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CONCLUSION

Pharmaceuticals have prolonged life and, at the same time, greatly improved the quality of life for millions of people around the world. They have enabled physicians to understand better the causes and manifestations of disease, while giving them the means to be much more effective in preventing and curing illness.

Of all the benefits of pharmaceuticals, however, only those that save costs by reducing mortality and alleviating some types of morbidity are included in formal calculations of their cost-effectiveness. Nevertheless, the evidence shows that drugs are cost-effective.

Drug therapy usually is the least expensive form of medical treatment, generally provides net benefits and reduces net costs and often produces benefits that greatly exceed costs. In a cost-conscious age, pharmaceuticals are of special value.

PRIMARY REPORTS

1. The Societal Impact of Pharmaceuticals: An Overview
   John G. Adams, Ph.D., Former Vice-President, Scientific & Professional Relations, PMA

2. Benefits and Costs of Human Vaccines in Developed Countries: An Evaluative Survey
   Burton A. Weisbrod, Ph.D. and John H. Huston, Ph.D., University of Wisconsin, Madison

3. Cost-Effectiveness and Cost-Benefit Analysis of Immunization Programs in Developing Countries: A Review of the Literature
   John G. Haaga, Ph.D., Cornell University

4. Economic Evaluations of Medicines: A Review of the Literature
   Judith L. Wagner, Ph.D., Director, Technology Research Associates, Inc.

5. Cost-Benefit and Cost-Effectiveness Analysis of Pharmaceutical Intervention
   Thi D. Dao, Ph.D., Deputy Director, Office of Policy Analysis, PMA

6. The Role of Survey Research in the Assessment of Health and Quality-of-Life Outcomes of Pharmaceutical Interventions
   Amiram Vinokur, Ph.D., et al, Institute of Social Research, University of Michigan

7. Beta-Blocker Reduction of Mortality and Reinfarction Rate in Survivors of Myocardial Infractions: A Cost-Benefit Study
   A. D. Little, Inc.

8. Use of a Beta Blocker in the Treatment of Glaucoma: A Cost-Benefit Study
   A. D. Little, Inc.

9. Use of Beta Blockers in the Treatment of Angina: A Cost-Benefit Study
   A. D. Little, Inc.

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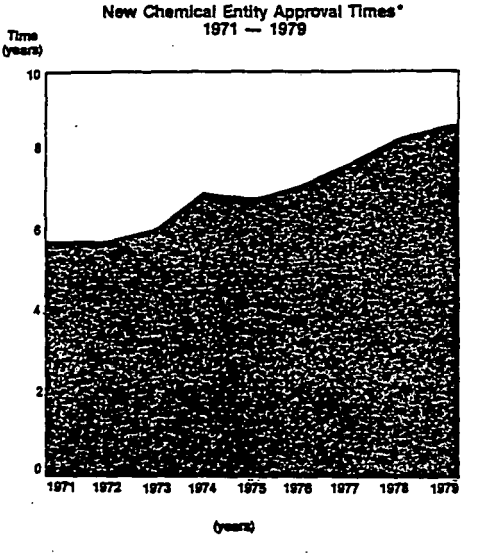
APPENDIX B

[Submitted with Statement of Lewis A. Engman, President, Pharmaceutical Manufacturers Association, Before the Committee on the Judiciary, United States Senate on S.255, the "Patent Term Restoration Act of 1981" (April 30, 1981:)]

The Time Factor in New Drug Development

Even after a new drug has been discovered, it takes 7-10 years to develop it and get it approved for sale.



*Approval Time = time from IND filing to NDA approved by the Food and Drug Administration

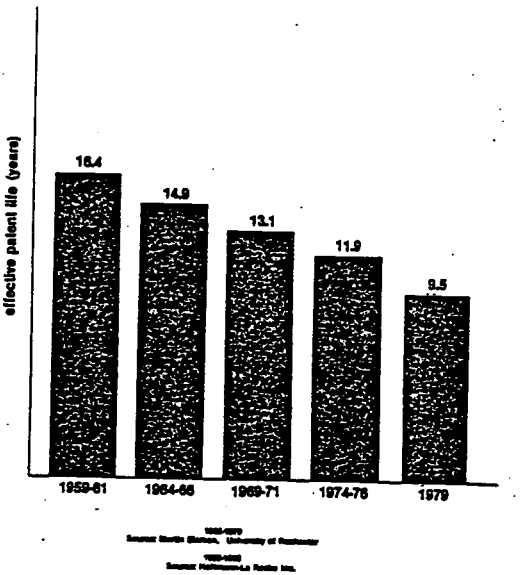
Source: Martin M. Shapiro, Ph.D., "Consequences of the Delays in Patent Protection for New Drugs," CEDR, 1980.

[Submitted with Statement of Lewis A. Engman, President, Pharmaceutical Manufacturers Association, Before the Committee on the Judiciary, United States Senate on S.255, the "Patent Term Restoration Act of 1981" (April 30, 1981):]

Declining Patent Protection

These 7-10 years are, in effect, deducted from a drug's patent life. Thus, instead of having 17 years in which to recover its investment like firms in most other industries, the pharmaceutical innovator has only about half that time.

Patent Life Erosion



[Submitted with Statement of Mark Novitch, M.D., Deputy Commissioner, Food and Drug Administration, Office of Assistant Secretary for Health and Human Services Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, on H.R. 3605 (a 1¼-page bill to establish an ANDA procedure for post-1962 drugs) (July 25, 1983:)]

LENGTH OF PATENT PROTECTION FOR POST-62 DRUG PRODUCTS

Between 1963 and 1978 FDA approved over 330 new drug products for the first time. Approximately 205 of these products are considered products which will be candidates for ANDAs under a post-1962 ANDA policy. The remaining post-1962 approved products are not considered ANDA candidates for one of the following reasons. The product is: (1) an antibiotic and is covered under the "form 6" procedures; (2) in a class of products not covered by the ANDA policy, e.g., insulin, radiopharmaceuticals, LVPs, medical devices, etc.; (3) no longer marketed (either FDA has withdrawn approval or the sponsor has discontinued marketing). Between 1979 and 1983, FDA estimates that another 40-50 products were approved which would be suitable ANDA candidates.

FDA examined the patent status of the 205 1963-1978 candidate products and found that the effective patent life of these products averaged about 12.5 years. However, for products approved in the late 1970s, the effective patent life has averaged only 9 to 10 years. These estimates do not necessarily include all applicable patents, since relevant processes or use patents may extend patent protection. In addition, a number of these products had no, or very little, patent protection following approval. A breakdown and list of these products is provided below.

For the 205 drug products approved between 1962-1978, 15 products or 8 percent of the drugs had no effective patent life at the time of approval. Another 36 products, or 18 percent, had comparatively little protection. See table below:

Status Patent	No. Products	Percent of Total
Never patented	3	2
Off-patent before approval	12	6
Less than 7 years patent protection	36	18
TOTAL	51	25

Present data for these drug entities were obtained from the following sources:

1. The Merck Index, Ninth Edition, Published by Merck & Co.
2. 1976 Basic Patents for Major Drugs, Noyes Development Co., 1969.
3. The U.S. Generic Drug Market, Frost & Sullivan, 1976 and 1980.
4. Innovation in the Pharmaceutical Industry, David Schwartzman, The Johns Hopkins University Press, 1976.
5. Dr. Martin Eisman, Center for the Study of Drug Development, the University of Rochester, School of Medicine and Dentistry, Rochester, N.Y.
6. Telephone queries with individual drug sponsors.

POST-1962 ANDA-CANDIDATE PRODUCTS WITH LESS THAN 7 YEARS EFFECTIVE PATENT LIFE*

Products With No Effective Patent Life After Approval Date

- Natural Substances/Never Patented (3)

Approval Date	Chemical/"Generic" Name	Trade Name
1970	Lypressin	Diapid
1970	Lithium Carbonate	Lithonate
1978	Lithium Citrate	Lithonate-S

- "Old Chemicals"/Patents Expired Before Approval Date (12)

Approval Date	Chemical/"Generic" Name	Trade Name
1964	Sulisobenzone	Uval
1966	Piprobromain	Vercyte
1967	Clofibrate	Atromid-S
1967	Dextrothyroxine	Choloxin
1970	Mitotane	Lysodren
1974	Dopamine	Intropin
1974	Sodium Nitroprusside	Nipride
1975	Calcitronin-Salmon	Calcimar
1975	Dacarbazine	DITC
1976	Lactulose	Cephulac
1976	Lomustine	Ceenu
1977	Carmustine	Bicnu

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* Covers only ANDA-candidate products approved between 1962 and 1978; 205 products were approved during this time period. Includes expiration date of "chemical" or "product" patent only; does not cover "use" or "process" patents.

Products With Less Than 7 Years Effective Patent Life After Approval (36)

Approval Date	Chemical/"Generic" Name	Trade Name
1964	Orphenadrine Citrate	Norgesic
1964	Mestranol & Norethynodrel	Enovid-E
1967	Monoxynol & Idophor	IO Prep
1967	Diphenidol HCl	Vontrol
1968	Lidocaine HCl & Dextrose	Xylocaine HCl w/Dextrose
1969	Testolactone	Teslac
1970	Flavoxate HCl	Urispas
1970	Floxuridine	FUDR
1971	Propoxyphene Napsylate	Darvon-N
1971	Tretenoin	Retin-A
1971	Flucytosine	Ancobon
1971	Propoxyphene Napsaaylate & Acetaminophen	Darvon-N w/ASA
1971	Megestrol Acetate	Megace
1972	Bupivacaine HCl	Marcaine HCl
1972	Bupivacaine HCl w/ Epinephrine	Marcaine HCl w/Epinephrine
1972	Desonide	Tridesilon
1972	Dexamethasone Sodium Phosphate & Xylocaine	Decadron w/Xylocaine
1973	Betamethasone-17-Benzoate	Benisone
1973	Dexamethasone Acetate	Decadron-LA
1974	Halcinonide	Halog
1975	Oxybutynin Chloride	Ditropan
1975	Betamethasone Dipropionate	Diprosone
1975	Clotrimazole	Lotrimin
1975	Clonazepam	Clonopin
1976	Prazepam	Verstran
1976	Naproxen	Naprosyn
1976	Danazol	Danocrine
1976	Beclomethasone Dipropionate	Vanceril
1977	Clemastine Fumarate	Tavist
1977	Disopyramide Phosphate	Norpace
1977	Azatadine Maleate	Optimine
1977	Lorazepam	Ativan
1977	Desoximetasone	Topicort
1977	Chlordiazepoxide & Amitriptyline	Limbitrol
1978	Sodium Valproate	Depakene
1978	Hydrocortisone Valerate	Westcort

APPENDIX C

EXPORTS OF PHARMACEUTICAL AND MEDICINAL PRODUCTS to countries that Both (a) Require, in Applications for Market Approval, at Least Some of the Safety and Effectiveness Data and Information that Section 104 of H.R. 3605 / S. 2748 Mandates FDA Release and (b) Do Not Effectively Recognize Product Patents

1983

(in U.S. dollars)

Country	1983 Dollars
Argentina	$29,598,743
Austria	28,534,110
Canada	185,762,008
Chile	6,425,637
Columbia	25,627,437
Finland	2,831,316
Greece	13,346,025
Mexico	37,227,033
Norway	1,656,800
Venezuela	31,322,270
Ecuador	7,948,230
India	8,895,291
Iran	4,194,037
Peru	12,554,083
Poland	5,914,782
Spain	56,833,053
Soviet Union	950,198
Yugoslavia	3,989,632
Egypt	11,974,266
Kuwait	2,504,820
	$478,089,771

Source: EM455, F.T. Exports, Foreign Trade Room
Department of Commerce Main Building
U.S. Bureau of the Census

APPENDIX D

[FDA's "Technical Comments" on the June 2, 1984 Discussion Draft of the Patent Term Restoration/ANDA legislation (retyped verbatim):]

TECHNICAL COMMENTS ON JUNE 2 DISCUSSION DRAFT
ANDA/PATENT TERM RESTORATION LEGISLATION

Comments are keyed to page and line number of the June 2 draft.

GENERAL COMMENT

1. The June 2 draft fails to include a transition provision. We have pointed out in previous comments that a transition provision is needed to protect the agency from a substantial increase in workload during the first few years immediately following enactment. As currently drafted, the bill would immediately open to ANDA eligibility all drug products approved from 1962 through 1981 other than those that are subject to patent protection. FDA's analysis of resource requirements associated with a possible post-1962 ANDA procedure established that the immediate eligibility for ANDA approval for drug products approved between 1962 and 1972 would produce unacceptable backlogs of ANDAs (reaching a peak of about 1,300 applications more than 180 days old). However, the agency found that by taking an initial 5-year group, allowing three years for processing, then adding the next 5-year group for a second three year period, it could handle the workload with the addition to staff of only four persons. If the agency were to timely process an initial 10 year period of applications, its analysis showed that it would need 21 additional ANDA reviewers, and these extra reviewers would need to be relocated after the initial submissions had been processed, because FDA estimated that the increased level of staffing would not be needed beyond the first three years.

To prevent unacceptable backlogs of pending applications and to avoid substantial resource increases that would be needed for only a relatively short period of years, a transition provision should be incorporated in the bill. As we have pointed out, a transition provision that opened only the 1962-67 period to ANDA approvals for the first three years after enactment would alleviate the immediate resource impact of the legislation but would still make immediately available for ANDA approval most of the drugs that would be available under the bill as currently drafted, including six of the drugs that are among the top selling prescription drug products.

ANDA PROVISIONS

2. The definition of the term "therapeutic alternative" has been deleted from the June 2 draft, but the bill still includes the concept (page 3, lines 24-27; page 4, lines 1-3) and the associated petition procedure for combination drugs (page 6, line 24; page 7, line 9). The petition procedure would permit prospective applicants to seek permission to file for ANDA approval of combination drugs that have not been previously approved. These new combinations would be required to include at least one ingredient that is the same as an ingredient in a listed (previously approved) drug. Because ANDA approval would appear to be authorized for a combination of active ingredients that had not been previously approved, the petition procedure and its associated "therapeutic alternative" concept are plainly inconsistent with the medical and scientific rationale that supports FDA's current ANDA procedure.

In addition, the petition procedure appears to be inconsistent with FDA's combination policy, 21 CFR 300.50, which generally requires a showing through appropriate studies comparing the combination with its individual active ingredients that each ingredient contributes to the safety or effectiveness of the combination drug. A number of provisions in the June 2 draft would appear to restrict FDDA to consideration only of the safety and effectivenes of the different active ingredient in the new combination rather than to the new combination as a whole:

- ANDAs for new combinations would be required to include information showing that the different active ingredient had been previously approved (apparently either as a single ingredient or as part of another combination), or that the different ingredient was no longer a new drug, and any other information with respect to the different active ingredient with respect to which a petition was filed as the Secretary may require (page 3, lines 1-8).

- The petitions procedure (page 6, line 24 -- page 7, line 9) requires that a petition for ANDA eligibility for a new combination be approved unless the Secretary finds that investigations are needed to show the safety or effectiveness of the active ingredients in the new drug which differ from the listed drug.

- Approval of an ANDA authorized through the petition procedure may be denied if the ANDA fails to contain information required by the Secretary respecting the active ingredient in the new drug which is not the same as in a previously approved drug (page 9, lines 6-11).

- Approval of an ANDA authorized through a petition may be denied if the application fails to show that the new drug can be expected to have the same therapeutic effect as the listed drug (page 9, lines 12-24).

Under FDA's current policy, approval of combination drugs that have not been previously approved would require data showing that the new drug (not just one of its ingredients) will have its intended effect. Consistent with the agency's current policy, the abbreviated procedure should be limited to drugs with the same active ingredients. Combinations of drugs with active ingredients different from previously approved drugs should be the subject of investigations to establish whether they are safe and effective.

For these reasons, the petition procedure that would authorize ANDA approval for combination drugs that have not been previously approved should be removed from the bill. The statutory ANDA procedure should be limited to duplicate versions of previously approved drugs under previously approved conditions of use.

3. Page 6, line 24. If a petition procedure consistent with FDA's current policy for ANDA approval and the approval requirements for new combination drugs were to be incorporated in the bill, it should eliminate consideration of ANDAs for drugs with different "active ingredients." The procedure should be limited to minor differences in route of administration, dosage from, or strength. Under FDA's current ANDA policy, different "active ingredients" as therapeutic alternatives are not permitted. There may be circumstances in which route of amdinistration, dosage form or strength may differ slightly from those for a previously approved drug product. However, it should be stressed that even minor changes would not routinely be subject to implementation through ANDAs without clinical data.

4. Page 10, lines 6-14. The June 2 draft provides for denial of ANDA approval if the information submitted in the application or other information available to the Secretary shows that the inactive ingredients of the drug are unsafe or the composition of the drug is unsafe due to the type or quantity of inactive ingredients or the manner in which the inactive ingredients are included in the new drug. We had suggested such a revision, but our suggested revision also included, as a ground of denial, the failure of the information submitted to provide sufficient information to establish the safety of the inactive components or the composition of the new drug for its intended uses. Because it is the applicant's obligation to provide the information needed to support ANDA approval, the provision should be revised to provide for denial of ANDA approval if the information submitted is insufficient to show the safety of the inactive ingredients or composition of the product for its intended use. The following revision is suggested:

> (H) information submitted in the application is insufficient to show that (i) the inactive ingredients of the drug are safe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is safe under such conditions because of the type of quanitity of inactive ingredients included or the manner in which the inactive ingredients are included, or (iii) such information or any other information available to the Secretary shows that the inactive ingredients are unsafe or the composition of the drug is unsafe under such conditions.

5. Page 11, lines 1-5. The June 2 draft continues to provide that the 180 day period for ANDA approval or disapproval runs from the initial receipt of the application. Consistent with the statutory provision for full NDAs, the period should run from the filing of the application, rather than the time of submission. There should be no implication that FDA may not refuse for filing an ANDA that is facially deficient nor should the agency be required to develop different procedures to deal with such problems than those already established for full NDAs. The provision should be revised to read as follows:

(4)(A) Within 180 days of the filing of an application under paragraph (2), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

6. Page 11, line 6 et. seq. The June 2 draft continues to condition the effective date of ANDA approval on the patent information field for pioneer drugs and on the patent status of pioneer drugs. FDA would continue to be required to consider whether an ANDA is the "first application which contains" a certification, to hold application approvals pending applications for preliminary injunction to district courts, to hold the approval of applications pending a request for a reexamination of patentability to the Patent Office, and to hold the approval of subsequent applications until the first application involved in a patent dispute has been marketed for 180 days.

As pointed out previously, the provisions which key the effective date of ANDA approval to the patent status of the pioneer product would impose burdensome requirements upon the agency. Although the requirements are not intended to require judgmental determinations by the agency with respect to patent status, the complexisty of the recordkeeping requirements and effective date of ANDA approval provisions will be burdensome and will be inconsistent with the kind of recordkeeping for which the agency is currently responsible. From a pracatical viewpoint, moreover, a successful litigant in a patent suit would learn of a court decision before FDA could be officially notified and could attempt to pressure the agency to issue an approval prior to the official notification.

As also pointed out previously, the patent status of the pioneer product would be adequately protected through a notice provision like that already incorporated in the revised bill. See page 5, lines 10-22 (ANDA applicant required to notify patent owner of application which applicant believes does not infringe a valid patent). Notification of the pioneer firm by the applicant, which would precede ANDA approval in every case by six months or more, would enable the pioneer manufacturer to protect its patent rights through judicial remedies and would not require FDA to divert its limited resources to issues that are peripheral to its primary public health protection responsibilities.

The complex effective date provisions, which would impose a burdensome requirements on FDA, ovbiously are intended to prevent duplicate product marketing before issues concerning the pioneer's patent status are resolved. Those provisions should be replaced by a provision which prohibits the duplicate applicant from marketing the duplicate product -- even if it has received ANDA approval -- until the patent issues are resolved. Since the patent issues will already be involved in litigation before the courts, a statutory prohibition on marketing could be easily enforced as part of the litigation. Note that the patent term extension provisions already authorize a court to establish by order the effective date of approval for a duplicate product involved in a patent infringement suit (page 44, line 25 et. seq.). Under such an approach, FDA would be relieved of complex administrative responsibilities and it would be permitted -- as it is now -- to act on ANDAs without regard to patent controversies.

7. Page 20, lines 2-6. The June 2 draft continues to provide for the amendment of section 505(e) to authorize the withdrawal of pioneer NDA approval if the patent information for the pioneer product was not filed "within 30 days after the receipt of written notice from the Secretary specifying the failure to file such information." The agency continues to be concerned that the provision may impose additional burdens on the agency if it contemplates that FDA would be expected to take affirmative action to require pioneer manufacturers to supply information to the agency conerning the patent status of their products.

8. Page 23, line 9 et. seq. The June 2 draft continues to establish effective dates for the approval of paper NDAs based on the applicant's certification of the patent status of the pioneer drug product. Although paper NDAs may be less attractive to generic manufacturers if a post-1962 ANDA procedure were available, the new provisions would impose additional burdens on the agency that could be resolved by a less burdensome procedure, discussed above, which would require notification by the paper NDA applicant to the pioneer NDA holder and a statutory prohibition on market introduction pending the resolution of the pioneer product's patent status.

Patent Extension Provisions

9. Page 34, line 17. The June 2 draft continues to require the applicant to submit the Commissioner of

Patents a brief description of the applicant's activities during the regulatory review period and the significant dates applicable to such activities. The Commissioner of Patents would be required to send a copy of the application containing the information to the Secretary who would be required within 30 days to determine the applicable regulatory review period. See page 35, lines 9-19. These burdens could be eliminated if the applicant were required to determine the regulatory review period in its application to the Commissioner of Patents. The applications could be made available to the FDA for inspection or audit at FDA's discretion, on the same enforcement basis that other reports, such as income tax filings, are regulated. Since the patent term extension is tacked on to the end of the patent term FDA continues to believe that there is no public health reason to require the agency to determine the regulatory review period under a restrictive 30-day time schedule. The validity of the regulatory review period may be adequately addressed through applicant determination and a discretionary enforcement approach.

10. Page 35, line 20 et. seq. The June 2 draft continues to provide for a due diligence determination to be made by the Secretary if petitioned to do so within 180 days after the publication of the patent extension determination. The June 2 draft, despite our earlier comment, also continues to provide that the authority to make the due diligence determination may not be delegated to an office below the Commissioner of Food and Drugs. FDA had objected that the agency did not have an adequate perspective to make a due diligence determination. This objection was raised with respect to the first draft, which would have permitted the due diligence determination to be made by the FDA organizational component directly responsible for the application. As pointed out previously, the due diligence determination will be even more difficult if the determination may be made only by the Office of the Commissioner. In effect, the revised bill would require a de novo review by personnel who have not had any prior familiarity with the application or with the problems associated with the development of the product or its investigation and approval. Since patent term extension is subject to a 14 year cap, counts only 1/2 of the investigational period, and is limited to a 5 year extension in any event, it continues to be FDA's view that a requirement for a de novo due diligence determination would clearly impose a burdensome resource requirements on the agency with

little, if any, public benefit in the earlier availability of generic drug products. In FDA's experience, based on the latest year for which calculations were made, the average new chemical entity gaining NDA approval would have been entitled, under the proposed formula, to the maximum 5 years of patent term restoration (based only on review time). Assuming that the average application was pursued with diligence, it would seem unlikely that the 5 year maximum extension would ever be reduced for lack of due diligence. Nonetheless, FDA will have been required to promulgate regulations, review petitions, and prepare due diligence determinations. As a practical matter, therefore, it appears that a complex system is being established that will require FDA resources to implement and maintain for no public benefit.

11. Page 36, line 8 et. seq. The due diligence determination is required to be published in the FEDERAL REGISTER with a statement of the factual and legal basis for the determination. The June 2 draft still provides that any interested person may require the Secretary to hold an informal hearing on the determination. The owner of the patent involved is entitled to notice and may participate in the hearing. The Secretary is provided only 30 days after the completion of the hearing to affirm or revise the determination of due diligence. There is no provision that would limit judicial review. See page 36, line 20 et. seq.

The FDA continues to regard the due diligence provision as imposing unnecessary and burdensome requirements on the agency. While the petition requirement may limit the number of determinations, the procedural restrictions imposed on the agency would provide no public health benefit and may divert scarce resources from more important matters, especially the review of other new drugs. In view of the limitations associated with patent term restoration, as noted above, the due diligence provision should be deleted on the ground that it will provide no public health benefit.

[Statement of Mark Novitch, M.D. Deputy Commissioner, Food and Drug Administration, Office of Assistant Secretary for Health, Department of Health and Human Services Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, on H.R. 3605 (a 1½-page bill to establish an ANDA procedure for post-1962 drugs) (July 25, 1983):]

Dr. NOVITCH. Thank you, Mr. Chairman. I appreciate the opportunity to discuss the extension of the new abbreviated new drug application [ANDA] procedure to drugs first approved after 1962, post-1962 drugs.

You have proposed legislation that would authorize ANDA's for post-1962 drugs. As you know, ANDA's were first used by the Food and Drug Administration [FDA] under the Drug Efficacy Study Implementation [DESI] program for the approval of generic versions of drugs first approved only for safety between 1938 and 1962, the year in which Congress amended the Federal Food, Drug, and Cosmetic Act to require that drugs be shown to be effective as well as safe.

A similar procedure has not been established for post-1962 drugs. In recent years, however, patents have begun to expire for many post-1962 drugs. As a result, generic drug manufacturers have become increasingly interested in changing FDA's drug approval system to eliminate the current requirement for the submission of full reports of safety and effectiveness studies for duplicate versions of drugs already approved in accordance with a full new drug approval [NDA] submitted by the pioneer manufacturer.

FDA, too, is interested in streamlining its approval system for post-1962 drugs so as to reduce requirements for duplicative testing, which wastes resources and causes unnecessary human testing. For this reason, FDA is actively engaged in developing a proposal for an ANDA system for post-1962 drugs and to establish such a system through rulemaking.

A post-1962 ANDA procedure would be consistent with a number of FDA programs that have aided the marketing of generic drugs. In addition to the pre-1962 ANDA procedure, FDA has permitted generic applicants for post-1962 drug products to rely on reports of studies published in the open scientific literature. This has become known as the paper NDA policy. It eliminates the need to duplicate the expensive clinical and animal testing for safety and effectiveness, but it is limited by the availability of published literature.

In addition, the agency in the mid-1970's developed a vigorous program to review and assure the bioequivalence of generically available drugs. In 1980, we began to publish a list of all approved drugs with therapeutic equivalence evaluations to aid States and purchasers of generic drugs to substitute such drugs with confidence.

The development of a post-1962 ANDA procedure raises a number of important and difficult issues. Because we are currently in the process internally of reaching a position on proposed rulemaking that would address these issues, I am not in a position to comment specifically either on FDA's internal working drafts or on

the specific amendment contained in your bill. I can, however, identify and discuss some of the issues that must be dealt with before a post-1962 ANDA system can be instituted.

First, should there be a minimum preeligibility period to assure maximum protection of the public health? When a new drug is first approved for marketing, that does not mean that there is nothing further to be learned about its safety or effectiveness. Approval is based on carefully evaluated evidence in numbers of patients sufficient for us to conclude that the risk of unanticipated side effects is small and justified in comparison to the drug's benefits.

What makes the initial marketing period so important is that it gives us an opportunity for the first time to look for reactions of low incidence, especially serious ones, that could not reasonably be expected to appear in clinical trials. In most cases, due to patent protection, the innovator's drug is the only one on the market for the first several years after FDA approval.

For this reason, any adverse drug effects will be used only by that manufacturer's drug and will be reported only to that manufacturer. Because the innovator manufacturer is familiar with the preapproval testing, it is in a good position to evaluate the adverse reactions.

There will, however, be drugs that have no patent protection after FDA approval, and which may therefore be immediately marketed by both the innovator firm and by generic manufacturers. We therefore believe that it is important to consider whether there should be a preeligibility period, on the order of a few years, during which ANDA's would not be permitted. One may argue that generic drug firms are required to report adverse drug reactions to FDA, and that FDA can therefore evaluate their significance.

But most adverse drug reaction reports are to some extent evaluated by the firm receiving them, and the quality and timeliness of that review is important to the process.

FDA regulations require that only unexpected adverse reactions or clinical failures be reported by the firm to FDA within 15 working days. The others are submitted quarterly during the first year. If adverse reaction reports were received by firms unfamiliar with the clinical trials, and, because of the nature of their business, lacking ties with the research community, we are concerned about the adequacy of the reports we would receive. The holder of the pioneer NDA is frequently of considerable help to FDA in identifying adverse reaction trends and other drug effects bearing on the safe and effective use of a newly developed drug therapy.

Second, should there be a lengthier preeligibility period before ANDA's are permitted to avoid disincentives to drug innovation? This is a controversial issue on which many people have expressed strong views, and we believe it is a legitimate subject for debate. Those who oppose establishing a preeligibility period to preserve incentives for drug innovation argue that Congress has established a patent system for the specific purpose of encouraging invention and that FDA should not impose requirements designed to achieve the same objective.

Others argue that, as a public health agency, FDA cannot ignore the effects of changes in the drug approval system on the incentive to develop new drug therapies. That will improve the health of the American people. They also note that some drugs cannot be patented, and that others have little patent life remaining after FDA approval.

If one assumes that there should be a preeligibility period to preserve incentives for innovation, at least for some drugs, one must then address the question of how long such a period should be. Should it track the patent period, on the assumption that it is intended primarily for drugs for which patents are unavailable; or should it be some shorter period that is still regarded as adequate to encourage innovation but that would allow competitive products to enter the market sooner?

The third issue is, what kind of transitional provisions should be included in any post-1962 ANDA system to assure that FDA's administrative capacity is not overwhelmed by an early flood of ANDA's and that the agency can concentrate its resources on those drugs most likely to be marketable without patent restrictions assuming that ANDA is approved? We believe that a phased implementation period is essential to avoid being inundated by more applications than we can reasonably handle.

Although these are not the only issues that must be considered in determining what kind of post-1962 ANDA system best serves the public interest, I think they illustrate that we are not dealing with a simple subject that lends itself to an easy solution. Although we believe that we have the legal authority to implement a post-1962 ANDA system and that we should continue to pursue our efforts to establish such a system through rulemaking, we stand ready to work with the committee on the problems associated with developing appropriate procedures for the approval of generic versions of drugs first approved after 1962.

At this point, Mr. Chairman, I would like to express our views on H.R.1554, a bill to eliminate the statutory prohibition in section 301(l) of the Federal Food, Drug, and Cosmetic Act which prevents a drug manufacturer from making representations regarding FDA approval in labeling or advertising of any drug. • • •

Mr. Chairman, that concludes my formal statement. We will be happy to attempt to address any questions you or other members of the committee may have.

Mr. KASTENMEIER. I was just trying to determine that you had, in fact, concluded.

Mr. STAFFORD. Yes, I shortened it a little bit. The data that is included at the end of my short statement is submitted in our full statement and I think supports the overall concept of patent restoration and I think since there is general agreement that that is desirable, I would refrain from going through those statistics.

Mr. KASTENMEIER. Thank you very much, Mr. Stafford. It was very brief and to the point.

Professor Dorsen.

Mr. DORSEN. Thank you very much, Mr. Chairman. I am pleased to appear before your subcommittee today.

By way of introduction, I have been on the faculty of New York University School of Law since 1961, have taught courses in constitutional law, antitrust law, the legal process and legislation, among others, and am currently Frederick and Grace Stokes Professor of Law.

Since 1980, I have also taught regularly as a visiting professor at Harvard Law School. I have written several books and law review articles and have often testified before Congress on constitutional issues. I served as president of the Society of American Law Teachers during 1972 and 1973.

From 1976 to 1977, I was chairman of the Department of Health, Education and Welfare's Review Panel on New Drug Regulation, and under my direction, the panel produced five volumes of studies on the drug regulation process. Since December 1976, I have been serving as national president of the American Civil Liberties Union, but I am, of course, testifying here as an individual.

I was asked by representatives of a coalition of research-oriented pharmaceutical companies to review section 202 of the proposed patent extension legislation, to determine if the bill presents any serious constitutional problems. In my judgment, constitutional problems do exist and they are substantial.

With the consent of the subcommittee, I would like to submit a statement for the record that fully expresses the reasons for this conclusion, but in this oral presentation, I shall merely outline the essential elements.

First——

Mr. KASTENMEIER. Without objection, your full and complete statement will be made part of the record. We are very pleased to have it.

Mr. DORSEN. Thank you very much, Mr. Chairman.

It is undisputed that patent grants are propery rights protected by the fifth amendment to the Constitution. Title 35, United States Code, section 261 states: "Patents shall have the attributes of personal property." Many Supreme Court rulings unambiguously affirm this property right. The right of exclusive use is an integral component of the patent grant and the property right. With particular pertinence to the problem before us, the Court of Appeals for the Federal Circuit in the recent *Bolar* decision has confirmed that protection of this right is necessary for the innovator properly to reap the fruits of its creative labor.

As the Commissioner of Patents stated earlier today, the *Bolar* decision stated the obvious. Section 202 of the proposed statute

would abrogate the right recognized in the *Bolar* decision by making it lawful for an infringer to make and sell, as well as to use, patented substance during the period of the patent grant if done for the purpose of securing approval from the FDA.

Section 202, in an unprecedented invasion of the rights of patent holders, raises a basic issue under the takings clause of the fifth amendment. The provision requires the Government—the constitutional provision—requires the Government when it acquires private property for public purposes to pay just compensation for all takings. This provision was designed in the words of the Supreme Court "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole."

This policy has particular force in the realm of patent grants. The Constitution plainly states that the patent system is founded on the public policy "to promote the progress of science and the useful arts." The system has been a great success. It has made a major contribution to the country's technological preeminence. The reliance which has been placed on our patent system by inventors should not be chilled by retroactively stripping away existing rights.

Apart from the patent area, the Supreme Court has recognized that the right to exclude others from the use of a possession is the touchstone of private property. Justice Brandeis wrote that "[a]n essential element of individual property is the legal right to exclude others from enjoying it."

Recently, in the *Kaiser-Aetna* case, the court ruled that the Federal Government could not require a privately developed and operated marina to open itself to the use of the general public without the payment of just compensation.

Section 202 seeks to accomplish with pharmaceutical patents precisely the result prohibited by the Supreme Court in *Kaiser-Aetna* with respect to the marina. It seeks to interfere with a patent holder's right of exclusive use in a manner which the Court of Appeals for the Federal Circuit, the specialized appellate court with exclusive jurisdiction over patent appeals, characterized as worthy of substantial monetary damages.

Section 202 is also vulnerable under a long line of cases that recognized that takings can occur when Government regulation prevents an owner from using his property, even though the Government does not specifically occupy the property or transfer to a third person.

The reason is, that deprivation of use defeats an owner's reasonable investment-based expectations. Just yesterday, the Supreme Court, in a case entitled *Ruckleshaus* v. *Monsanto,* a case involving trade secrets, confirmed the critical importance of reasonable investment-backed reliance to the interpretation of the taking clause.

This decision thoroughly supports the position I am taking today; indeed, our position is a stronger case. Since *Ruckleshaus* v. *Monsanto* is so recent, having been decided just yesterday, I shall welcome the opportunity to write the subcommittee concerning its important relevance to the constitutional issue presented by section 202.

The police power exception of the fifth amendment's taking clause is designed to protect the public health, morals, and safety. It is inapplicable to section 202. Police power cases all involve property taken to terminate specific nuisances or dangers to the community. A patent is neither a nuisance nor a danger. Indeed, the Constitution itself recognizes that it is economically desirable and socially useful.

Nor is section 202 analogous to certain zoning ordinances which have not been considered takings because they provide "an average reciprocity of advantage." There are two reasons for my conclusion about the inaptness of that doctrine. First, the nebulous doctrine has never been applied, as far as I know. In addition the rights of patents, which, after all, are uniquely subject to constitutional protection.

Second, the proposed legislation does not grant average reciprocity of advantage. On the contrary, a substantial imbalance is present in this bill between the patent extension provision in section 201 and section 202, which presents the constitutional problem. With minor exception, section 201 extends patent life only for patents that will come into being after enactment of the bill. Thus, most existing patents would not qualify for extension.

On the other hand, section 202 would apply retrospectively to deprive every patentee of the exclusive right to use. In other words, the economic benefits of patent extension are speculative and not evenly shared, while the negative economic impact on the property rights of patentees from section 202 is certain and universal.

Although retroactive laws are not invariably unconstitutional, retroactive legislation has been a well of constitutional problems because, as one authority has put it, one of the fundamental considerations of fairness recognized in every legal system is that settled expectations, honestly arrived at with respect to substantial interests, ought not be defeated.

Retrospective legislation in the patent area presents an especially clear case of unfairness because the Government is a party to the patent grant. In addition, patent owners have always relied on the expressed terms of the patent statute and on constitutionally grounded public policy when they disclosed their inventions.

To avoid the constitutional difficulties inherrent in retroactive legislation, Congress has traditionally been careful to legislate prospectively. Thus, it has limited the effect of new statutes on existing patent right. The Patent Act of 1952 provides: "Any rights or liabilities now existing under such repealed section or parts thereof shall not be affected by this repeal."

If Section 202 were merely prospective in its application, applying only to patents issued after enactment, the taking problem would be avoided entirely. The rights of property involved here are substantial and the constitutional infirmities significant.

Might I just add one final word. I just learned today that Prof. Henry Monaghan, who teaches constitutional law at Columbia Law School, working independently, has reached conclusions similar to the ones that I have stated here concerning the unconstitutionality of section 202. With the permission of the committee, I would like to introduce into the record of this hearing a copy of Professor

Monaghan's constitutional analysis. We will try to deliver it no later than tomorrow.

Mr. DORSEN. Thank you very much, sir.

[The statement of Mr. Dorsen follows:]

STATEMENT OF NORMAN DORSEN

My name is Norman Dorsen. I have been on the faculty of New York University School of Law since 1961, and have taught courses in Constitutional Law, Antitrust Law, The Legal Process and Legislation, among others, I am currently Frederick and Grace Stokes Professor of Law. Since 1980 I have also regularly taught as a Visiting Professor at Harvard Law School. I have written several books and law review articles and have often testified before Congress on constitutional issues. I served as President of the Society of American Law Teachers during 1972 and 1973.

From 1976 to 1977 I was Chairman of the Department of Health, Education, and Welfare, Review Panel on New Drug Regulation. Under my direction the Panel produced five volumes of studies on the drug regulation process. Since 1977 I have published articles on the regulatory process in the Annals of Internal Medicine and the Food Drug Cosmetic Law Journal.

I was asked by representatives of a coalition of research based pharmaceutical companies to review Section 202 of the proposed Patent Extension legislation to determine if the bill presents any serious constitutional problems. In my judgment, constitutional problems do exist and they are substantial.

DESCRIPTION OF SECTION 202

Section 202 would reverse existing patent law which now gives the owner of a patent the *exclusive* right to make, use and sell the patented invention. 35 U.S.C. §§ 154 and 271(a). It would allow a third party to make, use or sell a patented invention for purposes "reasonably related" to the submission of information to obtain premarketing approval under the Food, Drug and Cosmetic Act in order to engage in the commercial manufacture, use or sale of the drug after patent expiration. The constitutional problem arises because Section 202 does not just apply prospectively to patents that will come into being after its enactment, but it also reaches back and takes away exclusive rights of current patent holders. After analyzing the existing statutory rights that will be taken from the patent holder under the bill, I am forced to conclude that Section 202 very likely violates the Fifth Amendment's prohibition against the taking of property for a public use without just compensation.

THE "BOLAR" DECISION

Section 202 takes from the patent owner the same patent rights which the Court of Appeals for the Federal Circuit has declared belong exclusively to the owner under the present patent law. In *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.*, —— F.2d ——, No. 84-560, slip op. (Fed. Cir. Apr. 23, 1984), the court held that Bolar, a generic drug manufacturer, unlawfully infringed a patent owned by Roche when, during the patent term, Bolar used the patented substance to prepare a submission to the Food and Drug Administration for the purpose of enabling Bolar to market the drug after the Roche patent expired. The Court of Appeals agreed with Roche that such "use" by Bolar of Roche's patented drug during the term of the patent grant for the purpose of engaging in federally mandated premarketing tests was part of the exclusive patent grant reserved to the patent owner. Having determined that Bolar's unauthorized use infringed Roche's patent, the Court of Appeals then held that "Roche is entitled to a remedy," in the form of an injunction or damages. *Bolar, supra,* at 16. It ordered that specific relief was to be fashioned in the first instance by the District Court to which the case was then remanded and before which it is now pending. In directing that remand, the Court of Appeals recognized that although the infringement involved a small amount of material, "the economic injury to Roche is, or is threatened to be, substantial . . . ." *Bolar,* supra, at 19. See also *Pfizer, Inc.* v. *International Rectifier Corp.,* 217 U.S.P.Q. 157 (C.D. Cal. 1982).

IMPACT OF SECTION 202 ON THE "BOLAR" DECISION

Section 202 of the proposed legislation would reverse the *Bolar* decision in its entirety, not just for the patent involved in that case, but for all exisitng drug patents. Indeed, the bill would go beyond the infringing conduct involved in *Bolar* by making it lawful for an infringer to make and to sell as well as to use the patented substance during the period of the patent grant, if done for the purpose of securing

FDA approval of a new drug. It would also reverse existing patent law by prohibiting courts from issuing an injunction against making, using or selling the substance for that purpose, and it would withdraw from the patentee his current right to collect damages for such infringement.

THE NATURE OF THE CONSTITUTIONAL PROBLEM

Because patent rights are a form of property, taking such rights from the owner raises a basic issue under the Fifth Amendment. The Constitution recognizes that from time to time it will be necessary for the govenment to acquire private property for public purposes, but by requiring "just compensation" for such taking, the Fifth Amendment protects the individual whose property is taken for the common good from being made to carry a burden that should, in fairness, be shared by the community at large. The Supreme Court has described the purpose of this clause in the following terms;

"[The] Fifth Amendment's guarantee that private property shall not be taken for a public use without just compensation was designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Armstrong* v. *United States,* 364 U.S. 40, 49 (1960).

We tend to think of civil rights in terms of First Amendment rights of free speech and expression, but the "taking" clause of the Fifth Amendment is also a civil right, one which stands as a bulwark against governmental appropriation of vested property rights. The Constitution imposes restraints upon government's ability to confiscate property just as it imposes restraints upon government's ability to confiscate our right to speak or the right of a newspaper to publish without censorship.

THE CONSTITUTIONAL POLICY IN SUPPORT OF PATENTS

Any analysis of how Section 202 fits within the Fifth Amendment's "taking" clause must first look at the nature of the property that this bill will affect—the patent grant.

I am always impressed when reminded by patent lawyers that the Constitution is itself the source of authority for the patent system. Unlike many governmental activities that surround our daily lives, the right to grant patents is not implied from some other general power, but is expressly decreed in Article I, Section 8, and the policy behind that authorization is plainly stated. A patent system is authorized in order "to promote the progress of Science and useful Arts. . . ." In applying Fifth Amendment principles to patent property, it is therefore important to keep in mind that patent grants are a reflection of a public policy that is as old as the Republic and one that has independent constitutional stature. It is well known that the patent system has been a great success. It has made a major contribution to this country's technological preeminence. The reliance which has been placed on our patent system by inventors and by those who underwrite research and development should not be chilled by retroactively stripping away existing rights.

PATENT GRANTS, INCLUDING EXCLUSIVE USE RIGHTS, ARE PROPERTY RIGHTS PROTECTED BY THE FIFTH AMENDMENT

Patent rights are property rights

Existing patent law declares that a patent is a property right. Title 35, U.S.C. § 261 states: "patents shall have the attributes of personal property." Patents are not only defined as property; they also contain the essential elements of property. By statute, a patent grants its holder the right to exclude others from making, using or selling the patented invention during the term of the patent. 35 U.S.C. §§ 154, 271(a). A patent embodies "the right to dispose of a thing in every legal way, to possess it, to use it, and to exclude everyone else from interfering with it," [1] which is the definition of property.

Supreme Court rulings unambiguously reaffirm that patents are property rights protected by the Fifth Amendment. In *William Cramp & Sons Ship & Engine Building Co.* v. *International Curtis Marine Turbine Co.,* 246 U.S. 28, 39-40 (1918), the Court wrote that it is "indisputably established" that "rights secured under the grant of letters patent by the United States were property and protected by the guarantees of the Constitution and not subject therefore to be appropriated even for public use without adequate compensation." Similarly, in *Hartford-Empire Co.* v.

[1] *Black's Law Dictionary* 1095 (rev. 5th ed. 1979).

