when the Pharmaceutical Benefit Scheme grants support from the Social Security Fund.

3.25 The Health Department claims that the exclusion of a drug from availability at retail outlets should not be regarded as regulatory constraint because some drugs are too expensive in the face of available alternatives to be obtainable under the Drug Tariff, and in fact some drugs will never be available in that way.

3.26 Earlier in this report we remarked that it was never intended to guarantee a rewarding market through the patent system for an invention, to which we add the general observation that if the necessary price is too great to attract public consumption of the invented commodity that is a factor which the patentee must accept. We also commented earlier that it is not the function of our Committee to assess a desirable term on the basis of the price which the State decides to pay for pharmaceuticals, and which in any case will vary from medicine to medicine, and from time to time. While the pharmaceutical industry may believe that the State never pays sufficient for its products, unlike other areas of manufacture, it at least has an opportunity to negotiate for an acceptable price in return for a substantial market under the Pharmaceutical Benefit Scheme.

3.27 It has been our objective in proposing the regulatory constraint extension scheme to eliminate from consideration factors demanded by the existing legislation which we think inappropriate, and in particular the extent of financial return. It has also been our understanding up to the present that Ministerial consent to distribute a drug is quite unrelated to inclusion on the Drug Tariff to provide Social Security Fund support. We believe that approval for restricted distribution, which may vary in degree, does not provide real release from marketing restraint, and we therefor chose general retail availability as the point of cessation of regulatory constraint whether or not it is accompanied by Social Security Fund support.

3.28 Our proposal is directed to the restoration of that portion of the patent term during which full marketing opportunity has been denied by regulatory constraint, with a maximum of four years, and without attempting to assess the volume of sales which is likely to result. On that basis, and unless we have misunderstood the submissions of Professor North and the Department of Health, we do not see a need to reconsider that aspect of our proposal.

3.29 In paragraph 3.9(P.R) reference is made to proposed U.S. Government legislation to compensate for delays associated with the pre-marketing review process of the Food and Drug Administration. This legislation has now been signed by the President under the title of the Drug Price Competition and Patent Term Restoration Act of 1984. The first portion of this Act relates to abbreviated new drug applications which involve drugs which have previously been listed as approved, and includes reference to their interaction with patent law. It is the second portion of this Act which deals with the opportunity of patentees to have their patent term extended to compensate for erosions by the regulatory constraint process. The original material which concerned animal drugs and agricultural chemicals has been divided out into other pending legislation. The new Act is only applicable to regulatory marketing constraint occurring after the patent has been granted (bearing in mind the United States patent term runs from grant), the extension application must be made before the expiry of the patent and within 60 days from the date upon which the product has received commercial marketing approval, and only one extension will be granted. The maximum extension available is five years and deductions from the qualifying period will be made for periods when the patentee did not act with due diligence and also one half of certain other periods involved in the review.

3.30 In paragraph 8.3 (P.R.) we indicated that the relevant period of constraint should be that involving the granting of marketing clearance in New Zealand and we sought specific comment on the point.

3.31 The P.M.A and others strongly argued that the delays occurring outside New Zealand should be taken into account. It was claimed that from a practical view point the information that must be assembled for overseas clearance applications is much the same as is required in New Zealand and much of it is obtained outside New Zealand. We were told that in practise application is made in the home country first and the material assembled for this purpose then is used for applications in overseas countries. Efficacy and safety tests and clinical trials are not all repeated in all countries. Reference was made also to the fact that overseas approvals do assist New Zealand applications.

3.32 In many cases proper applications for clearance could be made, and registration obtained, no earlier in New Zealand because the supporting information is not available. It is submitted that time taken overseas to generate the information required for a New Zealand registration (even though used also for applications in other countries) should be treated as part of the time taken to secure marketing clearance for New Zealand.

3.33 The Department of Health told us that applications for approval in New Zealand are treated independently of overseas approvals and that there are cases where approval is granted in New Zealand before it is granted in overseas countries such as United States of America. However we are not satisfied that this wholly negates the industry view.

3.34 In any case it will be a matter for evidence to show that complying with the requirements of obtaining marketing clearance in New Zealand involved a period of time during which the patent term was running with no ability to exploit the invention. If that includes a period when necessary work was being done outside New Zealand we now consider that it should not be disregarded.

COMMITTEE'S FURTHER CONCLUSIONS

4.1 The Committee has carefully reviewed the preliminary report in the light of the further submissions received and overseas developments, and has kept in mind the philosophy of the patent system which has been traversed in Section 7 of our earlier report and in particular in paragraph 7.1 (P.R).

4.2 We referred in our earlier report to the CER Agreement and the likelihood that a difference in the term of patent protection between New Zealand and Australia would be seen as a potential barrier to free market access. Clearly there is merit in harmonization of the laws of the two countries in this area, and indeed in the whole area of industrial and intellectual property law. The same might be said of the position internationally but realistically progress to that end will be slow.

4.3 The Industrial Property Advisory Committee in Australia reported in August 1984 the results of an extensive review of the Australian patent system. Substantial adoption of the recommendations of that Committee will bring about a greater divergence in the patent laws of the two countries than exists at present. Notwithstanding this we believe that there is merit in having the same basic patent term and that this should be resolved at Government level.

4.4 As previously indicated we have endeavoured to assess what is most desirable for New Zealand in the hope that the views we express may be of assistance when the question of patent term calls for discussion.

4.5 The Australian IPAC Committee was unable to reach unanimity on the point. The majority recommended retention of the sixteen year term for patents and elimination of procedures for granting extensions of the term. A minority of two favoured reduction of the patent term to ten years and a minority of three came to the same conclusion as expressed in our preliminary report.

4.6 We have considered carefully the majority recommendation in Australia which we understand to be based primarily on an attempt to balance social cost and benefit in the Australian context. While we accept the importance of those considerations we are inclined to think that the complexity of the inter-related issues and influences in the absence of empirical evidence render the selection of any period of years as appropriate for the term of patent protection as almost arbitrary. While the patent system is accepted as valuable (as we accept it) we believe it is more a matter of evaluating proposals for change. In this respect we believe it is of great importance to take into account (but equally difficult to measure) the perception of the industrialised international community. We believe that patent laws which are recognised as providing strong protection are important to the industrial development of New Zealand. That importance goes not just to foreign

investment decisions but to a greater degree to facilitating the transfer of technology. Overseas research based organisations will be more willing to make available by licence and otherwise, new technology (including the vital knowhow necessary fully to employ new techniques) when assured of secure protection. This view was adopted by the Government in connection with the recent negotiations for revision of the Paris Convention. The negative impact of being seen to erode the relatively strong patent protection available in New Zealand must not be overlooked.

4.7 In the chemical field it is easy to be influenced by the high sums paid by the Government under the pharmaceutical benefit scheme and by the costs of agricultural chemicals. On the other hand the benefits brought to New Zealand by the research based chemical companies cannot be denied and the information contained in the PMA submissions is very compelling.

4.8 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.

4.9 We have found wide recognition of the fact that a substantial part of the patent term is consumed in securing clearances to market new products. This is acknowledged even by the Department of Health. It should be said that this can be offset to some extent by the greater facilities available to market and distribute a product once clearance is obtained than was the case when the sixteen year patent term was adopted. Nevertheless it is clear that in those industries where clearance to market is needed the effective patent term has been substantially eroded and the industries affected are at a disadvantage as against other industries where such clearances are not required. If that is accepted it is less than consistent to agree with the Australian recommendations which will yield the end result that the patentees disadvantaged in the manner indicated will have less opportunity to overcome their disadvantage than they have under the present law.

4.10 As in Australia we were presented with few arguments in support of an effective reduction in potential patent protection. The arguments against the present provisions for prolongation of the patent term on a case by case basis were directed to the complexity of the procedures and the element of uncertainty flowing from them.

4.11 We adhered to the view that the same basic patent term should apply in all fields of technology. And there should be available a procedure to enable restoration, at least in part, of such of the patent term as is lost through regulatory constraints on marketing.

4.12 The majority of the Committee adheres to the views set out in the preliminary report that the basic term for a New Zealand patent should remain at sixteen years, that there should be a procedure for extension to compensate for regulatory delays for a maximum period of four years and that the existing provisions for extensions on grounds of war loss and inadequate remuneration should be eliminated.

4.13 Some sympathy was expressed for the submission of the PMA that the arbitrary maximum period of four years to compensate for regulatory delay should be extended perhaps to ten years where the evidence in a particular case dictates. There was also some support for a basic term of 20 years for all patents with no extensions which has the merit of simplicity and certainty. However there appears no justification for such gratuitous extension of patent protection in those areas of technology where the full term is to be enjoyed without constraint.