United States, 323 U.S. 386, 415, *Clarified*, 324 U.S. 570 (1945), the Court stated "[t]hat a patent is property, protected against appropriation both by individuals and by government, has long been settled."

The right of exclusive use is an integral component of the patent grant and concomitant property right

In exchange for the benefits derived from innovation and invention, society, through a government patent, grants an inventor three co-equal rights: exclusivity of manufacture, exclusivity of use and exclusivity of sale. Each of these rights is necessary for the innovator to reap the commercial fruits of his creative labor. Because the right to exclude others from its use is the sole source of a patent's economic value, the protection of this trilogy of rights is critical to the viability of the patent system.

The federal courts have long recognized that an infringement of a patent holder's rights of esclusive use or manufacture is as fundamental a conversion of property as an infringement of his right of exclusive sale. The unauthorized making of a patented product is an infringement because it allows a competitor to stockpile the product and flood the market immediately following expiration of the patent.[2] Similarly, reconstruction of a patented product involves economic activity directly traceable to the patent. Accordingly, courts have held that reconstruction other than by the patentee or its licensee violates the patentee's exclusive right to make the product.[3]

The right of a patent holder to exclusive use of his invention has also been protected rigorously. As the Supreme Court has put it, "an inventor receives from a patent the right to exclude others from its use for the time prescribed in the statute." *Continental Paper Bag Co.* v. *Eastern Paper Bag Co.*, 210 U.S. 405, 425 (1908).[4] Indeed, it is recognized that, "The very nature of the patent right is the right to exclude others." *Smith International, Inc.* v. *Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir.), *cert. denied*, 104 S. Ct. 493 (1983). In line with this longstanding policy, the mere testing of a patented product for commercial purposes has been prohibited—both in connection with pharmaceuticals [5] and other products.[6] The purpose of exclusive use is evident: to preserve all commercially valuable uses for the patentee to exploit as he sees fit.[7] Tests and other uses of a patented product having a commercial purpose reduce the economic potential and value of the patent during its term. Under law all such economic benefits belong to the patent holder.

Even outside the patent area, the Supreme Court has recognized that the right to exclude others from the use of a possession is the touchstone of property. Justice Brandeis wrote that "[a]n essential element of individual property is the legal right to exclude others from enjoying it." *International News Service* v. *Associated Press*, 248 U.S. 215, 250 (1918) (dissenting opinion). Recently, in *Kaiser-Aetna* v. *United States*, 444 U.S. 164 (1979), the Court ruled that the federal government could not require a privately developed and operated marina to open itself to the use of the general public without the payment of just compensation. The Court held that:

"The 'right to exclude,' so universally held to be a fundamental element of the property right, falls within this category of interests that the Government cannot take without compensation." 444 U.S. at 179–80.

Section 202 seeks to accomplish with pharmaceutical patents precisely the result prohibited by the Supreme Court in *Kaiser-Aetna* with respect to the marina. It seeks to abridge a patent holder's existing statutory right of exclusive use in a manner which the Court of Appeals for the Federal Circuit—the specialized appellate court with exclusive jurisdiction over patent appeals—characterized as worthy of substantial monetary damages.[8]

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[2] See e.g., *Underwood Typewriter Co.* v. *Elliott-Fisher Co.*, 156 F. 588, 590 (C.C.S.D.N.Y. 1907); *American Diamond Rock Boring Co.* v. *Sheldon*, 1 F. 870, 872–73 (C.C.D. Vt. 1880).

[3] See, e.g., *Wilbur-Ellis Co.* v. *Kuther*, 377 U.S. 422, 424 (1964).

[4] See also *Aro Manufacturing Co., Inc.* v. *Convertible Top Replacement Co., Inc.*, 377 U.S. 476, 484 (1964), where the Supreme Court stated: "unauthorized use, without more, constitutes infringement."

[5] See e.g., *Roche Products Inc.* v. *Bolar Pharmaceutical Co., Inc.*, slip op. No. 84-560 (Fed. Cir. Apr. 23, 1984); *Pfizer, Inc.* v. *Int'l Rectifier Corp.*, 217 U.S.P.Q. 157, 162 (C.D. Cal. 1982).

[6] See e.g., *Radio Corp. of America* v. *Andrea*, 90 F.2d 612, 614 (2d Cir. 1937) (radio components).

[7] See *Kaz Manufacturing Co.* v. *Chesebrough-Pond's Inc.*, 211 F. Supp. 815 818 (S.D.N.Y. 1962), aff'd, 317 F.2d 679 (2d Cir. 1963).

[8] *Bolar*, slip op. at 11.

Section 202 "takes" property in violation of the fifth amendment

The law has long recognized that a "taking" of property can occur even if the intrusion amounts to something less than a physical invasion by the government. Chief Justice John Marshall early pointed out that the Constitution is one of enumeration not definition, and so, like most of the great constitutional clauses, the "taking" clause is not confined to its literal text. Two threads run through the decided cases which explain the meaning of "taking." The first is an outgrowth of the traditional concept, where the government physically strips the property owner of a part of the bundle of rights that constitutes his property interest. The second line of cases does not involve physical takings, but rather takings through governmental regulation of an owner's use of his property where the regulation so frustrates legitimate expectations regarding the economic potential of that property that compensation is required.

Kaiser-Aetna is a leading case in the classical takings line of cases. In that case, the owners of the private pond, who had invested substantial sums to dredge and improve it into a marina, were faced with an effort by the Corps of Engineers to convert the pond into a public aquatic park. Despite the government's claim that its Commerce Clause powers to regulate navigable waters authorized public access, the Court ruled that the government lacked the authority to destroy the owner's right to exclude others from the marina without payment of compensation.

Where such a traditional taking occurs, the fact that only a small fraction of the entire property right is involved does not deprive the owner of Fifth Amendment protection. In *Loretto* v. *Teleprompter Manhattan CATV Corp.*, 458 U.S. 419 (1982), it was held that a state law which authorized the permanent attachment of cable TV installations on apartment house premises constituted a taking which requires just compensation under the Fifth Amendment, even though the connector occupied only a tiny fraction of the property.[9]

In the second line of just compensation cases the law recognizes that takings can occur when governmental regulation prevents an owner from using his property—even though the government does not physically occupy the property itself or transfer it to a third person. The reasoning underlying these cases is straightforward: where governmental regulation deprives an owner of the use of his property in a way that defeats reasonable investment-based expectations, significant and valuable property rights are effectively "taken" from the owner, bringing into play the protections afforded by the Fifth Amendment.[10] As one would expect, decisions analyzing the effect of such government regulation tend to be highly fact oriented, since the outcome will turn in large part on a determination of the owner's reasonable expectations. But, the rule of law is clear: even a statute which furthers an important public policy will be held to constitute a "taking" where it frustrates distinct and legitimate investment backed expectations.

The leading case is *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393 (1922). In that case, Justice Holmes held for the Court that a statute which regulated subsurface mining in a way that effectively deprived the owner of coal mining rights of the right to mine his coal was a "taking." By contrast, when the facts demonstrated that a state statute pursuant to which the Grand Central Terminal was designated a landmark did not interfere with the owner's investment-based expectations as to the use of the property, the Court found that there had been no "taking" even though the landmark statute prevented the terminal building's owners from further developing their property by constructing an office tower atop the termal. *Penn Central Transportation Co.* v. *New York City*, 438 U.S. 104 (1978).

There is a strong basis for concluding that Section 202 would be held to constitute a "taking" both under the reasoning of cases like *Kaiser-Aetna*, where a direct appropriation and transfer of the owner's rights was involved, and under cases like *Pennsylvania Coal*, where government regulation frustrated reasonable investment-based expectations.

As to the classic "taking" line of cases, the *Bolar* decision and other patent and nonpatent cases demonstrate that the right of exclusive use is fundamental to the ownership of patents—even more than it is for other forms of property, since the sole source of a patent's value is exclusivity. The economic significance of this right is beyond dispute. The *Bolar* court expressly stated that the value of the patentee's right to exclusive use for pre-marketing test purposes was substantial. The impressive efforts of the generic pharmaceutical companies to secure passage of Section

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[9] In *Loretto* the Supreme Court made it clear that a nominal payment for a compulsory taking cannot meet the "just compensation" mandate of the Fifth Amendment.

[10] *See Penn Central Transportation Co.* v. *New York City*, 438 U.S. 104, 124 (1978).

202, and the equally vigorous efforts of some of the leading research-based pharmaceutical companies to oppose it, provide perhaps the strongest proof that the rights at stake have great commercial value.

If Section 202 becomes law, the exclusive right to make, sell and use the patented product for pre-marketing tests would be taken from the patentee and transferred to the infringer. Indeed, the taking contemplated by Section 202 is even more offensive than the taking condemned in the *Kaiser-Aetna* case. There, the government sought simply to give the general public an easement in a private marina. Here, the transfer is from a business to its competitor. Generic pharmaceutical firms will be given a special commercial advantage at the expense of research-based companies, in effect, a free ride to use, make and sell the research-based patentee's invention for a commercial purpose long before the patent expires.

This "free rider" provision underscores the fact that the equities have all run against the proposed Section 202. The company holding the patent funded the product's research and development and incurred costs associated with informing the medical profession and general public of its value and use. Having shouldered all the commercial expense and risk of bringing a new product to market, it is entitled to reap the patent benefits over the full life of its patent. We can assume that the bill seeks to achieve a valid overall purpose, but that objective is not substitute for the Fifth Amendment's requirement of fair treatment to a party whose property is being taken for public purposes.

Alternatively, if one examines the bill under the governmental regulation line of the Fifth Amendment cases, the provision also presents serious constitutional problems. The distinct investment-based expectations held by owners of existing patents are founded upon the substantive protections written into the patent statute. The statute as it existed when the patent was granted established the scope of these property rights and expectations—and it includes a 17-year exclusive right to "make" and "use" the patented product. Section 202 withdraws from the patentee a central element of those rights, and thereby deprives an owner of property in a way that defeats his reasonable expectations.

The police power exception is inapplicable

Under certain circumstances, governmental regulation in the exercise of its police power to protect the public health, morals and safety can provide an exception to the taking clause of the Fifth Amendment. However, this exception is not coterminous with the reach of the police power and the mere invocation of the police power does not relieve the government of its "just compensation" obligation.

An examination of the police power cases demonstrates that the takings involved all sought to terminate specific nuisances or to halt isolated noxious uses of property that were a danger to the health, morals or safety of the community. Classic instances involved the operation of a brickyard within a residential area; [11] the prohibition of gravel excavation below the water line; [12] the cutting down of infected cedar trees to prevent a spread of the infection to neighboring groves; [13] and the halting of nonessential gold mining during a wartime emergency labor shortage when miners were needed to produce war materials instead. [14]

It is manifest that these cases are radically different from the case presented by Section 202. The property uses that would be affected by Section 202 are not nuisances. Indeed, the patented substances are economically desirable and socially useful, and the exclusivity rights that would be extinguished are consistent with the policy of the Patent Statute and with Article I, Section 8, Clause 8 of the Constitution.

No "reciprocity of advantage" is present

Section 202 is not analogous to certain zoning ordinances which have not been considered "takings" because they provide an "average reciprocity of advantage." See, e.g., *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 415 (1922). In these cases, the Supreme Court has held that the zoning regulation at issue did not constitute a "taking" because the property owner was also advantaged by the regulation.

In this respect, a comparison with the *Grand Central Terminal* case is instructive. In *Grand Central*, while the owners were prevented by New York's Landmarks Law from building above the Terminal itself they nevertheless received from the government "transferable development rights" to build on nearby parcels. Here the pro-

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[11] *Hadacheck* v. *Sebastian*, 239 U.S. 394 (1915).
[12] *Goldblatt* v. *Hempstead*, 369 U.S. 590 (1962).
[13] *Miller* v. *Schoene*, 176 U.S. 272 (1928),
[14] *United States* v. *Central Eureka Mining Co.*, 357 U.S. 155 (1958).

posed legislation does not grant any such reciprocity. On the contrary, a substantial imbalance is present in this bill between the patent extension section—Section 201, which with minor exceptions extends patent life only for patents that will come into being *after* enactment of the bill (thus, most existing patents would *not* qualify for extension)—and Section 202, which would apply retrospectively and prospectively and subject *every* drug patent to the loss of the patentee's exclusive right to use.

Congress cannot take back property rights in patents simply because it created those rights

The retroactive repeal of existing patent protection cannot be sustained as an exercise of the independent power of Congress to create patents, because it accomplishes the very opposite.[15] All property rights are created by the government because it is the government through its laws that permits private property to exist. Congress can no more appropriate by legislative fiat one's rights in a patent than it can appropriate one's rights in land. As the Supreme Court has noted:

"A patent for an invention is as much property as a patent for land. The right rests on the same foundation, and is surrounded and protected by the same sanctions." *Consolidated Fruit-Jar Co.* v. *Wright,* 94 U.S. 92, 96 (1877).

There is thus no constitutionally significant difference between patent rights and other property rights; the Fifth Admendment's prohibition against uncompensated takings is applicable, in full force, to patents and the holder's right of exclusive use associated with that patent.

Similarly, with respect to the *Bolar* case itself, the legislation would take from Roche its court-determined right to obtain potentially substantial damages from Bolar for conduct held to be patent infringement at the time it occurred.

PROSPECTIVE APPLICATION OF SECTION 202 WOULD AVOID THE "TAKING" PROBLEM

If Section 202 were merely prospective in its application, applying only to patents issued after enactment, the "taking" problem would be avoided entirely. While a retroactive law is not invariably unconstitutional, when retroactivity results in a "taking" of property, the Fifth Amendment is implicated, and if the legislation runs afoul of Fifth Amendment protections, it is unconstitutional.

Even though the Supreme Court recently upheld the constitutionality of a retroactive amendment to the ERISA statute under the Contract Clause where the effective date of the act was geared to the date the legislation was introduced, *Pension Benefit Guaranty Corp.* v. *R.A. Gray & Co.,* 52 U.S.L.W. 4810 (June 18, 1984), retroactive legislation has, nevertheless, been a well of constitutional problems.[16] One authority has written that "It is a fundamental principle of jurisprudence that retroactive application of new laws involves a high risk of being unfair." Sands, *Sutherland's Statutes and Statutory Construction* § 41.02 (4th ed. 1972). The author explains:

"One of the fundamental considerations of fairness recognized in every legal system is that settled expectations honestly arrived at with respect to substantial interests ought not be defeated." Id. at § 41.05.

Indeed, just this week, House and Senate conferees agreed to eliminate the retroactive feature of the legislation that was the subject of the *Pension Benefit* decision because of its perceived unfairness. See Cong. Rec. H6683 (June 22, 1984).

Retroactive legislation in the patent area presents a more clearcut case of unfairness than a retroactive pension statute because the government is a party to the patent grant. Patent owners rely on the express terms of the statute and on constitutionally grounded public policy when they disclose their inventions. The issue raised by Section 202's retroactive application has been addressed in earlier judicial decisions. *See McClurg* v. *Kingsland,* 42 U.S. (1 How.) 202, 206 (1873) (new patent

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[15] This point was made forcefully by Professor Laurence Tribe in his testimony concerning home video recordings. See Home Recording of Copyrighted Works: Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary, 97th Cong., 2d Sess. 1216 (1982).

[16] In *United States Trust Co.* v. *New Jersey,* 431 U.S. 1, 21-22 (1977), the Court invalidated a retroactive state statute that impaired preexisting contract rights when less drastic alternatives were available to the legislature. Compare also *Lynch* v. *United States,* 292 U.S. 571 (1934) (federal government prohibited from impairing its own contract obligations by legislation that cancelled war risk life insurance policies), and *Allied Structural Steel* v. *Spannaus,* 438 U.S. 234 (1978) (declaring invalid a state statute which materially altered the terms of a preexisting pension plan causing a permanent and immediate change in the expectations of the parties), with *Home Building & Loan Ass'n* v. *Blaisdell,* 290 U.S. 398 (1934), and *Energy Reserves Group, Inc.* v. *Kansas Power & Light Co.,* 103 S. Ct. 697, 706–08 (1983) (permitting state legislation that impaired preexisting contracts).

legislation "can have no effect to impair the right of property then existing in a patentee"); *Diebold, Inc.* v. *Record Files, Inc.*, 114 F. Supp. 375, 376 (N.D. Ohio 1953) ("The constitutional principle of due process prohibits the retroactive application of the new statute and a resultant invalidation of the plaintiff's patent claims").

To avoid the constitutional difficulties inherent in retroactive legislation, Congress has traditionally been careful to limit the effect of new statutes on existing patent rights. This was most evident in the Patent Act of 1952, which revised and codified the patent laws and repealed prior laws. There, Congress specifically provided that "any rights or liabilities now existing under such [repealed] sections or parts thereof shall not be affected by this repeal." Act of July 19, 1952, c. 950, § 5, 66 Stat. 815.

Whatever validity retroactive legislation may have in other areas of the law, it is plain that such statutes cannot abrogate the protections afforded by the Takings Clause of the Fifth Amendment. Since Section 202 seeks to accomplish just such an abrogation of Fifth Amendment rights, its constitutionality is seriously jeopardized.

CONCLUSION

In sum, as a matter of constitutional law, Congress without providing just compensation cannot abridge patent and property rights it has conferred and upon which inventors and investors have reasonably relied. This is precisely the aim of Section 202. The rights involved arfe substantial and the constitutional infirmities significant.

Mr. KASTENMEIER. Does that conclude your statement?

Mr. DORSEN. Yes, it does.

Mr. KASTENMEIER. Mr. Schuyler, we call on you.

Mr. SCHUYLER. Thank you, Mr. Chairman. It is always a pleasure to appear before this subcommittee.

I have—we all listened attentively this morning to Commissioner Mossinghoff and his analysis of this bill. I am in general agreement with what he said. He covered many of the points which I would address myself, so in the interest of time, Mr. Chairman, I will submit my prepared statement for the record and not prolong this hearing.

[The statement of Mr. Schuyler follows:]

STATEMENT OF WILLIAM E. SCHUYLER, JR.

My name is William E. Schuyler, Jr. For more than 40 years, I have been extensively involved in the patent profession in both the public and private sectors. During the period 1969-71, I served as the Commissioner of Patents and during that term represented the U.S. in negotiating the Patent Co-operation Treaty. I was appointed Ambassador and Head of the U.S. Delegation to the 1981 session of the Diplomatic Conference for Revision of the Paris Convention for the Protection of Industrial Property.

I am appearing today at the request of a coalition of many of our nation's leading research based pharmaceutical companies who asked me to review H.R. 3605 and provide the Committee with my views on the content and practical application of the bill in light of my experience in patent prosecution, litigation, international negotiation, and as a former Commissioner of Patents.

At the outset, let me make three key points:

o Provisions of this bill encourage premature litigation by patent owners in many situations where substantive commercial controversies will not later materialize.

o By denying extension to many patents on worthy inventions, the bill in its present form is a very real disincentive to research in those areas.

o By compelling the Executive Branch to disclose trade secrets of U.S. manufacturers to foreign competitors, that industry and our economy will be adversely affected by a loss of jobs

and by an unfavorable change in the balance of trade.

Patent Litigation

I would first like to focus on the provisions of Title I relating to patent infringement and validity issues. Provision is made for an Abbreviated New Drug applicant to notify a patent owner that an application has been submitted to obtain approval to engage in commercial manufacturing of a patented drug before the applicable patent expires. For forty-five days after such notice, the applicant is precluded from seeking a declaratory judgment that the patent is invalid or not infringed. If the patent owner sues the applicant for patent infringement within the forty-five day period, then approval of the ANDA will be delayed until the litigation is decided, but in no event more than 18 months. As the Committee is well aware, trial of complex civil suits, like patent suits, is almost never completed within 18 months. An average pendancy of four years would be a better estimate, due primarily to congestion in the courts.

Because the applicant may serve such notice at the time of first submitting an ANDA to the Food and Drug Administration, applicants will, at minimal expense, have the opportunity to serve the notice with respect to inumerable drug products. Patent owners will likely respond to virtually every notice by filing suits for patent infringement -- for a couple of reasons: First, failure of the patent owner to respond may support an estoppel or laches defense in subsequent litigation.

Second, the eighteen-month delay in approval of the infringing product will afford short term protection to the patent owner.

As a result, it is likely that the courts will be inundated with patent litigation of issues that will not necessarily result in commercial controversies. That will certainly complicate the current congestion in the Federal Courts, and cause even longer delays in civil litigation.

This bill is saving generic manufacturers a number of years and tens of millions of dollars now required to obtain approval of a new drug application by permitting them use of the data generated by the innovator. Even a two year delay of approval of an ANDA from the submission of a completed ANDA, as proposed in an earlier draft of the bill, leaves the scales balanced heavily in favor of the generic manufacturers.

To limit the litigation triggered by this bill to those situations involving bona fide commercial controversies, I suggest that the timing of the notices to the patent owner be made coincident with filing of a completed ANDA. At that point the infringer will have invested sufficiently in his application to show his true intent to reach the commercial market, and the numbers of law suits will be dramatically reduced by weeding out some of the notices of invalidity which border on the frivolous. Also, the abitrary and unrealistic eighteen month period for litigation should be eliminated, with the Court having discretion to make effective the ANDA before final adjudication only if the patent owner fails to reasonably cooperate in expediting the action.

Patents Ineligible for Extension

Title II excludes various types of patents from eligiblity for restoration and places substantial limitations on the length of restoration. Reportedly, the drafters of this legislation have chosen to do this because they believe certain types of patents are amenable to manipulation of patent issuance, and therefore expiration dates, and because they believe Congress has not received data on significant regulatory review delays on other than new chemical entity products. (See House Energy and Commerce Committee Report on H.R. 3605, page 30.) The first rationale has been addressed by provisions in the bill that limit the term of an extended patent to no more than 14 years after regulatory approval of the covered product. Moreover, there is a provision that limits restorable time to that occuring after the patent issues but before regulatory approval. In light of these two very substantial limitations, the patent exclusions set forth in Section 156(a) are excessive and unnecessary. If the second rationale is true, it is irrelevant because the bill does not grant restoration in the absence of regulatory delay. More importantly, any arbitrary exclusion of patents eligible for restoration may unwittingly skew research to less than optimal therapies.

Exclusion 4 produces the greatest deleterious effect by providing that a patent claiming a product (or a method of using the product) may be extended only if the product is not claimed

and the product and approved use are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended.

To appreciate the mischief generated by this provision, one must have some understanding of pharmaceutical research and patent practice.

Pharmaceutical research is normally conducted on families of compounds sharing similar structural features and (it is hoped) similar biological characteristics. The object is to study a sufficient number of compounds in the family so that enough commercial candidates will appear to provide a likelihood of generating at least one commercial compound. I should note in passing that the research and development expenses to bring one commercial compound from discovery to commercialization have been estimated to be on the order of $70-85 million dollars.

The practice of pharmaceutical research to concentrate on families of compounds leads inevitably to the filing of patent applications on these families of compounds which were discovered. Since a patent application must be filed at an early stage of research to avoid potential loss of patent rights, only preliminary screens of the compounds will have been conducted. There is generally no suggestion at the time the patent application is filed as to which members of the family (if any) will be commercially successful.

Divisional Applications

In the normal course of examining a pharmaceutical patent application, the Patent Office frequently requires that the claims in the application be divided into several applications for "subfamilies", depending on the classification system employed by the Patent Office and on the Examiner's decision as to the appropriate scope of protection for a single application. The patent owner must then select one of the subfamilies for examination in the originally-filed ("parent") application and file additional applications (called "divisional applications") claiming each of the other promising subfamilies of compounds. These divisional applications would contain the same disclosure as the parent application but each would contain claims directed to a different subfamily. The decision to divide the application into a number of subfamilies is made solely by the Patent and Trademark Office.

With this as background, it will be apparent to the Committee that the later-issued divisional applications would be precluded from extension by exclusion number 4 because of the earlier-issued parent application disclosing the entire family of compounds and their intended use. Since the patent owner generally has no idea at the time of filing the "divisional application" which member of the family of compounds (if any) will be commercially successful, he is unable to insure that the commercial compound is claimed in the parent application. Exclusion 4 would therefore arbitrarily deny extension to patents covering approved products merely because an earlier issued patent discloses the product. It is unnecessary and should be

eliminated.

First filed, later issued applications

The committee should also appreciate that patents do not always issue in the order in which they are filed. Some applications encounter difficulties and problems in the Patent Office, while others are allowed quickly. By making the issue date the operative criterion, this provision of the bill could injure a party whose earlier-filed patent issues later. For example, a research-based pharmaceutical company might discover a family of compounds which appear, in preliminary screens, to have utility for treatment of certain forms of cancer. If this company files an application directed to these compounds, it is certain to face a rigorous examination by the Patent Office because of the general skepticism with regard to cancer treatment. Continuing along with the example, suppose that other researchers at this company develop a new and patentable process for preparing these compounds and that a second patent application is filed claiming the process. Because of the requirements of patent law that a patent application claim a useful invention, the second patent application would necessarily have to disclose the compounds which are made by the new process and their therapeutic utility. If the second-filed application issues first (as well it might), the first-filed application directed to the compounds would be ineligible for extension under exclusion 4.

Interferences

The United States Patent System awards a patent to the first inventor, not necessarily to the first person to file an application. If two applications are filed claiming the same invention, a contest occurs (called an "interference") to determine priority of invention and thus ownership of the resulting patent. This contest can occur not only between two or more applications, but also between one or more applications and an issued patent. If in such a situation the owner of the patent application were determined to have priority over an issued patent, his resulting patent would nevertheless be barred from extension because his invention had been claimed in an earlier-issued patent. As a result of winning the interference he loses his right to an extension. This is but another example of the injustice created by exclusion 4. It should be eliminated for it serves no useful purpose.

Genus/Species

Moreover, a certain type of patent, known as a "species patent" would be ineligible for extension under exclusion 4 if the owner also owns a "genus" patent.

Because pharmaceutical research requires a continual exploratory and refining process along parallel pathways, new candidates for commercialization are, not uncommonly, chemical

"species" falling within a broad class ("genus") of chemical compounds claimed in a patent.

Frequently, the compound approved by FDA is not even specifically mentioned in the original patent, but is identified only after years of additional expensive research. An early promising compound may later be found to exhibit a problem such as an undesirable side effect, requiring the inventor to abandon it in favor of other "species" compounds falling under the same genus patent. Species patents can be obtained on later developments that are not specifically disclosed in the original genus patent if they meet the statutory requirements of novelty, usefulness, and unobviousness. Such patents are more important today than ever, because, with the advent of new drug delivery systems and the new biotechnologies, substantial new health care advances frequently occur many years following the original grant of the genus patent. But, the existence of a generic claim in the earlier patent will preclude extension of the later patent to a commercially viable "species."

Denial of extension of the term of species patents acts as a research disincentive and serves to curb and impair scientific research in this fruitful area, denies the public the benefit of important medical advances, and reduces jobs in the research-based pharmaceutical industry.

Because of its inherent faults, I recommend the removal of exclusion 4 from the bill.

Other Restraints on Extension

The effects of exclusions 2 and 8 are well considered together. Exclusion 2 would deny extension to a patent which has been previously extended, while exclusion 8 would deny extension to a patent claiming another product (other than the one with respect to which extension is now sought) or method of using or manufacturing another product, which product has been previously approved by the FDA.

Bearing in mind that the extension of a patent is limited by the bill to the particular compound and the use approved, the fact that a patent covers one compound which has already been approved (and with regard to which the patent may have been extended) should not prevent an extension with respect to an additional compound claimed by that same patent. Please let me emphasize that I am not recommending serial extensions, but simply the applicable extension of the original term with regard to a second compound claimed by the patent. If the two products under consideration were claimed by separate patents, each patent would be eligible for extension with respect to the applicable product and the approved use. No different outcome should result because the two products happen to be claimed in the same patent. Exclusion 2 should be deleted to rectify this inequity.

Exclusion 8 is much the same, except that it would deny extension to a patent with respect to a particular product merely because it also claims a previously-approved product (even though the patent was not extended with respect to this previously-approved product). As an example of the reach of this exclusion,

it is easy to conceive of a patent covering a family of compounds, one of which is rapidly approved as (e.g.) a topical antifungal. Because of the timely approval of this antifungal compound, the patent is not eligible for extension with regard to that compound. Included in the same family of compounds, however, is a compound which is useful for treatment of a more life-threatening disease, such as cancer. The approval process for this compound, both in the clinical testing and in the registration process, could be lengthy indeed and it might be many years after the issuance of the patent that this cancer-treatment compound is approved for commercial sale. To deny extension to the patent with respect to the cancer-treatment compound because of the previous approval of the antifungal compound would appear unjust. For this reason, exclusion 8 should be deleted.

It appears that the criteria for extension are designed to prevent supposed abuses in the patent system by which patent owners might to extend their period of exclusivity. I respectfully submit, however, that any such abuses of the patent prosecution process are adequately addressed by the provisions of the bill limiting the maximum extension of five years, and limiting any extended patent life to 14 years from the date of regulatory approval. Alleged abuses of the patent prosecution process cannot result in prolonging a patent beyond the term of 14 years after the date of regulatory approval.

Disclosure of Proprietary Data

Allow me to focus a moment on section 104, which would hurt American companies trying to compete overseas by forcing disclosure of confidential data, including trade secrets. It gives unfair advantage to foreign companies seeking health registrations in their own countries. Most foreign countries give preference to their own nationals, making it easier for them to obtain approval to market drug products. At present, a number of countries do not even recognize drug product patents. Of these, more than half require submission of a substantial amount of technical information to obtain drug marketing approvals; and the number is increasing. These countries account for some $ 585 million dollars of total pharmaceutical exports from the U.S. The point is that if confidential data are disclosed to the public, we make it much easier for foreign companies to use those data to obtain approval and a head start in their countries.

The bill strikes two blows against American companies. First, it deprives American companies of trade secrets obtained at great cost (often measured in tens of millions of dollars). Second, it deprives American companies of the ability to make first use of these costly data to obtain approval overseas, thereby hurting their ability to compete effectively in those foreign markets, with adverse side effects on the balance of trade and domestic employment. To avoid this disaster, I believe it is essential that this valuable proprietary data be protected.

Conclusion

For reasons stated, I recommend removal of exclusions 2, 4 and 8 from the bill. While the revisions I have suggested will resolve some basic problems, there are many additional technical points requiring careful attention. Also, I should point out that there are serious constitutional questions raised in the bill, one being the legislative overruling of the Roche v. Bolar decision as to patents issued prior to the effective date of the legislation. These questions also deserve careful attention in order to avoid future successful legal attack on the legislation.

Mr. KASTENMEIER. Thank you, Mr. Schuyler, and the text of your statement will appear as part of the record. I think I might say that it does not surprise me that your views might coincide with those of Commissioner Mossinghoff.

Well, I would like to go back and talk to Professor Dorsen. I am not sure I fully comprehend the constitutional objections made, although I get the unsettling feeling that one proceeds dangerously if one fools around at all with changing the law with respect to intellectual property because differentially you are likely to affect people or interests in different ways, and therefore, could therefore be accused, to the extent that one interest may be preferred over another, for that to be contemplated as a taking.

We have all sorts of analogs, particularly more recently perhaps, in intellectual property and copyright, where the Supreme Court, in *Sony* v. *Betamax* did not feel that finding a fair use in that case—and the limitation on intellectual property rights of movie producers—was an unconstitutional taking.

How do you reconcile that?

Mr. DORSEN. Well, I think they are two rather different cases. Fair use has been a well-established doctrine in copyright for many, many decades.

Mr. KASTENMEIER. But it doesn't precede the Constitution, though.

Mr. DORSEN. No, but it has been accepted by the Supreme Court in all copyrights that have been issued. They have been subject to a doctrine that is very well known. As the Commissioner of Patents said this morning, this would be an absolutely unprecedented restriction on patent rights that were issued, relying on the exclusive right to use.

Just yesterday, in a case that I have not had time fully to analyze, Justice Blackmun said, for a unanimous Supreme Court, with respect to a trade secret, which is at a lower level of protection than a patent—it is not mentioned in the Constitution—Justice Blackmun said, "The right to exclude others is central to the very definition of the propery interests."

The *Bolar* case, which again, the Commissioner said was self-evident, is a case where the court recognized that the right to exclude

others entirely during the life of the patent has been almost ipso facto part of the property right. To go back now and say that the patents that were issued don't have that exclusive right, which is central to property, would be surprising. It seems to me very plain that there is a substantial constitutional problem here.

Mr. KASTENMEIER. Are you also saying that insofar—that differential patent extensions or classes, depending on, say, when the patent was obtained or on other grounds, is also—has constitutional infirmities?

Mr. DORSEN. I did not address that point in my testimony and before giving a considered opinion, I would like to study it. My first inclination is that that is a different sort of problem. Extension prospectively wouldn't interfere with the settled expectations that people had of the patent term and the right to exclude during the patent term when they received the patent. So there might be a substantial difference there, as you suggest.

Mr. KASTENMEIER. Of course, there is also the argument that—we had this during this copyright—that with respect to subsume, extension of underlying copyright, that insofar as the changes not reward creators for creating something prospectively, that it really found no constitutional grounds for it. That is to say, reward an author who had been dead for 20 years by extending his copyright was, in fact, not encouraging the creative arts; it was a windfall, and therefore, as a matter of public policy, it would make sense to reward prospectively new creations by more generous terms, but not by rewarding—by increasing rights of those who have long since would be unaffected.

Mr. DORSEN. May I comment on that——

Mr. KASTENMEIER. Yes.

Mr. DORSEN [continuing]. Because I see your point and I appreciate it, but I think there are some problems with it. The first problem is that to begin a process for the first time of impairing the sanctity of patent rights in a new way has got to have an effect on incentive, because if it is done once, it can be done a second time.

Second, on a more narrow argument, the fact that people received patents under existing law, the Patent Law of 1952, and the entire history that is laid out in my paper and I am sure in others, means that their investment-backed expectations are being defeated and that is just flatly inconsistent with what the Supreme Court said just yesterday in the *Trade Secrets* case.

Mr. KASTENMEIER. Is there any—assuming for the sake of argument that the bill does constitute a taking, could it be resolved by providing for a compulsory license where the pioneer company—the research company would receive a reward for use of their patent for certain periods of time, but would not necessarily control whether or not that use were granted?

Mr. DORSEN. Well, again, I didn't address that specifically, but as I remember from my days as an antitrust teacher, that doctrine is one of the most treacherous, complicated, and befuddling doctrines in all of antitrust law. The problem of both deciding when the compulsory license would take place and valuing a whole host of patents would be enormously difficult thereof. Frankly, I think it might make the problem worse rather than better, but that, again,

I didn't address and I am sure there are people better versed on that subject that I am.

Mr. KASTENMEIER. I would like to ask Mr. Stafford, why do—how is it that a majority of the companies represented in your major association, other than your particular research coalition, agree to the 3605 bill? How is that their interests differ from the group of 10 for whom you so eloquently speak?

Mr. STAFFORD. Well, if I might start by answering that with the comment that if the concept of compulsory licensing were introduced into the patent system for pharmaceuticals, we might begin to become unified. [Laughter.]

In my view, compulsory licensing would be the very antithesis of the patent system and would greatly undermine the incentives for research as it has done in Canada, where it has virtually destroyed the pharmaceutical patent system. I appreciate that you are talking about him only on a limited basis, but any nose under the tent in that area, I think, could unify the research-based industry rather quickly.

I will now go to your question. The differences that we have with the PMA don't go to the basic thrust of the bill. We agree with the broad compromise that was reached—that is, when I say "we," I mean the coalition which I am speaking for.

We agree that there should be an expedited procedure for bringing generic drugs to the marketplace which were approved originally by the FDA after 1962. We also agree that patent restoration will be in the best interests of everyone who is served by the pharmaceutical industry, including the consumers.

However, I believe Mr. Lewis' comments put it in the right context. The PMA is a trade association and it has joined together for those purposes which the companies are permitted to work together on, specifically legislation and regulation. However, outside of those areas, we are vigorously competitive, and that includes everyone in the group that I am speaking for.

The PMA is not a monolithic organization. Each company must make its own judgment based on their best perception of the interests of the different groups that they serve, including their employees and their stockholders and the publics they serve, such as the medical profession and the consumer. Each company must make its own judgment.

Our group of companies has consistently, throughout the drafting period of this bill, voiced objections to provisions in this bill. However, the negotiations, the discussions with Congressman Waxman's staff were left up to the PMA president.

As it became apparent that the broad understanding was not being implemented in a way which would either encourage research or do the proper job of facilitating approval of ANDA's, these companies took a position that changes to the bill are necessary if they are to support it.

Why any individual company makes its judgment, I think you almost have to talk on a company-by-company basis.

Mr. KASTENMEIER. Well, the reason I asked that is to see if there was a simpler explanation. For example, 2 years ago, I think it is fair to say that while PMA did finally approve of H.R. 6444, there were a number of key companies in the group, in the association,

that had very significant reservations about it, primarily because the bill was made prospective only, that is to say, one had to get a patent. It wouldn't have extended any patent before the year 2000.

Now, there was a, I think, public policy reason for proceeding in that way, but nonetheless, several of the large pharmaceuticals had such very important therapies already in the pipeline that wouldn't have been protected, that wouldn't have been given an extension, that as a matter of policy, they would have resisted that particular formula and probably didn't speak because—at the end—because it did seem overall that the bill, on balance, was beneficial to research houses in the long term, but there were clearly precise economic reasons for either the enthusiasm or lack of enthusiasm for that particular bill, traceable to that feature alone.

Mr. STAFFORD. Well, if there was disagreement over that bill, it is not difficult to see why there could be great disagreement over this bill, since, while that bill did include the prospective-only feature, and that greatly limited, I think, the incentive aspect of that bill—that is my view—this particular bill does a great many other things to the pharmaceutical industry. The pharmaceutical industry is really not an industry of hard assets. We don't have barrels of oil in the ground and we don't have mile-long assembly lines.

What we have is innovation. We have people in laboratories and we have know-how, and all of that is tied to protection of the intellectual property system. We view this bill—unlike the bill that you referred to which might or might not have encouraged additional innovation—as a bill which cuts into the incentive for research by setting up procedures for attacks on patents. It takes away retroactively rights under patents for drugs which already lost time at one end due to FDA procedures and now would lose time under this bill at the other end. The bill, in referring to the Bolar section, effectively grants amnesty to people who may have been already violating patents in anticipation of some relief.

So I think that this bill has many more provisions in it which are controversial and which do more damage to the patent system, as compared with the patent restoration bill that went to the floor of the House, and therefore you could have greater differences in views as to the extent to which it might encourage innovation.

Mr. KASTENMEIER. I must confess I have not studied this bill yet in detail. I take it, however, that the provisions—certainly the two titles are not severable. That is the abbreviated new drug applications—that title is reflected in the language in the patent section, I take it. That is to say, I could not ask you hypothetically if—is it title I alone that you object to? You have expressed a number of very specific objections to the second title, but I take it the way the bill is written, that they are interdependent, that title I is reflected in the language in title II. Is that correct?

Mr. STAFFORD. I think that may be true as a matter of draftsmanship, but I think it is also true as a matter of the broad understanding which was reached between the different groups who were anxious to see a generic drug bill passed and those groups are anxious to see a patent restoration bill passed.

I would think that skilled draftsmen could separate those concepts into two completely separate bills, as they have been in the

past, but if the understanding is to be achieved with the bill amended as we suggested, then they would stay together.

Mr. KASTENMEIER. In other words, you have suggested seven amendments which, if adopted, would lead you to support the bill, or at least withdraw your opposition, is that your position?

Mr. STAFFORD. Yes, sir.

Mr. KASTENMEIER. While I didn't ask them, I assume that the case would be that certainly the generics group would then oppose the bill. Is there—do you think there is any way that the people that Mr. Lewis speaks for—could you, do you think, and your group get together with the generics or are your differences really so great that they couldn't be bridged?

Mr. STAFFORD. We haven't had any discussions with that group to my knowledge. I would anticipate there would be some fundamental differences, but I really couldn't speculate as to what their position might be on our suggestions.

Mr. KASTENMEIER. Thank you.

I was going to ask Mr. Schuyler if he had seen Mr. Mossinghoff's analysis of the flow chart, since he is familiar with the Patent Trademark Office and whether he could indicate whether he agrees or disagrees with this analysis.

Mr. SCHUYLER. Mr. Chairman, I have not had an opportunity to study that analysis. I saw it for the first time this morning and did not undertake to study it, but I know Mr. Tegtmeyer very well and if it was prepared under his supervision or his direction, I would have great confidence in it.

Mr. KASTENMEIER. Thank you.

I am going to now yield to the gentleman from California, Mr. Moorhead.

Mr. MOORHEAD. In the development of a drug or a pharmaceutical product—when you first plan it, you consider and determine whether to make the expenditures that are necessary; you determine how much money you are going to have to spend and what you can hope to get off the product. Under this legislation, there is one portion of it that would give coverage to drugs in the pipeline and some people have said that this would be an unfair enrichment to the companies because they have made their financial decisions based upon the law as it now is, and we give protection or additional coverage to drugs that are in the pipeline, it would really be unfair and an additional cost on the public. Is this true? Do you feel that it would?

Mr. STAFFORD. Decisions on drugs, as to what could indicate whether he agrees or disagrees with this analysis.

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Mr. STAFFORD. Decisions on drugs, as to what expenditures will be made to develop those drugs, is a continuing process, even after the drug is approved. Some of the most important developments in pharmaceuticals have related to work done on drugs after they reached the market, so that this is a continuing process and is not made at the beginning and fixed at that time, because as you learn more, you are constantly making judgments as to what direction to go and how much should be expended.

In terms of whether this provision is an unfair enrichment, no, I would not agree that it would be an unfair enrichment to grant extension for drugs in the pipeline. Certainly drugs which are in the IND stage, investigational stage, those final decisions as to the expenditures have not been made.

Second, this bill proposes that those drugs receive only a 2-year maximum extension and for the drugs currently in the pipeline at the FDA, you are probably talking about an 8- to 10-year shortening of their effective patent life already, so even if you were putting it in the context of simple fairness, 2 years of extension would not be an unjust enrichment.

Mr. MOORHEAD. I wanted your comments. As you know, I have supported this bill in a much more pure concept than it is at the present time and certainly back patent extension legislation, but these are the arguments that you get and we have to have answers for. We have to know whether the arguments that might be used against it are valid and I wanted your answer insofar as that was concerned.

There is another question that I had that concerned me. We don't—at least I don't know everything about the pharmaceutical business—let's assume that the bill passed and at the end of the period of time that you had for exclusive license on the product, almost immediately a generic would appear on the market in competition. How badly would that hurt your business? Would it wipe it out? Would you still be selling through prescriptions the product and be able to make most of the money that you had been making or would it wipe you out altogether?

Mr. STAFFORD. If it appeared on the market after the patent expired?

Mr. MOORHEAD. Yes.

Mr. STAFFORD. No, it would not wipe us out. We sell—our company successfully sells many products which have been off patent for many years. It certainly would not wipe out the industry, but it is important that adequate patent protection be afforded if you are going to go through the process of year after year after year of research investment, as we have done with one of our major divisions, waiting for the first successful product. But we have stayed

the course now—well, too many years—and recently we completed a major new research facility, again searching for additional new products and we will continue to stay the course. But there must be adequate patent protection. However, when the patent expires and competition develops, as we endorse in our position on this bill, it certainly would not wipe us out.

Mr. MOORHEAD. There is the additional question I raised this morning with another witness, with Mr. Mossinghoff, but we have been doing everything that we could think of in Congress to try to improve international trade; to try to improve international agreements that would protect our patents and be able to get us—get our patent owners in this country more protection and—I have a bill that is in that I would like to see passed that would protect the process that might be patented for production of various products that also are patented. We haven't been able to get that very far along yet, but I think it is important that we do because so many other countries have given their own industries that protection.

But if we pass legislation that enables American companies to deal with patented products almost as their own, to experiement with it and to tear down some of the formal protections that a patented product had had before, as most people feel this bill would do, what is going to be the respect that our patents have abroad?

Are we going to find that other countries will feel that no protection should be granted at all? They will go ahead and perhaps put these products on the market to beat the generics in this country?

Mr. STAFFORD. I agree with your comment. I think that will be the result and I think that is what the Commissioner of Patents said this morning would result if there is any weakening of our patent system. It is no coincidence in my view that we have a strong patent system in the United States and we also have the World leadership in pharmaceutical technology. I do think it would be a very unfortunate precedent. I think the U.S. Government is at present urging better protection for pharmaceuticals in the patent systems of other countries. The experience in Canada has been a very unfortunate one in terms of the research in that country. Since they have introduced compulsory licensing and undermined the patent system for pharmaceuticals, many companies have either moved their research out of that country or greatly limited their expansion.