4.14 The PMA pressed for the longer period of regulatory delay extensions and for the retention of extensions on the ground of inadaquate remuneration. In support of this view reference is made to the two tier system for approval of pharmaceuticals for marketing in New Zealand being a requirement first, for registration which is directed to efficacy and safety, and secondly (after a Health Department encouraged delay of some two years), for incorporation within the Drug Tariff which is directed to questions of price and full market access. In addition reference was made to the small size of the New Zealand market and the need to attract marketing facilities to this country particularly for products having small and even uneconomic demand. The majority of the Committee sees no justification for providing a potential maximum period of protection in New Zealand greater than that of most overseas countries and therefore does not support the PMA arguments.

4.15 The provisions for patent term extension on the ground of war loss currently serve no purpose and could well be eliminated subject to the introduction of appropriate relief should circumstances arise in the future. The removal of the ground for extension of inadequate remuneration is more difficult. Those who consider that the provisions should be repealed rely on the following arguments:

(1) The difficulty in determining what is adequate and what is inadequate remuneration, and of the degrees of inadequacy with reference to periods of possible extension.

(2) The uncertainty that is involved in considering extensions of term at, or after, the expiry of the initial term. Inadequate remuneration cannot be demonstrated until the end of the term and the present procedures involve extensive delays thereafter.

(3) The philosophical question whether it is a function of patent law to remunerate adequately patentees when the basic contract between the inventor and the State is disclosure by the inventor in return for a specified monopoly period, successful exploitation being a simple commercial risk which the inventor must take.

4.16 The contrary argument to support this ground of extension may be summarized as:

(1) The fact that the provision has been part of the patent law for many years and that no good grounds other than procedural difficulties have been shown for extinguishing the right.

(2) It is desirable to retain the provision for the exceptional case where no regulatory delay has been involved but where circumstances are such that exploitation has been precluded. This is likely perhaps in areas other than the chemical field where commercial exploitation requires other complex and time consuming innovation before it can take place.

(3) The equitable argument that to encourage continuing research a fair return should be available to the patentee who has conferred on the public the benefits of a meritorious invention where the commercial success has been limited by reasons beyond the control of the patentee.

4.17 As already indicated the majority of the Committee favours elimination of the ground of extension for inadequate remuneration.

4.18 If a separate ground for prolongation of the patent term is provided based upon regulatory delay, it can be expected that a good many of the applications for prolongation currently filed on the ground of inadequate remuneration will be dealt with under the new ground. In those cases the proposed new procedure should provide for a decision well before the expiry of the initial term.

4.19 If inadequate remuneration is retained as a ground it should be possible to devise a procedure to overcome the major difficulties experienced at present by requiring the initial application for extension to be made earlier so that a decision whether or not any extension of term is justified is made before the expiry of the patent term. The ultimate duration of the extension may not be settled until the remuneration during the basic term is known but there seems no reason why a more satisfactory two stage procedure should not be devised.

4.20 Upon further consideration the Committee is of the view that a right of opposition to applications for extensions of term whether or not limited to a maximum of four years should be retained.

4.21 In addition the Committee considers that section 41(1)(j) of the Patents Act should be amended to read:

> "That the Patent or any extension of the term thereof was obtained on a false suggestion or representation".

This will add an additional ground for revocation of a patent where it has been extended improperly.

RECOMMENDATIONS

5.1 That before any change is made in the term of patent protection in New Zealand, and the provisions for prolongation of that term, an attempt be made to achieve harmonisation with the corresponding provisions in Australia.

Subject to the minority and alternative view traversed in the body of this report, the majority recommendations as to the most desirable situation for New Zealand are:

5.2 That the term for patent protection in New Zealand should be sixteen years as at present with provision for case by case prolongation with a maximum extension of four years, where it is shown that the effective patent term has been shortened by regulatory constraints preventing or restricting exploitation of the invention by the patentee.

5.3 That the present provisions for extensions of term on the grounds of war loss or inadequate remuneration be repealed.

Should this recommendation not be implemented, however, then procedures should be formulated to ensure that decisions prolonging the term of patents are made prior to the expiry of the initial term. These should include a requirement for earlier application than presently is provided for in sections 31 and 32 of the Patents Act, speedier advertisement of such applications (such as in the daily press instead of the Patent Office Journal), and if necessary a two stage procedure so that even if the length of extension is not finally determined, at least a decision of wnether or not any extension is justified is made at an early date.