Mr. MOORHEAD. I want to make a suggestion. I know it is pretty late on this thing. Most of us that believe in patent extension to give additional time would like to see a bill passed. I know I had one pharmaceutical concern come to me and they had just gotten a license to put the drug on the market 16 years and 9 months after they got their patent, so that there were 3 months left on it.

There is obviously a serious problem, but with the Pharmaceutical Association having supported a compromise and most of the opponents also supporting the compromise, it is very difficult for us to make changes without you being able to work out some kind of modification also with some of these people involved.

You have got, it looks like, virtually all the industry and the opponents have come together, and yet we know there are some problems with the legislation. I would hope that you would discuss some of your suggestions with the other people in the industry and

with the people in the organizations that found objection to this kind of legislation in the past. We don't have very much time.

I think this bill will pass basically in the form that it came out of the Commerce Committee, unless there can be some adjustment within this vast area of people that have agreed with. So I think you have a job to do. We will seriously consider your suggestions, but it has to go through the whole Congress—it has already gone through one major committee and there is a very good chance that the legislation will pass in the form that is agreed to unless some awfully hard work is done in selling some modifications.

Mr. STAFFORD. We will continue to talk to the other members of the PMA and to anyone else who will listen to our comments.

Mr. MOORHEAD. I have no further questions.

Mr. KASTENMEIER. My colleague's comments are, I expect, rather realistic in terms of this session of the Congress. As I understand, the other body, the Senate, Senator Hatch is starting hearings tomorrow, which means this whole issue is being reached somewhat late in the process, in the legislative process.

In any event, I yield to my colleague from Oklahoma, the author of 3502.

Mr. SYNAR. Thank you, Mr. Chairman.

Mr. Dorsen, can you help me out? I just graduated from law school 6 years ago and I may have missed it. Can you cite for me a case where the courts have found an act of Congress unconstitutional under the Constitution's fifth amendment taking clause?

Mr. DORSEN. Several cases, I think, are cited. The *Mahon* case is one. *Pennsylvania Coal Company* v. *Mahon,* in an opinion by Justice Holmes, with one dissenting vote. I believe it was 1922.

Mr. SYNAR. Did that involve an act of Congress or a State statute?

Mr. DORSEN. That was a State statute.

Mr. SYNAR. My question was act of Congress.

Mr. DORSEN. Act of Congress, I am sorry. I believe the *Lynch* case may have been such a case.

Mr. SYNAR. But you are not for sure, are you?

Mr. DORSEN. I am not so—at 352 U.S.—I am not certain.

Mr. SYNAR. OK. Let me also ask you another question. If we don't undo the *Roche* case, are we not, for all practical purposes, extending the patent life 2 years?

Mr. DORSEN. No, that is a very key question and I think it is good that you put it that directly. I just think with respect to—that misapprehends what a patent right is.

Mr. SYNAR. Let's explore that——

Mr. DORSEN. May I——

Mr. SYNAR. No, let's explore that, because——

Mr. DORSEN. I would like to answer the question.

Mr. SYNAR. Well, I want you to answer the question I was to ask you.

Mr. DORSEN. OK, all right.

Mr. SYNAR. I don't want you going all over the board——

Mr. DORSEN. All right.

Mr. SYNAR. I have been here since 10 in and out and this is the first time I have gotten to ask questions so I want to try to keep it focused in.

You know, when we started this thing, the problem that we had was the fact that we had to come together to try to have a meeting of the minds on trying to get generics on the market as quick as possible after the patent, as well as giving the protection to the pharmaceutical for a 17-year period.

That compromise that we hammered out was basically to accomplish the two purposes which I think it does. First of all, we say that there will be no economic benefit to the generics; there will be no money made until that 17-year period runs out, period. Therefore, no economic benefit, protection of the patent for the pharmaceutical.

At the same time, we guarantee that that full 17 years will be allowed by the pharmaceuticals. The compromise which we have struck accomplishes both those purposes.

Now tell me in your words why that is unfair and why that violates the patent law.

Mr. DORSEN. Well, I am not here—in case there is any question in your mind—to discuss the compromise that obviously was the product of a great deal of work by very serious people acting in the public interest. I have no doubt that the objectives of the people, including Mr. Waxman, with whom I have worked in the past, were of the highest. I don't think, though, that it is a very good idea to compromise the Constitution, and I do think that in the course of developing legislation with the highest motives and the best interests of the country as a whole, sometimes people neglect to look at what the consequences of legislation may be.

I am here only because I am suggesting to you, as I said in my remarks earlier, and as other respected scholars who have looked at this legislation have concluded, that there is a serious constitutional problem in connection with the legitimate, reasonable investment-backed expectations of the people who develop the patents and rely on the law.

Mr. SYNAR. But you can't cite us a case——

Mr. SYNAR. There is no case that has decided this one way or another.

Mr. SYNAR. It is just your guess against our guess, isn't it?

Mr. DORSEN. I am sure that I can be wrong. There is no case either way. There is no case either way, but there is law here. This is—the Supreme Court, just yesterday, in a case I have not had an opportunity to study—it just came down in the unanimous opinion by Justice Blackmun—indicted to be sure, but reiterated the doctrine that I am relying on in connection with trade secrets, which are not at the same constitutional level as patents.

I am personally not trying to upset the legislation. I would like to see legislation passed. I don't think it does any good to do it if there is a constitutional problem. You will have litigation for 10 years.

Mr. SYNAR. With all due respect, I don't think there is a constitutional problem and I don't think that you do, but let me ask you—[Laughter.]

Let me ask you this——

Mr. DORSEN. I didn't hear the last comment. I will try to ignore it.

Mr. SYNAR. Let me ask you this question, reading from the opinion on the *Bolar* case. "Parties seem to think in particular that we must resolve a conflict between the Food and Drug and Cosmetic Act and U.S.C. 301392 in 1982 and the Patent Act of 1952, or at least the acts' respective policies and purposes. We decline the opportunity here," and I emphasize this, "however, to engage in the legislative activity proper only for the Congress."

How do you—what do you think about that statement?

Mr. DORSEN. I think it is a very sound statement.

Mr. SYNAR. Is that not what we are trying to do——

Mr. DORSEN. Absolutely, and I encourage it. But I encourage it to be done within constitutional bounds.

Mr. SYNAR. OK.

Mr. Stafford, let me ask you a question if I could. I was interested in the comments of the position paper dated June 16, 1984, signed by the American Home Products, Bristol-Myers, Johnson & Johnson and others which criticizes the compromise because it would, and I quote, "force the patent owners to litigate the validity of a patent well before and ANDA filing, at a time when the applicant," and I emphasize this, "has incurred only minimal expense."

Now, this subcommittee, as you are probably aware, is especially involved in the access-to-justice issues, and I don't think there is anywhere in the law where economic commitment is a prerequisite for justice. How do you justify that a generic drug company has to belly-up some money before they are able to challenge a patent's validity?

Mr. STAFFORD. Under the present law, a party is not free to challenge the validity of a patent without some action by the patent holder.

Mr. SYNAR. Does it have to be economic?

Mr. STAFFORD. No, I am looking at it the other way. Under the present law, anyone who wants to challenge a patent is not free to go into court and challenge the validity without some overt act by the patentee.

Mr. SYNAR. Yes.

Mr. STAFFORD. This would change that. This would permit a person seeking an ANDA to do a nominal amount of work and then put the burden on the patentee to bring an action defending his patent or they would then be free to bring an action to challenge the validity. So that is the change in the law.

Mr. SYNAR. Well, maybe I misunderstand this. It says "force the patent owners to litigate the validity of a patent well beinformation the ANDA filing, at a time when the applicant has incurred only minimal expense." What does that mean?

Mr. STAFFORD. The bill went through some change there and I am not——

Mr. SYNAR. It seems like to me what you are saying with that in your statement that was signed by all the dissident companies is that as a prerequisite to going—to try to get justice, somebody has to have some economic action——

Mr. STAFFORD. Under the——

Mr. SYNAR. We never considered that.

Mr. STAFFORD. Under the present law, it is necessary that there be some case or controversy in existence before it will be looked at by the courts. That is true under the present law.

A person who wants to infringe, or if they think the patent is invalid, go ahead and market a drug product cannot, before they take some action which causes the patentee to challenge them, bring an action for invalidity. That is the law right now. I would defer to patent experts sitting with me.

Mr. SYNAR. Yes.

Mr. STAFFORD. This bill turns that around and permits them to shift the burden to the patentee, who has a presumption of validity of his patent, to go into to court to protect his interest.

Mr. SYNAR. Yes. So you are not saying that the people have to have a minimum expense. They just have to have a cause of action or some act has to be done?

Mr. STAFFORD. Well, at the present time, if they marketed the product and action was brought against them by the patentee, they could defend the action on the grounds of invalidity.

Mr. SYNAR. OK.

Mr. Chairman, I apologize for having to run in and out. I think you did express that we are in the middle of negotiations on bankruptcy and I apologize to the witnesses for that. These hearings have been exceptionally helpful, but as my colleague from California, I think, very gratiously and very diplomatically pointed out, we have a serious problem here, a problem where the Pharmaceutical Manufacturers Association negotiated for an industry that now is not claiming that they were negotiating for them. We have an industry that has agreed with the generics, our elderly groups, and, as I pointed out earlier, my mother feels that this has been a good agreement.

I don't know if there is any way we can resolve what concerns these dissident companies have. I think they need to look for their remedy, not here in Congress, but with those who negotiate for them, because we in Congress are only going to be as good or bad as those people who represent those groups that are negotiating for them and regretably, in a situation where you have six or seven companies who now disclaim the PMA and their negotiations, we are in a position where I think we can do very little to help you.

This is a good piece of legislation. It is a good compromise. As you heard from the generics earlier, they are not totally satisfied. Obviously the PMA people are not totally satisfied, and that may mean that we are getting very, very close.

But I hope that following these hearings, Mr. Chairman, we can move to an expeditious markup and join our sister committee of Energy and Commerce, which Mr. Moorhead and I serve on and move forward as quickly as possible with respect to this legislation.

Mr. STAFFORD. Could I make a brief comment on that statement? We represent 10 companies and we represent about 50 percent of the research dollars spent on pharmaceutical R&D in this country. We don't regard ourselves as a dissident minority, but as a responsible group of companies whose——

Mr. SYNAR. Mr. Stafford, what was the vote at the PMA Executive Board on this?

Mr. STAFFORD. Excuse me?

Mr. SYNAR. What was the vote?

Mr. STAFFORD. What was the vote? The vote of the people present—there were a lot of votes taken——

Mr. SYNAR. How about the people present? What was the vote? Was the vote not 22 to 11 or 22 to 12?

Mr. STAFFORD. That was based upon a canvass after the meeting, I believe. Of those present at the meeting, it was 12 to 11.

Mr. SYNAR. But the vote was 22 to 12, was it not?

Mr. STAFFORD. Well, I wasn't—I didn't participate in that canvass so I—but I think basically the Board is split about 2 to 1. I would agree with you, Congressman, the Board is split about 2 to 1.

Mr. SYNAR. 2 to 1 in favor of the legislation.

Mr. STAFFORD. That is correct.

Mr. SYNAR. That is correct.

Mr. STAFFORD. I believe that the other members, though, would not disagree that our amendments would improve the bill.

Mr. SYNAR. Was Mr. Engman not negotiating for you all?

Mr. STAFFORD. He was asked by the Board to continue the negotiations with Congressman Waxman. At such time as a draft emerged, there were many meetings, including one at which the group of the Board that looked at it voted 9 to 1 to reject the draft. There were a lot of discussions after that.

Mr. SYNAR. But I think for the record, it is important to show, Mr. Chairman, that the vote, when it came down to this compromise, as we have it before us today, that the vote of the PMA was 22 to 12, and later changed to 23 to 11.

Mr. STAFFORD. I don't think it was ever suggested otherwise—and I think Mr. Lewis agreed when he was here this morning speaking on behalf of the PMA—that any individual company has been in the past and would be in the future free to make their own positions known with respect to legislation which they think would adversely affect their industry.

Now, just one more comment, really, the purpose of this broad compromise was to facilitate the marketing of products which were approved post-1962, where the patents had expired. That is, in fact, stated in the PMA statement, that these ANDA's would be granted only after the expiration of patents, but that, of course, is not what the bill says. That statement is not correct. The bill sets up various ways by which drugs which are still on patent can be challenged and can be utilized to gain marketing approval.

What started out as an effort to facilitate the marketing of drugs which had gone off patent and which are being held up according to the persons who want to get them marketed by the FDA—the FDA does have pending regulations, but they haven't issued them because of the status of this bill—has shifted over to be a bill which includes many provisions which permit an attack on the patent system and that is where we fell out of bed and that is what our view is.

Mr. SYNAR. Thank you, Mr. Chairman.

Mr. KASTENMEIER. Let me ask Mr. Stafford: Have you testified yourself before the Waxman subcommittee?

Mr. STAFFORD. No. I think the only hearings were last year and that was on a page-and-a-half bill, not on this bill, and no, I did not testify.

Mr. KASTENMEIER. One of the reasons is the benefit of your position. One thing you said at the outset is that you were discussing those—as I recall—those matters which related to patent—to the matter of patents, rather than to the matter of FDA or regulatory aspects which you may differ with. Is that correct?

Mr. STAFFORD. Primarily. I think, because of the jurisdiction of the committee—you are referring to my comment that I was going to focus primarily on the patent matters, although I did allude to some of the issues which relate to the FDA's situation should this bill become law——

Mr. KASTENMEIER. Because to the extent that you may wish to comment on the other aspects, I think it would be appropriate to do this also since you have had no other House forum to do that——

Mr. STAFFORD. Well, we are quite——

Mr. KASTENMEIER [continuing]. Directly.

Mr. STAFFORD [continuing]. Concerned about provisions of this bill as it affects the FDA. As the FDA itself noted in technical comments which it provided to the staff of Energy and Commerce, this bill would obligate the FDA to process an enormous number, of perhaps thousands of ANDA's with no opportunity to make a judgment as to any transition period. Going back to the original understanding that is referred to, part of that understanding was that the FDA would make a judgment and a listing of such drugs as it thought should be available for ANDA's. The FDA presumably would work forward from 1962 on and that would include many of the drugs which the generic companies are seeking to market at a very early time.

We are concerned that the FDA will have to devote valuable resources to processing the ANDA's and they are really, unfortunately, not doing the job on new drugs, original new drugs now and this situation is both costly and damaging to the American consumer.

We are also quite concerned about the provision on the disclosure of trade secrets that would result from this bill and similarly, we think the 10-year transition period, which limits the FDA in granting an ANDA for a very limited class of drugs, is unfair and so arbitrary really as to be unconscionable in my view.

Mr. KASTENMEIER. Thank you, Mr. Stafford, and indeed, we appreciate the position of the panel speaking on behalf of the research coalition, the companies listed in the statement. We, therefore, thank Mr. Stafford, Professor Dorsen and Mr. Schuyler for their testimony here.

Again, we may need to be in touch with you on various questions about the legislation before us, which is—which we may not have had an opportunity to explore with you today.

Mr. STAFFORD. We would welcome the opportunity to work with any members of the committee or their staff on language with respect to any parts of the bill or any other issues that you might raise.

Mr. KASTENMEIER. Our last witness this morning—and we are going to have to recess because, as you will note, there is a record vote on the Tax Reform Act on the House floor. We will be able to come back in about 10 or 12 minutes, hopefully, and I hope to have Mr. Moorhead with me, to greet Dr. Cape, who is the chief execu-

tive officer of Cetus Corp., in the fascinating field of biogenetics, which has definite application to the matter before us today and other matters before this committee.

But pending that time, we will recess for 12 minutes and then we will greet Dr. Cape. Until that time——

Mr. STAFFORD. Thank you, Mr. Chairman.

Mr. KASTENMEIER [continuing]. The subcommittee is in recess.

[Recess.]

Mr. KASTENMEIER. The committee will come to order.

Our last witness today is Dr. Ronald E. Cape. Mr. Cape is the founder and chief executive officer of the Cetus Corp. Cetus, a biotech company, produces both pharmaceuticals and agricultural products using biotechnology techniques.

We have a copy of your printed statement, Dr. Cape, so without objection, we will make this part of the record and you may proceed as you wish.

TESTIMONY OF RONALD E. CAPE, CHAIRMAN, CETUS CORP., EMERYVILLE, CA, ACCOMPANIED BY HAROLD C. WEGNER, WEGNER & BRETSCHNEIDER

Dr. CAPE. I thank you, Mr. Chairman, for allowing me to testify today, and inasmuch as you have the statement, I will decline to recite it to you and I have a few brief oral remarks.

Our company operates in Emeryville and Palo Alto, CA, and in Madison, WI. We are one of the major independent biotechnology companies in the United States. At my side is our attorney, Mr. Wegner.

As a founder of Cetus, I watched our company grow in just a few years to a position where we now have an excellent chance to unlock the secrets of cancer detection, treatment and possibly prevention. As you know, these opportunities exist directly as a result of the dexterity with recombinant DNA demonstrated by pioneering U.S. biotechnology companies.

You may rightly ask, why now, in June 1984, in the final stages, as it were, we are voicing our concerns about H.R. 3605? It is simply because this is the first instance in which we have had an opportunity to present our views. Contrary to what has been said here today by several participants, all the players affected have not been consulted.

Cetus was never a participant in the negotiations between the large multinational pharmaceutical firms and the generic industry for the obvious reason that we are not a member of either group. Unfortunately, however, their compromise, arrived at without consulting us and companies like us, has important negatives for Cetus and, I believe, for the other leading small biotechnology companies.

These companies are the new players. The whole world acknowledges, as does the recent OTA report, that these pioneering biotech companies, primarilly those based in California, vividly exemplify the present gratifying U.S. lead in genetic engineering. Why our vital interests are not addressed by the lengthy Waxman compromise is easy to see. Biotechnology has no flow of drugs of any kind

now coming off patent. We are just at the beginning of the development process.

So it is not now, but at the turn of the century, that our patents will start to expire, and the pipeline of biotechnology products will begin benefiting the generic industry at that time.

Thus, for us, the compromise is not a compromise. We give up a great deal on the front end and we get virtually nothing in return. This, for us, is a quid with no quo.

We support the broad objectives of cheaper generic drugs and their general availability. The idea of providing off-patent generic drugs is worthy and deserves general support.

However, the wording in the bill needs fine-tuning or a totally unexpected side effect of the ANDA provisions will be to deny the domestic biotechnology industry the benefits of our progress in the cancer field, as well as many other vital areas of health care.

The period of exclusivity now available in the absence of ANDA's is necessary to firms like Cetus because the relatively unreliable patent situation in biotechnology today does not afford sufficient assurance of future protection to justify the very large investment required and which we are now making in research and development.

The two principal effects would be dramatically decreased cancer research, coupled with a move of biotechnology across the Pacific. I am sure that these outcomes, these unexpected outcomes which I am now bringing to your attention, I think for the first time, are viewed with surprise and alarm by everybody here today.

Patent term restoration provides no balancing compensation in our case. We have no immediate concern about the limitations on patent term extension. Biotechnology holds significant promise for the cure and prevention of disease, particularly the killer diseases against which we have so far been relatively impotent. I am talking mainly, of course, about cancer, but there are others. Pioneer patents resulting from the pursuant of these targets won't expire earlier than the year 2001.

This is an emerging industry, and at this point in time, a patent term extension from the year 2000 to 2006 is not very comforting, let me assure you. What such an extension would give us is no consolation at all for what this distressing compromise would inflict upon us and on the U.S. leadership in biotechnology which companies like ourselves have achieved.

Therefore the wording of H.R. 3605 inadvertently—I am sure inadvertently—cripples biotechnology. Imagine that you wish to invest, say, $30 million in a new recombinant DNA product that may, just may treat a specific cancer. If the clinical trials don't work perfectly, you have to write off the research and try again. And again.

Why in the world would anyone wish to take such risks? The answer must lie in a fair certainty of an exclusive position for a reasonable period of time should development prove successful, in order to recoup the tens of millions of dollars invested in the new drug.

Biotechnology is unique in the pharmaceutical world. There is absolutely no track record for the enforcement of a recombinant DNA patent. Zero! It doesn't exist. The only reassurance that we

now have in the mid-1980's is based upon freedom from ANDA competition. Cetus and other pioneering biotechnology companies definitely need the assurance that our breakthrough research will be rewarded by exclusive marketing rights to these very breakthroughs.

If the promise at the end of the long, risk-filled development process is taken away under H.R. 3605, will we shift our research into simply improving upon the present generation of aspirins, tranquilizers and the like? Don't get me wrong; there is nothing wrong with a better Valium. I would personally be delighted to see one developed, but that is not what we do. It is not what we want to do.

But the compromise makes that more attractive than the directions we have chosen to date. It is certain that the level of research on significant new biotech based anticancer products will diminish if the promise of reward diminishes.

Japan is providing a better climate. The Japanese help their industry by providing in the health ministry regulations up to 6 years of guaranteed exclusivity. I can't imagine us countering their determination to catch up with us; their repeated acknowledgement of our lead, by limiting our opportunities. Please—I will repeat it, please, we invented this technology; we are in a race; we are winning the race; everybody is chasing us. Let's not shoot ourselves in the foot.

As an example of shooting ourselves in the foot, assume that Cetus and a Japanese company is each attempting to be first with an identical drug product, each in its home market, in its home country. If both drugs are approved at the same time, the Japanese company would have an exclusive period in Japan under Health Ministry regulations. But with an ANDA, the Japanese company could quickly enter the U.S. market. Does this sound familiar?

Already, every major American biotechnology company, out of necessity, is looking into cooperative ventures with the Japanese. This is an alternative to investing tens of millions of dollars in seeking regulatory approvals here.

Mr. Chairman, biotechnology interests are far different from those of the established drug industry. It would be a major policy mistake to equate the interests of the emerging biotechnology companies with those of the powerful established drug companies. Yet, that seems to be exactly what has been done. Maybe we should be flattered, and maybe in 25 years, the shoe will fit—I guess I should say, not if we shoot ourselves in the foot that the shoe is supposed to fit. But it doesn't now fit, and to assert that it does renders a great disservice to an emerging industry observers around the world regard with awe and with envy.

The new biotech companies, even the strongest of us, need every penny we have and then some to compete effectively as we are determined to do. Our interpretation of the compromise is that we would be required to allocate a rather substantial amount of our resources to fighting people who would be bird-dogging us with ANDA's.

Mr. KASTENMEIER. Dr. Cape, let me interrupt, to see if I understand what you are saying.

You are saying that the biotechnology companies are, in fact, different from the traditional drug research companies in what connection? You start out with—you don't really start out with a new chemical compound which you seek a patent for and you go through this preclinical and clinical testing and seek FDA approval—do you go through the same process?

Dr. CAPE. Identical.

Mr. KASTENMEIER. Identical. In what respects are you different?

Dr. CAPE. Our pipeline is empty. Basically we are starting to fill the pipeline now. When our pipeline is full, a period of 10, 15, 20 years from now, then this kind of quid pro quo makes sense. At the present time, with all of us in a situation where extending our patent from sometime way in the future to sometime a little bit further in the future is no big favor, and forcing us to fight off people is detrimental to our industry. Every time we make a breakthrough, there will be 25 companies filing ANDA's, requiring our Patent and Trademarks Department to be tripled or quadrupled in size to deal with them all. Backing away from all the theory we have heard today, and just being pragmatic, it is going to represent an enormous load, an additional unnecessary and negative load on the biotech industry.

Mr. KASTENMEIER. I see. Actually, from your standpoint, two years ago when we were dealing with H.R. 6444, which didn't have an abbreviated new drug application feature and was prospective only—year 2000 was the first year that you could have an extension—and did adversely affect some large companies with—that is, in terms of expectations with a great deal in the pipeline—that would have been more or less an ideal bill for you since it wouldn't—it was prospective only; it didn't contain collateral concessions to your competitors perhaps that this bill appears to contain——

Dr. CAPE. That is correct.

Mr. KASTENMEIER. Is that correct?

Dr. CAPE. Yes, and I guess my appeal is—I will use the word again, a "pragmatic" one. That is just what is going to happen, we think, if this sort of compromise without some amendments—and we do have specific wording that we would like, of course, to suggest, having given it some thought, is permitted to exist in its present form.

So I only have less than a minute of concluding remarks to say and that is, we believe that H.R. 3605 should survive, but it should be amended to avoid impeding biotech research. We think that biotechnology is the unintentional victim, the orphan, if you like, of the compromise to facilitate availability of generic drugs.

Representative Waxman sponsored legislation to help orphan drugs. Maybe, pursuing that metaphor, we are orphan companies which, at this point in time, as a strategic question on the part of our Government, need some kind of help and this would be the kind of help that could fit into that picture.

We are all for letting the generic houses have access in the way contemplated in this H.R. 3605 to existing drugs, but we think that there should be exclusion for future drugs which are the products of biotechnology and, in this way, the resolution would support, rather than undermine, our efforts to make these advances. This

technology was invented in California and developed in the United States far more effectively than anywhere else in the world and we should make these advances available to the American public as soon as possible.

That completes my oral presentation. Thank you again, Mr. Chairman.

[The statement of Dr. Cape follows:]

STATEMENT OF DR. RONALD E. CAPE
CHAIRMAN AND CHIEF EXECUTIVE OFFICER
CETUS CORPORATION
BEFORE THE
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE
ADMINISTRATION OF JUSTICE
OF THE
COMMITTEE ON THE JUDICIARY
U.S. HOUSE OF REPRESENTATIVES
HEARINGS ON H.R. 3605
JUNE 27, 1984

Mr. Chairman and Members of the Subcommittee:

My name is Ronald E. Cape. I am the Chairman and Chief Executive Officer of Cetus Corporation. Accompanying me is Harold C. Wegner of Wegner & Bretschneider, an attorney for Cetus and an adjunct Professor of Law at Georgetown University.

Since 1971, Cetus has pioneered the commercial application of biotechnology in the development of new or improved products and processes for human and animal healthcare and for the production of food, energy and chemicals. Cetus-modified microorganisms are currently used in the commercial production of antibiotics, vitamin B_{12}, and an animal vaccine containing components developed by Cetus through recombinant DNA technology.

Cetus has produced two potential therapeutic products through recombinant DNA that are now in human clinical trials. Preclinical data has indicated that these two products, beta-interferon and interleukin-2, may have significant value in the treatment of certain cancers and infectious diseases, including AIDS.

At Cetus Corporation we are proud that our pioneering efforts over the past decade have contributed to the development of the

biotechnology industry. We are now in a position to demonstrate the promise of this industry by making new therapeutics and diagnostics available to the American consumer. However, continued success in meeting this goal depends upon whether our substantial investment of time and resources can be protected on an exclusive basis for a reasonable period.

Stimulation of biotechnology is important and not at all inconsistent with the objectives of H.R. 3605. We are in complete agreement with the goals of H.R. 3605 to foster availability of drugs through the generic drug industry and to foster a return on the investment made to develop new pioneer drugs. Our concern is that the present form of the bill, as it relates to biotechnology companies, requires revision before those goals can be reached in a fair and reasonable manner.

Cetus has not been included in the discussions of the past months between the generic and research-based pharmaceutical companies, which have resulted in this Bill. We were not invited to these lengthy negotiations, nor did there appear to be any reason to become involved in a process that would reach the laudable goal of providing inexpensive, off-patent drugs to the public. After all, our potentially most significant products, such as the potential cancer therapeutics, are still in clinical trials or in our research laboratories. The patents covering these products will not expire until the turn of the century.

We understand the desire to "balance" the benefits gained by the established pharmaceutical companies through extension of the patents on their marketed drugs with the ANDA process of Title I of the bill. We make no comment on whether this is the appropriate balance in the context of the varying interests of the established pharmaceutical companies and the generic drug industry. However, this compromise does have an inadvertent but

substantial negative impact on companies such as ours. Title I will severely hamper our efforts to bring new products to the market, and yet no immediate counterbalancing benefit will be provided to us under Title II.

Congress, more than any other institution in America, recognizes the importance of incentives to domestic industry, including biotechnology. Congress also fully recognizes the important role that biotechnology is playing in the development of new drugs, including the search for products to detect and treat cancer. We read H.R. 3605 to possibly provide a disincentive to this vital research, albeit unintentional.

An amendment is needed to avoid the new biotechnology research disincentives for development of our vitally important industry, without therewith removing a single pharmaceutical product now in the marketplace from eligibility for an Abbreviated New Drug Application (ANDA).

Biotechnology, including its most modern tools of recombinant DNA and monoclonal antibody research, holds the promise of unlocking the secrets of the diseases that the established pharmaceutical industry has failed to unlock through usual chemical means. Thus, we are close to the early detection and treatment of cancer and highly infectious diseases such as AIDS.

We fully agree with the general principle that after the expiration of a patent, generic competition should be permitted, and indeed encouraged. Unfortunately, the present bill achieves this objective in a manner which creates several disincentives to future biotechnology research and could result in the delay of important new biotechnology products and reduce the number of drugs that will become available to the generic industry.

We support the concept that inexpensive drugs should be available after the pioneer has had a reasonable period for an exclusive position. Legislation meeting that objective could be passed, without affecting the biotechnology industry in an inequitable fashion.

I. CANCER DETECTION AND TREATMENT, THE PROMISE OF BIOTECHNOLOGY

We take particular pride in what the American biotechnology community has accomplished in just a few years, and, more importantly, in what can be done in the next decade in the important areas of cancer detection and treatment. There will not be a single "cure" for cancer. But many specific types of cancer will be "fingerprinted" for early detection. Above all, ongoing research efforts hold the promise of actual cures for specific cancers.

II. THE RIGHT CLIMATE FOR BIOTECHNOLOGY RESEARCH - THE BIG RISKS

Millions of dollars are required for research and regulatory approval of the breakthrough drugs being pioneered by the emerging biotechnology companies. Such an investment is undertaken in the hope that a particular recombinant DNA or monoclonal antibody invention can be developed in a safe and effective drug. In cancer treatment, a particular success may help only a small fraction of the population that has or will get cancer; with each success further research is needed for the next type of cancer.

Biotechnology companies in the United States can survive, and even flourish, in the expensive and risky world of cancer research with the current protections of the FDA and the patent system:

- Under FDA regulations, third parties are restricted from copying the exact approved formulation (but are totally free to either reduplicate the regulatory work or to make a different, competitive product).

- The patent rights in biotechnology under the present scheme are quiet rights, by and large free from short range litigation.

III. WHILE JAPAN PROVIDES GOVERNMENTAL STIMULATION TO BIOTECHNOLOGY RESEARCH, CONGRESS SHOULD NOT PROVIDE A DISINCENTIVE TO DOMESTIC-BASED BIOTECHNOLOGY RESEARCH

The limited period of exclusivity that is today fairly certain provides the necessary incentive for future and continued cancer research. Both the United States and Japan presently provide this climate.

Just in the past ten years, Japan has made many statutory and regulatory changes to benefit pharmaceutical and biotechnological research. The patent law was greatly strengthened for pharmaceutical product protection; pricing policies for pharmaceuticals have put a premium on pioneer research; high technology drugs are given a period of up to six years exclusivity for marketing independent of the patent right.

Congress is keenly aware of the threat of international competition in biotechnology. Just this year the Office of Technology Assessment (OTA) has published a report manifesting the urgent need for progressive legislation. Commercial Biotechnology: An International Analysis (Washington, D.C.: U.S. Congress, Office of Technology Assessment, OTA-BA-281, January 1984) ("OTA Report"). The report summarizes that:

> Although the United States is currently the world leader in both basic science and commercial development of new biotechnology, continuation of the initial preeminence of American companies in the commercialization of new biotechnology is not assured. Japan and other countries have identified new biotechnology as a promising areas for economic growth and have therefore invested quite heavily in R&D in this field.
> [OTA Report, page 3.]

IV. AMERICAN-BASED BIOTECHNOLOGY RESEARCH

With the present wording of H.R. 3605, the biotechnology industry is trapped in ways obviously unintended and undoubtedly unforeseen which hit directly at the heart of the two present regulatory safeguards, freedom from ANDA competition and quiet patent title.

A. ANDA Freedom for a Reasonable Period

Exclusivity for a reasonable period of time is now a guarantee under the present law, as there is no ANDA possibility. Biotechnology needs a certain period of exclusivity free from ANDA competition for future drugs, as patent litigation would seriously dilute our clinical and research efforts. A number of finally litigated patent infringement test cases in modern biotechnology are necessary before conservative reliance can be placed exclusively on the patent system. In the modern biotechnology areas of both recombinant DNA and hybridomas, the total number of such finally litigated test cases is zero. Particularly throughout this decade when biotechnology patent case law has not been crystallized, we need freedom from ANDA's. Otherwise, it becomes virtually impossible to justify the investment in the sophisticated level of research necessary to enter the biotechnology marketplace.

To optimize present investment in biotechnology research, there simply must be a promise independent of the patent system that,

after spending the tens of millions of dollars for research and regulatory review, a marketing position can be secured against "me too" competitors unwilling to incur these substantial costs and risks. Provision for an abbreviated new drug application (ANDA) immediately is unthinkable. Such competitors will discourage companies such as ours from making these investments.

Japan and the major European countries all give the pioneer a reasonable period of exclusivity for pharmaceuticals independent of the patent right.

It would be ironic when Japan provides an exclusive period for marketing of up to six years for new drugs under its Health Ministry regulations, for America to turn the opposite way and eliminate ANDA freedom altogether, except for the limited circumstances of the bill.

B. The Litigation Incentives

The two titles of the bill taken together provide a strong incentive to litigate patents at the earliest stage. Whatever merit this may or may not have for more traditional areas of "big drug" research, this is the last thing needed for the relatively small and young biotechnology drug companies. At present, there is zero precedential law directly on point for biotechnology patent infringement in recombinant DNA and monoclonal technoligies. A carte blanche to foster early litigation will force the new American biotechnology industry to allocate a larger share of its resources for litigation of its patents, as opposed to investments in cancer research itself.

Cetus has had substantial funding and has a first class patent department. We expect the company to do quite well. Others may not be so fortunate.

C. The Cash Flow of Biotechnology is Unique

Biotechnology companies are unique in the pharmaceutical field not only in terms of the patent situation, but more importantly from the viewpoint of their infant position in a major industry. Development of these products requires large investment of risk capital over a long period of time before substantial return can be realized.

Unlike the rich and established pharmaceutical companies, the vitality of the biotechnology industry is dependent upon careful conservation of cash. The major drug companies may invest money in patent litigation or the uncertainties of exclusivity. We do not believe this is an appropriate basis for the independent biotechnology companies. Yet, the promise of cancer detection and therapy is being met by the smaller, independent biotechnology companies that have shown the initiatives of the past few short years.

V. PATENT TERM RESTORATION

A. Cetus Supports (but Can Live Without) Patent Extension

Cetus supports patent term "extension" or "restoration", and perhaps that is a necessary goal for the traditional established drug companies. But, in the context of the 1980's, with Cetus' patent position on any new drugs expected to run to the year 2000, whether the patent expires in the year 2006 instead of the year 2001 is hardly a major factor in today's biotechnology investment decisions.

B. Section 202 and Pre-Expiration Testing

Recombinant DNA technology will not go off patent on any major scale until after the year 2000. Whether a third party starts his clinical trials after a patent expires in 2001 or gets an early jump in the year 1999, is not just vitally important to our industry at this time. What is critical is that we provide Americans with new biotechnology drugs and methods of disease detection during the next ten years to create a new industry for future generations.

VI. AMENDMENTS TO TITLE I TO KEEP FUTURE BIOTECHNOLOGY RESEARCH OPEN

Cetus and the other biotechnology independents must be given relief from the inequitable and unintended effects of Title I. Whatever happens in Title II may have long range importance, but is clearly not of immediate benefit to such independents.

Cetus is sympathetic to the goal of post-patent expiration drug competition. We wish to cooperate with Congress in achieving the goal of price competition, while providing a safe harbor for biotechnology research to continue and grow in California and elsewhere in the United States. We believe that this goal most sensibly would be achieved by providing a prospective exemption to new drugs from biotechnology research (recombinant DNA and hybridomas). Let the generic industry have all existing drugs now on the market, if that is the will of the traditional drug industry and the generics.

A. Cancer Research, Not Painkillers and Antidepressants

A biotechnology company is not fungible with any of the old line pharmaceutical companies. What is good for the majors is not necessarily good for our developing industry. Cetus speaks for its own very real concern that its research in high technology areas such as cancer will suffer in the absence of special Congressional recognition of the unique problems caused by ANDA competition for biotechnology products.

Biotechnology research should be left out of the bill, or be given a more equitable treatment. Otherwise Cetus and the other biotechnology companies will be unable to address some of the more important life-saving areas such as cancer detection and treatment in their fullest capacities.

The more general non-biotechnology pharmaceutical industry is not the concern of the biotechnology companies. We are not impacted directly by whether the generic industry should or should not use traditional chemical synthetic routes to make a slightly different proprietary product with the same indication as the old product. We are thus not in the business of determining whether there should be a slightly better painkiller, a more precisely acting antidepressant, or a different sleeping pill. These are the primary concerns of the established pharmaceuticals companies.

B. Prospective Relief is All Cetus Asks

Cetus has no interest in taking away any existing drug from the marketplace. We only seek the incentives for future research gained through an exception to H.R. 3605 for biotechnology.

This is far more in the public interest than the present wording of H.R. 3605, which even gives equitable relief in the case of some already approved drugs. Certain drugs already approved (but only since January 1, 1982) would be taken away from the supply of drugs to the generics under proposed 21 USC §505(j)(4)(D)(i). Biotechnology needs at least the same freedom.

VII. SECTION 202 ENCOURAGES LITIGATION

Cetus is deeply troubled by Section 202 and particularly the invitation to litigate that is built into 35 USC §271(e)(2) and §271(e)(4).

If the relief sought in Title I is not forthcoming, biotechnology companies will indeed have to beef up their litigation budget and cut down on their future plans for at least domestic R&D expansion. The fuel of Section 202 added to the fire of a broad Title I is unacceptable.

With an exemption from ANDA's proposed under Title I, then the effects of Section 202 on biotechnology would be greatly reduced.

VIII. EVERYONE BENEFITS FROM STRONG AMERICAN BIOTECHNOLOGY

All benefit from a strong domestic biotechnology industry:

A. The Public...

The majority of cancer victims today die, despite some significant progress in chemotherapy. All suffer a significant impaired quality of life due to the side effects of this chemotherapy. Many physicians resist such treatment until there is no other recourse. Biotechnology products offer not only the promise of improved therapy, but the avoidance of these terrible

effects. These products will be used much earlier in the course of therapy with much better results. The keys to a virtual revolution in chemotherapy are available from modern biotechnology of the 1980's. If biotechnology is given the climate to grow, some cancers are sure to be successfully detected and attacked in the 1980's, more in the 1990's, and then at some point in the next century cancer may become a disease of the past.

Whether we reach the promise of the 1990's already in this decade or perhaps only in the next century will be governed largely by the regulatory climate: Will money be put into cancer research or will better aspirin substitutes, Valium's and the like be where America puts its money?

B. American Industry ...

The United States and Japan are struggling for preeminence in biotechnology. We welcome this open competition, and everyone in both countries and indeed the world will benefit. But as Japan improves its regulatory climate and incentives for biotechnology, America should not move backward to cripple our competitive efforts.

C. The Generic Industry ...

The generic industry has shown no interest in moving into complex biotechnology. Virtually no products are available for an ANDA even without any restrictions, and the technology is far different and more sophisticated than conventional pharmaceuticals.

For the future, if the generic industry of the 1990's wants to move into biotechnology, a strong patent and regulatory climate now will lead to a large number of products which then may be available for such expansion. Without a strong system now, there may be no market to enter.

We hope that we may have the opportunity to aid the committee in recognizing the effect of this bill on our industry, and the need for careful consideration of the issues raised today. We hope to achieve an early resolution of these matters so that the objectives of the bill can be met in the fairest and most reasonable way.

Thank you, Mr. Chairman.

Mr. KASTENMEIER. Thank you, Dr. Cape.

Do you have an additional problem with respect to the testing of patents in the genetic engineering field as to their validity? Are you real sanguine about that or is that——

Dr. CAPE. We will both say something about that, but again, rather briefly, the problem is that we are in early days, as the British would say. There is nothing clarified by actual decisions, by actual contests. There is a great deal of patent activity on the part of the major biotech firms, there is no question about it, and all of us have optimistic expectations, but that is all in the future and nothing is definite.

We sure don't want that complicated so that every time a patent is granted the patentee, as I said, by being bird-dogged by a host of ANDA's, where, as somebody has pointed out earlier here today, the burden is on the patentee and triggers are fired by other people.

Mr. Wegner, would you like to add——

Mr. WEGNER. Yes, Mr. Chairman; I think that we have no track record in the enforcement of recombinant DNA or monoclonal antibody patents, the two areas of technology that we are dealing with in Cetus or any of the biotechnology companies.

There is—*Diamond* v. *Chakrabarty*—we all know that this opened the door to patenting of life forms, but all it said—this was the Supreme Court case of 2 years ago—all this said was that these new inventions will have to be judged by regular patentability standards. We have special situations in biotechnology. Sometimes we are creating a polypeptide which will have certain activity which may be very similar to a natural polypeptide.

What doctrines will evolve in the scope of protection? We have a product-by-process doctrine going back to *Cochran* v. *Badischa. Anilin,* the first organic chemistry case back from the Supreme Court back in the last century which says that the scope of a product patent which is defined in terms of a process is limited to that particular process. How will the Federal circuit interpret these patents in the future? How will the validity be determined? I think there is no track record in any Federal circuit level and to my knowledge, any district court level on a recombinant DNA patent enforcement.

It is a wild card. Where are we going to go? We need some certainty in biotechnology so that if we invest the 10's or 30's or any millions of dollars, we know that for a certain period of time, we are going to have a quiet patent title.

Now, what Congressman Synar talked about earlier today, is that it will be easier to challenge validity of a patent. We have no objection to a challenge of validity of a patent. If a patent is valid, it should stand; if it isn't, it shouldn't. But what will happen as a byproduct of this bill, if it applies to biotechnology, if we strip away the freedom from ANDA's, is that every time a new effective drug comes on the market, there will be a validity challenge. Will Cetus, will the other companies have to enlarge their patent departments, hire New York law firms and spend their money in patent litigation to defend the validity of their patents or will they put it in new cancer research?

The threat is very real. It is not imagined. The Koprowski patent is a basic hybridoma patent. When its counterpart Japanese application was published for opposition, 27 opponents opposed this patent. That was just last year. We don't need this litigation. We need to put our money into cancer research.

Mr. KASTENMEIER. For many of your therapies and your discoveries, I take it you need FDA approval for marketing. Do you also have substances or materials for which you do not or which you may need EPA approval?

Dr. CAPE. That is presently under rather broad discussion. There was an article in the New York Times about it this very morning in which I noted with some chagrin that somebody in the Office of the Executive used the phrase, "Let's not shoot ourselves in the foot," and I figured I had been upstaged today.

But the fact is that there are regulatory vacuums; these should be filled in one way or another, we believe. The fact remains, however, that most of our work either falls into the FDA category or environmental categories.

We anticipate having to address precisely the same regulatory sequence of events that major companies do and we budget for it and we expect to behave that way.

Mr. KASTENMEIER. I notice that the report speaks of so-called unpatentable drugs, stating that if the active ingredient drug is approved for the first time in an ANDA after the enactment of the bill, then a certain section provides FDA may not make the approval of a paper NDA for a drug that contains that active ingredient effective until 4 years after the approval of the NDA if certain conditions are met.

Are you affected, then, by these—by that section, the so-called unpatentable drug?

Mr. WEGNER. No, we are not, Congressman. I am glad you raised that point because none of the witnesses had raised it. That is another infirmity in the bill.

We would have to certify that the invention is unpatentable to benefit from this provision. Now, we don't think our inventions are unpatentable. We are anxiously awaiting the test cases that will come out—whether it is next year, 10 years from now—and we may not have control over those test cases. We hope that our patents are very fine.

Cetus has developed an excellent in-house patent department, and procures good patents. We hope that they won't be our cases, but what the test case will be, who the parties are, nobody knows, and what these first test cases will decide will determine what will happen in the not-too-distant future.

So we do not benefit from this section because we cannot certify the inventions are unpatentable.

Mr. KASTENMEIER. Thank you.

I would like to yield to my colleague from California.

Mr. MOORHEAD. Thank you. It is good to have another——

Mr. KASTENMEIER. Incidentally, for the record, and I think the reporter has for the record, the other gentleman speaking is Harold C. Wegner.

Mr. MOORHEAD. I am going to ask you a rather general question to begin with, but which is one that requires some specifics.