5.4 That section 41(1)(j) of the Patents Act be amended to provide a further ground for revocation of a patent where an extension of the term has been obtained on a false suggestion or representation.

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APPENDIX A

LIST OF PERSONS OR ORGANIZATIONS MAKING SUBMISSIONS ON THE PATENT MONOPOLY TERM AND EXTENSIONS THEREOF

AGRICULTURAL CHEMICAL & ANIMAL REMEDIES MANUFACTURERS' ASSOCIATION OF NEW ZEALAND INC.
ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY.
AUTOMOTIVE PRODUCTS LTD.

BALDWIN, SON & CAREY.
BUCHANAN, ELSPETH.

CIBA-GEIGY.

DEPARTMENT OF HEALTH.
DOUGLAS PHARMACEUTICALS LTD.

EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES' ASSOCIATIONS.

FEDERATED FARMERS OF NEW ZEALAND (INC).
FISHER & PAYKEL.

GLAXO NEW ZEALAND LTD.

MASON & PORTER LTD.
MONSANTO COMPANY

NEW ZEALAND GROUP OF THE ASSOCIATION INTERNATIONALE POUR LA PROTECTION DE LA PROPRIETE INDUSTRIELLE.
NEW ZEALAND INSTITUTE OF PATENT ATTORNEYS.
NEW ZEALAND MANUFACTURERS' FEDERATION INC.
NORTH, PROF. J.D.K.

PACIFIC PHARMACEUTICALS LTD.
PARKER, PROF. J.E.S.
PHARMACEUTICAL MANUFACTURERS' ASSOCIATION (N.Z.) INC.
PHARMACEUTICAL MANUFACTURERS' ASSOCIATION (U.S.A.).

SCHERICO LTD.

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APPENDIX B

GENERAL SUMMARY OF ADDITIONAL SUBMISSIONS RECEIVED SUBSEQUENT TO FIRST REPORT

AGRICULTURAL CHEMICAL & ANIMAL REMEDIES MANUFACTURERS' ASSOCIATION OF N.Z.

The view is expressed that paragraphs 8.2 and 8.3 of the Report do not encourage high technology transfer to New Zealand because while a maximum total term of 26 years is now obtainable the proposals limit the maximum to 20 years. The Association again draws attention to the enormous expenditure of money and time required for development of these inventions, together with the trial period for regulatory purposes and the necessary farmer instructional use activities. The submission asserts that due to regulatory delay the effective patent term has been reduced from 14 years in 1962 to 6-8 years in 1982. AGCARM urges that the maximum regulatory delay extension should be 10 years, and that time spent in overseas toxicological and environmental studies to satisfy New Zealand authorities should be taken into account. The Association believes that our legislation should be futuristic in its approach.

ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY.

This submission claims that the patent term set by the Patents Act 1953 is 30 years out of date and that any increase will only affect 15% of granted patents, but to that small group the term is crucial. The provision of the proposed regulatory period is not considered adequate to rectify the present situation in New Zealand. The increase in the time between discovery and marketing of 3-5 years in 1960 to 10-12 years now, is reiterated together with assertions of the enormous cost and risk borne by innovative companies which all consumer countries should share. Attention is also drawn to the greater period involved in discovering new pharmaceuticals. Complaint is made that the regulatory delay extension mechanism recommended by IPAC does not take into account the delay involved in getting marketing authority in the country of origin.

The Association further complains of the depressed return from New Zealand where pricing restraints are exercised.

It is asserted by the Association that the savings to the National Health Scheme due to patented medicines falling into the public domain is only about 0.1% of the total health cost.

The final summary observes that while a marketing delay extension is not unattractive, it is not sufficient compensation for present difficulties, and a term of at least 20 years appears necessary.

DEPARTMENT OF HEALTH.

Concern is expressed at the proposal to compensate pharmaceutical patentees for regulatory delay loss, and particularly to the point of availability of drugs at retail pharmacies. The Department believes that quantification by the Commissioner of the delay will be time consuming and involve the Department in additional investigations beyond its administrative capacity. It is claimed that exclusion of a drug from availability at retail outlets is not "regulatory delay" because some drugs are too expensive in the face of available alternatives to be made available, and in fact some will never be put on the Drug Tariff.