We only have a brief period of time with this bill and we have got to make decisions on it relatively fast. I think our committee has until August 7th and that is all and we are going to be in adjournment much of that time. Would you tell us in outline form, perhaps, exactly and specifically in the bill the things that you object to and how you would change them.

Mr. WEGNER. I think I would probably need several hours to go through the entire bill.

Mr. MOORHEAD. I wish you would, then, and——

Mr. WEGNER. All right.

Mr. MOORHEAD [continuing]. Present that in written form to the committee so that it is in the record of the committee.

Mr. WEGNER. I will be glad to do that.

[The information follows:]

WEGNER & BRETSCHNEIDER

Analysis of H.R. 3605, by Harold C. Wegner
Committee Insert to Testimony on June 27, 1984
Subcommittee on Courts, Civil Liberties
and the Administration of Justice

In response to your request during the June 27, 1984 hearings on H.R. 3605, I am pleased to provide my personal analysis of the proposed legislation. This letter is written as my personal response, and does not necessarily reflect the views of Cetus Corporation.

Stimulation of future research in this country should be a primary concern of congressional action. Maintenance of a stable patent law will foster research in particular by avoidance of international repercussions which would adversely affect American exports of pharmaceuticals. Amidst many concerns, the manifest unconstitutionality of Section 202 is most striking; this is clearly suggested in the Supreme Court's June 26, 1984 ruling in Ruckelshaus v. Monsanto Co., -- U.S. --, 52 LW 4886 (1984).

The "delicately balanced compromise" embodied in H.R. 3605 is primarily directed to exploitation of existing drugs. Let all the existing off-patent drugs go immediately or as soon as possible to the generic industry. This goal is very much in the public interest, but is one that can be achieved without doing violence to the patent law and future research incentives.

WEGNER & BRETSCHNEIDER

Analysis of H.R. 3605, by Harold C. Wegner
Committee Insert to Testimony on June 27, 1984
Subcommittee on Courts, Civil Liberties
and the Administration of Justice

I. TITLE I ANDA FREEDOM SHOULD BE INDEPENDENT OF PATENTS

Abbreviated New Drug Application (ANDA) freedom should have nothing to do with the presence or absence of a patent. ANDA requirements should stand on their own merits. There is no incentive to develop pioneer products under an expired patent.

The enlighted approach of the last Congress in the Orphan Drug Act should be applied, independent of the patent laws. Not one single existing drug now on the market would be affected by this approach. The public would be the primary beneficiary, as pharmaceutical companies could elect the best drug for clinical development, patented or not, and not merely the best patented drug. Additional drugs could be put into the pipeline, giving the generics and public alike more competition and a wider selection of therapies.

A. Patents Should be Divorced from the ANDA

1. Public Safety

The public safety requires a minimum period without ANDA competition. The Japanese Health Ministry provides its citizens with such a safety factor of up to six years. America should do no less for its own citizens.

If the drug is patent-protected, then the public safety is incidentally assured because the patent holder can elect to take measures to defer ANDA approval for much longer than the minimum period needed for safety determination. But should this safety be keyed to the private patentee's interests in maintaining his patent right? If the drug is seemingly good but the patent weak, should this make a difference in quick ANDA approvals for new drugs?

2. Minimum Periods of Exclusivity to Encourage Research

In 1984, when the generic drug industry seeks literally a generation of new products that have been free from ANDA's since 1962, surely the appetite of the generics and the public for new generic drugs will be more than completely satisfied by giving ANDA's on existing products. Future products should be given some period of freedom from an ANDA.

The Waxman bill in its present form discourages much drug research, and would lead to a concentration of the pioneer industry in major drug houses with fewer and fewer competitive products. This is the antithesis of the free competition that is a primary object of the Waxman bill.

a. Eliminating the Second Drug

Within the scope of a "garden variety" patent to a new class of compounds, there are literally thousands of possible compounds within the scope of the broadest claim, and often ten or twenty or more compounds actually made that are disclosed in the patent.

To be sure, the present bill does encourage the patentee to quickly select one of these drugs as soon as possible for clinical trials. But what happens to the second drug that misses out in the screening? What happens to the thousandth drug that is within the scope of the patent, but not immediately synthesized?

Public policy quite clearly favors the development of several drugs, and not just one, even when the products are roughly equivalent. A certain percentage of the population may develop side effects only to one of the drugs. Perhaps these side effects are only recognized late, even after approval of the first drug. Advanced clinical testing may show that the second is actually far better.

Equally important is the competitive factor that is so important in maintaining reasonable prices for drugs. It is fundamental that if a company is encouraged to place a second

drug in the marketplace in competition with the first, everyone benefits from such competition.

b. Orphaned Projects

Some drugs may not be developed as products usable with patients until late in the life of a patent, or not even be considered for development until after the patent has expired. The present wording of the bill provides zero exemption from ANDA competition where the patent has expired or is invalid. Patent validity and expiration surely have no rational relationship to whether it is in the public interest to develop a new, life-saving product and release it for safe public use.

3. The Bill Favors the Big Multinational Drug Company

For the major multinational established drug companies working in the ordered world of conventionally produced drugs, it is possible to predict with a relatively high degree of certainty whether a valid patent can be obtained for a particular drug. These same multinational drug companies also have the resources to immediately commence regulatory tests for a promising product.

B. "Unpatentable" Drugs [21 USC §505(j)(4)(D)(ii)]

Proposed 21 USC §505(j)(4)(D)(ii) would give a four (4) year period of exclusivity for future drugs, but only if the drug is certified as being unpatentable.

This provision takes no account whatsoever of those cases where the patent has not yet been granted (which can occur in an interference), where the patent has expired, or where a court may find a patent invalid.

C. Amendment to Title I to protect Orphan Drugs

In the hearings of June 27, 1984, Dr. Cape proposed that freedom from ANDA competition be provided for cancer inventions. That proposal would take care of biotechnology research in the cancer area. A broader solution for all future research patterned after the Cape proposal is considered here:

1. Patent-Free ANDA Freedom

Proposed 21 USC §505(j)(4)(D) should be modified as follows to provide a reasonable, prospective patent-free period of ANDA freedom:

If an application submitted under subsection (b) for a drug is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

Parallel wording changes are required in 21 USC §505(c)(3)(D).

2. ANDA Freedom Should Not be Patent Based

If, after a reasonable period of exclusivity, the patent is invalid, then clearly there is no reason why a generic competitor should wait a moment longer to seek his approval. The patent owner has his remedy in court. Indeed, the principles of the patent system antedate the birth of modern pharmaceutical chemistry. The same principles of damages and injunctive relief developed largely for machines and mechanical devices and instruments can be used in the pharmaceutical field, as they have been used.

II. "PATENT INFORMATION"

"Patent information" must be promptly filed by a pioneer or that pioneer forfeits any right to hold up an ANDA prior to expiration of the patent, as explicitly provided under proposed 21 USC §505(j)(2)(vii)(I).

There is no demonstrated need for including "patent information" in Title 21, a drug law. The obvious objective of the generic industry is to avoid doing a simple patent infringement search; quite clearly, that objective will not necessarily be met through the voluntary patent information reporting requirement, which in some ways is inferior from the patentee's standpoint to the traditional remedy under patent code.

III. PATENT EXTENSION

A. The Glickman-DeWine Bill, H.R. 5529 as a Model

The Glickman-DeWine Agricultural Patent Reform Act of 1984, H.R. 5529, is a good example of positive legislation that fosters the introduction of new products and that gives both the possibility of an active ingredient free from side-effects of existing products and further competition for existing products.

One of the important points that must be remembered as a principal benefit of a new patented product is that it is almost always in competition with existing, and often patented, products. Where the incentives are provided by the patent system to introduce many competitive products, each product being patent protected, then the consumer benefits by diversity of products and price competition.

B. "Evergreening" with Multiple Patents

Evergreening of the patent right is a new term of art that is understood to mean that the patentee in some instances obtains far more than a 17 year exclusive period through multiple patents.

Whether this is a big problem as suggested by the generics or a minor problem as answered by the drug industry, the simple solution is a cap on the total period of extension keyed to the earliest effective filing date for the product under 35 USC §120.

The simple capping of the term based upon a fixed number of years eliminates the need for the unduly complicated paperwork that creates an undue administrative burden on the Patent and Trademark Office and patentees alike.

Some earlier proposals had included reference to 35 USC §119, which deals with a foreign priority right. This solution is not possible without creating an express violation of the Paris Convention. In fact, the Paris Convention provision helps American industry in countries like Japan where the American receives a one-year bonus through his priority right being excluded from the reckoning of the term of the patent grant.

IV. CONSTITUTIONAL AND POLICY CONSIDERATIONS IN THE BOLAR CASE

The generic industry wishes to test drugs patented by others prior to patent expiration, and to retroactively overrule Roche Products, Inc. v. Bolar Pharmaceutical Co. Inc, __ F.2d __ , 221 USPQ 937 (Fed. Cir. 1984). Such retroactive application would be a violation of the Fifth Amendment. See Ruckelshaus v. Monsanto Co., __ U.S. ___, 52 LW 4886 (1984).

The proposal to overrule Bolar is found in the first portion of Section 202, namely proposed 35 USC §271(e)(1). The other portions of Section 202 are considered infra.

Prospectively or retroactively, overruling Bolar would dangerously imperil American efforts to sell drugs abroad on an exclusive basis, undermining more than a generation of efforts to stimulate broad patent rights in overseas patent systems. The

great strength of American foreign rights has both brought money to our shores and spread the cost of new drug development here to the shoulders of Europeans, Japanese and others.

A prospective reversal of Bolar tied to patent term restoration may be equitable and fair. A fair compromise under H.R. 3605 without Section 202 should be tied to patent term restoration. As the quid pro quo for the patent extension, the patentee's extension should exclude the Bolar activity. It is proposed that 35 USC §156(b) be rewritten in its entirety as follows:

> The rights of the patentee during the extension shall be limited to the approved product, exclusive of the use thereof under section 505(j) of Title 21, United States Code.

A. The Interface Between Drug Regulatory and Patent Laws

The Bolar case is typical of the era of heightened concern for public welfare that has made regulatory approval of drugs so expensive and time-consuming, upon which the need for patent term restoration legislation is based. As well recognized by Congress, and as judicially recognized in Bolar, __ F.2d at ___, 221 USPQ at 941, there is an approximately ten year loss in the life of a patent: Even though the patent term commences from the

grant of the patent, the right to market a drug, patented or not, commences only after a lengthy regulatory process that is generally completed long after the patent term starts running.

Of partial solace to the patentee is the knowledge that a generic competitor cannot come on the market immediately after expiration of the patent, but can only start domestic regulatory tests for approval after expiration thereof. This translates into an effective market entry barrier of up to about two years after expiration of the patent, but this still only partially compensates the patentee for the tremendously long pendency and expense of an approval for a pioneer drug.

B. The Bolar Facts

The Bolar case appears to have been engineered as a test case to attempt to judicially change the patent statute.

Flurazepam hydrochloride is a Roche drug which took many years for pioneer regulatory approval. Generic competitor Bolar wished to market flurazepam hydrochloride immediately upon the expiration of the patent (which expired earlier this year), and thus wished to do its own regulatory tests prior to expiration. It was exactly this pre-patent expiration testing for commercial

purposes that was confirmed as an infringing "use" under 35 USC §271(a) in the Bolar case.

C. The Court's Ruling in Bolar

1. The Patent Right has Always Covered Commercial Tests

Anglo-American jurisprudence for patent law goes back to at least the seventeenth century, and was first codified as part of the Statute of Monopolies of 1624; colonial patents were granted starting with Massachusetts in the 1640's; Congress was given an express constitutional mandate to write a patent law; and we had our very first federal patent statute in 1790. Throughout our history, the patent right has consisted entirely of the right to exclude others from making, using or selling the invention for any business purpose. As the Bolar court itself notes with respect to the 1952 codification of the patent law, "[35 USC §] 271(a) prohibits, on its face, any and all uses of a patented invention." __ F.2d at ___, 221 USPQ at 939.

To be sure, there is an "experimental use" exception dating back to the landmark opinion more than 170 years ago of the nation's first great jurist on patent law, Justice Story, in Whittemore v. Cutter, 29 F.Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600). It has been apparent for more than a full century

that this exception could not cover a commercially oriented use as contemplated by Bolar. ___ F.2d at ___, 221 USPQ at 939-940.

2. The Total Absence of Any Holdings Favoring Bolar

Bolar's briefs and that of its amicus are notable by their failure to cite a single case from the Supreme Court, or any Circuit, that even remotely has a holding "on all fours" with the holding sought. A long list of cases is cited which shows the absence of any doctrine to support the Bolar position. ___ F.2d at ___, 221 USPQ at 939-940. Indeed, the clarity of the law is so striking that there has been virtually no need to litigate this point, although there is the noteworthy decision of a District Court, Pfizer, Inc. v. International Rectifier Corp., 217 USPQ 157 (C.D. Cal. 1982), cited with approval in Bolar, ___ F.2d at ___, 221 USPQ at 942.

3. Bolar Recognized its Odyssey into Judicial Legislation

Bolar itself recognized that it was seeking judicial legislation to transform an experimental use exception in the law into what could be more aptly termed a commercial use exception. Thus, as pointed out in the Bolar case itself, Bolar recognized:

that its intended use of [flurazepam hydrochloride] does not fall within the "traditional limits" of the experimental use exception as established in [the cited cases] or those of other circuits. Its concession here is fatal.
[Bolar, ___ F.2d ___, 221 USPQ at 940]

Later, the point is reemphasized:

Bolar argues that even if no established doctrine exists with which it can escape liability for patent infringement, public policy requires that we create a new exception to the use prohibition. Parties and amici seem to think, in particular, that we must resolve a conflict between the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§301-392 (1982), and the Patent Act of 1952, or at least the Acts' respective policies and purposes. We decline that opportunity here, however, to engage in legislative activity proper only for the Congress.
[Bolar, __ F.2d at __, 221 USPQ at 941; emphasis supplied in part]

C. Section 202 is a Proscribed Fifth Amendment "Taking"

1. Taking the Patentee's Property

Proposed 35 USC §271(e)(1) takes away a major part of the patentee's right to exclude others. As clearly seen from the Bolar opinion itself, the infinger Bolar was attempting to effectively cut off two years of exclusive marketing by the patent owner.

2. The Right to Exclude is All the Patentee is Given

At first blush, one may wonder whether elimination of a patentee's right to exclude others in the final two years of his patent is a substantial encroachment on his patent right. To understand whether this is a substantial encroachment or not, one must go to the essence of what constitutes "patent property".

There is nothing other than the exclusionary right that exists. There is only the right to exclude others that is given by a patent. Nothing more.

Accordingly, taking away the patent owner's right to exclude strikes at the very heart of the patentee's right.

WEGNER & BRETSCHNEIDER

Analysis of H.R. 3605, by Harold C. Wegner
Committee Insert to Testimony on June 27, 1984
Subcommittee on Courts, Civil Liberties
and the Administration of Justice

The June 26, 1984, Supreme Court opinion in Ruckelshaus v. Monsanto Co., __ U.S. ___, 52 LW 4886 (1984), follows more than a century of case law which confirms the exclusionary nature of an intellectual property right:

> The right to exclude others is generally "one of the most essential sticks in the bundle of rights that are commonly characterized as property." Kaiser Aetna [v. United States], 444 U.S. [164], at 176 [(1979)] With respect to a trade secret, the right to exclude others is central to the very definition of the property interest.

While Monsanto deals with trade secrets and not patents, the Supreme Court has recognized the fundamental exclusionary nature of the patent right for more than a full century. The early case law is summarized by one pronouncement nearly 75 years ago, Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 425 (1908), quoting with approval from Bloomer v. McQuewan, 14 How. 539, 549:

> The franchise which the patent grants consists altogether in the right to exclude every one from making, using, or vending the thing patented, without the permission of the patentee. This is all that he obtains by the patent.

Analysis of H.R. 3605, by Harold C. Wegner
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The Monsanto determination of a property right has generated some surprise; the surprise is this reaction, and hardly the decision itself, which is nothing more than hornbook law going back more than a century. The Supreme Court in James v. Campbell, 104 U.S. 356 (1882), noted the "exclusive property in [a] patented invention" and that it:

> cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser ****

Later, in Hollister v. Benedict Manufacturing Co., 113 U.S. 59 (1884), the Court reiterated its James pronouncement in the context of the Fifth Amendment "taking" issue:

> It was authoritatively declared in James v. Campbell, 104 U.S. 356, that the right of the patentee *** was exclusive *** and stood on the footing of all other property, the right to which was secured, as against the government, by the constitutional guaranty which prohibits the taking of private property for public use without compensation,***
> [113 U.S. 59 at 67; emphasis supplied]

D. Constitutional Questions in the Revision of the Patent Law

1. Prospective Reversal, Unwise but Surely Constitutional

In a period of nearly two full centuries, Congress has consistently chosen to draft a broad patent law, operating under the Constitutional mandate of Article I, Section 8, Clause 8, which empowers Congress to pass laws which Promote the Progress of the Useful Arts. It did so first in 1790, borrowing in turn from the broad definition of a patentable invention of the 1624 Statute of Monopolies.

Whether Congress should now prospectively enact a statutory exception to the scope of the patent right as a matter of public policy may be seriously questioned on that ground, but not on Constitutional grounds. Thus, Article I of the Constitution gives Congress the power to enact, or even refrain from enacting, a patent law, if that is what Congress wishes to do. As seen from the 1978 environmental law changes considered in Monsanto, a prospective limitation of intellectual property rights is clearly constitutional and not in violation of the Fifth Amendment "taking" clause.

2. Retroactive Reversal, Both Unwise and Unconstitutional

Drugs now on the market after years of regulatory testing that are protected by existing patents quite clearly were put on the market based upon the expectation that the United States would maintain the broad patent rights mandated by Title 35 of the United States Code.

All that the patentee is given by the grant of letters patent is the right to exclude others; taking away that exclusionary right is taking away the heart of the patentee's right. The Monsanto case clearly governs this situation and graphically illustrates why retroactively narrowing the patent right would be just as much a Fifth Amendment "taking" as if the government permitted a third party, without compensation, to put a railroad through one's private pastureland.

IV. INFRINGEMENT BY FILING A PIECE OF PAPER

The second numbered paragraph of Section 202, proposed 35 USC §271(e)(2) creates infringement-by-filing-a-piece-of-paper. This proposal does serious damage to the integrity of the American patent system, with far ranging domestic and international implications.

WEGNER & BRETSCHNEIDER

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A. More than Three Centuries of Common Law Traditions

Infringement-by-filing-a-piece-of-paper is a radical departure from more than three full centuries of our common law patent jurisprudence. Our Anglo-American patent system dating back more than three full centuries has consistently defined the patent right as a property right, which consists entirely of the right to exclude others from making, using or selling an invention. Other systems, notably Japan, have similar definitions but also include the act of importation of a patented invention.

B. A Legal Non Sequitur

The proposed infringement-by-filing-a-piece-of-paper would make the act of filing a regulatory application with the government an act of infringement of a private patent.

But, the total right under a patent is a private right of property, which consists entirely of the right to exclude others. Surely, no private party can exclude a third party from filing a government report. And, indeed, the legal fiction is confirmed by the final paragraph of Section 202, proposed 35 USC §271(e)(4), which would bar any right of recovery, injunctive or monetary damages, from the act of infringement-by-filing-a-piece-of-paper.

C. An Advisory Opinion Procedure Should Not be Fostered

The totality of the patent right is the right to exclude others, as seen from a long line of nineteenth century Supreme Court precedent, summarized in Continental Paper Bag Company v. Eastern Paper Bag Company, 210 U.S. 405, 425 (1908). But, 35 USC §271(e)(4) would eliminate this right. The object of the second and fourth paragraphs of Section 202 is clear: Advisory opinions on the validity of a patent are desired.

The Constitutional perils associated with an advisory opinion stem from the earliest days. In the patent field, courts have strictly refused to entertain jurisdiction of patent cases in the absence of a clear actual controversy. There may well be an actual controversy in the sense of existing patent jurisprudence when a completed ANDA is filed, based upon the same type of infringing activity as exemplified in the Bolar case. If so, then surely a patentee can sue for patent infringement at the time a completed ANDA is lodged by the would-be generic manufacturer.

V. THE THIRD PARAGRAPH OF SECTION 202

Undoubtedly the most curious and redundant provision of H.R. 3605 is the third provision of Section 202, which provides a new

35 USC §271(e)(3) which eliminates a patentee's relief from actions under the first portion, 35 USC §271(e)(1). But, that first portion of Section 202 excludes certain acts from the category of patent infringement.

If something is not an act of patent infringement under §271(e)(1), then why is a separate paragraph needed to say that the patentee shall not have relief for acts by a third party that are under that paragraph?

The same constitutional objections that apply to the Bolar case in terms of retroactivity apply with equal force under this portion as well.

VI. AMERICAN RIGHTS ABROAD

While the American automobile, machinery and other industries have faced international setbacks, the American domestic pharmaceutical industry maintains its top worldwide position for pioneer drugs.

A. Stimulating American Sales Abroad Helps America

Maintaining this position may be considered far more important than maintenance of our leadership position in some

other areas. While Americans as exporters contribute to the flow of cash to our shores and provide employment for our citizens, in the healthcare field, the American worldwide initiative has two further benefits:

First, the revenue earned from foreign sales of pioneer drugs pours money for investments in new drugs back into our laboratories in the United States. The increased profits that American pioneers make abroad permit further research into new chemical entities here, all to the benefit of the American consumer.

Second, it is quite natural that each pioneer pharmaceutical manufacturer is most familiar with his own "home market", and that his first country of choice for regulatory testing of a drug, absent special circumstances, will be that home market. To the extent that the pharmaceutical industry is focused upon the American R&D community, this means that it is more likely that a new drug will appear here, at home, before it appears in Europe or Japan, when all other factors are equal.

B. America and the Diplomatic Conferences on Patents

Americans anchor their foreign patent rights on a document now over a century old, the historic Paris Convention of 1883,

which has been amended only on a handful of occasions, most recently by the 1967 Stockholm Revision.

While the first 80 years of the Paris Convention were an era of progress and protection of patent rights, America in the most recent time has faced a difficult struggle against dilution of its rights abroad. We are now in the midst of ongoing sessions of a Paris Convention revision that has met periodically over the past five years in Geneva and Nairobi. Since Stockholm, the Paris Convention has been administered by the United Nations, and the one country-one vote problem has led to a rearguard action to sustain the Stockholm text.

Our State and Commerce Departments have been fighting the good fight, and so far have met with remarkable success in stopping the possibility of retrogressive treaty enactments. At the heart of the third world position for treaty "reform" has been the dilution of exclusive rights, and in particular the creation of an exclusive compulsory license of foreign (i.e., American) rights. It would be the height of irony for America, after having successfully fought off the international pressure of a weighted third world majority, to now unilaterally and domestically create a far worse example of the taking of property rights, as would happen by the overuling of Bolar.

C. The American Patent Law as a Model in the Past

It is not just the developing countries that have studied the American model. In the pharmaceutical field a generation ago, neither Germany nor Japan had strong "compound protection" for pharmaceuticals. (At that time, a pharmaceutical compound was unpatentable; the only recourse that a pioneer had was through an "analogy process" claim.)

The Germans in 1967 and the Japanese in 1975 passed progressive legislation to strengthen their domestic pharmaceutical industries by repeal of their respective bans on compound claims. The express purpose of the 1975 Japanese code revision was to strengthen the incentives for pioneer drug research.

D. The U.S. "Imprimatur" for ANDA-Like Foreign Approvals

Grant of an abbreviated new drug application (ANDA) in the United States can have benefit in foreign countries. To the extent that an American manufacturer can tell a foreign government that his ANDA drug is approved here in the United States, it may be expected that foreign governments will more readily grant approvals there, in the foreign market.

The earlier the ANDA here, therefore, the earlier the possibility of foreign market erosion. As Americans are the leaders in the export of pioneer pharmaceuticals, it is the American export sales which are dealt the damage by this change in the law.

E. Avoidance of a Negative Role Model

If modern, industrialized countries such as Germany and Japan revise their codes to copy positive examples of American law to provide incentives for their pioneer industries, imagine the opposite side of the coin in countries totally devoid of any pioneer industry.

What happens when America, with a pioneer industry, sharply restructures its own code to the derogation of that pioneer industry? Undoubtedly, the message will be sure and swift. More than likely, the code revisions in third world countries would be far more extensive, and go beyond the pharmaceutical industry: If Americans, with their pioneer industries, are willing to look to the short range consumer interest at the expense of research incentives, then why should a totally consuming society not jump on the bandwagon?

WEGNER & BRETSCHNEIDER

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F. America Immediately Risks a $585,000,000.00 Annual Market

Former PTO Commissioner William E. Schuyler's prepared statement succinctly summarizes some of the genuine concerns for loss of American rights abroad, particularly in areas of the world without patent protection. Commissioner Schuyler points out that American drug companies make some $585,000,000.00 per year in foreign sales only in these countries without patent protection. (see page 12 of his testimony before this subcommittee on June 27, 1984).

Commissioner Schuyler points out that:

> The bill strikes two blows against American companies. First, it deprives American companies of trade secrets obtained at great cost (often measured in tens of millions of dollars). Second, it deprives American companies of the ability to make first use of these costly data to obtain approval overseas, thereby hurting their ability to compete effectively in those foreign markets, with adverse effects on the balance of trade and domestic employment.

Again, I wish to emphasize my support for the objectives of the bill insofar as Congress would permit easy generic access to off-patent drugs. The public deserves no less. As these objectives can be fully met without doing violence to the patent system, we would do well to give the public these generic drugs now, but without the intricacies of the bill that are totally unnecessary and a step backward.

Mr. WEGNER. I think the problem right now is we don't know what we need. We don't want to just stand still. We don't want to come back to Congress every session saying, "Well, last Congress you did this, now we need something else."

It is too short a time, but let's not stand in the way of getting the cheap drugs to the generic industry; let's not stand in the way of patent restoration for the traditional multinational companies. Let's, right now, if you have to go through with your bill to meet the major objectives, take biotechnology out of the bill; add a sentence. We don't want to take a single drug that is now on the market off the market and we don't want to take a single drug away from the generics that are now on the market.

All we ask is that you take biotechnology products out of the bill. Take biotechnology products out of the ANDA program. Then look at what we need in the next Congress and maybe there are some positive things you can add instead of treading water, but just take us out of the bill.

Dr. CAPE. Let me add one thing here, speaking partly in my capacity as president of the trade association, the Industrial Biotechnology Association. We have a fair number of contacts in Washington and the question is frequently asked, and certainly the two OTA reports on biotechnology have put it in Congress' lap in numerous ways. "What can we do for you?" is the question that the various Washington centers of possible activity ask us, and our answer, as you can well imagine, is most frequently, "We really don't need too much help. We are in reasonably good shape. "One of the big stories around the world is how much money we have, how exciting the science is, what the hopes are in terms of what our targets will accomplish if we succeed, and there are many cases of feedback where it looks like we will, but I know the one thing we frequently say, and I said it twice already, is don't shoot us in the foot, particularly don't shoot us in the foot inadvertently, when you are focusing basically on another problem that doesn't really have anything to do with us.

Mr. MOORHEAD. How many of the groups that are actively in support of this group are in the biotechnology field?

Dr. CAPE. I would have to make a calculation and give you the answer, but the Industrial Biotechnology Association represents approximately half a dozen major drug companies. It is not just genetic engineering companies.

Mr. MOORHEAD. Are any of them in support of the bill?

Dr. CAPE. Some of them are in the PMA section on one side of it, and some of them are on the other side.

Mr. WEGNER. Congressman, one thing—if I may add—we differ from these multinational companies that may have a certain percentage of biotechnology in this pipeline question. I think this is something which Dr. Cape mentioned briefly but I think it is worth his elaboration on.

We have nothing coming out of our pipeline now. We depend only on new products. I think that is a very important point.

Dr. CAPE. Yes, I guess I should be very specific and say in this particular regard that I am speaking for the interests of—as they would say in the stock market—the pure-play biotechnology companies. This activity, although it is sufficiently important that it is

gaining in its percentage at the larger companies, is still very, very minor in the context of their total businesses. With us, it is all we have got.

Mr. MOORHEAD. The biotechnology industry, of which your company is a prominent member, holds much promise for the development of new drugs and significant products. It is clear that substantial investments in research and development will need to be made and that sufficient incentives to innovate will need to exist, especially if the United States is to maintain its position as a leader in the area.

Do the patent term restoration provisions of this bill provide these incentives?

Dr. CAPE. I would be inclined to say that they are not of major importance to us. Maybe you would like to——

Mr. WEGNER. In other words, Congressman, right now, the survival of the independent biotechnology companies, the increased investment in these companies depends on the performance of the next 10 to 15 years. We need to get products into our pipeline and once we have a steady flow of products, then we can look at the longer range and see whether a patent expires in the year 2002 is extended to the year 2004. That is fine.

The other factor that I have been very surprised and pleased to see is how quickly cancer drugs are moving along in the pipeline. The FDA recognizes the importance of cancer drugs, and in many cases, the restoration may not even be applicable to our industry.

Dr. CAPE. As Mr. Kastenmeier asked me earlier, a pure patent extension or restoration bill with nothing else is all good news, but it is not superimportant good news to us. All our patents are starting right now and they are going to expire so far in the future that it is hard for us to make a distinction between expiring in 2000 or 2005. It is not a big deal to us.

Mr. MOORHEAD. Could any changes be made to this bill that would enhance the incentives that you have?

Mr. WEGNER. I think the best we could do with this bill would be to tread water. What Dr. Cape is saying is that title II doesn't really help us. It doesn't reach our major objectives of what we are going to do in the next 10, 15 years. We do not have the luxury of being a big company. Title I hurts us. Title II has some objectives which the generic industry favors and may well be to the public good of permitting an early challenge of patents.

In our biotechnology industry, we will be faced with the situation, if this bill applies to biotechnology, in which as every new product comes out, we are going to be defending the validity of the patent for that product.

Now, if that is good public policy for a major drug industry, the established international drug industry, that is fine, but for our industry, if this bill comes into law, we will have to budget money for defending the validity of each and every patent that comes down the pike.

Mr. MOORHEAD. OK, let's get to the other side of the question I asked you before. You say you don't know that some of these other companies are in biotechnology, but they are also on the other side also in pharmaceuticals and they may support it, how—do you

have any idea whether any of these companies would fight against taking biotechnology out of the bill?

Dr. CAPE. I can only guess and I can't imagine why any of those companies with which we are associated with in our association would fight against it. I can't think of any valid reason.

Mr. MOORHEAD. What are the implications of the ANDA provisions in this bill for companies like Cetus?

Dr. CAPE. Again, go ahead.

Mr. WEGNER. Well, in biotechnology, unlike the traditional drug fields, we have an untested patent situation. We have zero cases on point on the enforcement and final adjudicated appeals, for example, on recombinant DNA, hybridomas. We can't rely upon the 4-year freedom from an ANDA, because we believe we all have good patents in this field.

We cannot certify that the drugs are unpatentable, so there is zero if the patent is challenged. We are subject to this same 18-month challenge, so as a practical matter, what will happen?

Many companies, domestic and international, are in interferon, interleukin and all of these various other areas. Everybody is trying to be first. There is surely going to be litigation on these patents, encouraged, fostered by the synergy of title I and title II. We are going to be thrown into the test vat of litigation with no settled principles to determine how you interpret the scope of these biotechnology patents. This is a field day for litigation. Nothing more encourages litigation than having an absence of settled principles. So this is what makes us a special case.

The other question you ask is who the big drug houses are who also have biotechnology. I don't have any statistics and I don't think Dr. Cape does either. It must be a very minor portion of their total overall profits in their business. The pure players that Dr. Cape has mentioned are the ones that are concerned. These are the people who are primarily focused on this biotechnology problem.

Mr. MOORHEAD. I have just one other question. Is there anything else that you feel would help your case that you haven't been asked that you would like to get into the record?

Dr. CAPE. I appreciate the question, but my personal view as to what would help the biotechnology companies—I have the opportunity so I will take 15 seconds to say it, but I don't think it addresses this bill at all—is that we are all benefiting from the goose that laid the golden egg. The goose that laid the golden egg is the brilliant and successful decision, made by the Federal Government and supported by Congress for the last two generations, to support basic research almost with a passion.

It seems to me tragic that at the present time this support for basic research is being eroded. Rather than responding to a challenge with all these excellent and valid objectives which were being supported with the same enthusiasm that we saw in the early 1960's for the space race, we instead are seeing an erosion of that support for basic research at NIH and at the universities. We are playing into the hands of the overseas competitors who announce repeatedly—and so does our OTA—that the one thing we do far better than anybody else is basic research and it ultimately benefits people like us and our Government is throttling it.

I am desperately looking for ways in which I can lend my personal effort and the influence of people I can associate with to reverse that trend. Unfortunately, that has nothing to do with today's discussion, but thank you for giving me the opportunity to say that.

Mr. KASTENMEIER. Well, on that note, we conclude the hearings today. The committee thanks Dr. Cape and Mr. Wegner for their appearance here and I think it was very useful to include you in the panel in terms of the discussion of the larger aspects of the legislation before us in its other implications.

That concludes the hearing today and on the third week in July, when the Congress returns, we will take up prospective markup of this bill, H.R. 3605 or take whatever disposition the committee cares to on this subject.

Accordingly, the committee stands adjourned.

[Whereupon, at 3:40 p.m., the subcommittee was adjourned, to reconvene subject to the call of the Chair.]

98TH CONGRESS
2D SESSION

H. R. 3605

[Report No. 98-857, Part I]

To amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs.

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 1983

Mr. WAXMAN (for himself, Mr. MADIGAN, Mr. WYDEN, Mr. SIKORSKI, Mr. WIRTH, Mr. LELAND, Mr. MARKEY, Mr. SWIFT, Mr. BRYANT, and Mr. WEISS) introduced the following bill; which was referred to the Committee on Energy and Commerce

JUNE 21, 1984

Additional sponsors: Mr. GORE, Ms. KAPTUR, Mr. OWENS, Mr. MARTINEZ, Mr. BEDELL, and Mr. SYNAR

JUNE 21, 1984

Reported with amendments, referred to the Committee on the Judiciary for a period ending not later than August 1, 1984, for consideration of such portions of the amendment as fall within that committee's jurisdiction pursuant to clause 1(m) of rule X, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, ~~That this Act may be cited as the "Drug Price Competition Act of 1983".~~

~~SEC. 2. Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following new sentence: "Clause (1) of the previous sentence shall not apply in the case of an application for a drug for which a previous application has been approved in accordance with subsection (c), if the drug with respect to which such subsequent application is filed meets appropriate standards of identity, strength, quality, purity, stability, bioavailability, and bioequivalence in relation to the drug approved in the previous application.".~~

That this Act may be cited as the "Drug Price Competition and Patent Term Restoration Act of 1984".

TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

SEC. 101. Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by redesignating subsection (j) as subsection (k) and inserting after subsection (i) the following:

"(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

"(2)(A) An abbreviated application for a new drug shall contain—

"(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a 'listed drug');

"(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug,

"(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

"(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and

such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

"(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

"(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

"(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

"(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

"(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

"(I) that such patent information has not been filed,

"(II) that such patent has expired,

"(III) of the date on which such patent will expire, or

"(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

"(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant has given the notice required by clause (ii) to—

"(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(II) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is

made to obtain approval to engage in the commerical manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

"(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients of the drug or of the route of administration, the dosage form, or strength which differ from the listed drug.

"(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

"(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

"(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

"(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug,

"(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

"(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

"(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

"(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

"(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

"(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

"(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by

the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

"(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

"(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

"(H) information submitted in the application or any other information available to the Secretary shows

that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

"(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

"(J) the application does not meet any other requirement of paragraph (2)(A); or

"(K) the application contains an untrue statement of material fact.

"(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

"(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

"(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

"(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

"(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the eighteen month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision, or

"(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

"(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

"(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

"(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other

application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using such drug for any known therapeutic purposes the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of four years from the date of the approval of the application under subsection (b) unless the Secretary determines that an

adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.

"(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

"(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

"(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

"(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

"(I) a list in alphabetical order of the official and proprietary name of each drug which has been ap-

proved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

"(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

"(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

"(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

"(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary the Secretary shall, in revisions made under clause (ii), include such information for such drug.

"(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

"(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

"(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (5), or

"(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

"(7) For purposes of this subsection:

"(A) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(B) A drug shall be considered to be bioequivalent to a listed drug if—

"(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

"(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.".

SEC. 102. (a)(1) Section 505(b) of such Act is amended by adding at the end the following: "The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent

infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.".

(2) Section 505(c) of such Act is amended by inserting "(1)" after "(c)", by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and by adding at the end the following:

"(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by

the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when the application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.".

(3)(A) The first sentence of section 505(d) of such Act is amended by redesignating clause (6) as clause (7) and inserting after clause (5) the following: "(6) the application failed to contain the patent information prescribed by subsection (b); or".

(B) The first sentence of section 505(e) of such Act is amended by redesignating clause (4) as clause (5) and inserting after clause (3) the following: "(4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or".

(b)(1) Section 505(a) of such Act is amended by inserting "or (j)" after "subsection (b)".

(2) Section 505(c) of such Act is amended by striking out "this subsection" and inserting in lieu thereof "subsection (b)".

(3) The second sentence of section 505(e) of such Act is amended by inserting "submitted under subsection (b) or (j)" after "an application".

(4) The second sentence of section 505(e) is amended by striking out "(j)" each place it occurs in clause (1) and inserting in lieu thereof "(k)".

(5) Section 505(k)(1) of such Act (as so redesignated) is amended by striking out "pursuant to this section" and inserting in lieu thereof "under subsection (b) or (j)".

(6) Subsections (a) and (b) of section 527 of such Act are each amended by striking out "505(b)" each place it occurs and inserting in lieu thereof "505".

SEC. 103. (a) Section 505(b) of such Act is amended by inserting "(1)" after "(b)", by redesignating clauses (1) through (6) as clauses (A) through (F), respectively, and by adding at the end the following:

"(2) An application submitted under paragraph (1) for a drug listed under subsection (j)(6) for which investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not con-

ducted by or for the applicant or for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

"(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

"(i) that such patent information has not been filed,

"(ii) that such patent has expired,

"(iii) of the date on which such patent will expire, or

"(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not

claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

"(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant has given the notice required by subparagraph (B) to—

"(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(ii) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.".

(b) Section 505(c) of such Act (as amended by section 102(a)(2)) is amended by adding at the end the following:

"(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

"(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

"(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

"(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is

brought before the expiration of such days, the approval may be made effective upon the expiration of the eighteen-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision, or

"(ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district

where the defendant has its principal place of business or a regular and established place of business.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection and if the holder of the approved application

certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using for any known therapeutic purposes such drug, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of four years from the date of the approval of the application previously approved under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.".

SEC. 104. Section 505 of such Act is amended by adding at the end the following:

"(l) Safety and effectiveness data and information which has been submitted in an application under subsection

(b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

"(1) if no work is being or will be undertaken to have the application approved,

"(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

"(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

"(4) if the Secretary has determined that such drug is not a new drug, or

"(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

"(m) For purposes of this section, the term 'patent' means a patent issued by the Patent and Trademark Office of the Department of Commerce.".

SEC. 105. (a) The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States

Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by sections 101, 102, and 103 of this Act, within one year of the date of enactment of this Act.

(b) During the period beginning on the date of the enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act except in accordance with such section.

SEC. 106. Section 2201 of title 28, United States Code, is amended by inserting "(a)" before "In a case" and by adding at the end the following:

"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act.".

TITLE II—PATENT EXTENSION

SEC. 201. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 155A:

"§ 156. Extension of patent term

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

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

"(2) the term of the patent has never been extended;

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

"(4)(A) in the case of a patent which claims the product or a method of using the product—

"(i) the product is not claimed in another patent having an earlier issuance date or which was previously extended, and

"(ii) the product and the use approved for the product in the applicable regulatory review period are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended; or

"(B) in the case of a patent which claims the product, the product is also claimed in a patent which has an earlier issuance date or which was previously extended and which does not identically disclose or describe the product and—

"(i) the holder of the patent to be extended has never been and will not become the holder of the patent which has an earlier issuance date or which was previously extended, and

"(ii) the holder of the patent which has an earlier issuance date or which was previously extended has never been and will not become the holder of the patent to be extended;

"(5)(A) in the case of a patent which claims a method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product—

"(i) no other patent has been issued which claims the product or a method of using the product and no other patent which claims a method of

using the product may be issued for any known therapeutic purposes; and

"(ii) no other method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product is claimed in a patent having an earlier issuance date;

"(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product—

"(i) the holder of the patent for the method of manufacturing the product (I) is not the holder of a patent claiming the product or a method of using the product, (II) is not owned or controlled by a holder of a patent claiming the product or a method of using the product or by a person who owns or controls a holder of such a patent, and (III) does not own or control the holder of such a patent or a person who owns or controls a holder of such a patent; and

"(ii) no other method of manufacturing the product primarily using recombinant DNA technology is claimed in a patent having an earlier issuance.

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

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

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

"(8) the patent does not claim another product or a method of using or manufacturing another product which product received permission for commercial marketing or use under such provision of law before the filing of an application for extension.

The product referred to in paragraphs (4), (5), (6), and (7) is hereinafter in this section referred to as the 'approved product'. For purposes of paragraphs (4)(B) (5)(B), the holder of a patent is any person who is the owner of record of the

patent or is the exclusive licensee of the owner of record of the patent.

"(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

"(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

"(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

"(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.

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

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

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

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

"(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regula-

tory review period occurred for commercial marketing or use. The application shall contain—

"(A) the identity of the approved product;

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

"(C) the identity of every other patent known to the patent owner which claims or identically discloses or describes the approved product or a method of using or manufacturing the approved product;

"(D) the identity of all other products which have received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and which are claimed in any of the patents identified in subparagraph (C);

"(E) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to de-

termine the period of the extension under subsection (g);

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

"(G) such patent or other information as the Commissioner may require.

"(2)(A) Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify—

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

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

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than thirty days after the receipt of an application from the Com-

missioner, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(E) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

"(B)(i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than ninety days after the receipt of such a petition. The Secretary of Health and Human Services may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

"(ii) The Secretary making a determination under clause (i) shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for

such determination. Any interested person may request, within the sixty day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

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

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

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

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

"(f) For purposes of this section:

"(1) The term 'product' means:

"(A) A drug product.

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

"(2) The term 'drug product' means the active ingredient of a new drug, antibiotic drug, new animal drug, or human or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Virus-Serum-Toxin Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

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

"(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

"(B) Any reference to section 503, 505, 507, 512, or 515 is a reference to section 503, 505, 507, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

"(1)(A) In the case of a product which is a drug product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a drug product is the sum of—

"(i) the period beginning on the date—

"(I) an exemption under subsection (i) of section 505, subsection (d) of section 507, or subsection (j) of section 512, or

"(II) the authority to prepare an experimental drug product under the Virus-Serum-Toxin Act,

became effective for the approved drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, 507, or 512 or the Virus-Serum-Toxin Act, and

"(ii) the period beginning on the date the application was initially submitted for the approved drug product under section 351, subsection (b) of such section 505, section 507, section 512, or the Virus-Serum-Toxin Act and ending on the date such application was approved under such section or Act.

"(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a food or color additive is the sum of—

"(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

"(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date

such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

"(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a medical device is the sum of—

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

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

initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

"(4) A period determined under any of the preceding paragraphs is subject to the following limitations:

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

"(B) If the patent involved was issued before the date of the enactment of this section and—

"(i) no request for an exemption described in paragraph (1)(B) was submitted,

"(ii) no request was submitted for the preparation of an experimental drug product described in paragraph (1)(B),

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

"(iv) no clinical investigation described in paragraph (3) was begun or product devel-

opment protocol described in such paragraph was submitted,

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years.

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

(b) The analysis for chapter 14 of title 35 of the United States Code is amended by adding at the end thereof the following:

"156. Extension of patent term.".

SEC. 202. Section 271 of title 35, United States Code is amended by adding at the end the following:

"(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

"(2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

"(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

"(4) For an act of infringement described in paragraph (2)—

"(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

"(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug, and

"(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug.

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

SEC. 203. Section 282 of title 35, United States Code, is amended by adding at the end the following:

"Invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure—

"(1) by the applicant for the extension, or

"(2) by the Commissioner,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.".

Amend the title so as to read: "A bill to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications and to amend title 35,

United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.".

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

JUL 20 1984

Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts, Civil Liberties,
and the Administration of Justice
Committee on the Judiciary
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In response to your letter of July 6, 1984, I am enclosing answers to questions on patent term extension legislation which you have addressed to me. I hope that my responses are helpful when you consider H.R. 3605.

Sincerely,

Gerald J. Mossinghoff
Commissioner of Patents and Trademarks

Enclosures

Q. Proponents of this bill claim that it will lead to "cheaper drugs today, better drugs tomorrow". Your testimony seems to imply a disagreement with that conclusion at least insofar as you criticize the limited grant of patent extension for drugs. Would you support this bill, and recommend a Presidential signature if it passed as reported by the Energy and Commerce Committee?

A. My major criticism of H.R. 3605 is its complexity due to the efforts by its drafters to cure the alleged problem of drug companies' prolonging their market position by obtaining a chain of patents generally relating to the same product. I have not seen credible evidence that such a problem exists. The policy reflected in H.R. 3605 would permit extension usually only for the earliest product patent and not for new uses, such as cancer treatments, discovered and patented later. To carry out this policy, the Patent and Trademark Office would be required to make determinations which our examiners are not trained to make at this time. These involve determinations on infringement, rather than patentability, and are usually made by the courts.

While I have critized the bill because of those and other shortcomings, I remain strongly in favor of the overall compromise, of establishing ANDA procedures and patent term restoration. However, contrary to representations by others, H.R. 3605, as presently worded, would not permit the Patent and Trademark Office to perform only ministerial functions. Should the bill be passed as reported by the Energy and Commerce Committee, without at the very least providing that the PTO only engage in purely ministerial functions rather than the complex determinations now required by the bill, it would be extremely difficult for us to recommend to the President that he sign this legislation.

Q. What historical precedent is there for Congress modifying the terms of a patent during its term? Did Congress make any similar changes --- i.e. contraction of the rights of a patent holder --- when it enacted the 1952 Patent Act?

A. I am not aware of any instance in which Congress narrowed or otherwise modified the scope of a patent during its term. When Congress enacted the patent laws in 1952, it basically codified patent laws then in existence and modified some provisions in view of prevailing court decisions. In the area of defining what constitutes an infringement, the 1952 act increased, or at least clarified, patentees' rights.

Q. Under the terms of the bill the PTO will be permitted to charge fees for patent term extensions equal to the costs of administrating the program. What is a ball-park guess about what these costs will be?

A. Due to the many assumptions which have to be made to guess what the level of work may have to be in the individual case, it is difficult to arrive at a firm cost estimate of administering this program. However, the fee may be in the range of $1500 to $2000 per case.

Q. It is my understanding that Congressman Waxman's staff gave your office a series of examples of supposed abuses which would occur if Congress were to permit patent term extension under the same conditions as were found in H.R. 6444 (the Judiciary Committee reported version from last Congress). Does this information support the rather complex rules found in H.R. 3605?

A. Please see the attached analysis

The nineteen examples of commercial drug products furnished by the staff of Congressman Waxman have been reviewed to determine the eligibility for patent term extension under three approaches: (1) HR 3605; (2) HR 6444 and (3) the modified (hereinafter PTO) approach that I recommended in my testimony before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the Committee on the Judiciary on June 27, 1984 which would preserve the eligibility requirements of HR 6444 and calculate the term of extension according to 156(c)(1) and (2) of HR 3605 with the additional provisions that --

> No term of any extended patent may exceed twenty-five years from the date of filing of the earliest U. S. patent application with provides support under Section 120 of this title for any claim of the patent to be extended; and
>
> In no event shall more than one patent be extended for the same regulatory review period for any product.

This review has been based on several assumptions. It has been assumed that there has been no failure to act with due diligence. It has also been assumed that legislation embodying these three approaches became effective before the patent term expired of each patent reviewed. The regulatory review periods considered for an extension have been assumed to constitute those periods occuring after the patent under consideration has been granted and which fall between the dates of the IND and NDA filing as the testing phase, and the period between the dates of the NDA filing and NDA approval as the agency approval phase. It should also be noted that only one patent can be extended for the same regulatory review period for any product in each of the second and third approaches identified above. Further, it has been assumed that the mere mention of another U. S. application in a series of copending applications or a claim of foreign priority would entitle the patentee to claim the benefit of these applications under 35 USC 120 or 119. Other assumptions made on a case-by-case basis are explained in the individual example.

For the purpose of comparing the three approaches, specific answers have been supplied for the analysis under HR 3605 regarding the eligibility of a patent for extension and the length of extension, if eligible. In view of the complexity of HR 3605 and the short time frame available to make this analysis, these answers can only be considered approximations. Further, this review has been based only on the patents identified by the staff of Congressman Waxman. No independent research has been conducted to find other patents disclosing or claiming the approved product and its approved use for the purpose of analyzing their disclosures and claims to determine whether the patents identified by Congressman Waxman's staff would be eligible for patent term extension, as required by the provisions of HR 3605.

The nineteen examples broadly demonstrate that the far simpler approaches of HR 6444 or the PTO do not result in patent term extensions which are markedly different from those available under HR 3605. In many instances, the results were about the same and in some instances HR 3605 was more generous.

Doxapram: 3,192,206 - compound
3,192,221 - method of making, compound
3,192,230 - method of making
3,301,757 - composition, method of use

None of the patents would be eligible for an extension under any of the approaches because the regulatory review period terminated prior to the grant of all the patents.

Sulfameter: 3,203,951 - compound
3,214,335 - composition and method of use

It is further assumed that the NDA approval date is 7/1/66. Under HR 3605, the first patent would not be entitled to an extension because of the 14 year rule of section 156(c)(3) and the second patent would not be eligible for an extension under sections 156(a)(4)(A)(i) and (ii). Under the other two proposals, the first patent would be eligible for an extension of about 1.25 years under each, OR the second patent would be eligible for an extension of about 0.7 years under the other two proposals, but only one patent would be eligible for an extension.

Butaperazine Maleate: 2,985,654 - compound
3,885,034 - method of use

Under HR 3605, the first patent would appear to be entitled to an extension of about 3.3 years, under HR 6444 it would be entitled to an extension of about 3.8 years and under the PTO proposal it would be entitled to an extension of about 3.3 years. The second patent would not be entitled to an extension under any approach since the regulatory period terminated before the patent was granted.

Hydroxyurea: 3,119,866 - product, method of making
3,968,249 - method of using

Neither of the patents would be eligible for an extension under any of the approaches because the regulatory review period terminated prior to the grant of both patents.

Calusterone: 3,262,949 - compound
3,937,827 - method of using

Under HR 3605, the first patent would appear to be entitled to an extension of about 1.8 years, whereas the extension under HR 6444 would be about 0.3 years and no extension would be available under the PTO approach because of the 25 year rule. The second patent would not be eligible for any extension under any of the three approaches because the regulatory review period terminated before the patent was granted.

Metaproterenol Sulfate: 3,341,594 - compound
3,422,196 - composition and method of use

Under HR 3605, the first patent (3,341,594) would be eligible for an extension of about 3 years and the second patent (3,422,196) would not be eligible for an extension under sections 156(a)4(A)(i) and (ii). Under the other two proposals, the first patent would be eligible for an extension of about 1.5 years (PTO) or 2.5 years (6444) or the second patent would be eligible for an extension of about 0.1 years (PTO) or 1.1 years (6444), but only one patent could be extended for the same regulatory review period for the product.

Miconazole Nitrate: 3,717,655 - compound
3,839,574 - composition, method of use

The first patent would not be entitled to an extension under HR 3605 because of the 14 year rule, but would be entitled to an extension of about one year under each of the HR 6444 and the PTO approaches. The second patent would not be entitled to an extension under any of the approaches because the regulatory review period terminated before the second patent was granted.

Cimetidine: 3,950,333 - compound
4,024,271 - composition and method of use

Under HR 3605, neither patent (3,950,333 and 4,024,271) would be entitled to an extension. The first patent would not be entitled to an extension under the 14 year rule of section 156(c)(3) and the second patent would not be eligible for an extension under sections 156(a)(4)(A)(i) and (ii). Under the other two proposals, it would appear that the first patent to the compound would be eligible for an extension of 1.1 (PTO) or 1.3 years (6444) OR the second patent to the composition and method of use would be eligible for an extension of 0.25 years (PTO and 6444), but only one patent would be eligible for an extension.

Cyclobenzaprine HCl: 3,454,643 - compound
3,882,246 - method of use

Under HR 3605, the first patent would be eligible for an extension of about 4.3 years, whereas the second patent would not be eligible for an extension under section 156(a)(4)(A)(i). Under HR 6444, the first patent would not be entitled to an extension because of the 27 year rule whereas the second patent would appear to be entitled to an extension of about 2.3 years. Finally, under the PTO approach, the first patent would not be entitled to an extension because of the 25 year provision, while the second patent would appear to be entitled to an extension of about two years.

Probucol: 3,576,883 - compound
3,862,332 - composition, method of use

Under HR 3605, the first patent would be eligible for an extension of 3.8 years, whereas the second patent would not be eligible for an extension under Sections 156(a)(4)(A)(i) and (ii). Under HR 6444, the first patent would appear to be eligible for an extension of about 5.75 years or the second patent would be eligible for an extension of about 2 years. Under the PTO approach, the first patent would be eligible for an extension of about 4.1 years or the second patent would be eligible for an extension of about 0.3 years but only one patent could be extended.

Timolol Maleate: 3,655,663 - compound
3,657,237 - method of making
3,718,647 - method of making
4,195,085 - composition, method of use

Under HR 3605, the first patent would be eligible for an extension of 2.1 years, but none of the other patents would be eligible for an extension: no extension on the second patent under section 156(a)(5)(A)(i), no extension on the third patent because of sections 156(a)(5)(A)(i) and (ii), and no extension would be available for the fourth patent under any approach because the regulatory period terminated before the fourth patent was granted. Under HR 6444, any one of the first three patents would be eligible for an extension of about 3.6 years, whereas under the PTO approach any one of the first three patents would be eligible for an extension of about 2.1 years. In each of the last two approaches, only one of the patents would be eligible for an extension.

Amcinonide: 3,048,581 - compound
4,158,055 - method of use

Under HR 3605, the first patent would appear to be entitled to an extension of about 3.8 years, but the second patent would not be eligible for an extension because of section 156(a)(4)(A)(i). Under the other two approaches, the first patent would be eligible for an extension of 2.1 years (6444) or 3.5 years (PTO), or the second patent would be eligible for an extension of 0.3 years under each approach, but only one patent would be entitled to an extension.

Ampicillin Trihydrate: 2,985,648 - compound
3,157,640 - compound

The first patent would not be entitled to an extension under HR 3605 because of the 14 year provision of section 156(c)(3), but would be eligible for an extension of about 0.5 years under each of the other two approaches. The second patent would not be eligible for an extension under any of the approaches because the regulatory review period terminated before the second patent was granted.

Cephalexin Monohydrate: 3,275,626 - method of making
3,507,861 - compound
3,655,656 - compound - monohydrate
3,781,282 - method of making and intermediate compound

It is unclear whether the approved product in this situation is covered by patents to a method of making cephalexin compounds described in 3,275,626 or cephalexin compounds claimed in 3,507,861. Note Eli Lilly and Co. v. Premo Pharmaceutical Laboratories, 630 F.2d 120, 207 USPQ 719 (3rd Cir. 1980). If the approved product is not claimed in the prior patent, no patent would be entitled to an extension under any proposal because the first two patents do not cover a product which has been the subject of regulatory review and the last two patents were granted after the termination of regulatory review.

If the approved product was considered to be covered by the first two patents, then it would appear that the first patent (3,275,626) would be eligible for an extension of about 1.25 years under HR 3605, whereas the second patent (3,507,861) would not be entitled to an extension under the 14 year rule. Under the other two proposals, extensions on the first patent would be 2.6 (PTO) or 4 years (6444), or on the second patent would be 0.3 (PTO) or 0.7 years (6444), but only 1 patent would be eligible for extension. None of the proposals would permit extensions of the product patent (3,655,656) or the process of making patent (3,781,282) because the regulatory review period terminated before these patents were granted.

Loxapine Succinate: 3,412,193 - method of use
3,546,226 - compound

Under HR 3605, the first patent would appear to be eligible for an extension of about 3.25 years even though the use claimed is not the approved use of the approved product, whereas the second patent would be eligible for an extension of 1.2 years. Under HR 6444, the patents would appear to be eligible for extensions of 6.25 and 2.5 years respectively, whereas under the PTO approach, the patents would be eligible for extensions of 3.8 and 1.5 years respectively, but only one patent would be eligible for an extension under both of the latter approaches.

Prazosin: 3,511,836 - compound
3,663,706 - method of using
4,092,315 - compound, method of making

Under HR 3605, the first patent would appear to be eligible for an extension of about 3.1 years, but the second patent would not be eligible for an extension because of section 156(a)(4)(A)(i) and the third patent would not be eligible for an extension under any approach because it was granted after the regulatory review period terminated. Under HR 6444, either the first patent could be extended for 5.25 years or the second patent could be extended for 3.25 years, but only one patent could be extended. Under the PTO appoach, either the first patent could be extended for 3.25 years or the second patent could be extended for 1.25 years, but only one patent could be extended.

Desoxymethasone: 3,099,654 - compound method of making
3,232,839 - compound, method of use

Under HR 3605, the first patent would be eligible for an extension of about 2.1 years, but the second patent would not be eligible because of sections 156(a)(4)(A)(i) and (ii). Under HR 6444, either patent would appear to be eligible for an extension of about 1.7 years, but only one patent would be eligible. Under the PTO approach, either patent would be eligible for an extension of 2.1 years, but only one patent would be eligible.

Cefamandole Nafate: 3,641,021 - compound
3,928,592 - composition
4,006,138 - compounds
4,168,376 - method of making

Under HR 3605, the first patent would appear to be eligible for an extension of about 3.3 years, but neither the second nor third would be eligible because of the provision in section 156(a)(4)(A)(i), and the fourth patent would not be eligible under any of the approaches because it was granted after the regulatory review period terminated. Under HR 6444, only one of the first three patents would be eligible for an extension of 4.9 years, 2.75 years or 1.6 years respectively. Under the PTO approach, only one of the first three patents would be eligible for an extension of 3.3 years, 2.25 years and 1.6 years respectively.

Mezlocillin Sodium: 3,974,142 - compound
4,009,272 - composition, method of use

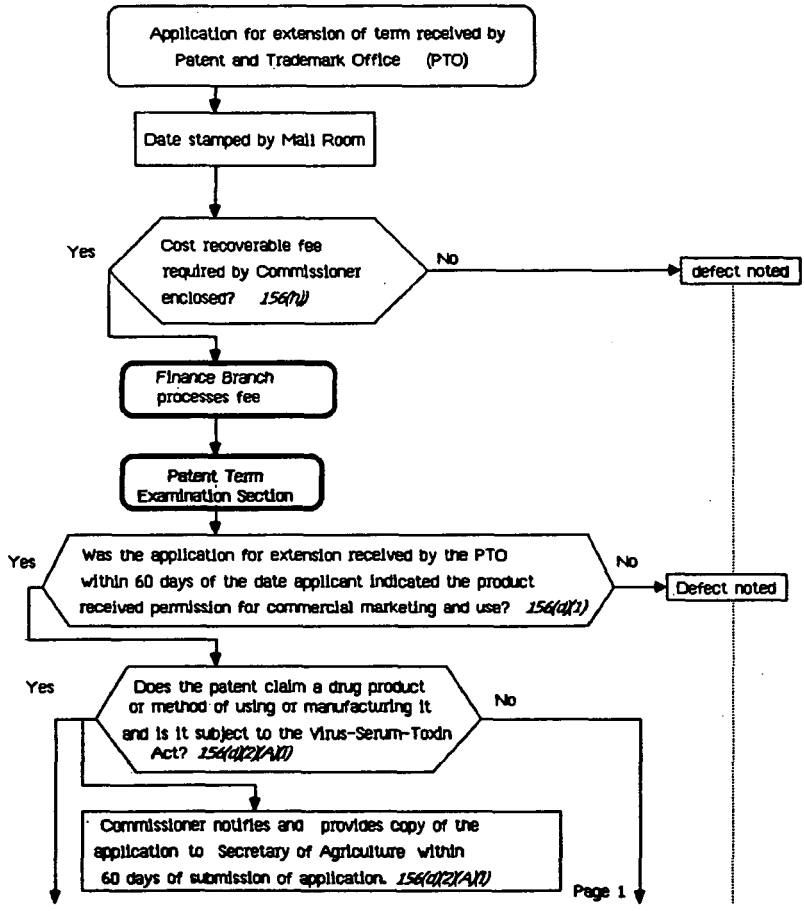
Under HR 3605, the first patent would be eligible for an extension of about 2.1 years, whereas the second patent would not be eligible because of the provisions of sections 156(a)(4)(A)(i) and (ii). Under HR 6444, either the first patent would be eligible for an extension of 5.2 years or the second patent would be eligible for an extension of 4.7 years, but only one patent could be extended. Likewise, under the PTO approach, either the first patent would be eligible for an extension of 3.1 years, or the second patent would be eligible for an extension of about 2.8 years.

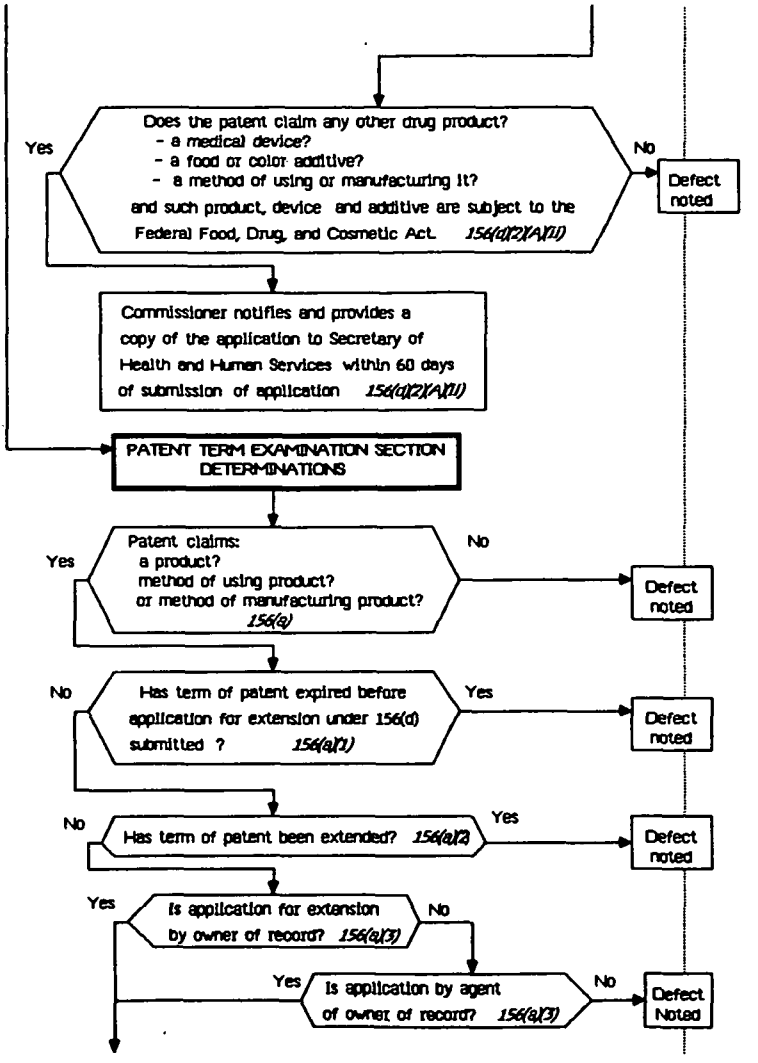
Q. What rationale, if any, is there for the grant of exclusive marketing authority to the Commissioner of the FDA with respect to unpatentable substances?

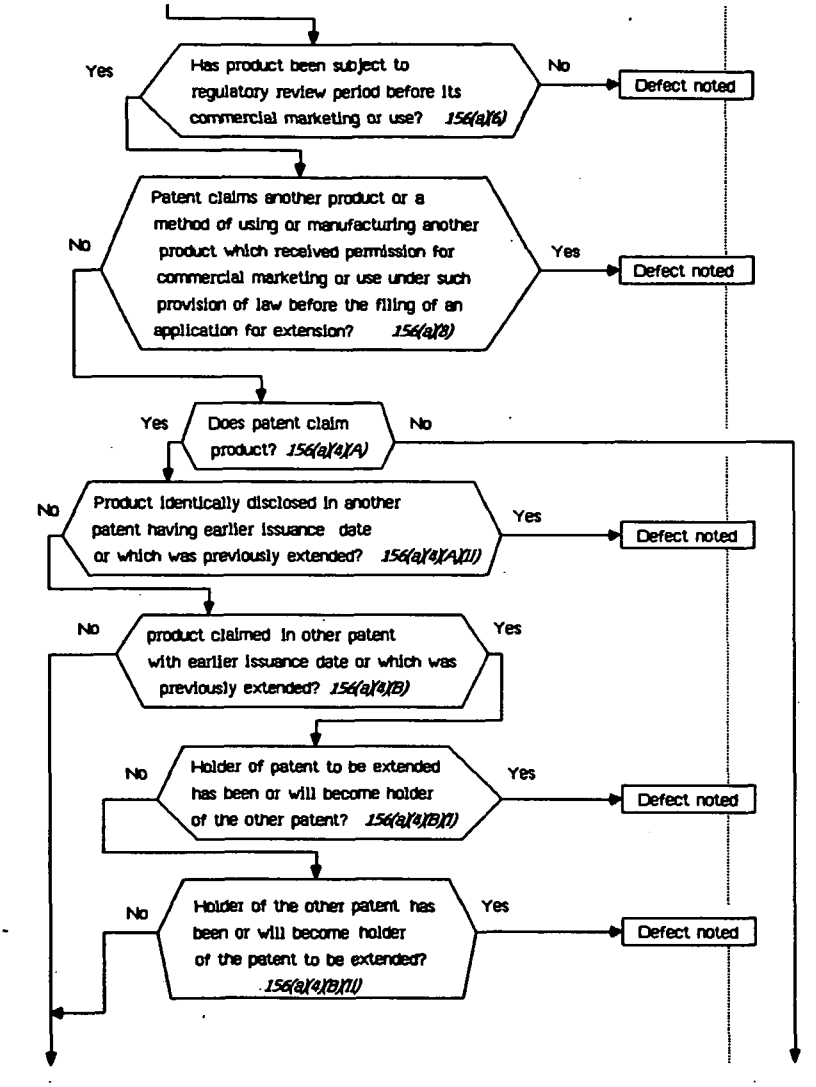
A. One reason for granting exclusive marketing authority to the Commissioner of the FDA may be that such authority could be helpful to encourage development of new drugs, even though they may not be patentable. This concept is similar to the protection for unpatented drugs for rare diseases or conditions as contained in the Orphan Drug Act, P.L. 97-414. If the public benefits from the development of such drugs, which otherwise might not have been undertaken, this authority should not be objectionable. I continue, however, to defer to the FDA on this point because the patent system, as such, is not involved in this consideration.

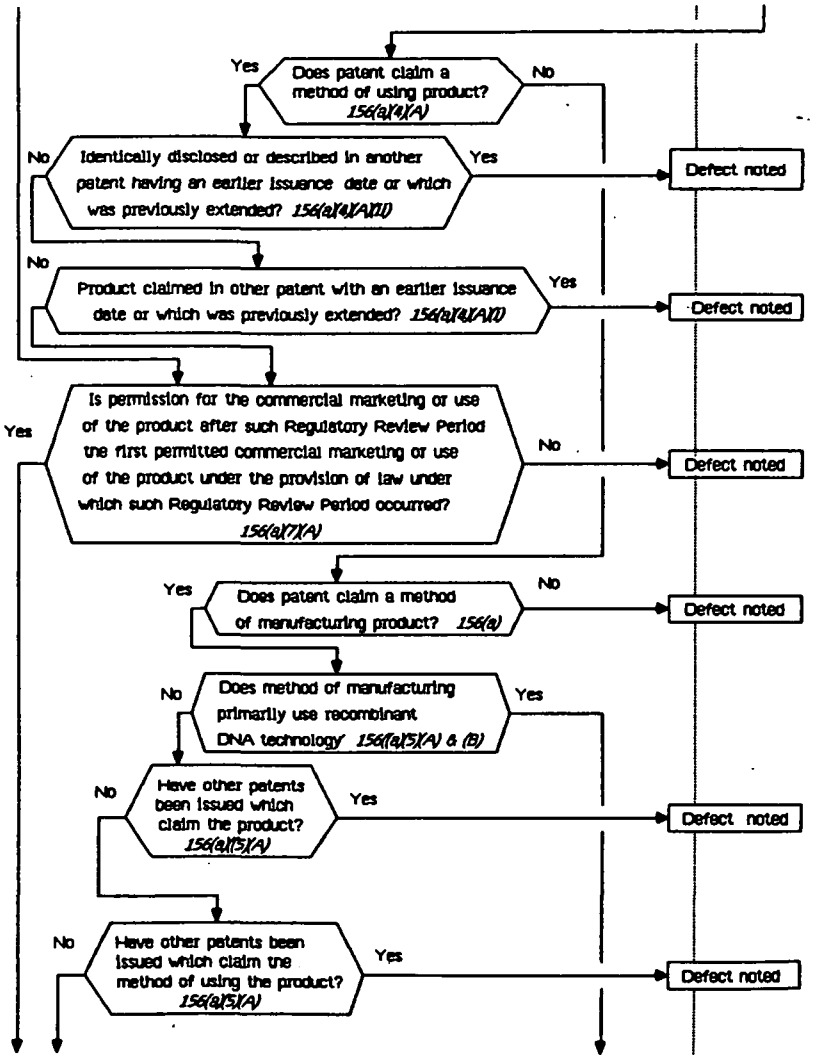
PATENT TERM EXTENSION

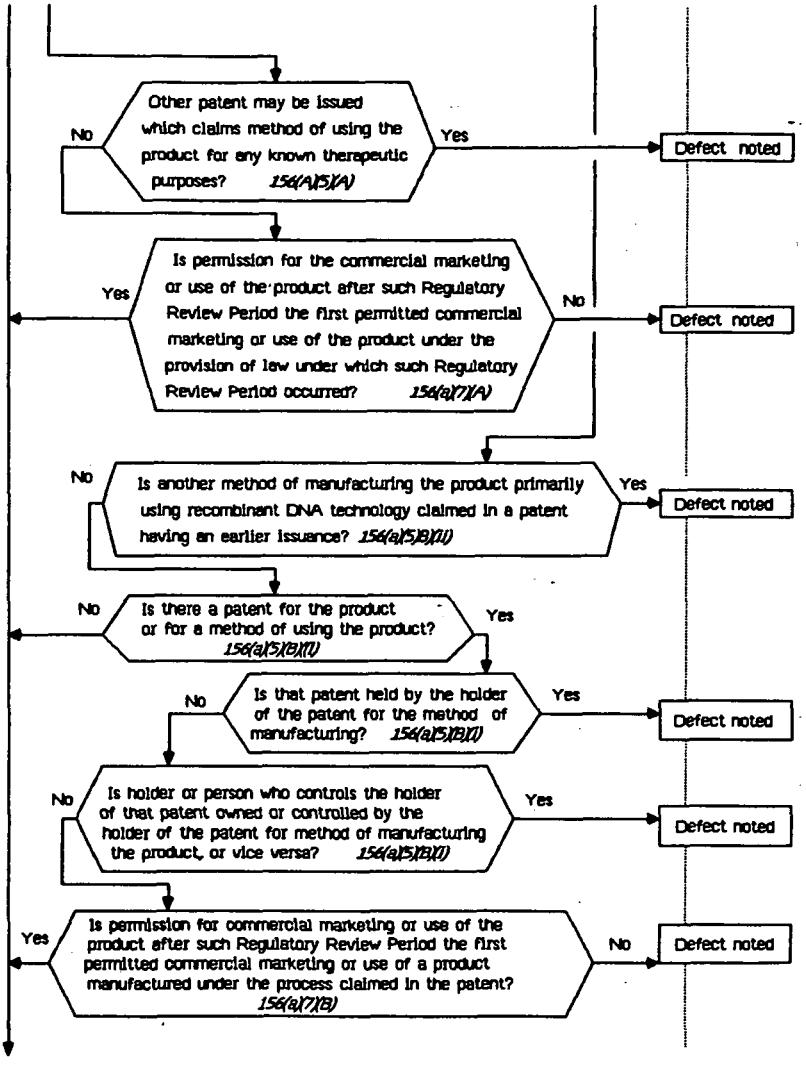
FLOWCHART OF PROCESSING UNDER 35 U.S.C. 156

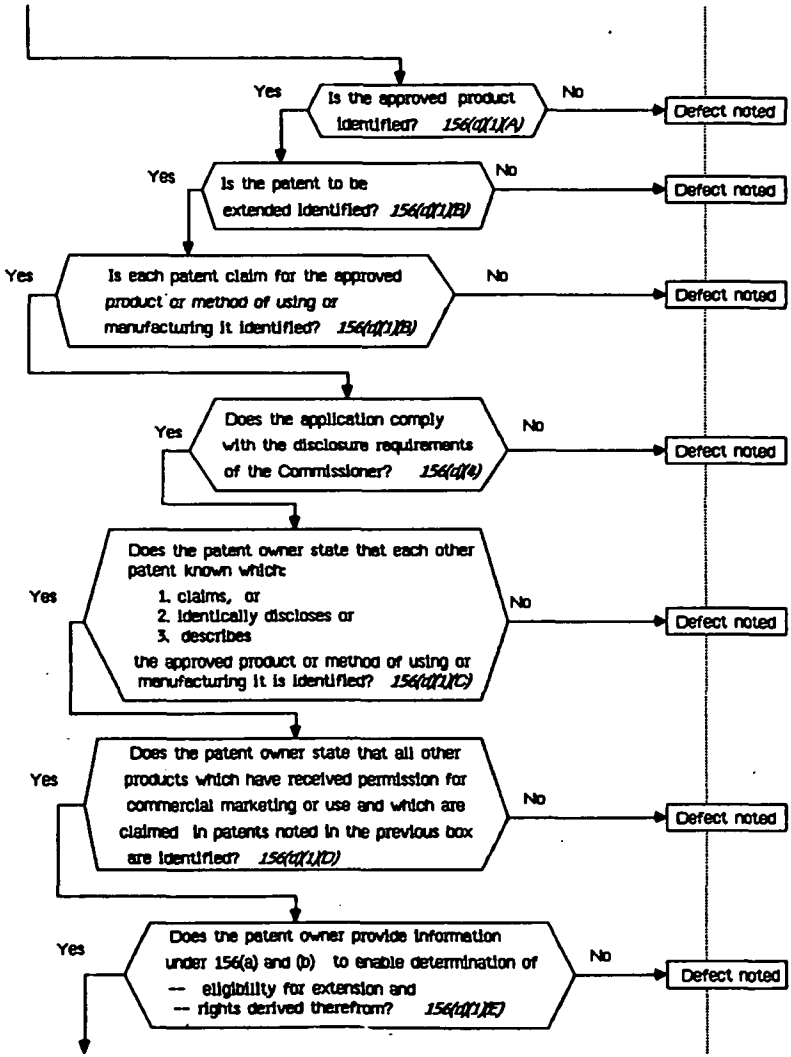


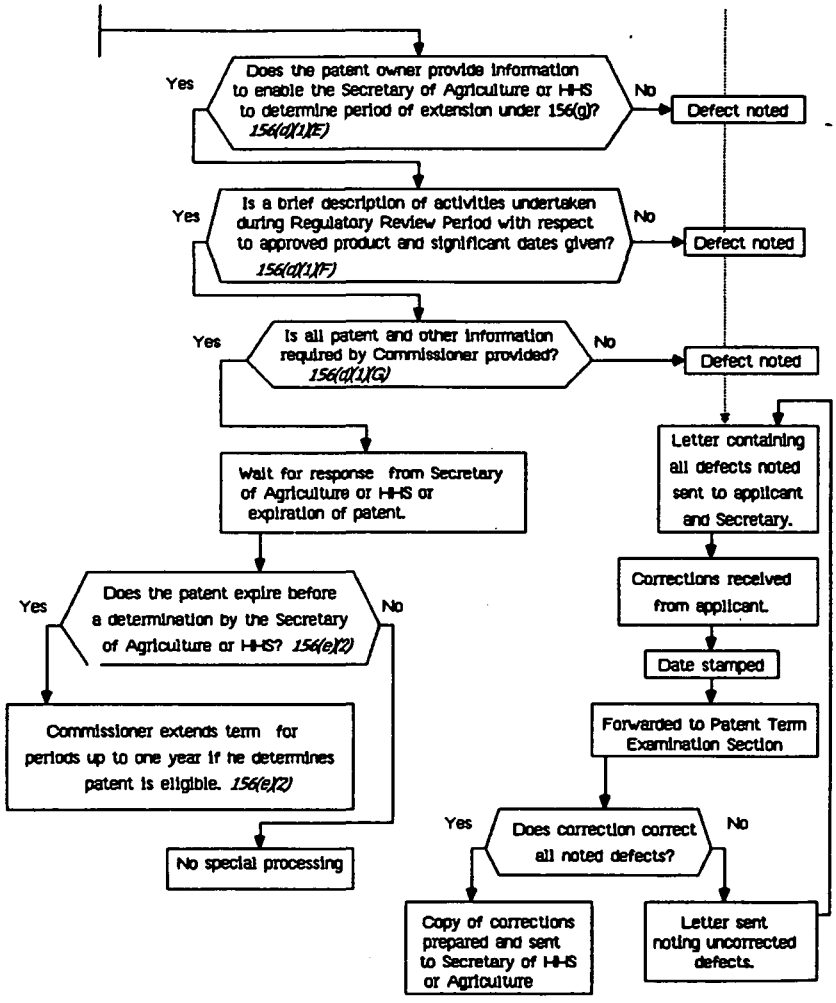

Does the patent claim any other drug product?
- a medical device?
- a food or color additive?
- a method of using or manufacturing it?
and such product, device and additive are subject to the Federal Food, Drug, and Cosmetic Act. 156(d)(2)(A)(ii)
Yes
No
Defect noted
Commissioner notifies and provides a copy of the application to Secretary of Health and Human Services within 60 days of submission of application 156(d)(2)(A)(ii)
PATENT TERM EXAMINATION SECTION DETERMINATIONS
Patent claims:
a product?
method of using product?
or method of manufacturing product?
156(a)
Yes
No
Defect noted
Has term of patent expired before application for extension under 156(d) submitted ? 156(a)(1)
No
Yes
Defect noted
Has term of patent been extended? 156(a)(2)
No
Yes
Defect noted
Is application for extension by owner of record? 156(a)(3)
Yes
No
Is application by agent of owner of record? 156(a)(3)
Yes
No
Defect Noted


Has product been subject to regulatory review period before its commercial marketing or use? 156(a)(5)
Yes
No
Defect noted
Patent claims another product or a method of using or manufacturing another product which received permission for commercial marketing or use under such provision of law before the filing of an application for extension? 156(a)(8)
No
Yes
Defect noted
Does patent claim product? 156(a)(4)(A)
Yes
No
Product identically disclosed in another patent having earlier issuance date or which was previously extended? 156(a)(4)(A)(ii)
No
Yes
Defect noted
product claimed in other patent with earlier issuance date or which was previously extended? 154(a)(4)(B)
No
Yes
Holder of patent to be extended has been or will become holder of the other patent? 156(a)(4)(B)(i)
No
Yes
Defect noted
Holder of the other patent has been or will become holder of the patent to be extended? 156(a)(4)(B)(ii)
No
Yes
Defect noted

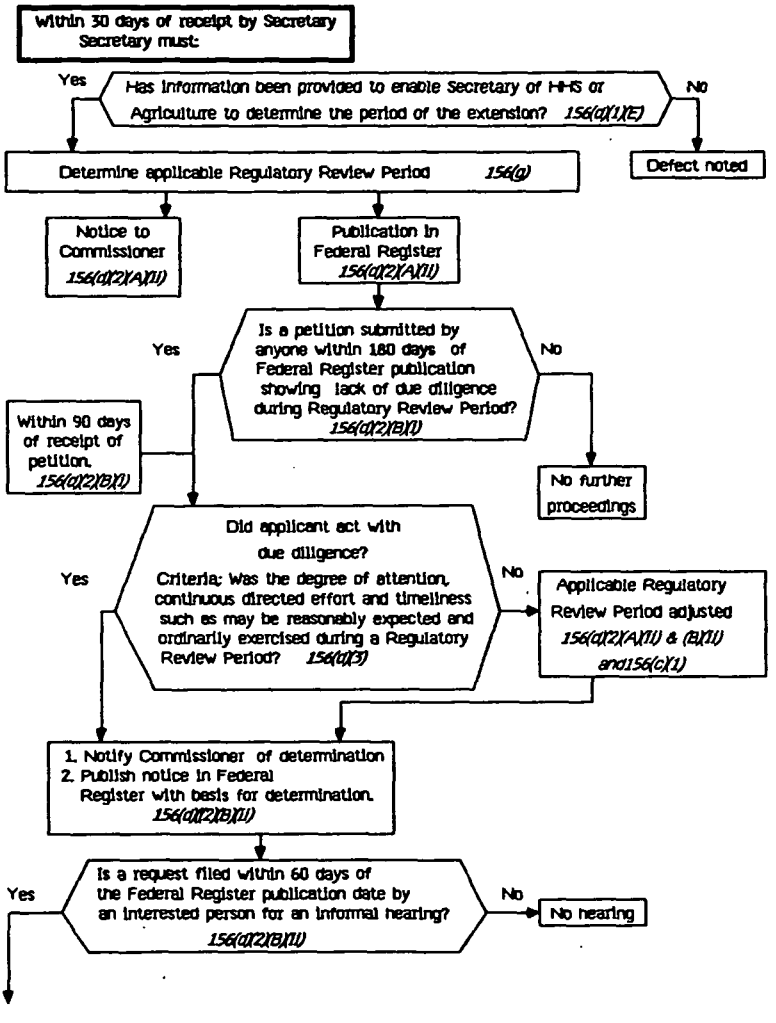

Does patent claim a method of using product? 156(a)(4)(A)
Yes
No
Identically disclosed or described in another patent having an earlier issuance date or which was previously extended? 156(a)(4)(A)(I)
No
Yes
Defect noted
Product claimed in other patent with an earlier issuance date or which was previously extended? 156(a)(4)(A)(I)
No
Yes
Defect noted
Is permission for the commercial marketing or use of the product after such Regulatory Review Period the first permitted commercial marketing or use of the product under the provision of law under which such Regulatory Review Period occurred? 156(a)(7)(A)
Yes
No
Defect noted
Does patent claim a method of manufacturing product? 156(a)
Yes
No
Defect noted
Does method of manufacturing primarily use recombinant DNA technology 156(a)(5)(A) & (B)
No
Yes
Have other patents been issued which claim the product? 156(a)(5)(A)
No
Yes
Defect noted
Have other patents been issued which claim the method of using the product? 156(a)(5)(A)
No
Yes
Defect noted

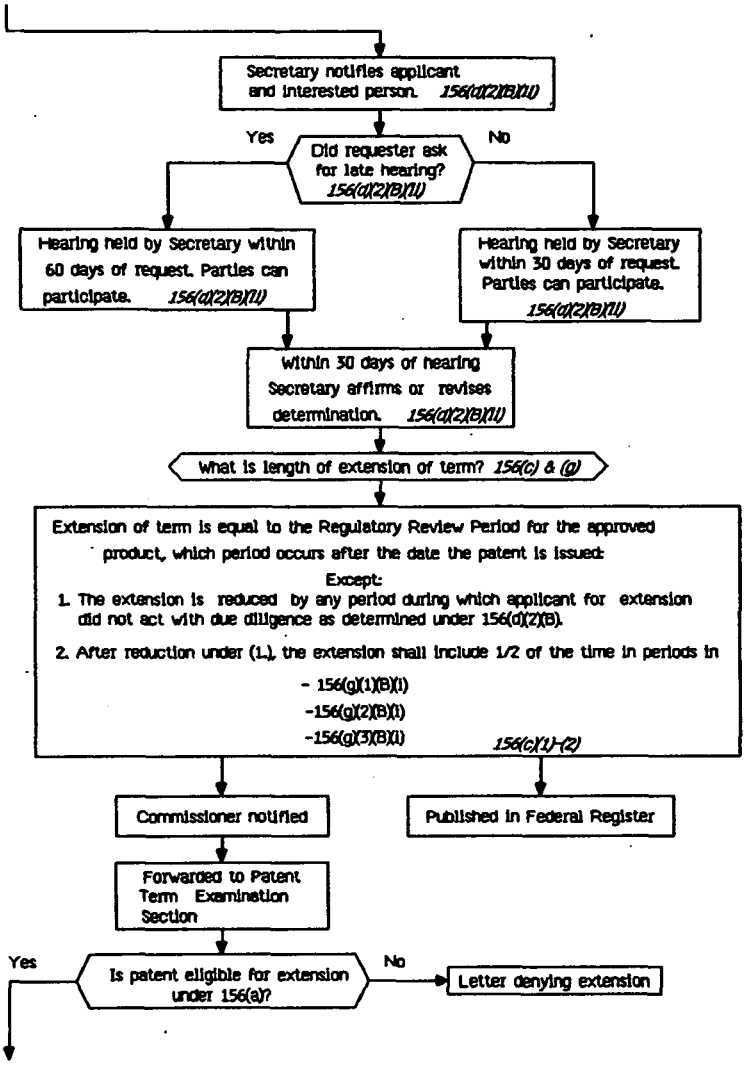

Other patent may be issued which claims method of using the product for any known therapeutic purposes? 156(A)(5)(A)
No
Yes
Defect noted
Is permission for the commercial marketing or use of the product after such Regulatory Review Period the first permitted commercial marketing or use of the product under the provision of law under which such Regulatory Review Period occurred? 154(a)(7)(A)
Yes
No
Defect noted
Is another method of manufacturing the product primarily using recombinant DNA technology claimed in a patent having an earlier issuance? 156(a)(5)(B)(I)
No
Yes
Defect noted
Is there a patent for the product or for a method of using the product? 156(a)(5)(B)(II)
No
Yes
Is that patent held by the holder of the patent for the method of manufacturing? 156(a)(5)(B)(I)
No
Yes
Defect noted
Is holder or person who controls the holder of that patent owned or controlled by the holder of the patent for method of manufacturing the product, or vice versa? 156(a)(5)(B)(I)
No
Yes
Defect noted
Is permission for commercial marketing or use of the product after such Regulatory Review Period the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent? 156(a)(7)(B)
Yes
No
Defect noted

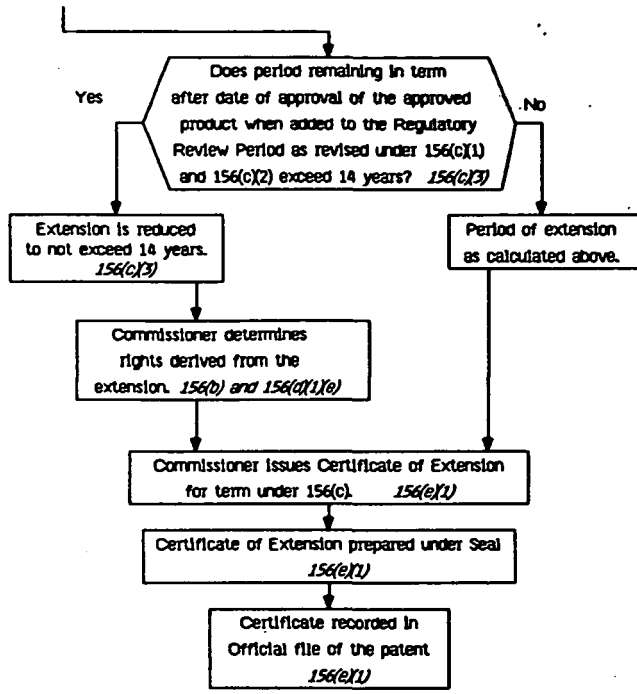

Yes
Is the approved product identified? 156(d)(1)(A)
No
Defect noted
Yes
Is the patent to be extended identified? 156(d)(1)(B)
No
Defect noted
Yes
Is each patent claim for the approved product or method of using or manufacturing it identified? 156(d)(1)(B)
No
Defect noted
Yes
Does the application comply with the disclosure requirements of the Commissioner? 156(d)(4)
No
Defect noted
Yes
Does the patent owner state that each other patent known which:
1. claims, or
2. identically discloses or
3. describes
the approved product or method of using or manufacturing it is identified? 156(d)(1)(C)
No
Defect noted
Yes
Does the patent owner state that all other products which have received permission for commercial marketing or use and which are claimed in patents noted in the previous box are identified? 156(d)(1)(D)
No
Defect noted
Yes
Does the patent owner provide information under 156(a) and (b) to enable determination of
— eligibility for extension and
— rights derived therefrom? 156(d)(1)(E)
No
Defect noted


Does the patent owner provide information to enable the Secretary of Agriculture or HHS to determine period of extension under 156(g)? 156(d)(1)(E)
Yes
No
Defect noted
Is a brief description of activities undertaken during Regulatory Review Period with respect to approved product and significant dates given? 156(d)(1)(F)
Yes
No
Defect noted
Is all patent and other information required by Commissioner provided? 156(d)(1)(G)
Yes
No
Defect noted
Wait for response from Secretary of Agriculture or HHS or expiration of patent.
Does the patent expire before a determination by the Secretary of Agriculture or HHS? 156(e)(2)
Yes
No
Commissioner extends term for periods up to one year if he determines patent is eligible. 156(e)(2)
No special processing
Letter containing all defects noted sent to applicant and Secretary.
Corrections received from applicant.
Date stamped
Forwarded to Patent Term Examination Section
Does correction correct all noted defects?
Yes
No
Copy of corrections prepared and sent to Secretary of HHS or Agriculture
Letter sent noting uncorrected defects.