The Department concedes that the present situation, where decisions on extensions are promulgated up to three years after the normal patent term, is discouraging for generic marketing companies who may subsequently be forced to compensate patentees.

Nevertheless although the Department does not support the present prolongation system it regards it as preferable to the Committee's proposals since the current procedure allows all parties to be aware of the position. It suggests that the proposed procedure will result in the same delays with arguments as to where the fault lies.

The foregoing has been followed by a further submission in which it is stated that the approach taken by the Department has the approval of the Minister of Health.

It is contended that cases have arisen where generic medicine manufacturers have opted not to introduce medicines because of the uncertainty of the outcome of pending patent term extension applications, and the deferment of generic marketing is costly to the taxpayer.

The Department has also claimed that it has been prevented from obtaining a cheaper product because subsequent process patents have been granted during the life of the original patent.

It further observes that patent prolongation applications are increasing and that any recommendation on term extensions will essentially become a recommendation on pharmaceutical pricing.

For these and earlier expressed reasons it does not support a regulatory delay extension scheme and sees great advantage in a finite period of patent protection devoid of extension opportunities. To that end it would accept a prolongation of pharmaceutical patents by two years with no right of extension.

DOUGLAS PHARMACEUTICALS LIMITED.

A term of 16 years with no extension is favoured, and concern is expressed about the retrospective granting of term prolongations which discourages the introduction of competing products, and encourages delay by the patentee in processing prolongation applications. The submission urges the making of an order, to protect interim users of patented material, in every case, which would be in line with the practice in Australia and other countries.

The Committee is urged to recommend that prolongations of term should permit New Zealand owned pharmaceutical companies to manufacture and sell the pharmaceutical at a royalty of no more than 5% of their invoiced price. The opinion is given that this provision would not be contrary to Paris Convention obligations, and would develop local industry and associated skills.

Concern is expressed about the delay in pronouncing decisions on prolongation applications and it is suggested that applicants should be obliged to lodge applications 2 to 3 years before the patent expiry date. Extensions should not run beyond those granted in Australia.

The submission states that the revocation provisions should enable prolongation decisions to be re-opened and their validity re-considered.

EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES' ASSOCIATIONS.

This organization fully supports the contentions of the British Association and particularly as they affect the research-based sector of the industry.

FEDERATED FARMERS OF NEW ZEALAND (INC.)

This submission formally supports the Committee's findings on the adequacy of the 16 year term and its other recommendations. It believes that 'regulatory delays' should only include time lost through compliance with unnecessarily rigorous statutory requirements, as distinct from the time taken to evaluate the efficiency and safety of these products, without which responsible development cannot take place. The competing and conflicting factors involved in this question, and the need for adequate development funds are acknowledged, but the Federation believes that the Committee has achieved a reasonable balance in its Report. The submission also refers to a need to survey over the period 1945 - 1980 animal remedies and pesticides to establish to what extent materials, which have been sold exclusively under patent rights, continue to be available, or are required but are not available, after their terms have expired. The Federation observes that newer chemicals frequently replace patented materials either within the sixteen year patent period or upon expiry because (a) they have become environmentally unacceptable; (b) they are too toxic to the operator; or (c) because of their technical limitations such as efficacy and side effects.

GLAXO NEW ZEALAND LIMITED.

While applauding the recognition of erosion of term through regulatory delay, there is criticism of the failure to give credit for the time necessary to accumulate sufficient knowledge to satisfy the requirements of the regulatory authority. It is pointed out that the submission to the New Zealand Health Department is only sensibly made after corresponding submissions in the originating and key countries, and when any resulting difficulties there have been resolved. It is asserted that this imposes a minimum period of three to four years between the filing of the New Zealand patent application and the drug submission after which the latter must be processed. In addition there will, under the Committee's proposals, be a loss of existing extension opportunities, and it is considered that the interim proposals are unsatisfactory, and that the solution lies in a twenty year term for pharmaceuticals.

NEW ZEALAND MANUFACTURERS FEDERATION (INC.).

The Federation accepts the recommendations on maintaining the existing patent term, and a substitution of a regulatory delay extension provision for existing extension provisions.