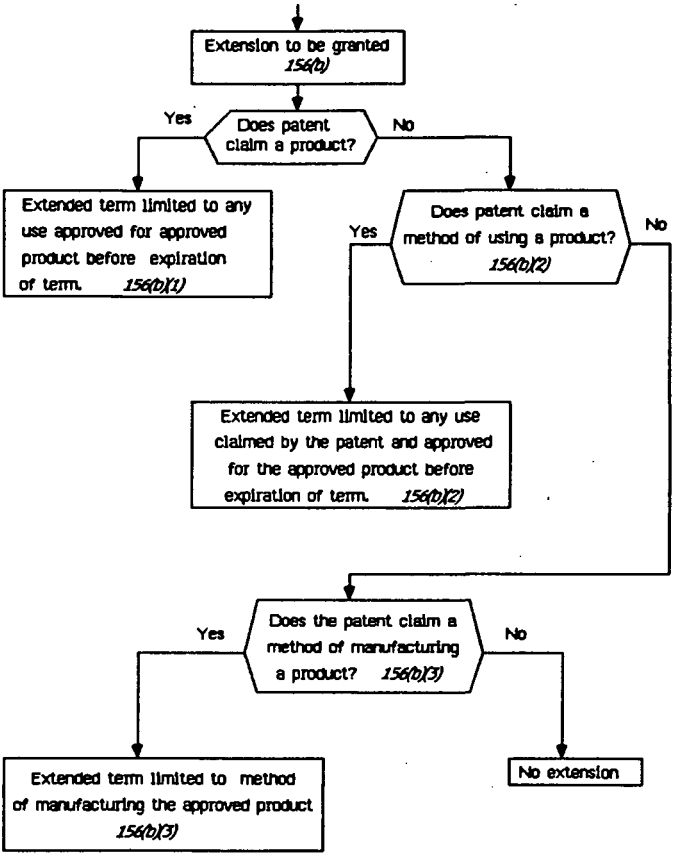
SECRETARY'S REVIEW



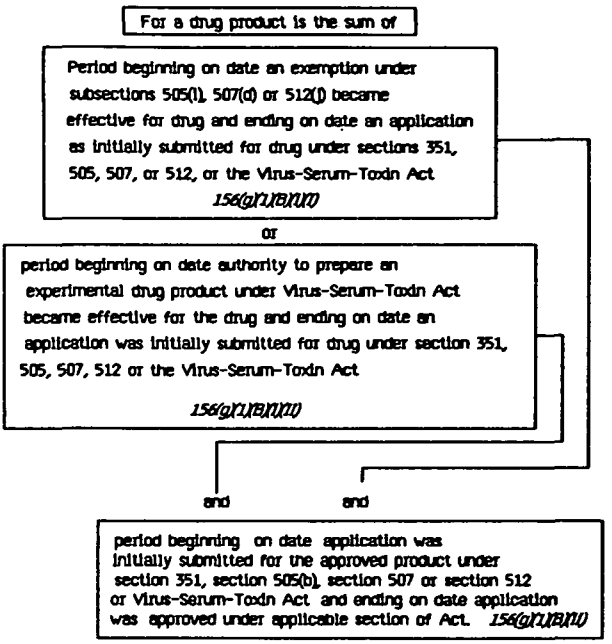

Secretary notifies applicant and interested person. 156(d)(2)(B)(i)
Yes
Did requester ask for late hearing? 156(d)(2)(B)(ii)
No
Hearing held by Secretary within 60 days of request. Parties can participate. 156(d)(2)(B)(ii)
Hearing held by Secretary within 30 days of request. Parties can participate. 156(d)(2)(B)(ii)
Within 30 days of hearing Secretary affirms or revises determination. 156(d)(2)(B)(ii)
What is length of extension of term? 156(c) & (g)
Extension of term is equal to the Regulatory Review Period for the approved product, which period occurs after the date the patent is issued:
Except:
1. The extension is reduced by any period during which applicant for extension did not act with due diligence as determined under 156(d)(2)(B).
2. After reduction under (1.), the extension shall include 1/2 of the time in periods in
- 156(g)(1)(B)(i)
-156(g)(2)(B)(i)
-156(g)(3)(B)(i)
156(c)(1)-(2)
Commissioner notified
Published in Federal Register
Forwarded to Patent Term Examination Section
Yes
Is patent eligible for extension under 156(a)?
No
Letter denying extension

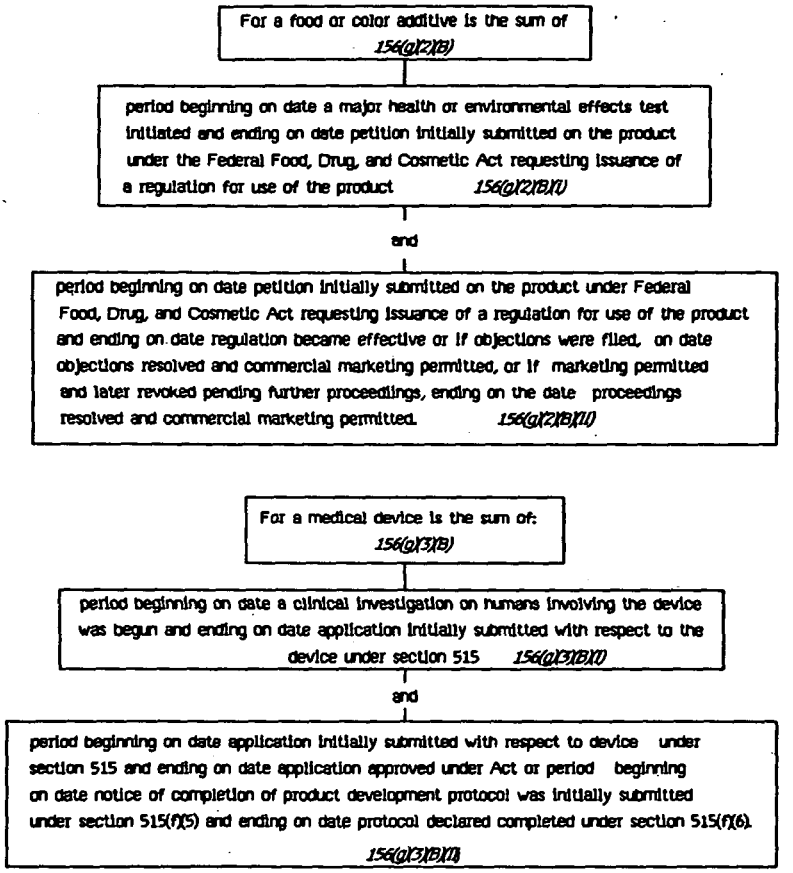

Does period remaining in term after date of approval of the approved product when added to the Regulatory Review Period as revised under 156(c)(1) and 156(c)(2) exceed 14 years? 156(c)(3)
Yes
No
Extension is reduced to not exceed 14 years. 156(c)(3)
Period of extension as calculated above.
Commissioner determines rights derived from the extension. 156(d) and 156(d)(1)(a)
Commissioner issues Certificate of Extension for term under 156(c). 156(e)(1)
Certificate of Extension prepared under Seal 156(e)(1)
Certificate recorded in Official file of the patent 156(e)(1)

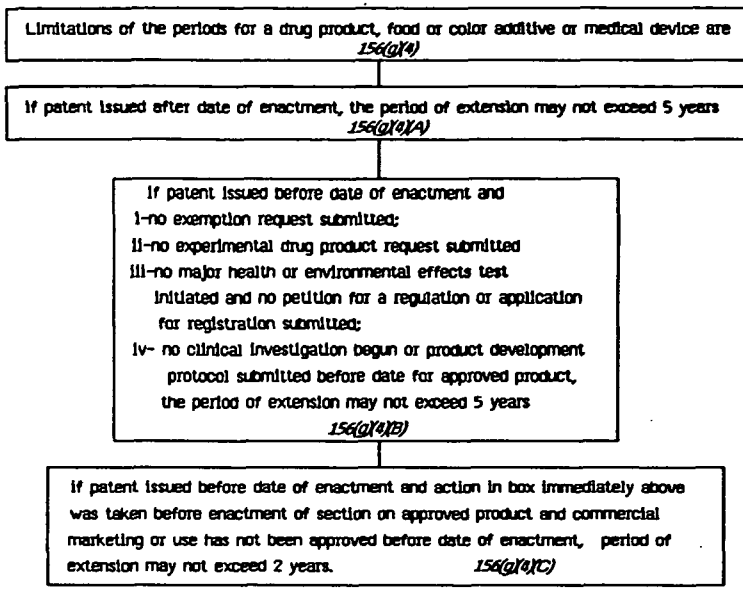
Rights derived from extension



The Regulatory Review Period *156(g)*




For a food or color additive is the sum of
156(g)(2)(B)
period beginning on date a major health or environmental effects test initiated and ending on date petition initially submitted on the product under the Federal Food, Drug, and Cosmetic Act requesting issuance of a regulation for use of the product 156(g)(2)(B)(i)
and
period beginning on date petition initially submitted on the product under Federal Food, Drug, and Cosmetic Act requesting issuance of a regulation for use of the product and ending on date regulation became effective or if objections were filed, on date objections resolved and commercial marketing permitted, or if marketing permitted and later revoked pending further proceedings, ending on the date proceedings resolved and commercial marketing permitted. 156(g)(2)(B)(ii)
For a medical device is the sum of:
156(g)(3)(B)
period beginning on date a clinical investigation on humans involving the device was begun and ending on date application initially submitted with respect to the device under section 515 156(g)(3)(B)(i)
and
period beginning on date application initially submitted with respect to device under section 515 and ending on date application approved under Act or period beginning on date notice of completion of product development protocol was initially submitted under section 515(f)(5) and ending on date protocol declared completed under section 515(f)(6).
156(g)(3)(B)(ii)


Limitations of the periods for a drug product, food or color additive or medical device are 156(g)(4)
If patent issued after date of enactment, the period of extension may not exceed 5 years 156(g)(4)(A)
If patent issued before date of enactment and
I-no exemption request submitted;
II-no experimental drug product request submitted
III-no major health or environmental effects test initiated and no petition for a regulation or application for registration submitted;
IV- no clinical investigation begun or product development protocol submitted before date for approved product,
the period of extension may not exceed 5 years 156(g)(4)(B)
If patent issued before date of enactment and action in box immediately above was taken before enactment of section on approved product and commercial marketing or use has not been approved before date of enactment, period of extension may not exceed 2 years. 156(g)(4)(C)

84-50

STATEMENT BY THE
AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS
TO THE HOUSE SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES, AND THE
ADMINISTRATION ON JUSTICE, COMMITTEE ON JUDICIARY ON
H.R. 3605, GENERIC DRUG - PATENT TERM RESTORATION

June 27, 1984

The AFL-CIO would like to take this opportunity to commend you for holding hearings on the Abbreviated New Drug Application (ANDA) - Patent Term Extension legislation. Organized labor urges the members of the Subcommittee to support this legislation which would resolve the long-standing problem of making generic drugs available to all Americans at low cost while dealing fairly with the patent rights of drug manufacturers.

The AFL-CIO strongly supports this legislation which, if passed, will make as many as 125 prescription drugs available to consumers in generic form and save purchasers $1 billion over the next 12 years. Although the AFL-CIO has had deep reservations about the issue of patent extension, we are pleased that the sponsors of this legislation were able to develop a compromise that would expedite the approval of generic drugs and allow manufacturers to make up time lost on their patents as a result of pre-market approval, without extending the current 17 year time limit.

As a nation, we now spend $350 billion on health care services. Over $20 billion is spent on drugs and 80 percent of this amount is paid for out-of-pocket by health care consumers who are extremely vulnerable to increases in the cost of prescriptions. Since 1980, drug prices have risen by a total of 37 percent, compared to a 13 percent increase for other commodities in the Consumer Price Index (CPI). According to the U.S. Bureau of Labor Statistics, in 1983 the price of cardiovascular medicines rose by 12.5%, sedatives increased by 22% and the price of cancer therapy drugs rose by a whopping 24%.

Employers who are faced with health insurance premiums rising at annual rates of 25 to 40 percent are pressuring organized labor to accept reductions in collectively bargained health care benefits. There has been pressure on labor at the bargaining table to drop drug coverage, discontinue payment for eyeglasses and cut back on preventive care services. The AFL-CIO has been working with its affiliated local and international unions to develop

initiatives which will reduce health care costs without reducing benefits. These initiatives include providing coverage in contracts for preadmission testing, preadmission certification, mandatory second surgical opinion, preventive care and early diagnosis and treatment. Unions which have made, or are in the process of making, provision in their contracts to cover the cost of generic drugs, often find that many of the most frequently prescribed drugs do not yet have on the market approved generic substitutes.

By allowing manufacturers of generic drugs to file a scaled-down drug application, called an ANDA, this legislation would remove the duplicative testing requirements that prevent a generic drug from coming on the market for up to 3-5 years after the patent of an equivalent brand name drug expires. This delay works to the disadvantage of the consumer by perpetuating the monopoly the original manufacturer has had on a brand name drug and giving the manufacturer leeway to keep prices high.

The AFL-CIO believes that if the Food and Drug Administration certifies that generics are chemically and therapeutically equivalent to brand name drugs, which have already been approved, they ought not to be required to perform additional and costly tests before being allowed to penetrate the market. Consumers have been waiting far too long for legislation to be passed which would expedite the approval process of generic drugs.

We are encouraged that the majority of the Pharmaceutical Manufacturers Association (PMA) has endorsed this bill. In the past, organized labor has taken the position that patent term extension legislation is anti-competitive, forces consumers to pay top dollar for prescription drugs and prevents lower cost substitutes from coming on the market. We are prepared, however, to support the provisions of this bill which would allow manufacturers whose drugs were approved prior to their product coming onto the market to make up for time lost on their patent, in exchange for shortening the approval process for generic drugs. However, if the patent term provisions are expanded in any way, we would be forced to reevaluate our support for this legislation.

Thank you for giving us the opportunity to share our views on this issue with the Subcommittee and we urge you to contact us if we can be of further assistance on this issue.

ARNOLD & PORTER

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JAMES F. FITZPATRICK
DIRECT LINE: (202) 872-6878

July 23, 1984

The Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts, Civil
Liberties and the Administration
of Justice
2232 Rayburn House Office Building
Washington, D. C. 20515

Dear Chairman Kastenmeier:

In response to your request of July 6, 1984, we are enclosing answers to those questions which were addressed to the "second panel," i.e., the coalition of research-based pharmaceutical companies. If you wish, we are prepared to provide additional information in response to the questions that were propounded or to discuss them in person with members of the Committee or its staff. We would of course be pleased to answer any other inquiries.

Sincerely,

James F. Fitzpatrick

Enclosures

cc: Members, Subcommittee on
Courts, Civil Liberties
and the Administration of Justice
David Beier, Assistant Counsel
Thomas Mooney, Minority Counsel

Question 1(a):

Doesn't the bill really amount to a clarification of the case law -- pre-Bolar -- that parties could experiment with patented products? By analogy, didn't the Supreme Court do the same type of thing when it read the concept of "fair use" in copyright law to include some types of home taping?

Answer:

First: H.R. 3605, which would reverse Bolar, does not represent a "clarification of the case law" -- as the question states, rather it totally reverses the doctrine of "experimental use" as that body of law has developed over the last 200 years. In Bolar, the District Court found that "[Bolar's] experimentation is commercial preparation . . . for post-expiration competition." Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc., 572 F. Supp. 255, 257 (E.D.N.Y. 1983), rev'd, 733 F.2d 858 (Fed. Cir. 1984) (emphasis supplied). When the Court of Appeals analyzed the doctrine of "experimental use" in light of that finding, it concluded that the "experimental use" exception was never intended to encompass experiments conducted with a business purpose in view. Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc., 733 F.2d 858 at 862-63 (Fed. Cir. 1984). The fact is that Bolar did not create new law, but reaffirmed a long standing rule.

Second: the question also implies that there is an analogy between the "fair use" doctrine in copyright law as described in Sony Corp. v. Universal City Studios, 104 S. Ct. 774 (1984) and the infringing activities involved in the Bolar case. However, there is an overriding difference between the two. The activity in Sony involved noncommercial home recording television broadcasts for later viewing at home (i.e., "time shifting"). By contrast, the patent infringement in Bolar (which would be legalized under Section 202 of H.R. 3605) was done for strictly commercial purposes.

When the Supreme Court in Sony decided that home recording was within the "fair use" exception to copyright protection, it laid great stress on the noncommercial nature of that "time shifting." In evaluating the defense that a copyright infringement is within the "fair use" exception, the Court said that the very first factor to be considered is,

> ". . . that 'the commercial or nonprofit character of an activity' be weighed in any fair use decision. If the Betamax were used to make copies for a commercial or profit-making purpose, such use would presumptively be unfair." Sony Corp. v. Universal City Studios, supra, 104 S. Ct. at 792.

would be taken away and transferred to a competitor for use in securing a business advantage over the patentee.

After observing that, "time shifting for private home use must be characterized as a noncommercial, nonprofit activity," id., the Court laid down the following rule:

> "[E]very commercial use of copyrighted material is presumptively an unfair exploitation of the monopoly privilege that belongs to the owner of the copyright, [but] noncommercial uses are a different matter." Id. at 793 (emphasis supplied).

The contrast could not be sharper between the private, noncommercial use of the copyrighted works in Sony and the plainly "commercial purposes" of the infringement in Bolar. Bolar, supra, 733 F.2d at 863. As the Bolar Court of Appeals declared:

> "Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the '053 patent. Bolar may intend to perform 'experiments,' but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention." Id.

No doubt exists as to the commercial nature of the activities that would be sanctioned under Section 202 of the bill. Rights that are now the property of the patentee

Question 1(b):

Assuming for the sake of argument that H.R. 3605 does constitute a taking, couldn't we easily resolve this problem by providing a compulsory license (wherein the pioneer company would receive payment for this limited use by the generic)?

Answer:

Where there has been a taking of property, the Fifth Amendment requires payment of "just compensation." As the Supreme Court has held, "just compensation" means that the payment "must be a full and perfect equivalent for the property taken" Monongahela Navigation Co. v. United States, 148 U.S. 312, 326 (1893). The owner must be put in as good a postion monetarily as if his property had not been taken. United States v. Reynolds, 397 U.S. 14, 16 (1970); United States v. Miller, 317 U.S. 369, 373 (1943).

Under those controlling standards, it would be unrealistic to assume that compulsory licensing at some arbitrarily designated rate would suffice as "just compensation," because the perfect equivalent of what is taken is the full value of the exclusive use of that property, not its mere value for licensing purposes. Payment of a nominal amount would not meet the constitutional requirement. Loretto v. Teleprompter Manhattan

CATV Corp., 458 U.S. 419 (1982). Indeed, the Court of Appeals in Bolar was "skeptical" to the suggestion that Roche's damages might have been nominal, and it observed that "the economic injury to Roche is, or is threatened to be, substantial, even though the amount of material used in the tests was small." Roche Products, Inc. v. Bolar Pharmaceutical Co., supra. 733 F.2d at 866.

The problem of calculating the perfect equivalent in monetary terms of valuable patent property which generic competitors are seeking to obtain and exploit commercially, would be bound to generate substantial claims litigation. The potential cannot be ignored that the government would have to pay very large sums for each such "taking" under the statute. Even if some independent procedures were devised to relieve the burden on the courts, the administrative process would still be complex and costly given the likelihood of numerous and substantial claims. See Hawaii Housing Authority v. Midkiff, 104 S. Ct. 2321, 2326 (1984). Unlike the usual eminent domain case, here the government would lose control over the number and size of the claims to which it would become subject, since it will, in effect, have delegated to the generic companies the decisions as to the identities and numbers of patents to be subjected to a Section 202 taking.

Furthermore, the suggestion of "compulsory licensing" of patents is bound to raise profound questions of patent policy. Not the least of them concerns the impact on, and credibility of this country's position in negotiating international protection of intellectual property with Third World nations. As declared in the New Jersey Patent Law Association's Statement dated June 26, 1984 on H.R. 3605:

> "Government and industry representatives of this country have for years preached throughout the world the evils of laws which deny or disregard deserved and necessary property rights in any form related to intellectual property. A recent example is the long and frustrating debate surrounding the revision of the Paris Convention and our leadership role in trying to dissuade the Third World developing countries from authorizing certain forfeiture and compulsory licensing provisions, a number of which would have less economic impact on patent holders and research companies than the proposed legislation. In denying recognition of an independent right in the valuable asset constituting the data base of an approved NDA, and in providing for a forfeiture and compulsory licensing result, the legislation in considerable measure adopts the attitudes of many Third World and Eastern Bloc countries. If this legislation passes in its current form, our political credibility in the world intellectual property community will be severely damaged."

Finally, it should be kept in mind that the grant to a competitor of a compulsory license is a concept usually reserved to remedy serious violations of law -- a remedy used against those who have abused their patent rights. Hartford-Empire Co. v. United States, 323 U.S. 386, clarified, 324 U.S. 570 (1945). It would be fundamentally unfair to apply this essentially punitive concept against those who have acted lawfully and in reliance on the provisions and intent of the patent laws.

We need only recall the unfortunate experience of Canada which followed the advent of compulsory licensing of pharmaceutical patents in that country in order to realize the serious effects on research and development to which compulsory licensing can lead. Canada had an active pharmaceutical research industry before compulsory licensing was introduced. Now, that industry is substantially diminished. As Mr. Stafford testified at the hearing, compulsory licensing "undermin[ed] the incentives for research . . . in Canada where it virtually destroyed the system." Testimony of John R. Stafford, June 27, 1984, Transcript, p. 108. Indeed, as we understand it, the Canadian authorities are actively engaged in seeking to undo that legislative experiment in compulsory patent licensing.

Question 1(c):

With respect to the Klein claims, isn't it true that the cases cited stand for the proposition that Congress may not reverse a pending court decision by totally depriving all Federal courts of jurisdiction to hear cases? For example, in Klein the Congress had attempted to deprive the Supreme Court and the Court of Claims of jurisdiction over claims against the government by former supporters of the Confederacy who had received a Presidential pardon. Thus, isn't that case distinguishable as involving both court stripping and an infringement on the Executive's authority to issue pardons?

Answer:

This question calls for an interpretation of United States v. Klein, 80 U.S. 128 (1872) on the assumption that it is the basis of the coalition's constitutional argument. It is not. The analyses presented by Professors Dorsen and Monaghan are based on the demonstrated proposition that Section 202 of H.R. 3605 would constitute a taking of property within the meaning of the Fifth Amendment. In light of the Supreme Court decision in Ruckelshaus v. Monsanto, 52 U.S.L.W. 4886 (1984), that point cannot seriously be disputed.

Klein would of course provide a wholly independent basis for challenging the legislation insofar as the bill reverses the rule of decision in the ongoing Bolar litigation itself. To do so would, as the Supreme Court indicated in Klein, allow the legislative branch to prescribe rules

of decision to the judicial branch in cases pending before the courts. Such action would "[pass] the limit which separates the legislative from the judicial power." United States v. Klein, 80 U.S. 128, 147 (1872). However, the issues raised by Section 202 go far beyond the separation of the judicial and legislative powers in a single case. Our more fundamental concern is the impact which Section 202 would have on all existing drug patents -- and the constitutional implications that would be raised under the taking clause of the Fifth Amendment.

Question 2:

If we accept your arguments on Roche v. Bolar, doesn't it necessarily follow that Congress can never diminish the intellectual property rights of a person once they have been granted? If this is so, how could the Supreme Court so easily deprive the movie industry of copyright interests in Sony v. Betamax?

Answer:

This question is answered in large part by our response to the first question of the series, but allow us a slight elaboration at the risk of repetition.

First, the Supreme Court did not "deprive" anyone of copyright interests in Sony Corp. v. Univeral City Studios, supra. All that was involved in that case was noncommercial private home viewing by individuals. Had the Supreme Court been faced in that case with commercial use of copyrights for competitive purposes, there can be little question that the basis for the 5:4 majority holding that private viewing was "fair use" would have disappeared. As the majority opinion declared,

> "If the Betamax were used to make copies for a commercial or profit-making purpose, such use would presumptively be unfair." Sony Corp. v. Universal City Studios, supra at 792.

Second, the Fifth Amendment does in fact prohibit Congress from taking property from any person without compensation. In this respect there is no distinction

between tangible property or intellectual property. Both categories share the same constitutional protections. Just a few weeks ago the Supreme Court decided in Ruckelshaus v. Monsanto, supra, that Monsanto's trade secrets were a form of intellectual property whose taking was subject to the protections of the Fifth Amendment. As to patent rights, the Supreme Court's earlier admonition in William Cramp & Sons Ship & Engine Building Co. v. International Curtis Marine Turbine Co., 246 U.S. 28, 39-40 (1918) bears repeating:

> "rights secured under the grant of letters patent by the United States were property and protected by the guarantees of the Constitution and not subject therefore to be appropriated even for public use without adequate compensation."

Question 3:

Do the members of the Research Coalition uniformly oppose any changes in the Abbreviated New Drug Approval process? Isn't that the reason for your opposition to the bill?

Answer:

The members of our coalition strongly endorse the objectives of H.R. 3605, which of course include accelerating the availability of safe and effective generic drug products. We believe, however, that the legislation as introduced contains a number of provisions that are unnecessary to accomplish its objectives, and create serious disincentives to research that will adversely affect the development of new drug therapies. Our coalition has proposed a limited number of amendments that address the problems we have identified. If these amendments are adopted, our coalition would strongly support H.R. 3605, including the provisions that establish a process for Abbreviated New Drug Applications.

It is important to note that our coalition is not alone in identifying problems with the current version of H.R. 3605. In testimony on H.R. 3605 and its Senate equivalent, S. 2748, the Patent and Trademark Office and the Food and Drug Administration -- the agencies charged with implementing the legislation -- both expressed serious reservations of their own. Indeed, it is interesting to note that the concerns expressed by the two agencies, when taken together, are nearly identical to concerns that have been consistently expressed by this coalition.

Question 4:

H.R. 3605 provides for limited patent extension for drugs which have been patented and which were approved by FDA after 1982. Do you support this coverage of drugs in the pipeline? Is it fair to provide an extension for these drugs when the basic investment decisions have already been made (i.e., isn't coverage of pipeline drugs a windfall to some companies)?

Answer:

There are several sections of H.R. 3605 that provide an extension of market exclusivity. One set of provisions authorizes up to two years of patent restoration for pipeline drugs not yet approved by FDA, while another section -- the so-called "transition provision" -- prohibits FDA from granting ANDAs for a period of 10 years for a limited category of drugs first approved by FDA after January 1, 1982.

Drugs approved by FDA prior to the passage of the bill, as well as drugs currently in the pipeline, were developed with the expectation that prospective competitors would have to file full NDAs to receive FDA approval, and our investment decisions were made on that basis. This bill, of course, substantially changes the rules for FDA approval, and it is entirely possible that some of these drugs will never recover their investment. We therefore support both the pipeline provision and transition provisions in principle, since they are intended to compensate for these changes.

As we have consistently noted, however, we do have a problem with the language of the bill's transition provisions, which we believe is too narrow. As drafted, the bill only protects new active ingredients, thus benefiting a handful of products. It discriminates against those companies that invested in research in areas such as new indications, new dosage forms, new delivery systems and innovative formulations by excluding such products from the transition provisions.

PHARMACEUTICAL MANUFACTURERS Association

LEWIS A. ENGMAN
PRESIDENT

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July 20, 1984

The Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts,
Civil Liberties and the
Administration of Justice
Committee on the Judiciary
U.S. House of Representatives
2137 Rayburn House Office Building
Washington, D. C. 20515

Dear Mr. Chairman:

In response to your request, enclosed are PMA's answers to your additional questions for the hearing record on patent term restoration.

Please contact me if you have any further questions or need additional information with respect to this legislation.

Sincerely,

Lewis A. Engman

Enclosures

1. Question: Does this bill in effect create a disincentive for pursuit of subsequent use patents by not providing for patent term extension once a prior product patent has been granted an extension?

For example, if drug Beta has been granted a product patent and is used for the treatment of heart failure and granted an extension, there would be less incentive to try to invent a new patented use for Beta (such as for infant diabetes) because the regulatory review period for the second use would not produce any patent term extension. Therefore, some will argue that research projects will be inappropriately oriented towards new product patents and not enough to subsequent use patents.

Answer: We do not believe the bill creates a disincentive for pursuit of subsequent use patents; but it is also true that the bill does not create the same kind of incentive for later use patents as it creates for the first patent relating to the product. We would have preferred fewer restrictions on patent term restoration but, because the bill represents a compromise between various interests, we were not able to achieve all of our preferences. Overall, the bill will increase incentives for R&D across the board.

2. Question: The bill provides the Commissioner of the FDA with authority to exclude others from the marketplace for certain unpatentable substances (such as lithium) if a new drug application has been approved. What is the purpose of this provision? Who will benefit from it? What are the antitrust implications of such a grant of market exclusivity? Doesn't this provision create a new second class four year patent administered by a Federal agency outside of either PTO or the Department of Justice?

Answer: The bill provides that abbreviated new drug applications for unpatentable products cannot be approved for 4 years from the date of approval of the pioneer NDA. A company wishing to market a competing product within that four years would have to obtain a full NDA.

This provision is in the bill to provide patent-type incentives to develop new drugs that are unpatentable for whatever reason. Beneficiaries will include those patients who will benefit from unpatentable medicines that otherwise might not have been developed and marketed. The orphan drug legislation enacted in the last Congress included a similar provision for unpatentable compounds which are used to treat certain diseases that do not affect large populations. No antitrust or other problems have been raised with respect to that legislation.

3. Question: Please explain the derivation of the 14-year rule and the five-year cap and how they will work?

Answer: The 14-year rule and the 5-year cap were compromises reached in the negotiations that resulted in the combined ANDA/Patent Term Restoration bill. The 5 year cap means that the amount of patent term restoration can never exceed 5 years. In earlier versions of the bill, the cap was seven years. The 14 year rule means that no patent term restoration can result in an effective patent life of more than 14 years. If a product's effective patent life would be 14 years or more without any restoration, it would not receive any restoration.

4. Question: What is the nature and extent of the problem we heard so much about last Congress -- "evergreening"?

Answer: We agree with the Commissioner of Patents and Trademarks that concerns over "evergreening" -- obtaining subsequent patents on a product in order to perpetuate market exclusivity -- are exaggerated. Subsequent patents for new uses, for example, are quite legitimate and should be encouraged. Therefore, we have argued that the limitations in the bill designed to deal with the perceived problem of evergreening are unnecessary and excessive. We agreed to their ultimate inclusion as part of the compromise which produced a bill which overall will produce net incentives for innovation.

5. Question: This bill provides for patent expansion for some drugs whose patents have already been granted. As to these drugs the bill differs from my bill last Congress; can you explain how this coverage will serve as an incentive for innovation when the invention has already occurred? How did you reach the 1982 to date of enactment cut off date?

Answer: For patented products which have not been marketed at the time of enactment, up to two years of extension is available if the regulatory review period has begun. If the regulatory review period has not begun, up to 5 years is possible. For these products that are patented as of the date of enactment, the "invention" may have occurred, but the very substantial and costly task of developing the patented compound into an FDA approved product will not have been completed. Reevaluations and decisions regarding the wisdom of continued investment occur throughout the preclinical and regulatory review periods. For every 10 products that enter phase I testing, only one results in an NDA being filed.

The second question addresses a different provision in the bill that would provide that abbreviated applications may not be approved for 10 years after NDA approval for drugs first marketed between January 1, 1982 and the date of enactment. This is a relatively short transition provision to assure that generic applications will not be approved the day after enactment of the legislation for pioneer drugs that have been marketed for a relatively short time. While any date delimiting such a transition period is admittedly arbitrary, the bill's sponsors decided upon 1982, the year in which the patent term restoration concept first received serious consideration in the U.S. Congress.

6. Question: The bill seems to hold in abeyance the approval of an ANDA for up to 18 months when a valid patent is in question. See page 26, lines 2-3. Why shouldn't we merely provide that the pioneer drug company may seek a preliminary injunction against a company seeking an ANDA for a product covered by an existing patent?

NOTE: Any such provision would have to clarify that Congress intends that the regular civil law standards apply to such injunction applications (e.g. irreparable harm and likelihood of success on the merits). Under current case law patent holders must prove "beyond question" that their patent is valid before they can obtain relief.

Answer: Experience has shown that a preliminary injunction in a patent infringement action is virtually impossible to obtain. Even with a revised judicial standard for preliminary relief, PMA companies remain doubtful that the courts would enjoin infringers prior to a final court determination on the merits.

In view of the tremendous risks and costs inherent in new drug development and the relatively limited costs facing a generic company wishing to challenge a patent, it is important that the legislation include a mechanism to prevent the generic company from funding an infringement lawsuit out of sales of the product during the litigation. The compromise reached in the bill provides that if a generic company intends to challenge the validity of a patent, it cannot market its product prior to the expiration of an 18-month period beginning with ANDA submission if the pioneer company brings a lawsuit which is not decided during that 18-month period.

7. Question: Is the basic purpose of this legislation to spur increased research and development? If so, couldn't we get more bang for the buck through tax credits, etc.?

Answer: The principal purpose of Title II of the legislation is to spur increased research and development of new drugs by providing for limited patent restoration. Existing tax credits and other incentives apply across-the-board to all industries. Pharmaceutical products as a class are unique in having less than half their patent life remaining after government approval for marketing. This legislation would cure some of that inequity by restoring a part of that lost patent life and, along with it, some of the incentive for pharmaceutical R&D that has been eroded over the past two decades.

8. Question: The bill has the net effect of overruling the recent Court of Appeals decision in Roche v. Bolar. Please explain why this change is necessary. Second, if the goal is to permit generics to commence limited testing shortly before a drug goes off patent -- shouldn't we limit this type of "experimental use" to 2 years?

Answer: The sponsors and supporters of the legislation have agreed from the beginning that generic products should not be approved for marketing prior to the expiration of a valid patent as extended under the legislation. In return, there has been a compromise agreement that preapproval testing could be conducted prior to the expiration of the patent, as extended, so that marketing could begin immediately thereafter. Therefore, the bill reverses the Roche v. Bolar decision to permit a generic company to "use" a patented product for the limited purpose of completing the testing necessary for FDA approval.

Since bioequivalence testing typically takes less than two years, a limitation on testing to the last two years of a valid patent should not be objectionable in principle, except for the difficult question of determining the validity of a challenged patent.

9. Question: The PMA testified before Congressman Waxman that there were 6 prerequisites to an acceptable ANDA bill. Have these conditions been met? Second, the bill provides a period of market exclusivity of 10 years for drugs approved between 1982 and date of enactment, how were these dates chosen? Why was 10 years used when in 1979 the Senate approved 7 years, and the Carter Administration urged 5 years?

Answer: In July of 1983, PMA testified before the Health Subcommittee on a brief one page bill that would have permitted ANDAs for post-1962 new drugs without any standards, restrictions, or transition period. Although the new 30 page proposal contained in Title I of H.R. 3605, as amended, does not meet all of the specific prerequisites noted in our earlier testimony, it is an acceptable compromise, especially considering that it is balanced by the salutory provisions of Title II, which of course was not part of Congressman Waxman's original proposal.

The ten-year marketing exclusivity provision is a transition period designed to assure that generic applications will not be approved immediately after enactment for pioneer drugs that have been marketed for a relatively short period of time. It will not apply at all to post-enactment approvals, but patent term restoration will become effective at that time, lessening the need for a continuing phase-in cushion. While any date delimiting such a transition period is admittedly arbitrary, the bill's sponsors decided upon 1982, the year in which the patent term restoration concept first received serious consideration in the U.S. Congress. Obviously, PMA's preference would have been a broader transition period.

The ten years is no more arbitrary than the 5 or 7 year periods mentioned in the question or the 15-year period suggested by an FDA executive several years ago. The principal differences between the earlier suggestions and the 10 year provision in the bill are that (a) the 10 years is limited to drugs approved during a discrete period of less than three years and (b) the Waxman ANDA provisions must be considered and evaluated along with the patent term restoration provisions of Title II, which of course were not part of the earlier proposals.

10. Question: The ANDA part of the bill will apparently open up a large market for generic manufacturers (e.g., 10 of the top 51 drugs which are to go off patent before 1986 have sales of over 1.34 billion dollars). Given that the major pharmaceuticals already control a large portion of the generic market in their own right, who will be the major beneficiaries of this legislation in the corporate world?

Answer: Beneficiaries will include research-based manufacturers who will have increased incentives for R&D resulting from patent term restoration, and companies marketing follow-on products who will be able to obtain ANDA approval more quickly from the FDA. Although research-based companies who decide to market products under ANDAs will benefit from the ANDA aspects of this legislation, this fact has had no apparent impact on the support of generic companies for the legislation.

The most important beneficiary of this bill is the consuming public who will benefit both from increased incentives for new medicines and from increased competition among manufacturers of established medicines.

11. Question: Section 101(b) of the bill provides that venue will lie only where the defendant resides or has his principal place of business. Why was this approach to venue taken in contravention of the general venue statute? Under the bill could a court transfer venue to a more convenient court?

Answer: The bill stipulates that any declaratory judgment action by the infringer is to be brought in the judicial district where the patent holder defendant has its principal place of business or a regular and established place of business. Thus the patent owner would not be subject to suit in every judicial district in which it is doing business as provided in the general venue statute. This limitation is balanced by the limited venue choices of a patent holder who elects to bring an infringement action under the bill. The bill is not intended to preclude a court from transferring venue to a more convenient court.

12. Question: The bill provides for a reduction of the possible patent term extension if the application failed to exercise due diligence (meaning the degree of attention, continuous directed effort, and timeliness as may be reasonably expected from, and are ordinarily exercised by, person during a regulatory review period). Can you provide some examples of what would and would not constitute due diligence?

Answer: The Report of the House Energy and Commerce Committee states:

> The Committee established a system for review of due diligence that requires the minimal amount of federal agency personnel time. The goal of the system is to assure that obvious delays during regulatory review, such as a prolonged period when human clinical trials on a drug product are not being conducted, are not counted towards patent extension. The system is not intended to cause a review of every action, but to identify significant periods of time when the loss of patent term resulted solely from the applicant's failure to pursue approval. Delays caused by the temporary unavailability of necessary testing facilities, or a scientific dispute involving tests required for approval or the interpretation of those tests, are examples of delays which can reasonably be expected to occur and would not be a basis for finding a lack of due diligence.

PREPARED STATEMENT OF
WILLIAM E. SCHUYLER, JR.

My name is William E. Schuyler, Jr. For more than 40 years, I have been extensively involved in the patent profession in both the public and private sectors. During the period 1969-71, I served as the Commissioner of Patents and during that term represented the U.S. in negotiating the Patent Co-operation Treaty. I was appointed Ambassador and Head of the U.S. Delegation to the 1981 session of the Diplomatic Conference for Revision of the Paris Convention for the Protection of Industrial Property.

I am appearing today at the request of a coalition of many of our nation's leading research based pharmaceutical companies who asked me to review H.R. 3605 and provide the Committee with my views on the content and practical application of the bill in light of my experience in patent prosecution, litigation, international negotiation, and as a former Commissioner of Patents.

At the outset, let me make three key points:

o Provisions of this bill encourage premature litigation by patent owners in many situations where substantive commercial controversies will not later materialize.

o By denying extension to many patents on worthy inventions, the bill in its present form is a very real disincentive to research in those areas.

o By compelling the Executive Branch to disclose trade secrets of U.S. manufacturers to foreign competitors, that indus-

try and our economy will be adversely affected by a loss of jobs and by an unfavorable change in the balance of trade.

Patent Litigation

I would first like to focus on the provisions of Title I relating to patent infringement and validity issues. Provision is made for an Abbreviated New Drug applicant to notify a patent owner that an application has been submitted to obtain approval to engage in commercial manufacturing of a patented drug before the applicable patent expires. For forty-five days after such notice, the applicant is precluded from seeking a declaratory judgment that the patent is invalid or not infringed. If the patent owner sues the applicant for patent infringement within the forty-five day period, then approval of the ANDA will be delayed until the litigation is decided, but in no event more than 18 months. As the Committee is well aware, trial of complex civil suits, like patent suits, is almost never completed within 18 months. An average pendancy of four years would be a better estimate, due primarily to congestion in the courts.

Because the applicant may serve such notice at the time of first submitting an ANDA to the Food and Drug Administration, applicants will, at minimal expense, have the opportunity to serve the notice with respect to inumerable drug products. Patent owners will likely respond to virtually every notice by filing suits for patent infringement -- for a couple of reasons: First, failure of the patent owner to respond may

support an estoppel or laches defense in subsequent litigation. Second, the eighteen-month delay in approval of the infringing product will afford short term protection to the patent owner.

As a result, it is likely that the courts will be inundated with patent litigation of issues that will not necessarily result in commercial controversies. That will certainly complicate the current congestion in the Federal Courts, and cause even longer delays in civil litigation.

This bill is saving generic manufacturers a number of years and tens of millions of dollars now required to obtain approval of a new drug application by permitting them use of the data generated by the innovator. Even a two year delay of approval of an ANDA from the submission of a completed ANDA, as proposed in an earlier draft of the bill, leaves the scales balanced heavily in favor of the generic manufacturers.

To limit the litigation triggered by this bill to those situations involving bona fide commercial controversies, I suggest that the timing of the notices to the patent owner be made coincident with filing of a completed ANDA. At that point the infringer will have invested sufficiently in his application to show his true intent to reach the commercial market, and the numbers of law suits will be dramatically reduced by weeding out some of the notices of invalidity which border on the frivolous. Also, the abitrary and unrealistic eighteen month period for litigation should be eliminated, with the Court having discretion to make effective the ANDA before final adjudication if the patent owner fails to reasonably cooperate in expediting

the action.

Patents Ineligible for Extension

Title II excludes various types of patents from eligiblity for restoration and places substantial limitations on the length of restoration. Reportedly, the drafters of this legislation have chosen to do this because they believe certain types of patents are amenable to manipulation of patent issuance, and therefore expiration dates and because they believe Congress has not received data on significant regulatory review delays on other than new chemical entity products. (See House Energy and Commerce Committee Report on H.R. 3605, page 30.) The first rationale has been addressed by provisions in the bill that limit the term of an extended patent to no more than 14 years after regulatory approval of the covered product. Moreover, there is a provision that limits restorable time to that occuring after the patent issues but before regulatory approval. In light of these two very substantial limitations, the patent exclusions set forth in Section 156(a) are excessive and unnecessary. If the second rationale is true, it is irrelevant because the bill does not grant restoration in the absence of regulatory delay. More importantly, any arbitrary exclusion of patents eligible for restoration may unwittingly skew research to less than optimal therapies.

Exclusion 4 produces the greatest deleterious effect by providing that a patent claiming a product (or a method of using

the product) may be extended only if the product is not claimed and the product and approved use are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended.

To appreciate the mischief generated by this provision, one must have some understanding of pharmaceutical research and patent practice.

Pharmaceutical research is normally conducted on families of compounds sharing similar structural features and (it is hoped) similar biological characteristics. The object is to study a sufficient number of compounds in the family so that enough commercial candidates will appear to provide a likelihood of generating at least one commercial compound. I should note in passing that the research and development expenses to bring one commercial compound from discovery to commercialization have been estimated to be on the order of $70-85 million dollars.

The practice of pharmaceutical research to concentrate on families of compounds leads inevitably to the filing of patent applications on these families of compounds which were discovered. Since a patent application must be filed at an early stage of research to avoid potential loss of patent rights, only preliminary screens of the compounds will have been conducted. There is generally no suggestion at the time the patent application is filed as to which members of the family (if any) will be commercially successful. As previously noted, such restriction does not accomplish the stated objectives of the bill and is unnecessary. It should be eliminated.

Divisional Applications

In the normal course of examining a pharmaceutical patent application, the Patent Office frequently requires that the claims in the application be divided into several applications for "subfamilies", depending on the classification system employed by the Patent Office and on the Examiner's decision as to the appropriate scope of protection for a single application. The patent owner must then select one of the subfamilies for examination in the originally-filed ("parent") application and file additional applications (called "divisional applications") claiming each of the other promising subfamilies of compounds. These divisional applications would contain the same disclosure as the parent application but each would contain claims directed to a different subfamily. The decision to divide the application into a number of subfamilies is made solely by the Patent and Trademark Office.

With this as background, it will be apparent to the Committee that the later-issued divisional applications would be precluded from extension by exclusion number 4 because of the earlier-issued parent application disclosing the entire family of compounds and their intended use. Since the patent owner generally has no idea at the time of filing the "divisional application" which member of the family of compounds (if any) will be commercially successful, he is unable to insure that the commercial compound is claimed in the parent application.

Exclusion 4 would therefore arbitrarily deny extension to patents covering approved products merely because an earlier issued patent discloses the product. Again, it is unnecessary and should be eliminated.

First filed, later issued applications

The committee should also appreciate that patents do not always issue in the order in which they are filed. Some applications encounter difficulties and problems in the Patent Office, while others are allowed quickly. By making the issue date the operative criterion, this provision of the bill could injure a party whose earlier-filed patent issues later. For example, a research-based pharmaceutical company might discover a family of compounds which appear, in preliminary screens, to have utility for treatment of certain forms of cancer. If this company files an application directed to these compounds, it is certain to face a rigorous examination by the Patent Office because of the general skepticism with regard to cancer treatment. Continuing along with the example, suppose that other researchers at this company develop a new and patentable process for preparing these compounds and that a second patent application is filed claiming the process. Because of the requirements of patent law that a patent application claim useful invention, the second patent application would necessarily have to disclose the compounds which are made by the new process and their therapeutic utility. If the second-filed application

issues first (as well it might), the first-filed application directed to the compounds would be ineligible for extension under exclusion 4.

Interferences

The United States Patent System awards a patent to the first inventor, not necessarily to the first person to file an application. If two applications are filed claiming the same invention, a contest occurs (called an "interference") to determine priority of invention and thus ownership of the resulting patent. This contest can occur not only between two or more applications, but also between one or more applications and an issued patent. If in such a situation the owner of the patent application were determined to have priority over an issued patent, his patent would nevertheless be barred from extension because his invention had been claimed in an earlier-issued patent. As a result of winning the interference he loses his right to an extension. This is but another example of the injustice created by exclusion 4. It should be eliminated for it serves no useful purpose.

Genus/Species

Moreover, a certain type of patent, known as a "species patent" would be ineligible for extension under exclusion 4 if the owner also owns a "genus" patent.

Because pharmaceutical research requires a continual exploratory and refining process along parallel pathways, new candidates for commercialization are, not uncommonly, chemical "species" falling within a broad class ("genus") of chemical compounds claimed in a patent.

Frequently, the compound approved by FDA is not even specifically mentioned in the original patent, but is identified only after years of additional expensive research. An early promising compound may later be found to exhibit a problem such as an undesirable side effect, requiring the inventor to abandon it in favor of other "species" compounds falling under the same genus patent. Species patents can be obtained on later developments that are not specifically disclosed in the original genus patent if they meet the statutory requirements of novelty, usefulness, and unobviousness. Such patents are more important today than ever, because, with the advent of new drug delivery systems and the new biotechnologies, substantial new health care advances frequently occur many years following the original grant of the genus patent. But, the existences of a generic claim in the earlier patent will preclude extension of the later patent to a commercially viable "species."

Denial of extension of the term of species patents acts as a research disincentive and serves to curb and impair scientific research in this fruitful area, denies the public the benefit of important medical advances, and reduces jobs in the research-based pharmaceutical industry.

Because of its inherent faults, I recommend the removal

of exclusion 4 from the bill.

Other Restraints on Extension

The effects of exclusions 2 and 8 are well considered together. Exclusion 2 would deny extension to a patent which has been previously extended, while exclusion 8 would deny extension to a patent claiming another product (other than the one with respect to which extension is now sought) or method of using or manufacturing another product, which product has been previously approved by the FDA.

Bearing in mind that the extension of a patent is limited by the bill to the particular compound and the use approved, the fact that a patent covers one compound which has already been approved (and with regard to which the patent may have been extended) should not prevent an extension with respect to an additional compound claimed by that same patent. Please let me emphasize that I am not recommending serial extensions, but simply the applicable extension of the original term with regard to a second compound claimed by the patent. If the two products under consideration were claimed by separate patents, each patent would be eligible for extension with respect to the applicable product and the approved use. No different outcome should result because the two products happen to be claimed in the same patent. Exclusion 2 should be deleted to rectify this inequity.

Exclusion 8 is much the same, except that it would deny extension to a patent with respect to a particular product merely

because it also claims a previously-approved product (even though the patent was not extended with respect to this previously-approved product). As an example of the reach of this exclusion, it is easy to conceive of a patent covering a family of compounds, one of which is rapidly approved as (e.g.) a topical antifungal. Because of the timely approval of this antifungal compound, the patent is not eligible for extension with regard to that compound. Included in the same family of compounds, however, is a compound which is useful for treatment of a more life-threatening disease, such as cancer. The approval process for this compound, both in the clinical testing and in the registration process, could be lengthy indeed and it might be many years after the issuance of the patent that this cancer-treatment compound is approved for commercial sale. To deny extension to the patent with respect to the cancer-treatment compound because of the previous approval of the antifungal compound would appear unjust. For this reason, exclusion 8 should be deleted.

It appears that the criteria for extension are designed to prevent supposed abuses in the patent system by which patent owners might to extend their period of exclusivity. I respectfully submit, however, that any such abuses of the patent prosecution process are adequately addressed by the provisions of the bill limiting the maximum extension of five years, and limiting any extended patent life to 14 years from the date of regulatory approval. Alleged abuses of the patent prosecution process cannot result in prolonging a patent beyond the term of

14 years after the date of regulatory approval.

Disclosure of Proprietary Data

Allow me to focus a moment on section 104, which would hurt American companies trying to compete overseas by forcing disclosure of confidential data, including trade secrets. It gives unfair advantage to foreign companies seeking health registrations in their own countries. Most foreign countries give preference to their own nationals, making it easier for them to obtain approval to market drug products. At present, a number of countries do not even recognize drug product patents. Of these, more than half require submission of a substantial amount of technical information to obtain drug marketing approvals; and the number is increasing. These countries account for some $ 585 million dollars of total pharmaceutical exports from the U.S. The point is that if confidential data are disclosed to the public, we make it much easier for foreign companies to use those data to obtain approval and a head start in their countries.

The bill strikes two blows against American companies. First, it deprives American companies of trade secrets obtained at great cost (often measured in tens of millions of dollars). Second, it deprives American companies of the ability to make first use of these costly data to obtain approval overseas, thereby hurting their ability to compete effectively in those foreign markets, with adverse side effects on the balance of trade and domestic employment. To avoid this disaster, I believe

it is essential that this valuable proprietary data be protected.

Conclusion

For reasons stated, I recommend removal of exclusions 2, 4 and 8 from the bill. While revisions I have suggested will resolve some basic problems, there are many additional technical points requiring careful attention. Also, I should point out that there are serious constitutional questions raised in the bill, one being the legislative overruling of the Roche v. Bolar decision as to patents issued prior to the effective date of the legislation. These questions also deserve careful attention in order to avoid future successful legal attack on the legislation.

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July 5, 1984

MEMORANDUM

TO: Members Of The House Subcommittee
On Courts, Civil Liberties And The
Administration of Justice

The Honorable Jack Brooks
The Honorable Romano L. Mazzoli
The Honorable Mike Synar
The Honorable Patricia Schroeder
The Honorable Dan Glickman
The Honorable Barney Frank
The Honorable Bruce A. Morrison
The Honorable Howard L. Berman
The Honorable Carlos J. Moorhead
The Honorable Henry J. Hyde
The Honorable Michael DeWine
The Honorable Thomas N. Kindness
The Honorable Harold S. Sawyer
David W. Beier III, Assistant Counsel

Enclosed is a response to Chairman Kastenmeier from Professor Dorsen of New York University School of Law to the questions raised at the recent hearing on H. R. 3605 with respect to the constitutional issues of Section 202 of that bill.

Sincerely,

Jack Lipson

Enclosure

New York University
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School of Law

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Norman Dorsen
Stokes Professor of Law

July 3, 1984

Hon. Robert Kastenmeier
Chairman, Subcommittee on Courts, Civil
Liberties and the Administration of Justice
Room 2232
Rayburn Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

In the course of my testimony before the Subcommittee on June 27, 1984, concerning the constitutional issues raised by Section 202 of H.R. 3605, two matters were raised that required a further submission. The first is a discussion of the relevance of Ruckelshaus v. Monsanto Co., which was handed down by the Supreme Court on June 26, 1984, only the day before the hearing. The second concerned Mr. Synar's question concerning Supreme Court cases holding congressional statutes unconstitutional under the Taking Clause of the Fifth Amendment. You were kind enough to grant me permission to address the Monsanto case in this letter, and I trust you would not object to my taking the opportunity to respond more fully to Mr. Synar at the same time. I shall address his question first.

1.

The Supreme Court has invalidated at least two federal statutes under the Taking Clause. The first case is the one I mentioned at the hearing, Lynch v. United States, 292 U.S. 571 (1934). The Court, in an opinion by Justice Brandeis, declared invalid the Act of March 20, 1933, which relieved the United States from all liability on its War Risk Insurance Policies. While the opinion discussed the Due Process clause, it is clear that the decision also rested on the Taking Clause. See 292 U.S. at 579.

The second case is Louisville v. Joint Stock Land Bank v. Radford, 295 U.S. 555 (1935). In that decision the Frazier-Lemke Act, which transferred valuable mortgage rights from one person to another, was held unconstitutional

under the Fifth Amendment as applied to a mortgage antedating its passage.

As my prepared statement noted, there are many cases in which federal and state regulatory action has been declared invalid under the Taking Clause. These cases are also precedent for the constitutional question concerning Section 202 because the Court has not distinguished in the standards it has employed depending on whether the taking was effected by a statute or a regulation or whether the taking was made by the federal government or a state.

A recent example is Kaiser-Aetna v. United States, 444 U.S. 164 (1979). In that case the Court held to be an unconstitutional taking certain U.S. Corps of Engineers regulations that required owners of a private pond, who had invested substantial sums to dredge and improve it into a marina, to convert the pond into a public aquatic park. In the course of his opinion Justice Rehnquist relied on a number of cases, including Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922), a case involving a state statute that was also referred to at the hearing.

Finally, it bears noting that the Supreme Court has explicitly included patent rights within the category of property protected by the Taking Clause. In William Camp & Sons Ship & Engine Building Co. v. International Curtis Marine Turbine Co., 246 U.S. 28, 39-40 (1918), Chief Justice White, speaking for a unanimous Court, said that "rights secured under the grant of letters patent by the United States were property and protected by the Constitution and not subject therefore to be appropriated even for public use without adequate compensation."

A number of other cases could be cited, but I hope I have allayed any suggestion that the Supreme Court has not vigorously enforced the Taking Clause in a wide variety of cases, including those involving congressional statutes.

2.

The above discussion leads naturally to the recent decision of Ruckelshaus v. Monsanto Co. which contains two holdings pertinent to the validity of Section 202. The first is that trade secrets constitute "property" that is protected by the Fifth Amendment. The second is that federal legislation reneging on a federal guarantee of exclusive use of trade secrets constitutes a compensable

taking under the Fifth Amendment. Inspection of Justice Blackmun's opinion reveals that its principles are applicable to the proposed taking of exclusive patent rights under Section 202 of the Patent Extension bill by the retroactive repeal of the Bolar decision.

The Monsanto decision involved the public disclosure provisions of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 61 Stat. 163 (1947), as amended, 7 U.S.C. § 135 et seq., which establishes a federal regulatory scheme governing the use, sale and labeling of pesticides. FIFRA requires companies to submit data, including trade secrets and other commercial and financial information, to the Environmental Protection Agency ("EPA") to obtain regulatory approval to market and use pesticides.

Throughout its history FIFRA has contained provisions governing public disclosure of data submitted by companies during the course of the regulatory process. The original version of FIFRA prohibited disclosure of "any information relative to formulas of products," see 52 U.S.L.W. at 4887, but was silent with respect to the disclosure of other data. In 1972, FIFRA was amended to provide for public disclosure of data submitted in support of a pesticide registration application, but the amendments specifically prohibited the disclosure of material that both the submitter and the EPA agreed was "trade secrets or financial information." In the event of disagreement, a federal district court was given jurisdiction to determine the issue by declaratory judgment. See 52 U.S.L.W. at 4887.

Congress again amended FIFRA in 1978, limiting registration applicants to a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. See 52 U.S.L.W. at 4888.

Monsanto had submitted data to EPA at various times throughout the period FIFRA was in effect. Subsequently, it filed suit in federal court seeking injunctive relief and a declaratory judgment that it had a property interest in certain of the data it had submitted and that a taking in violation of the Fifth Amendment would occur if EPA were to disclose such data or consider such data in evaluating another application for pesticide registration.

With respect to the first issue before it, the Court held that the commercial data involved, which was cognizable as trade secrets under state law, was property protected

by the Taking Clause of the Fifth Amendment. 52 U.S.L.W. at 4890. In so ruling, the Court noted that "[t]his general perception of trade secrets as property is consonant with the notion of 'property' that extends beyond land and tangible goods and includes the products of an individual's 'labor and invention'." 52 U.S.L.W. at 4890, citing 2 Blackstone, Commentaries, 405.

This holding is significant for purposes of analyzing Section 202 because it reaffirms that intangible property is protected by the Fifth Amendment. Like trade secrets, patents are also "products of an individual's labor and invention." In this light, and in view of the express language of the Patent Statute itself, it is now beyond question that patent rights are property rights.

The Monsanto Court next addressed the issue whether the public disclosure provisions of FIFRA effected a taking within the meaning of the Fifth Amendment. Its ruling on this point was in two parts. Prior to 1972, neither FIFRA nor any federal statute guaranteed the confidentiality of all data required under FIFRA. Thus, the Court first held, Monsanto had no reasonable investment-backed expectation that information submitted prior to 1972 would not be disclosed, 52 U.S.L.W. at 4892, and Monsanto had no right to compensation for such disclosure.

On the other hand, under the statutory scheme in effect from October 1972 through September 1978, the Court found that the federal government had explicitly guaranteed to Monsanto and other registration applicants an extensive measure of confidentiality and exclusive use. Thus, the Court's second ruling was that if EPA, consistent with the authority granted it by the 1978 FIFRA amendments, were to disclose trade secret data in a manner not authorized by the version of FIFRA in effect between 1972 and 1978, such conduct would frustrate Monsanto's reasonable investment-backed expectations concerning that data and thus constitute a taking of its property. 52 U.S.L.W. at 4892-4893.

The Court ultimately found that because the Tucker Act was available to Monsanto as a remedy for any uncompensated taking, Monsanto's challenge to the constitutionality of the statute was not ripe for resolution. But there was no ambiguity in the Court's conclusion that "EPA consideration or disclosure of health, safety, and environmental data will constitute a taking if Monsanto sumbitted the data to EPA between October 22, 1972, and September 30, 1978. . . ." 52 U.S.L.W. at 4893 (emphasis supplied).

The Court's analysis is of the utmost significance in analyzing the constitutional problem presented by Section 202. While the Court observed that the factors to be taken into account in determining whether governmental action has gone beyond "regulation" and effects a "taking" include the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations, the Court concluded that the force of the last factor was so overwhelming with respect to certain of the data submitted by Monsanto that it disposed of the taking question entirely. 52 U.S.L.W. at 4891.

This conclusion is obviously of direct applicability to analysis of Section 202, more particularly, in determining that public disclosure would frustrate Monsanto's reasonable investment-backed expectations with respect to trade secret data submitted between 1972 and 1978, the Court relied upon an observation common to both trade secrets and patents -- that the economic value of the property interest involved derives from the right to exclude others. The Court wrote as follows:

> The right to exclude others is generally "one of the most essential sticks in the bundle of rights that are commonly characterized as "property." Kaiser Aetna, 444 U.S. at 176. With respect to a trade secret, the right to exclude others is central to the very definition of the property interest. Once the data that constitutes a trade secret is disclosed to others, or others are allowed to use that data, the holder of the trade secret has lost his property interest in the data. That the data retain usefulness for Monsanto even after they are disclosed . . . is irrelevant to the determination of the economic impact of the EPA action on Monsanto's property right. The economic value of that property right lies in the competitive advantage over others that Monsanto enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge. 52 U.S.L.W. at 4892-4893.

The taking involved in Monsanto is directly analogous to the taking involved in Section 202. Both FIFRA (in the period 1972 through 1978) and the Patent Act (as it

currently exists) have created reasonable investment-backed expectations in the trade secret owner and patent owner, respectively, that such owners would be able to exclude all others from use of their property. Indeed, the case for the patent owner is stronger because the patent property right is grounded explicitly in Article I, Section 8 of the Constitution. As Monsanto makes clear, once the federal government, through a statutory amendment, destroys exclusivity rights that it has previously conferred, a compensable taking has occurred.

I appreciate the opportunity to supplement my testimony in this letter and would, of course, be pleased to respond to any further questions.

Sincerely,

Norman Dorsen

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June 28, 1984

David W. Beier III
Assistant Counsel
Subcommittee on Courts,
Civil Liberties and the
Administration of Justice
2137 Rayburn House Office Building
Washington, D. C. 20515

Dear Mr. Beier:

In connection with the Subcommittee's consideration of H. R. 3605, we enclose copies of a Statement prepared by Henry Paul Monaghan, Professor of Law at Columbia University.

The Statement addresses the constitutional problems that are presented by Section 202 of H. R. 3605 under the taking clause of the Fifth Amendment. As you will observe, his Statement also analyzes this week's decision by the Supreme Court in Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886 (June 26, 1984).

Sincerely,

Jack Lipson

Enclosures

June 28, 1984

HOUSE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON
COURTS, CIVIL LIBERTIES AND
THE ADMINISTRATION OF JUSTICE
ON H.R. 3605, THE PROPOSED AMENDMENTS
TO THE FOOD, DRUG, AND COSMETICS ACT
AND THE PATENT ACT

Statement of Henry Paul Monaghan
Thomas M. Macioce Professor of Law,
Columbia University

H.R. 3605, if enacted, would amend both the Food, Drug and Cosmetics Act and, more importantly here, the Patent Act.[1] This testimony is addressed to a single provision of the proposed legislation: section 202. Simply put, that section would permit any person to "make, use, or sell" a patented drug for the purpose of developing data for obtaining FDA approval of new drug applications. As applied to future drug patents, section 202 raises important policy issues for Congress. My concern is with section 202 insofar as it would apply to existing patents.

Section 202 radically alters existing law. Section 271(a) of the Patent Act, 35 U.S.C. § 271(a), presently provides that:

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[1] This statement has been prepared at the request of a group of research-based pharmaceutical manufacturers. But the views expressed are entirely those of the author.

> [W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.

There is no doubt that, during the life of an existing patent, section 271(a) presently bars any drug manufacturer from making, using or selling a patented drug for the purpose of taking the statutory and regulatory steps necessary to market a drug equivalent to the patented drug. Roche Products, Inc. v. Bolar Pharmaceutical Co., ___ F.2d ___ (Fed. Cir. 1984). This is but an aspect of the central prohibition accorded by the patent during its lifetime: the patent holder's right to exclude any use of the patent hostile to his economic interest. Thus, a generic drug manufacturer may not manufacture, use or sell a patented drug for federally mandated pre-marketing tests. Roche, supra. Section 202 would reverse that result. But, if applied to existing patents, section 202 is in my opinion a taking of property without just compensation, contrary to the fifth amendment to the Constitution of the United States.

I.

The Constitution grants Congress power "to promote the Progress of Science and useful Arts by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. 1, § 8, cl. 8. This power was designed to benefit the public by encouraging inventions and useful writings. But, equally plainly, these benefits are to be generated through "encouragement of individual effort by personal gain." Mazer v. Stein, 347 U.S. 201, 219 (1954). As the Framers understood, "the public good fully coincides . . . with the claims of individuals." The Federalist, No. 18 (Madison). "The patent laws promote . . . progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts." Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) quoting, Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974). Thus, as the Supreme Court has observed on recent occasion, while the patent and copyright laws

> perhaps regard the 'reward to the owner [as] a secondary consideration' . . . but they were 'intended definitely to grant valuable, enforceable rights' in order to afford greater encouragement to the production of works of benefit to the public.

Zacchini v. Scripps-Howard Broadcasting Co., 433 U.S. 562, 577 (1977) (citations omitted). This recognition simply confirms the express terms of the Patent Act itself, which provides that "patents shall have the attributes of personal property." 35 U.S.C. § 261. Those attributes include an exclusive right to make, use and sell the patented product. More simply, "the essence of a patent right is the right to exclude others from profiting by a patented invention." Dawson Chemical Corp. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980).[2]

It is, accordingly, plain that neither the government nor private parties are entitled to use the patent during its life without the owner's consent. "That a patent is property, protected against appropriation both by individuals and government, has long been settled." Hartford-Empire Company, 323 U.S. 386, 415 (1945). Indeed, an unbroken line of decisions makes plain that "the government cannot, after the patent is issued, make use of the improvement any more than

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[2] "It has been the judgment of Congress from the beginning that the sciences and the useful arts could be best advanced by giving an exclusive right to the inventor . . . . The language of complete monopoly has been employed." Continental Paper Bag Company v. Eastern Paper Bag Company, 210 U.S. 405, 429 (1908).

a private individual, without license of the inventor, or making him compensation." Cammeyer v. Newton, 94 U.S. 225, 235 (1876); Solomons v. United States, 137 U.S. 342, 346 (1890); see also Belknap v. Schild, 161 U.S. 10, 15-16 (1890). As the Court put it in United States v. Burns, 79 U.S. 246, 252 (1871):

> That the government of the United States, when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt. . . . The United States has no such prerogative as that which is claimed by the sovereigns of England, by which it can reserve to itself, either expressly or by implication, a superior dominion and use in that which it grants by letters-patent to those who entitle themselves to such grants. The government of the United States, as well as the citizen, is subject to the Constitution; and when it grants a patent the grantee is entitled to it as a matter of right, and does not receive it, as was originally supposed to be the case in England, as a matter of grace and favor.

See also United States v. Palmer, 128 U.S. 262, 271 (1888). The fact that the government has a need to appropriate the patent or deems it desirable to do so is not sufficient. The Constitution requires that there

be compensation for any appropriation. "The title of a patentee is subject to no superior right of the Government." United States v. Dubilier Condenser Corp., 289 U.S. 178, 189 (1937).

These long settled principles make plain that the property secured by the patent is protected by the taking clause. Of course, this is not to say that all legislation affecting outstanding patents is void. McClurg v. Kingsland, 42 U.S. 202, 206 (1844). For example, no one supposes that legislation prohibiting the sale of goods found to be harmful is invalid simply because the goods are manufactured pursuant to an existing patent. But it is equally plain that government legislation "may not take away the rights of property in existing patents." Id. Thus, retrospective legislation "can have no effect to impair the right of property then existing in a patentee. . . ." Id. That "right of property," it must be emphasized, is the patentee's exclusive power to make, use and sell the patented invention during the lifetime of the patent. 35 U.S.C. §§ 154 and 271(a). This right may not be appropriated by the government. And, it is, of course, clear that if the government cannot take property without compensation, it cannot avoid that constitutional bar

by authorizing private parties to effectuate the taking. E.g., Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 427-28, 432-33, n.9 (1958). The Court's very recent decision in Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886 (June 26, 1984) confirms this principle in strong terms.

II.

Section 202's animating premise seems to be a dissatisfaction with the length of time that it takes a generic drug manufacturer to be able to market his drugs because of FDA regulatory requirements. The basis for that dissatisfaction is not altogether apparent. FDA approval requirements seem to result in about a two-year delay in marketing a generic drug, Roche, supra at 13, a regulatory delay substantially less than that usually experienced by the pioneer drug manufacturer whose patented drug is copied. Roche, supra at 12-13. How the conflicting interests of pioneer and generic drug manufacturers are best accommodated in the future is a matter for careful legislative attention. But to materially interfere with existing patents works a considerable injustice to the holder of the pioneer patent who, as has been noted, has himself not only undertaken all the development risks, but who has already suffered appreciable delay in securing FDA approval.

What is more, such a retroactive application would appear to raise very considerable problems as a taking without compensation.

The core of the protection secured by the patent laws is the right to exclude others from use of the patent during the life of the patent. In exchange for granting the invention to the public at the expiration of the patent, the patent holder is permitted to prohibit any use of the patent that is hostile to his patent interests. This includes the right to bar a potential competitor from making any use of the patent that would move him closer to the competitive starting gate at the expiration of the patent. During the period of the patent, competitors must keep hands off the patented invention. The fact that at the patent's expiration date the potential competitor must then clear additional hurdles before mounting a competitive challenge, such as obtaining regulatory approval, is irrelevant to the existing patent right. This additional delay is not caused by the patent, nor does it amount to "an extension of the patent" in any legal sense. The delay is simply a competitive start-up cost imposed by the government wholly apart from the patent.

In its retroactive aspect, section 202 cuts deeply into the protection accorded by the patent. In effect, section 202 reallocates part of the patent holder's property to his competitors, a reassignment of property from the pioneer drug patent holder to his generic drug competitors. I assume that this reallocation could be justified as serving a plausible public purpose, Housing Authority v. Midkiff, 466 U.S. ___ (1984); Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886 supra at 4893. But if the reallocation amounts to a "taking," just compensation must be made. Midkiff and Monsanto make that plain. See also Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 425 (1982) ("It is a separate question, however, whether an otherwise valid regulation so frustrates property rights that compensation must be paid."). However, we cannot minimize the complexities of meeting the "just compensation" standard. Just compensation "must be a full and perfect equivalent of the property taken," Monongahela Navigation Co. v. United States, 148 U.S. 312, 326 (1893). The owner must be put in as good a position pecuniarily as if his property had not been taken. United States v. Reynolds, 397 U.S. 14, 16 (1970); United States v. Miller, 317 U.S. 369, 373 (1943).

III.

Thus, the critical issue is whether application of section 202 to existing patents amounts to a taking. The law governing whether or not a "taking" has occured is complex, often turning on an ad hoc factual appraisal. Ruckelshaus v. Monsanto Co., supra at 4891. Nonetheless, existing case law strongly suggests that section 202 would amount to a partial taking of existing patents.

There can be no pretense that, in its retrospective application, section 202 would be a rectifying noxious use of the patent, or that the existing patents are accorded such additional rights under H.R. 3605 that there is an "average reciprocity" between the new benefits and burdens. Nor is section 202 simply the destruction of one important feature of the property right, Andrus v. Allard, 444 U.S. 51, 65-66 (1979), in order to prevent illegal use of the property, such as a prohibited trade in certain goods. Id. at 66-67. Rather, section 202 represents an effort to cut into the core of the protection secured by the patent, the right to exclude, and to permit use by the patent holder's competitors.

In Kaiser Aetna v. United States, 444 U.S. 164 (1979), the Court held that the taking clause precluded

the government from creating without compensation a public right of access to a former inland pond that had been dredged and opened to a bay and ocean for use as a private marina. The Court said that "what petitioners now have is a body of water that was private property under Hawaiian law, . . ." Id. at 179. In these circumstances, the Court said, the "'right to exclude,' so universally held to be a fundamental element of the property right, falls within the category of interests that the Government cannot take without compensation." Id. at 179-80.

Kaiser Aetna is persuasive here; for there, as here, the government would simply take the prior right and assign it to others. Indeed, here the reassignment is not to the public generally but to the patent holder's competitors. Thus, this is not a situation where all that would occur is a narrowly focused, limited, temporary invasion of the patentee's right without real economic consequences to the economic interests secured by the patent. See Loretto v. Teleprompter Manhattan CATV Corp., supra, 458 U.S. at 433-34. See also Pruneyard Shopping Center v. Robbins, 447 U.S. 74 (1980), in which Kaiser Aetna was further elaborated and the Court emphasized that it was a case where impairment of the

right to exclude interfered with the owner's "reasonable investment-backed expectations." Id. at 83-84.

Even if section 202 in its retroactive reach could be viewed as other than an outright appropriation of the existing right to exclude and somehow characterized as a regulation, its impact would have severe consequences to the existing patent holders, causing damage to their reasonable investment-based expectations. Even purely "regulatory" statutes having such an impact raise significant issues under the taking clause. Penn Central Transportation Co. v. United States, 438 U.S. 104 (1978); Robbins, supra. But the crucial point to my eye is that section 202 is difficult to characterize fairly as a regulation, with an "incidental" impact upon existing property. Section 202 simply takes one of the recognized incidents of ownership, the right to exclude all use until the patent expiries, and partially reassigns it, not just to another person or to the public generally but to the patent holder's competitors. No one, least of all the generic drug manufacturers who would benefit so heavily by section 202, disputes that what is reassigned has important economic impact on the patent holder's "reasonable investment-backed expectations." Thus an "examination . . . into such factors as the

character of the government action, its economic impact, and its interference with reasonable investment-backed expectations," Robbins, supra, at 83; Loretto, supra, at 432, all point in the direction of a taking.[3]

The Supreme Court's decision this week in Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886 (June 26, 1984) completely settles the question of whether the application of section 202 to existing patents would constitute a taking. In that case, the Court held that trade secret data which had been submitted by Monsanto

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[3] In this respect, section 202 seems analogous to a physical appropriation of real or personal property. Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419 (1982). "Property rights in a physical thing have been described as the rights 'to possess, use and dispose of it' . . . to the extent that the government permanently occupies physical property, it destroys each of these rights." Id. at 435. So here also. The right secured by the patent -- to make, use and sell -- are all subject to permanent invasion, to what amounts to an easement in the patent holder's competitors. Even if not perfect, the analogy is suggestive. For it is clear that the protection of the clause is not confined to relief against physical appropriation, but rather to the "group of rights inhering in the citizen's relation to the physical thing, as the right to possess, use and dispose of it. . . ." United States v. General Motors, 323 U.S. 373, 377-78 (1945), quoted with approval in Pruneyard Shopping Center v. Robbins, 447 U.S. 74, 87 n.6, and Loretto, 458 U.S. at 435. Thus, in considering whether there is an invasion of the patent right, "reference to the uses for which the property is suitable, having regard to existing business or wants of the community," Bloom Co. v. Patterson, 98 U.S. 403, 408 (1908), must be made. Section 202's impact on existing patents is analogous to the taking of an easement in property, for which compensation must be paid.

to the Environmental Protection Agency was property within the meaning of the Fifth Amendment taking clause. Since the applicable statute in that case guaranteed Monsanto that the data submitted between the years 1972 through 1978 would be confidential and exclusive, the Court found that this formed "the basis of . . . Monsanto's reasonable investment-backed expectation with respect to its control over the use and dissemination of the data it had submitted." Supra at 4892.

The Court reiterated that, "The right to exclude others is generally 'one of the most essential sticks in the bundle of rights that are commonly characterized as property.'" (Citation omitted.) It proceeded to apply that principle to trade secrets, noting that "the right to exclude others is central to the very definition of the property interest." Id. It denied the government's claim that post-1978 amendments to the statute gave the agency a retrospective right to preempt Monsanto's property in its trade secrets. The notion that the government could "pre-empt" existing property rights in trade secrets was flatly rejected as inconsistent with the very thing that the taking clause of the Fifth Amendment was meant to prevent. Id. at 4893. No argument is needed to show that an attempt

retrospectively to impair patent rights is entitled to protection that is at least as great as that which the Supreme Court accorded to trade secret property in Monsanto.

IV.

It bears emphasis that nothing in the Supreme Court's recent decision in Pension Benefit Guaranty Corp. v. Gray & Co., 467 U.S. ___, 52 U.S.L.W. 4810 (June 19, 1984), is inconsistent with the foregoing analysis. There the Court upheld retroactive increases in the liability of employers participating in multi-employer pension plans. Writing for the Court, Justice Brennan rejected a challenge that retroactive application of the statute violated the due process clause of the fifth amendment, saying that the clause is satisfied "simply by showing that the retroactive application of the legislation is itself justified by a rational legislative purpose." 52 U.S.L.W. 4814. Other distinctions aside, it is important to emphasize that Pension Benefit did not involve any question under the Taking Clause. Not a line in the opinion even adverts to that clause. But like the contract clause, see id.

at 4814,* the Taking Clause imposes restrictions against retroactive legislation beyond those contained in the due process clause. Justice Brennan himself made that clear in San Diego Gas and Electric Company v. San Diego, 450 U.S. 621 (1981). At issue was whether a state whose regulation amounted to a taking was obligated to pay damages for the period during which the regulation remained in effect. The Court dismissed the appeal as not being properly before it. Justice Brennan authored a four-person dissent, id. at 636, which Justice Rehnquist indicated he would have had "little difficulty in agreeing with much of what is said" if the case were properly there, id. at 633-34. Justice Brennan concluded that the state must pay compensation. In the course of his

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* "Second, it is suggested that we apply constitutional principles that have been developed under the Contract Clause, Art. I, § 10, cl. 1 ("No State shall . . . pass any . . . Law impairing the Obligation of Contracts. . . ."), when reviewing this federal legislation. . . . We have never held, however, that the principles embodied in the Fifth Amendment's Due Process Clause are coextensive with prohibitions existing against state impairments of pre-existing contracts. . . . Indeed, to the extent that recent decisions of the Court have addressed the issue, we have contrasted the limitations imposed on States by the Contract Clause with the less searching standards imposed on economic legislation by the Due Process Clauses."

opinion, Justice Brennan drew a clear distinction between challenges based on due process and challenges based on the taking clause. Id. at 648-50, and n.14. See also Justice Black's opinion in Penn Central Trans. Co. v. New York City, 438 U.S. 104, 120-22, and n.25 (1978); and see, e.g., Pruneyard Shopping Center v. Robbins, 447 U.S. 74, 82-84 (1980) (distinguishing between taking and due process challenges); Loretto v. Teleprompter CATV Corp., supra at 425.

Any conceivable doubt on this point is put to rest by the decision in Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886, supra. In holding that retrospective application of a statute permitting the disclosure of trade secrets would amount to a taking, the Court did not even cite Pension Benefit, correctly perceiving that the latter case involved only the due process, not the taking clause.

V.

We have here a situation of gross injustice. Existing patent holders have an absolute right to exclude hostile use by others. Under section 202 as it now stands, part of that right would be taken from them, and given to their competitors. This non-compensated

transfer is tantamount to a claim, squarely rejected in Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 164 (1980), where the Court held that the government, "by ipse dixit, may not transform private property into public property without compensation . . . [even if only] for [a] limited duration." See also Loretto v. Teleprompter Manhattan CATV Corp., supra, 458 U.S. at 439. As the Supreme Court said in Beckwith, "[t]his is the very kind of thing that the Taking Clause of the Fifth Amendment was meant to prevent." 449 U.S. at 164; Ruckelshaus v. Monsanto Co., supra, 52 U.S.L.W. at 4893. In these circumstances, therefore, it seems likely that compensation must be paid if section 202 is to affect existing patents. Alternatively, of course, section 202 could be amended to make plain that it is intended to have no impact on the rights secured by existing patents.

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August 7, 1984

Honorable Peter W. Rodino, Jr., Chairman
Committee on the Judiciary
United States House of Representatives
2462 Rayburn House Office Building
Washington, D.C. 20515

Re: S. 2748 and H.R. 3605 To Amend the Procedures for New Drug Applications and To Authorize the Extension of Patents for Certain Regulated Products

Dear Chairman Rodino:

As counsel for the coalition of research based pharmaceutical companies, we have previously communicated with you concerning the Patent Term Restoration legislation referenced above. The coalition supports the legislation with certain amendments. We are writing to alert you to the views of other leading patent lawyers and constitutional scholars who share our concerns.

First, it has been brought to our attention that the Patent, Trademark and Copyright Law Section of the American Bar Association has just passed a resolution in opposition to Title II (the patent extension provisions) of H.R. 3605 and S. 2748, as presently drafted. A copy of the resolution is enclosed.

Second, our earlier correspondence argued that the current version of S. 2748 and H.R. 3605 raises substantial problems of constitutionality because Section 202 of the proposed legislation takes property from the patent owner without compensation and gives it to generic competitors. Recently the Congressional Reference Service ("CRS") has circulated a legal opinion which tends to support the legislation -- although it too concedes that "The constitutionality of § 202 is far from a settled question. . . ."

In response to the CRS opinion, two distinguished professors of constitutional law, Professors Henry Paul

Monaghan of the Columbia Law School and Laurence Tribe of the Harvard Law School have, independently, reviewed that analysis and have prepared legal opinions. Copies of these opinions are enclosed. Both these constitutional scholars conclude that the CRS analysis fails to dispel the constitutional problems that would be created if Section 202 were to be enacted in its present form.

Professor Monaghan states,

> "We have here a situation of gross injustice. Existing patent holders have an absolute right to exclude hostile use by others. Under section 202 as it now stands, part of that right would be taken from them, and given to their competitors. This non-compensated transfer is tantamount to a claim, squarely rejected in Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 164 (1980), where the court held that the government, 'by ipse dixit, may not transform private property into public property without compensation . . . [even if only] for [a] limited duration.'"

Professor Tribe states,

> "[T]he means used by Section 202 -- eliminating the patent holder's rights to exclude others during the patent's life -- entail takings of property in the most basic sense. . . .
>
> Section 202, in its retroactive application, therefore squarely fits the Supreme Court's criteria for a compensable taking."

The necessary conclusion is that there is no serious basis to doubt that the present bill constitutes a taking of property under the Fifth Amendment. It would be possible to amend the legislation to cure this defect, e.g., by limiting Section 202 to prospective patents or by limiting its application to those periods after an existing patent's life is extended under other provisions of the bill. Without such an amendment, however, the constitutionality of Section 202 remains highly uncertain.

Sincerely,

Jack Lipson

Enclosures

cc: Members of the House Committee on the Judiciary

August 6, 1984

MEMORANDUM OF LAURENCE H. TRIBE
REGARDING THE CONSTITUTIONAL ISSUES
POSED BY SECTION 202 OF THE
PATENT EXTENSION PROVISIONS OF
H.R. 3605 AND S. 2748

Introduction

I am the Tyler Professor of Constitutional Law at Harvard Law School, on whose faculty I have served since 1968. Recently, I was asked by representatives of a coalition of research-based pharmaceutical firms to evaluate the constitutional problems I perceive in Section 202, and in particular to assess the adequacy of the analysis and conclusions put forth in that regard by the American Law Division of the Congressional Research Service of the Library of Congress on July 24, 1984 (referred to hereinafter as the CRS memo). Although I have prepared this memorandum in response to that request for use by, and under the auspices of, that coalition, I wish to stress at the outset that the memorandum that follows reflects solely my own professional views as a constitutional analyst -- not my position as an advocate or my policy preferences as a citizen, and certainly not the views of any institution or group with which I might be associated.

Premises

Constraints of time -- in part my own but also and more relevantly, those of Congress and its staff -- require me to be brief. My analysis proceeds from the premise that the United States Supreme Court will not overturn the holding of the Court of Appeals for the Federal Circuit in Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984), which interpreted the word "uses" in 35 U.S.C. Section 271(a) in such a manner that a drug manufacturer infringes a patent when, during the patent term, the manufacturer uses the patented substance without the patent holder's authority to prepare a submission to FDA for the purpose of enabling that manufacturer to market the drug after the patent expires. Should the Supreme Court instead reverse that ruling (an outcome which, parenthetically, seems to me most unlikely), there would obviously be no need for Section 202, the thrust of which is to overturn Roche v. Bolar legislatively, so as to provide that it is not an infringement to make, use, or sell a patented invention for purposes "reasonably related" to the development and submission of information to obtain FDA's premarketing approval to engage in the commercial manufacture, use, or sale of the drug after patent expiration.

Because the constitutional problem addressed in this memorandum is Congress' authority retroactively to strip current patent holders of the exclusive user-control rights that Roche v. Bolar construed 35 U.S.C. §§ 154 and 271(a) to confer, arguments that are properly addressed to the Supreme Court -- such as the argument that Roche v. Bolar improperly made new law and was incorrectly decided under current law, whether because of alleged customary practice in the drug industry or for some other reason -- are irrelevant here. For it is only on the assumption that the Supreme Court is unmoved by those arguments, and that the law prior to enactment of Section 202 is indeed as the Court of Appeals for the Federal Circuit authoritatively pronounced it to be when it rejected those same arguments in Roche v. Bolar itself, that Section 202 matters at all.[1] To the extent that the CRS memo purports to find constitutional solace in the supposed ambiguity of Section 271(a), in the absence of any fully explicit Congressional definition of the word "uses" prior to the Roche v.

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[1] I discount as highly implausible, even if theoretically conceivable, the prospect that the Supreme Court would hold that Roche v. Bolar was correctly decided but that a conjectured industry practice of infringement had mistakenly but consistently rested on the contrary premise to such a degree that patent holders in subjective fact had no investment-backed expectations of the sort that they were objectively entitled to have.

Bolar decision, or in the supposed absence of prior judicial decisions going quite as far as Roche v. Bolar, that memorandum is therefore beside the point. Obviously, if Roche v. Bolar were found by a higher judicial authority to have gone too far in light of the statutory language or history, in light of relevant precedent, or in light of controlling considerations of policy or practice, then Section 202 would merely have restated the Supreme Court's view of pre-Section 202 law, and no "taking" problem would be posed. On the other hand, if the Supreme Court proclaims no such view, either leaving Roche v. Bolar undisturbed or expressly affirming its holding, then the pre-Section 202 law is as the Court of Appeals for the Federal Circuit declared it to be, and arguments to the contrary by the CRS or others deserve no further consideration, whether packaged "as a correction of a judicial misreading of . . . prior law," CRS memo at 4, or otherwise.

Fixing The Frame of Reference

The CRS memo is even more deeply misleading -- and indeed betrays a quite shocking lack of constitutional sophistication and understanding -- when it describes as "the first question that must be asked" the question

> "Whether Section 202 should be analyzed in the context whether it constitutes a 'taking' or whether it should be evaluated as a regulation of property . . . ." CRS memo at 2. (Emphasis added).

But, there is no such threshold question. For any regulation must, under the Fifth Amendment, "be analyzed" to determine "whether it constitutes a 'taking.'" The fact that a legislative measure must also be "evaluated as a regulation of property" and may indeed satisfy substantive as well as procedural due process constraints "as a rational means of pursuing the public goods through regulation of existing property rights," CRS memo at 4, is simply immaterial to the question whether compensation is constitutionally required.

The CRS memo betrays an almost embarrassing failure to grasp first principles when it chides the Supreme Court for "never [having] clearly established the standards for applying a 'taking' analysis or a due process analysis to [an economic] regulation. . . ." CRS memo at 2. Of course, the Court has established no "standards" for choosing between the two sets of analyses: in every case, as even a beginning student of constitutional law should recognize, both sorts of

analysis must be pursued. If a regulation fails even to pass substantive due process muster -- if, for example, it serves no legitimately public purpose, cf., Hawaii Housing Authority v. Midkiff, 104 S. Ct. 2321 (1984) -- then no amount of compensation can save it. Conversely, if a regulation meets substantive due process requirements -- and if the criteria laid down by the line of cases running from Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922), through Kaiser-Aetna v. United States, 444 U.S. 164 (1979), and Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886 (U.S. June 26, 1984), establish that the regulation effects a compensable "taking" -- then no amount of rationality and public desirability or indeed necessity can exempt the regulation from the Constitution's demand that just compensation be provided. In arguing "that, perhaps, a due process analysis is the more appropriate one," as though an analyst could somehow circumvent the inquiry into compensability, the CRS reveals only the shortcoming of its own effort at constitutional analysis.

That distressing conclusion is underscored by the CRS's remarkable suggestion that Congress might avoid the compensability inquiry by basing Section 202 on a legislative "conclusion that Roche was wrongly

decided" and "that Congress did not intend the word 'uses' in § 271(a) to extend so broadly." CRS memo at 3. Inasmuch as "[i]t is emphatically the province and duty of the judicial department to say what the law is", Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177-78 (1803), cf., United States v. Klein, 80 U.S. (13 Wall.) 128, 146-47 (1872), it is simply not up to Congress, much less its Research Service, to "correct" the manner in which courts have interpreted prior congressional enactments. See Immigration and Naturalization v. Chadha, 103 S. Ct. 2764, 2789-90 (1983) (Powell, J., concurring); Buckley v. Valeo, 424 U.S. 1, 120-24 (1976) (per curiam). Consumer Product Safety Commission v. GTE Sylvania, Inc., 447 U.S. 102, 118 n.13 (1980); United States v. Southwestern Cable Co., 392 U.S. 157, 170 (1968).