PROFESSOR J.D.K. NORTH

As a Professor of Medicine at Auckland University he has been involved in the assessment of many new drugs and has served as a foundation member of the Drug Assessment Advisory Committee. As an independent academic he does not believe the recommendations to be in the best interest of providing safe and effective drugs.

Professor North quotes the average times for drug development in United States between 1977 and 1979 as follows:

i.	Synthesis in the chemical laboratory	- 0.5 years
ii.	Animal pharmacology and toxicology	- 3.5 years
iii.	3 phases of clinical investigation testing for safety and efficacy in humans to acquire information in order to submit a new drug application	- 6 years
iv.	continued clinical investigation between submissions and approval of new drug application	- 2 years
	Total time to marketing	- 12 years

He states that the New Zealand application for registration [for distribution] would be made about the time of the U.S. application, (i.e. between ii. and iv. above), and that although the delay before approval is similarly an average of 2 years in New Zealand, this does not represent the time when the drug can be effectively marketed, since that depends upon support from the Pharmaceutical Benefits Scheme which might involve a further delay of 2 years. Professor North asserts that studies show that the effective patent life in U.S.A. has fallen from 13.6 years in 1966 to 6.8 years in 1981 and this results in an average life of 5.8 years in New Zealand.

Referring to the comment that the NZ market is less than 0.2% of the multinational world market, the submission stresses that if New Zealanders are not to suffer, the market here must be kept attractive.

Commenting on the savings from the introduction of generic products, the submission concedes that in general resulting changes in formulation are not life-threatening, but there have been several instances where, on marketing generics, dangerous side effects have been detected, and this is the price to be paid for the use of generics.

Responding to the Committee's comments on the lack of evidence of the threatened demise of drug companies, attention

is drawn to the number of patients throughout the world suffering from uncommon complaints for whom there are as yet no pharmaceutical treatments, and which it is submitted, cannot be developed unless sufficient finance is provided from expected sales.

Professor North believes a 20 year term for pharmaceutical patents is the answer, and that in considering the effect of regulatory delay regard must be had for the time taken to collect the information needed by government departments, and not just the time taken to consider the submissions. He considers it to be spurious to have regard only for the time between the making of the application for approval in New Zealand and allowance of it. He further believes that the proposed 4 year limitation of the extension for regulatory delay is not realistic since even then there would only remain for some of the most effective drugs, a four year marketing time as a reward for more than a decade of research. He is critical of the definition "granting permission to distribute through chemists on a full national basis" as not being sufficiently precise since effective marketing starts from the time when it has been approved under the Pharmaceutical Benefits Scheme for partial or complete refund from the Social Security Fund.

PACIFIC PHARMACEUTICALS LTD.

The retention of the 16 year term with no extensions is advocated, particularly as the benefit to the multinational of a longer term is small, while the impact on the taxpayer is large.

The regulatory delay extension proposals are strongly opposed since it is believed that pharmaceutical patentees would be able to compel an automatic 20 year term in every case.

The submission suggests that the regulatory delay provision will put the Department of Health under considerable pressure and cost to avoid extensions to their drug bill.

It is submitted that if extensions beyond 16 years are to be entertained they should be based on commercial considerations with every incentive for patentees to conclude the application speedily, and with orders in the form: "the extension runs from its date of allowance only and will not interfere with the action of competitors who launch the product on the market between the expiry of the patent and the date of the extension order".

PROFESSOR J.E.S. PARKER.

This submission is endorsed as being "On invitation from THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF NEW ZEALAND INCORPORATED".

The submission extends to 41 pages, the writer being the Associate Professor in Economics at Otago University. It asserts that -

a) Innovation is the basis for competition in the pharmaceutical industry;

b) This is often misunderstood with the imposition of inappropriate proposals by policy makers;

c) The effective patent term in N.Z. is short compared with other innovative nations;

d) The consequential deterioration of the pharmaceutical investment climate in New Zealand may be offset by an increased patent term;

e) The restriction of regulatory delay credits to New Zealand delays -

i) suffers from logical errors;
ii) is a deterioration of the present situation; and
iii) is likely to be a costly and clumsy attempt to rectify the situation.

Professor Parker advocates a 20 year term as a solution of the term erosion problem, (with the retention of existing extension opportunities), arguing that this would be simpler and achieve an improvement in the N.Z. investment climate, and tend to equate U.S. and N.Z. patent terms. His criticism of the regulatory delay extension proposal includes (1) individual drug delay assessment; (2) restriction to NZ delay; (3) cost factors arising from administrative and hearing activities, the affect upon the investment climate, and the implied character change for the Drug Assessment Advisory Committee; and (4) a reduction of the present maximum prolongation period of 10 years to 4 years.

PHARMACEUTICAL MANUFACTURERS' ASSOCIATION OF NEW ZEALAND.

The Association favours the principle that applications for prolongation should be concluded before the expiry of the normal term.

The PMA states that a survey of its members has shown a marked decline in profitability, a withdrawal of less profitable products, and a cancelling of the introduction of new products. It asserts that they are unable to pass on a full proportion of research and development costs in New Zealand. The point is made that a reduction in the encouragement (by an insufficient patent term) to find new pharmaceuticals leads to a reduction in the savings on institutional care, and by example it is alleged that the savings over a period of twelve years in the use of just one medicine amounted to seven times the savings for all generic prescriptions for one year. The PMA seeks (1) a basic 20 year term; (2) a regulatory delay extension opportunity with a potential of 10 years, the actual potential award equating with the longest, and not the typical, regulatory delay; and (3) an extension on the grounds of inadequate remuneration with a potential extension of 10 years.

To speed up attention to prolongation applications the Association suggests an increase in the number of persons in the Patent Office empowered to hear submissions on, and decide, such applications.

In regard to term the Association refers to the tendency for "technology exporting nations" to be equated with developed nations and "technology importing nations" to be equated with developing nations. In commenting on the observations in the Report that two thirds of patent administrations have a term less than 20 years, it asserts that a conclusion that New Zealand falls more into the second category than the first, is understating the current stage of development in this country and will not encourage future development. The Association submits that the Committee's concern about the number and complexity of prolongation applications will diminish if a twenty year term is adopted.

Answering the Committee's comment that no evidence had been advanced of the threatened demise of research based companies, the PMA has referred to a survey taken between 1979 and 1981 indicating that the operating profit for the prescription medicine sector (as a proportion of total assets) fell from 8% to a loss of 0.2% in contrast to a profit of 8% for all New Zealand companies in all sectors. New Zealand companies manufacturing prescription medicines are said to have incurred a loss of 1.7% as compared with a profit of 11.6% in 1979.

Supporting the assertion that profit margins have forced the withdrawal of products, or the launching of new products, the Association states that between 1979 and 1981 PMA members withdrew 23 prescription products and abandoned the introduction of 33 new products.

The Association's response to the Committee's observation that there is no evidence that increased development costs have not been included in new product prices, is that while the Department of Trade and Industry's approved selling price is calculated to give an adequate return on investment, it is, on average, 16% above the price which the Pharmaceuticals Benefit Scheme pays. It further claims that of 65 new products added to the Drug Tariff over three years, 50 were priced in New Zealand below the price in the country of origin.

The submission stresses that a decline in the availability of new and less profitable pharmaceuticals will contribute to a decline in health services and increase hospitalization costs, and that a reduction of the possible extension of term by 60% in a highly innovative area will not encourage innovation.

While agreeing with the principle of regulatory delay prolongations of term, the PMA disagrees with the suggested point from which that delay should be calculated, and urges that it should commence from the date of application for a patent in New Zealand. The Association also opposes what it believes to be the Committee's exclusion for delay credit of delays outside New Zealand. The Association however accepts that a relatively straightforward and fair system for extension of patent term based on regulatory delay could be evolved and it traverses the nature of the evidence required to allow assessment and to encourage diligence in obtaining marketing consent.

In maintaining its plea for a retention of the inadequate remuneration prolongation, the PMA comments that apart from references by the Committee to the time-consuming and administrative difficulties, reasons have not been given for the majority view favouring elimination of this form of extension. It believes that the provision of regulatory delay prolongations will diminish inadequate remuneration applications, and that there should be provision for worthwhile inventions which have not been exploited for many years until a willing licensee is found, or until medical practitioners have been convinced of a drug's usefulness.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION (U.S.A.).

In regard to regulatory delays the Association states that the actual pendency of an application before the New Zealand Health Authorities is at best one to one and a half years, and is only the final step in presenting the information required. Consequently the 4 year maximum extension is not sufficient to compensate for the expensive development and shortened effective patent life. The allowance of a 20 year term is requested as recommended in their first submission.

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