Surely a body entrusted by Congress to give it legal advice ought to realize that, under our tripartite system of separated powers, Congress is wholly without jurisdiction to sit as a reviewing tribunal, passing judgment, whether case by case or generically, over judicial constructions of extant federal legislation. The CRS memo confuses Congress' undoubted power to make retroactive changes in legislation, always subject to

Fifth Amendment limits, with a non-existent power of Congress, by wrapping its retroactive laws in jurisdictional or corrective garb, to escape otherwise controlling Fifth Amendment limits. Indeed, the principal case relied on by the CRS to affirm this extraordinary power -- Battaglia v. General Motors Corp., 169 F.2d 254 (2d Cir.) cert. den., 335 U.S. 887 (1948) -- expressly states the contrary -- opining

> "[T]hat the exercise by Congress of its control over jurisdiction is subject to compliance with at least the requirement of the Fifth Amendment. That is to say, while Congress has the undoubted power to give, withhold, and restrict the jurisdiction of courts other than the Supreme Court, it must not so exercise that power as to deprive any person of life, liberty or property without due process of law, or to take private property without just compensation." 169 F.2d at 257 (emphasis added).

That retroactive legislation does not automatically or even presumptively offend due process, an entirely unremarkable proposition reaffirmed by the Supreme Court in Pension Benefit Guaranty Corporation v. R. A. Gray & Co., 52 U.S.L.W. 4810 (U.S. June 18, 1984), hardly

supports the CRS' bald conclusion that such legislation need only be "a rational means of pursuing the public good," CRS memo at 4, in order to circumvent the compensation requirement where the legislation effects a taking of private property.

The CRS's "Taking" Analysis As Such

The CRS memo, once stripped of its various reasons for avoiding the takings issue, says next to nothing about the issue itself. In essence, it argues (1) that Section 202 "would modify an advantage that derives not from the patent law in and of itself but from the operation of law respecting FDA approval of drugs before they can be marketed," CRS memo at 4, and (2) that Section 202 "does not in the least touch upon the economic work of the patents during [their] term" because "[t]hey retain all the value the holders had in them." CRS memo at 6. Neither observation can withstand analysis.

As to the first, it is beyond dispute that the exclusivity of use that would be cut back by Section 202 derives solely from the patent law, however much the regulatory FDA environment may be responsible for the second-order economic consequences, after patent expiration, of either enforcing or eliminating this

exclusivity. It is this right to exclude others -- generally "one of the most essential sticks in the bundle of rights that are commonly characterized as property," Kaiser-Aetna, 444 U.S. at 176 -- that is peculiarly "central to the very definition of the property interest," Monsanto, 52 U.S.L.W. at 4892, no less with respect to patents, than with respect to the trade secrets that were at issue in Monsanto. Thus, however legitimate might be the end of preventing holders of drug patents from enjoying the benefits of their patents, beyond their expiration dates, the means used by Section 202 -- eliminating the patent holder's rights to exclude others during the patent's life -- entail takings of property in the most basic sense.

As to the CRS's second observation, it should suffice to quote the Supreme Court's reply in Monsanto:

> "That the data retain usefulness for [the owner] even after they are [compromised] . . . is irrelevant to the determination of the economic impact of the [government] action on [the owner's] property right. The economic value of that property right lies in the competitive advantage over others that [the owner] enjoys by virtue of its exclusive access, and disclosure or use

by others would destroy that competitive edge." 52 U.S.L.W. at 4892-93.

Finally, the CRS memo badly misconceives the fundamental law of takings when it opines that no taking exists whenever "the regulated entity still has a profitable use for his property." CRS memo at 6. On the contrary, when government either invades, or authorizes uninvited members of the public to share, someone's private property, the Supreme Court has uniformly found a compensable taking entirely independent of whether the non-taken residue retains significant economic value to its owner. See, e.g., Kaiser-Aetna, supra; Loretto v. Teleprompter Manhattan CATV Corp., 58 U.S. 419 (1982). It is only when government merely restricts the owner's own use of property, as in Pennsylvania Coal, supra, or Penn Central Transportation Co. v. New York City, 438 U.S. 104 (1978), or Andrus v. Allard, 444 U.S. 51 (1979), that a comparative assessment of the value destroyed and the value retained has been significant in the Supreme Court's analysis. Section 202, in its retroactive application, therefore squarely fits the Supreme Court's criteria for a compensable taking.

The Tucker Act As a Possible Answer

Although it therefore seems quite clear that Section 202 would effect a compensable taking from the holders of existing patents unless the Supreme Court were itself to overturn Roche v. Bolar as an interpretation of pre-Section 202 law, a strong argument may nonetheless be made that even the retroactive application of Section 202 would meet Fifth Amendment standards inasmuch as a Tucker Act remedy, 28 U.S.C. § 1491, would be available to those whose property would thereby be taken for public use by Section 202. As the Supreme Court recently held in Monsanto, such a remedy remains available unless Congress, in the statute that effects a taking of property, clearly withdraws the Tucker Act grant of jurisdiction to the Court of Claims to hear a suit for compensation. 52 U.S.L.W. at 4894.

To be sure, the history of Section 202 might be construed to suggest a congressional desire to make current patent holders -- rather than the taxpaying public, bear the brunt of the legislative overturning of Roche v. Bolar. If that construction were followed, then Section 202 would be an unconstitutional taking, without compensation, of existing patent rights. But

even if, as seems more likely, no exclusion of Tucker Act remedies is implied, the upshot is not to render compensation irrelevant but to make it an unavoidable economic cost of Section 202 -- albeit a cost of indefinite magnitude -- insofar as the Section is extended to existing patents, rather than being restricted to purely prospective operation. Thus, the Tucker Act does not so much provide a constitutional answer as pose an extra-constitutional question. Whether Congress wishes to preserve Section 202's retroactivity in the face of the fairly certain, but uncertainly large, budgetary impact of the legislation at issue presents choices of policy and priority on which the Constitution is silent and as to which I hold out no expertise.

TESTIMONY OF
U.S. REPRESENTATIVE LAWRENCE COUGHLIN
PATENT LAW REFORM
SUBMITTED TO THE
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE

June 26, 1984

Mr. Chairman, as a lawyer and former member of the Judiciary Committee as well as a sponsor of a patent term restoration bill (H.R. 3502) providing for up to a seven year patent extension for products subject to regulatory review, I wish to address one provision of H.R. 3605, the Drug Price Competition Act, which causes me particular concern.

H.R. 3605 would allow generic drug manufacturers submitting Abbreviated New Drug Applications to market a drug automatically eighteen months after notifying the patent holder of his intention to do so. The present statutory presumption of a patent's validity would be undermined by such a provision.

A patent should continue to be presumed valid unless it is successfully challenged in court. Since final adjudication of the validity of a patent is a lengthy process usually lasting more than eighteen months, this provision of the bill would allow applicants to begin marketing a drug before a court has ruled on the patent validity issue.

While the generic manufacture of drugs should be allowed and encouraged once a valid patent has expired or been found invalid by a court, the fundamental principle of a patent's validity should not be violated. By allowing a reasonable period of marketing exclusivity for pioneer drug manufacturers to recover their new drug research and development costs, the basic patent system provides an important incentive for drug companies to invest in new life-saving and health care-improving drugs.

Although the patent laws need to be improved and updated in some respects such as the patent term extension for regulatory reviews, it is important that the basic incentives and protections afforded by patent statutes not be weakened. The proposal to permit Abbreviated New Drug Applicants to market a drug automatically eighteen months after giving notice to a patent holder represents a major weakening of the patent law and should not be approved by your committee.

I would urge that this section of H.R. 3605 be amended to provide that a manufacturer submitting an Abbreviated New Drug Application to market a drug still under a patent be barred from doing so until a trial court has ruled that the patent is not valid or that it has not been infringed. At the same time, the court should have discretion to allow a manufacturer's Abbreviated New Drug Application (if approved by FDA) in cases where the patent holder is not diligent in prosecuting an infringement action.

Thank you for this opportunity to present my views to the subcommittee.

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H.R. 3605 would allow generic drug manufacturers submitting Abbreviated New Drug Applications to market a drug automatically eighteen months after notifying the patent holder of his intention to do so. The present statutory presumption of a patent's validity would be undermined by such a provision.

A patent should continue to be presumed valid unless it is successfully challenged in court. Since final adjudication of the validity of a patent is a lengthy process usually lasting more than eighteen months, this provision of the bill would allow applicants to begin marketing a drug before a court has ruled on the patent validity issue.

While the generic manufacture of drugs should be allowed and encouraged once a valid patent has expired or been found invalid by a court, the fundamental principle of a patent's validity should not be violated. By allowing a reasonable period of marketing exclusivity for pioneer drug manufacturers to recover their new drug research and development costs, the basic patent system provides an important incentive for drug companies to invest in new life-saving and health care-improving drugs.

Although the patent laws need to be improved and updated in some respects such as the patent term extension for regulatory reviews, it is important that the basic incentives and protections afforded by patent statutes not be weakened. The proposal to permit Abbreviated New Drug Applicants to market a drug automatically eighteen months after giving notice to a patent holder represents a major weakening of the patent law and should not be approved by your committee.

I would urge that this section of H.R. 3605 be amended to provide that a manufacturer submitting an Abbreviated New Drug Application to market a drug still under a patent be barred from doing so until a trial court has ruled that the patent is not valid or that it has not been infringed. At the same time, the court should have discretion to allow a manufacturer's Abbreviated New Drug Application (if approved by FDA) in cases where the patent holder is not diligent in prosecuting an infringement action.

Thank you for this opportunity to present my views to the subcommittee.

TESTIMONY OF
U.S. REPRESENTATIVE LAWRENCE COUGHLIN
PATENT LAW REFORM
SUBMITTED TO THE
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE

June 26, 1984

Mr. Chairman, as a lawyer and former member of the Judiciary Committee as well as a sponsor of a patent term restoration bill (H.R. 3502) providing for up to a seven year patent extension for products subject to regulatory review, I wish to address one provision of H.R. 3605, the Drug Price Competition Act, which causes me particular concern.

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Congress of the United States

Washington, D.C. 20515

July 23, 1984

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JUL 24 1984
JUDICIARY COMMITTEE

The Honorable Peter W. Rodino, Jr.
Chairman
Committee on the Judiciary
2137 Rayburn Building
Washington, D.C. 20515

Dear Mr. Chairman:

The Drug Price Competition and Patent Term Restoration Act of 1984 is before your Committee, and we believe changes in specific provisions should be considered to benefit the public and to insure fairness to pharmaceutical manufacturers.

In urging careful review of this legislation, we emphasize that we agree with the overall objectives of the bill--restoring patent life lost to regulatory review for innovative drug products and accelerating generic drug products to the marketplace. We do suggest, however, that the Congress may inadvertently open new fields of prolonged litigation and establish disincentives for research and development if we do not amend the bill.

A number of reputable drug manufacturers, several with plants in Pennsylvania, are disturbed that the legislation is not as carefully crafted as it might be. Their officials have pointed out at least seven major areas where judicious changes should be considered.

Summarized are key sections where modifications are recommended:

1. The bill would prevent the Food and Drug Administration (FDA) from obtaining additional safety and efficacy data before approving an abbreviated drug application. The FDA should be granted authority to require safety and efficacy data whenever necessary in individual circumstances.

2. The bill would overturn the principle affirmed in the recent Bolar case affecting prescription drugs which prevents a competitor from carrying out commercial marketing plans before a patent expires. This principle affects all patents. The bill should be modified so reversal of the principle would apply only to drug products whose patents have benefitted from extension.

3. The bill, in its patent restoration section, contains provisions to prevent extension of a patent specifically claiming a particular compound if that compound had been claimed generically under a prior patent. Provisions also apply to prevent extension of a patent on claims covering a second FDA-approved drug where one patent covers two approved drugs. In both instances, patent restoration is denied unfairly. Firms often cannot determine during patent application what drug or drugs eventually will be tested successfully and marketed. They also can expend considerable resources in developing each FDA-approved drug while only one restoration would be allowed for two FDA-approved drugs. These punitive provisions should be changed.

4. The bill technically would allow generic manufacturers to market a drug before patent litigation has been resolved. Marketing should not be permitted until at least a lower court judgment has been rendered on patent validity.

5. The bill could force a firm to defend its patent much sooner than would be the case under present law. A change is needed to require that the generic competitor's required notice to the patent holder take place only after the FDA has determined that the generic applicant has filed a complete abbreviated application rather than triggering a patent challenge merely on submission of a pro forma application to the FDA.

6. The bill would authorize release of valuable trade secret information under specified circumstances. This provision should be amended so that release of such data would take place only with concurrence from the holder of the original new drug application.

7. The bill would discriminate against companies which innovate in areas such as new dosage forms, new delivery systems, and creative formulations. These products would be unprotected within the legislation's transition provisions which apply only to so-called new chemical identities. For instance, an innovative dosage form to lessen side effects would be unprotected. Drug product innovations should receive the same protection as new chemical identities.

In working to enact long-overdue legislation in these fields, we must be careful that we do not create new and complex problems, adversely affect health care, and penalize the initiative and capital investment on which we must depend to develop the new products and innovations that serve our people. We believe the changes recommended are fair, practical, and prudent modifications, and should be given full consideration by your Committee.

Sincerely,

LAWRENCE COUGHLIN

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JOSEPH M. McDADE

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DANIEL A. MICA
11TH DISTRICT, FLORIDA

FOREIGN AFFAIRS
VETERANS' AFFAIRS
SELECT COMMITTEE ON AGING

Congress of the United States
House of Representatives
Washington, D.C. 20515

July 6, 1984

Honorable Robert Kastenmeier
Chairman, Subcommittee on Courts,
Civil Liberties, and the
Administration of Justice
2137 Rayburn HOB
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for taking the time to visit a few moments with me regarding my concerns on Section 104 of H.R. 3605, the Drug Price Competition and Patent Term Extension Act of 1984.

I do understand your concerns of jurisdiction, but I hope that you and the staff of the subcommittee will take this matter into consideration as the bill progresses. Our U.S. trade balance is really a serious problem, and I do believe that only for the most compelling of reasons should the Congress suggest changes in statute which may cause harm to our export opportunities.

Attached is a copy of my testimony for the record. Please alert the staff to a couple of changes on page two of the copy I gave to you earlier.

Again, thank you both for your courtesy and consideration.

Kind regards.

Sincerely yours,

DANIEL A. MICA, M.C.

DM:jl

THIS STATIONERY PRINTED ON PAPER MADE WITH RECYCLED FIBERS

STATEMENT OF THE HONORABLE DANIEL A. MICA, M.C.
A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF FLORIDA

Mr. Chairman and members of the Subcommittee. I thank you for the opportunity come before the subcommittee for just a few minutes today.

First, let me say that I support the goals of H.R. 3605, the Drug Price Competition and Patent Term Extension Act of 1984. This is important legislation. It provides objectives which we all seek--lower cost drugs available to our consumers--especially the elderly; and it provides our pharmaceutical and manufacturing companies propoer incentives for the necessary research to bring new, effective drugs onto the market.

I do have concerns over one section of the bill, section 104, and would ask the subcommittee to review this section carefully. I am not an expert in drug or patent law, nor of the intricacies of the Food and Drug Administration.

However, I have served this year as the ranking Democratic member of the Subcommittee on International Economic Policy and Trade, and section 104 does raise some questions, I believe, regarding the ability of our pharmaceutical firms to compete effectively in the international marketplace, and could harm our efforts to create jobs for Americans through a strong export market.

As I understand the bill, Section 104 would require the FDA to disclose certain confidential data, including trade secrets. I fear that mandating the public disclosure of safety and effectiveness data in an untimely manner could

allow foreign competitors to take this data and submit it to their government regulatory agencies to the disadvantage of our American firms. This would seem to have at least two disadvantages: first, a possible loss of export market share by American firms; and, second, a long term effect of fewer drugs available to American consumers as a result of the trade disincentive which this section may cause.

I am sure that I do not have to repeat to the members of the subcommittee the enormous deficit in international trade the U.S. now faces. I am advised that U.S. exports of pharmaceutical and medicinal products account for over two and a half billion dollars annually, and that section 104, if law, could jeopardize up to a half million dollars in U.S. exports. Needless to say, as a national policy we need to protect and expand our export market. The subcommittee will have before it experts with far more information than I to answer questions; I simply ask that the members recognize the potential consequences of this section, and give it the most careful consideration.

Thank you.

STATEMENT OF THE HONORABLE DANIEL A. MICA, M.C.
A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF FLORIDA

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I am sure that I do not have to repeat to the members of the subcommittee of the enormous trade deficit the U.S. faces. I am advised that U.S. exports of pharmaceutical and medicinal products account for over a half billion dollars every year. We need to protect and expand that figure in any way possible. The subcommittee will have before it experts with far more information than I to answer questions; I simply ask that the members recognize the potential consequences of this section, and give it the most careful review possible.

Thank you.

THE WHITE HOUSE

WASHINGTON

June 19, 1980

Dear Bob:

After speaking with you yesterday, I have explored this issue of drug patent life extension with retail pharmacists. I find general concurrence with the belief that further extending the patent life of drug products could have serious adverse consequences for consumers and should not be adopted until the issue has received thorough and careful consideration.

As I mentioned on the phone, I am concerned that this amendment will retard the development of generic drugs. The substantial savings available to consumers purchasing lower cost therapeutically equivalent generic drug products have been well-documented. Any action to extend the patent life of drug products will delay the availability of lower-cost generic substitutes and could result in a substantial loss of savings to consumers.

By stressing the cost saving aspects of generic drug use, I do not wish to down-play the consumer's interest in the discovery of new drug products. We recognize the right of drug companies to profit from their research and development of products. However, as the law now stands, we believe they are adequately protected. It is also not clear that the marketing of new chemicals has necessarily been severely affected by regulatory delay. There has been no demonstrated connection between FDA's delays in approval and a decline in drug research and development.

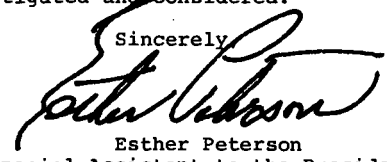
Even if a connection can be established, consumers have no assurances that the added income from the extended monopoly will be used for research and development.

In addition, serious consideration should be given to the possibility that regulatory reform (as embodied in the Drug Regulation Reform Act - H.R. 4258, S.1075) may be able to shorten FDA's approval time, without necessitating a change in the general patent laws.

Congressman Waxman, Chairman of the Subcommittee on Health and Environment of the House Interstate and Foreign Commerce Committee, will be holding hearings on drug patent problems in July. At these hearings, consumers could explain in greater detail concerns about extending drug patent protection. I believe the results of those hearings would be a valuable supplement to your more general hearings on industrial innovation.

I hope you will consider postponing any immediate action on this amendment until the needs of consumers and industry have been more fully investigated and considered.

Sincerely,



Esther Peterson
Special Assistant to the President
for Consumer Affairs

The Honorable Robert Kastenmeier
2232 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20510

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Norman Dorsen
Stokes Professor of Law

July 3, 1984

Hon. Robert Kastenmeier
Chairman, Subcommittee on Courts, Civil
Liberties and the Administration of Justice
Room 2232
Rayburn Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

In the course of my testimony before the Subcommittee on June 27, 1984, concerning the constitutional issues raised by Section 202 of H.R. 3605, two matters were raised that required a further submission. The first is a discussion of the relevance of Ruckelshaus v. Monsanto Co., which was handed down by the Supreme Court on June 26, 1984, only the day before the hearing. The second concerned Mr. Synar's question concerning Supreme Court cases holding congressional statutes unconstitutional under the Taking Clause of the Fifth Amendment. You were kind enough to grant me permission to address the Monsanto case in this letter, and I trust you would not object to my taking the opportunity to respond more fully to Mr. Synar at the same time. I shall address his question first.

1.

The Supreme Court has invalidated at least two federal statutes under the Taking Clause. The first case is the one I mentioned at the hearing, Lynch v. United States, 292 U.S. 571 (1934). The Court, in an opinion by Justice Brandeis, declared invalid the Act of March 20, 1933, which relieved the United States from all liability on its War Risk Insurance Policies. While the opinion discussed the Due Process clause, it is clear that the decision also rested on the Taking Clause. See 292 U.S. at 579.

The second case is Louisville v. Joint Stock Land Bank v. Radford, 295 U.S. 555 (1935). In that decision the Frazier-Lemke Act, which transferred valuable mortgage rights from one person to another, was held unconstitutional

under the Fifth Amendment as applied to a mortgage antedating its passage.

As my prepared statement noted, there are many cases in which federal and state regulatory action has been declared invalid under the Taking Clause. These cases are also precedent for the constitutional question concerning Section 202 because the Court has not distinguished in the standards it has employed depending on whether the taking was effected by a statute or a regulation or whether the taking was made by the federal government or a state.

A recent example is Kaiser-Aetna v. United States, 444 U.S. 164 (1979). In that case the Court held to be an unconstitutional taking certain U.S. Corps of Engineers regulations that required owners of a private pond, who had invested substantial sums to dredge and improve it into a marina, to convert the pond into a public aquatic park. In the course of his opinion Justice Rehnquist relied on a number of cases, including Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922), a case involving a state statute that was also referred to at the hearing.

Finally, it bears noting that the Supreme Court has explicitly included patent rights within the category of property protected by the Taking Clause. In William Camp & Sons Ship & Engine Building Co. v. International Curtis Marine Turbine Co., 246 U.S. 28, 39-40 (1918), Chief Justice White, speaking for a unanimous Court, said that "rights secured under the grant of letters patent by the United States were property and protected by the Constitution and not subject therefore to be appropriated even for public use without adequate compensation."

A number of other cases could be cited, but I hope I have allayed any suggestion that the Supreme Court has not vigorously enforced the Taking Clause in a wide variety of cases, including those involving congressional statutes.

2.

The above discussion leads naturally to the recent decision of Ruckelshaus v. Monsanto Co. which contains two holdings pertinent to the validity of Section 202. The first is that trade secrets constitute "property" that is protected by the Fifth Amendment. The second is that federal legislation reneging on a federal guarantee of exclusive use of trade secrets constitutes a compensable

taking under the Fifth Amendment. Inspection of Justice Blackmun's opinion reveals that its principles are applicable to the proposed taking of exclusive patent rights under Section 202 of the Patent Extension bill by the retroactive repeal of the Bolar decision.

The Monsanto decision involved the public disclosure provisions of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 61 Stat. 163 (1947), as amended, 7 U.S.C. § 135 et seq., which establishes a federal regulatory scheme governing the use, sale and labeling of pesticides. FIFRA requires companies to submit data, including trade secrets and other commercial and financial information, to the Environmental Protection Agency ("EPA") to obtain regulatory approval to market and use pesticides.

Throughout its history FIFRA has contained provisions governing public disclosure of data submitted by companies during the course of the regulatory process. The original version of FIFRA prohibited disclosure of "any information relative to formulas of products," see 52 U.S.L.W. at 4887, but was silent with respect to the disclosure of other data. In 1972, FIFRA was amended to provide for public disclosure of data submitted in support of a pesticide registration application, but the amendments specifically prohibited the disclosure of material that both the submitter and the EPA agreed was "trade secrets or financial information." In the event of disagreement, a federal district court was given jurisdiction to determine the issue by declaratory judgment. See 52 U.S.L.W. at 4887.

Congress again amended FIFRA in 1978, limiting registration applicants to a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. See 52 U.S.L.W. at 4888.

Monsanto had submitted data to EPA at various times throughout the period FIFRA was in effect. Subsequently, it filed suit in federal court seeking injunctive relief and a declaratory judgment that it had a property interest in certain of the data it had submitted and that a taking in violation of the Fifth Amendment would occur if EPA were to disclose such data or consider such data in evaluating another application for pesticide registration.

With respect to the first issue before it, the Court held that the commercial data involved, which was cognizable as trade secrets under state law, was property protected

by the Taking Clause of the Fifth Amendment. 52 U.S.L.W. at 4890. In so ruling, the Court noted that "[t]his general perception of trade secrets as property is consonant with the notion of 'property' that extends beyond land and tangible goods and includes the products of an individual's 'labor and invention'." 52 U.S.L.W. at 4890, citing 2 Blackstone, Commentaries, 405.

This holding is significant for purposes of analyzing Section 202 because it reaffirms that intangible property is protected by the Fifth Amendment. Like trade secrets, patents are also "products of an individual's labor and invention." In this light, and in view of the express language of the Patent Statute itself, it is now beyond question that patent rights are property rights.

The Monsanto Court next addressed the issue whether the public disclosure provisions of FIFRA effected a taking within the meaning of the Fifth Amendment. Its ruling on this point was in two parts. Prior to 1972, neither FIFRA nor any federal statute guaranteed the confidentiality of all data required under FIFRA. Thus, the Court first held, Monsanto had no reasonable investment-backed expectation that information submitted prior to 1972 would not be disclosed, 52 U.S.L.W. at 4892, and Monsanto had no right to compensation for such disclosure.

On the other hand, under the statutory scheme in effect from October 1972 through September 1978, the Court found that the federal government had explicitly guaranteed to Monsanto and other registration applicants an extensive measure of confidentiality and exclusive use. Thus, the Court's second ruling was that if EPA, consistent with the authority granted it by the 1978 FIFRA amendments, were to disclose trade secret data in a manner not authorized by the version of FIFRA in effect between 1972 and 1978, such conduct would frustrate Monsanto's reasonable investment-backed expectations concerning that data and thus constitute a taking of its property. 52 U.S.L.W. at 4892-4893.

The Court ultimately found that because the Tucker Act was available to Monsanto as a remedy for any uncompensated taking, Monsanto's challenge to the constitutionality of the statute was not ripe for resolution. But there was no ambiguity in the Court's conclusion that "EPA consideration or disclosure of health, safety, and environmental data will constitute a taking if Monsanto sumbitted the data to EPA between October 22, 1972, and September 30, 1978. . . ." 52 U.S.L.W. at 4893 (emphasis supplied).

The Court's analysis is of the utmost significance in analyzing the constitutional problem presented by Section 202. While the Court observed that the factors to be taken into account in determining whether governmental action has gone beyond "regulation" and effects a "taking" include the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations, the Court concluded that the force of the last factor was so overwhelming with respect to certain of the data submitted by Monsanto that it disposed of the taking question entirely. 52 U.S.L.W. at 4891.

This conclusion is obviously of direct applicability to analysis of Section 202, more particularly, in determining that public disclosure would frustrate Monsanto's reasonable investment-backed expectations with respect to trade secret data submitted between 1972 and 1978, the Court relied upon an observation common to both trade secrets and patents -- that the economic value of the property interest involved derives from the right to exclude others. The Court wrote as follows:

> The right to exclude others is generally "one of the most essential sticks in the bundle of rights that are commonly characterized as "property." Kaiser Aetna, 444 U.S. at 176. With respect to a trade secret, the right to exclude others is central to the very definition of the property interest. Once the data that constitutes a trade secret is disclosed to others, or others are allowed to use that data, the holder of the trade secret has lost his property interest in the data. That the data retain usefulness for Monsanto even after they are disclosed . . . is irrelevant to the determination of the economic impact of the EPA action on Monsanto's property right. The economic value of that property right lies in the competitive advantage over others that Monsanto enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge. 52 U.S.L.W. at 4892-4893.

The taking involved in Monsanto is directly analogous to the taking involved in Section 202. Both FIFRA (in the period 1972 through 1978) and the Patent Act (as it

currently exists) have created reasonable investment-backed expectations in the trade secret owner and patent owner, respectively, that such owners would be able to exclude all others from use of their property. Indeed, the case for the patent owner is stronger because the patent property right is grounded explicitly in Article I, Section 8 of the Constitution. As Monsanto makes clear, once the federal government, through a statutory amendment, destroys exclusivity rights that it has previously conferred, a compensable taking has occurred.

I appreciate the opportunity to supplement my testimony in this letter and would, of course, be pleased to respond to any further questions.

Sincerely,

Norman Dorsen

ND:bk

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HARRY E. WESTLAKE, JR. (D.C. BAR, OF COUNSEL)

July 6, 1984

Hon. Robert W. Kastenmeier, Chairman
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
U.S. House of Representatives
Washington, D.C.

Re: Drug Price Competition and Patent Term Restoration Act of 1984 (H.R. 3605)

Dear Congressman Kastenmeier:

This letter supplements my testimony on June 27, 1984, when I promised to provide your subcommittee with an overall analysis of H.R. 3605, and represents my own personal views, not necessarily those of any client.

The "delicately balanced compromise" embodied in H.R. 3605 is primarily directed to exploitation of existing drugs. Let all the existing off-patent drugs go immediately or as soon as possible to the generic industry.

Unamended, H.R. 3605 would unnecessarily harm America:

- Fewer pioneer cancer drugs would come to the marketplace.
- American exports to the multibillion dollar international pharmaceutical market would be jeopardized.
- Pioneer research would move overseas.
- Confidence in the patent system would be seriously eroded.

Amidst many concerns, the manifest unconstitutionality of Section 202 is most striking, and is clearly suggested in the Supreme Court's June 26, 1984 ruling in Ruckelshaus v. Monsanto Co., -- U.S. --, 52 LW 4886 (1984).

Very truly yours,

Harold C. Wegner

HCW22:rel

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July 6, 1984

Hon. Carlos J. Morehead
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
U.S. House of Representatives
Washington, D.C.

Re: Drug Price Competition and Patent Term Restoration Act of 1984 (H.R. 3605)

Dear Congressman Morehead:

In reply to your question to me during the hearings on June 27, 1984, I am pleased to provide my personal analysis of H.R. 3605. This letter is written as my personal response, and does not necessarily reflect the views of Cetus Corporation.

Stimulation of future research in this country should be a primary concern. A stable patent law must be maintained, particularly to avoid international repercussions that would adversely affect American exports of pharmaceuticals. Amidst many concerns, the manifest unconstitutionality of Section 202 is most striking, and is clearly suggested in the Supreme Court's June 26, 1984 ruling in Ruckelshaus v. Monsanto Co., -- U.S. --, 52 LW 4886 (1984).

The "delicately balanced compromise" embodied in H.R. 3605 is primarily directed to exploitation of existing drugs. Let all the existing off-patent drugs go immediately or as soon as possible to the generic industry. That is also very much in the public interest; but that can be done without doing violence to the patent law and future research incentives.

I. TITLE I ANDA FREEDOM SHOULD BE INDEPENDENT OF PATENTS

Abbreviated New Drug Application (ANDA) freedom should have nothing to do with the presence or absence of a patent. ANDA requirements should stand on their own merits. There is no incentive to develop pioneer products under an expired patent.

The enlighted approach of the last Congress in the Orphan Drug Act should be applied, independent of the patent laws. Not one single existing drug now on the market would be affected by this approach. The public would be the primary beneficiary, as pharmaceutical companies could elect the best drug for clinical development, patented or not, and not merely the best patented drug. Additional drugs could be put into the pipeline, giving the generics and public alike more competition and a wider selection of therapies.

A. Patents Should be Divorced from the ANDA

1. Public Safety

The public safety requires a minimum period without ANDA competition. The Japanese Health Ministry provides its citizens with such a safety factor of up to six years. America should do no less for its own citizens.

If the drug is patent-protected, then the public safety is incidentally assured because the patent holder can elect to take measures to defer ANDA approval for much longer than the minimum period needed for safety determination. But, should this safety be keyed to the private patentee's interests in maintaining his patent right? If the drug is seemingly good but the patent weak, should this make a difference in quick ANDA approvals for new drugs?

2. Minimum Periods of Exclusivity to Encourage Research

In 1984, when the generic drug industry seeks literally a generation of new products that have been free from ANDA's since 1962, surely the appetite of the generics and the public for new generic drugs will be more than completely satisfied by giving ANDA's on existing products. Future products should be given some period of freedom from an ANDA.

The Waxman bill in its present form discourages much drug research, and would lead to a concentration of the pioneer industry in major drug houses with fewer and fewer competitive products. This is the antithesis of the free competition that is a primary object of the Waxman bill.

a. Eliminating the Second Drug

Within the scope of a "garden variety" patent to a new class of compounds, there are literally thousands of possible compounds within the scope of the broadest claim, and often ten or twenty or more compounds actually made that are disclosed in the patent.

To be sure, the present bill does encourage the patentee to quickly select one of these drugs as soon as possible for clinical trials. But, what happens to the second drug that misses out in the screening? What happens to the thousandth drug that is within the scope of the patent, but not immediately synthesized?

Public policy quite clearly favors the development of several drugs, and not just one, even when the products are roughly equivalent. A certain percentage of the population may develop side effects only to one of the drugs. Perhaps these side effects are only recognized late, even after approval of the first drug. Advanced clinical testing may show that the second is actually far better.

Equally important is the competitive factor that is so important in maintaining reasonable prices for drugs. It is fundamental that if a company is encouraged to place a second drug in the marketplace in competition with the first, everyone benefits from such competition.

b. Orphaned Projects

Some drugs may not be developed as products usable with patients until late in the life of a patent, or not even be considered for development until after the patent has expired. The present wording of the bill provides zero exemption from ANDA competition where the patent has expired or is invalid. Patent validity and expiration surely have no rational relationship to whether it is in the public interest to develop a new, life-saving product and release it for safe public use.

3. The Bill Favors the Big Multinational Drug Company

For the major multinational established drug companies working in the ordered world of conventionally produced drugs, it is possible to predict with a relatively high degree of certainty whether a valid patent can be obtained for a particular drug. These same major multinational established drug companies also have the resources to immediately commence regulatory tests for a promising product.

B. "Unpatentable" Drugs [21 USC §505(j)(4)(D)(ii)]

Proposed 21 USC §505(j)(4)(D)(ii) would give a four (4) year period of exclusivity for future drugs, but only if the drug is certified as being unpatentable.

This provision takes no account whatsoever of those cases where the patent has not yet been granted (which can occur in an interference), where the patent has expired, or where a court may find a patent invalid.

C. Amendment to Title I to protect Orphan Drugs

In the hearings of June 27, 1984, Dr. Cape proposed that freedom from ANDA competition be provided for cancer inventions. That proposal would take care of biotechnology research in the cancer area. A broader solution for all future research patterned after the Cape proposal is considered here:

1. Patent-Free ANDA Freedom

Proposed 21 USC §505(j)(4)(D) should be modified as follows to provide a reasonable, prospective patent-free period of ANDA freedom:

> If an application submitted under subsection (b) for a drug is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

Parallel wording changes are required in 21 USC §505(c)(3)(D).

2. ANDA Freedom Should not be Patent Based

If, after a reasonable period of exclusivity, the patent is invalid, then, quite clearly, there is no reason why a generic competitor should wait a moment longer to seek his approval. The patent owner has his remedy in court. Indeed, the principles of the patent system antedate the birth of modern pharmaceutical chemistry, and the same principles of damages and injunctive relief developed largely for machines and mechanical devices and instruments can be used in the pharmaceutical field, as they have been used.

II. "PATENT INFORMATION"

"Patent information" must be promptly filed by a pioneer or that pioneer forfeits any right to hold up an ANDA prior to expiration of the patent, as explicitly provided under proposed 21 USC §505(j)(2)(vii)(I).

There is no demonstrated need for including "patent information" in Title 21, a drug law. The obvious objective of the generic industry is to avoid doing a simple patent infringement search; quite clearly, that objective will not necessarily be met through the voluntary patent information reporting requirement, which in some ways is inferior from the patentee's standpoint to the traditional remedy under patent code.

A. Drug Law or Patent Law: Which Way Will Be Used?

If the generics thought that they could avoid a simple patent search through the "patent information" provision of Title I, they are sadly mistaken. There is no penalty for failing to provide the "patent information" other than a waiver of the right to defer the ANDA grant.

For various reasons, either by willful act or through a pioneer tripping over a time limit, pioneers in some cases will elect the alternate remedy provided under 35 USC §287. Indeed, for some situations the patent provisions of 35 USC §287 may have a better result than the Waxman alternative.

B. "Evergreening" the Patent Information

"Evergreening" through multiple patents is discussed infra. A different kind of evergreening is possible for patent information, and for which there is no simple solution. There are many patents that can cover a particular drug, but only some of the patents may be used. Will "patent information" include sophisticated process patents that may or may not be necessary for making a particular drug? What patents reasonably cover a drug? Will a certificate of noninfringement be necessary to avoid a particular process patent? Will an 18 month deferral of the ANDA approval allow for conclusion of infringement discovery and trial?

C. Marriage of Patent and Regulatory Law

At the present time, there are but a handful of lawyers who are experts in both patent law and regulatory law. Both specialties are sufficiently demanding of technical and legal expertise of the very highest level that there has been no reason heretofore to merge these specialties. The scarcity of top talent in

both fields makes access to equal justice for the small businessman especially difficult.

Under the Waxman bill, the marriage of patent and regulatory law will require a dual specialization to manage the intricacies of the new practice. Access will be even more difficult for the less sophisticated concerns.

It is far easier for an expert government administrator to handle applications, day in and day out, under a single statute, than to represent clients before the agency. But, whether the bill can be administered is even in question. Commissioner Gerald Mossinghoff of the U.S. Patent and Trademark Office (PTO) presented a chart to the subcommittee on June 27, 1984, which was more complicated than a Monopoly game board and had almost every "square" imaginable, save (as pointed out by Congressman Sawyer) a point where you "Go Directly to Jail".

III. PATENT EXTENSION

A. The Glickman-DeWine Bill, H.R. 5529 as a Model

The Glickman-DeWine Agricultural Patent Reform Act of 1984, H.R. 5529, is a good example of positive legislation that fosters the introduction of new products, which gives both the possibility of an active ingredient free from side-effects of existing products, and further competition for existing products.

One of the important points that must be remembered as a principal benefit of a new patented product is that it is almost always in competition with existing, and often patented, products. Where the incentives are provided by the patent system to introduce many competitive products, each product being patent protected, then the consumer benefits by diversity of products and price competition.

B. "Evergreening" with Multiple Patents

Evergreening of the patent right is a new term of art that is understood to mean that the patentee in some instances obtains far more than a 17 year exclusive period through multiple patents.

Whether this is a big problem as suggested by the generics or a minor problem as answered by the drug industry, the simple solution is a cap on the total period of extension keyed to the earliest effective filing date for the product under 35 USC §120.

The simple capping of the term based upon a fixed number of years eliminates the need for the unduly complicated paperwork

that creates an undue administrative burden on the Patent and Trademark Office and patentees alike.

Some earlier proposals had included reference to 35 USC §119, which deals with a foreign priority right. This solution is not possible without creating an express violation of the Paris Convention. In fact, the Paris Convention provision helps American industry in countries like Japan where the American receives a one-year bonus through his priority right being excluded from the reckoning of the term of the patent grant.

IV. CONSTITUTIONAL AND POLICY CONSIDERATIONS IN THE BOLAR CASE

The generic industry wishes to test drugs patented by others prior to patent expiration, and to retroactively overrule Roche Products, Inc. v. Bolar Pharmaceutical Co. Inc, __ F.2d __ , 221 USPQ 937 (Fed. Cir. 1984), a violation of the Fifth Amendment. See Ruckelshaus v. Monsanto Co., __ U.S. ___, 52 LW 4886 (1984).

The proposal to overrule Bolar is found in the first portion of Section 202, namely proposed 35 USC §271(e)(1). The other portions of Section 202 are considered infra.

Prospectively or retroactively, overruling Bolar would dangerously imperil American efforts to sell drugs abroad on an exclusive basis, undermining more than a generation of efforts to stimulate broad patent rights in overseas patent systems. The great strength of American foreign rights has both brought money to our shores and spread the cost of new drug development here to the shoulders of Europeans, Japanese and others.

A prospective reversal of Bolar that is tied to patent term restoration may be equitable and fair. A fair compromise under H.R. 3605 without Section 202 should be tied to patent term restoration. As the quid pro quo for the patent extension, the patentee's extension should exclude the Bolar activity. It is proposed that 35 USC §156(b) be rewritten in its entirety as follows:

> The rights of the patentee during the extension shall be limited to the approved product, exclusive of the use thereof under section 505(j) of Title 21, United States Code.

A. The Interface Between Drug Regulatory and Patent Laws

The Bolar case is typical of the era of heightened concern for public welfare that has made regulatory approval of drugs so expensive and time-consuming, and upon which the need for patent term restoration legislation is based. As well recognized by Congress, and as judicially recognized in Bolar, __ F.2d at ___,

221 USPQ at 941, there is an approximately ten year loss in the life of a patent for even though the patent term commences from the grant of the patent, the right to market a drug, patented or not, commences only after a lengthy regulatory process that is generally completed long after the patent term starts running.

Of partial solace to the patentee is the knowledge that a generic competitor cannot come on the market immediately after expiration of the patent, but can only start domestic regulatory tests for approval after expiration thereof. This translates into an effective market entry barrier of up to about two years after expiration of the patent, but this still only partially compensates the patentee for the tremendously long pendency and expense of an approval for a pioneer drug.

B. The Bolar Facts

The Bolar case appears to have been engineered as a test case to attempt to judicially change the patent statute.

Flurazepam hydrochloride is a Roche drug which took many years for pioneer regulatory approval. Generic competitor Bolar wished to market flurazepam hydrochloride immediately upon the expiration of the patent (which expired earlier this year), and thus wished to do its own regulatory tests prior to expiration. It was exactly this pre-patent expiration testing for commercial purposes that was confirmed as an infringing "use" under 35 USC §271(a) in the Bolar case.

C. The Court's Ruling in Bolar

1. The Patent Right Has Always Covered Commercial Tests

Anglo-American jurisprudence for patent law goes back to at least the seventeenth century, and was first codified as part of the Statute of Monopolies of 1624; colonial patents were granted starting with Massachusetts in the 1640's; Congress was given an express constitutional mandate to write a patent law; and we had our very first federal patent statute in 1790. Throughout our history, the patent right has consisted entirely of the right to exclude others from making, using or selling the invention for any business purpose. As the Bolar court itself notes with respect to the 1952 codification of the patent law, "[35 USC §] 271(a) prohibits, on its face, any and all uses of a patented invention." __ F.2d at ___, 221 USPQ at 939.

To be sure, there is an "experimental use" exception dating back to the landmark opinion more than 170 years ago of the nation's first great jurist on patent law, Justice Story, in Whittemore v. Cutter, 29 F.Cas. 1120, 1121 (C.C.D. Mass. 1813)

(No. 17,600). It has been apparent for more than a full century that this exception could not cover a commercially oriented use as contemplated by Bolar. ___ F.2d at ___, 221 USPQ at 939-940.

2. The Total Absence of any Holdings Favoring Bolar

Bolar's briefs and that of its amicus are notable by their failure to cite a single case from the Supreme Court, or any Circuit, that even remotely has a holding "on all fours" with the present case. A long list of cases is cited which shows the absence of any doctrine to support the Bolar position. ___ F.2d at ___, 221 USPQ at 939-940. Indeed, the clarity of the law is so striking that there has been virtually no need to litigate this point, although there is the noteworthy decision of a District Court, Pfizer, Inc. v. International Rectifier Corp., 217 USPQ 157 (C.D. Cal. 1982), cited with approval in Bolar, ___ F.2d at ___, 221 USPQ at 942.

3. Bolar Recognized its Odyssey into Judicial Legislation

Bolar itself recognized that it was seeking judicial legislation to transform an experimental use exception in the law into what could be more aptly termed a commercial use exception. Thus, as pointed out in the Bolar case itself, Bolar recognized:

> that its intended use of [flurazepam hydrochloride] does not fall within the "traditional limits" of the experimental use exception as established in [the cited cases] or those of other circuits. Its concession here is fatal. [Bolar, ___ F.2d ___, 221 USPQ at 940]

Later, the point is reemphasized:

> Bolar argues that even if no established doctrine exists with which it can escape liability for patent infringement, public policy requires that we create a new exception to the use prohibition. Parties and amici seem to think, in particular, that we must resolve a conflict between the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§301-392 (1982), and the Patent Act of 1952, or at least the Acts' respective policies and purposes. We decline that opportunity here, however, to engage in legislative activity proper only for the Congress. [Bolar, __ F.2d at __, 221 USPQ at 941; emphasis supplied in part]

C. Section 202 is a Proscribed Fifth Amendment "Taking"

1. Taking the Patentee's Property

Proposed 35 USC §271(e)(1) takes away a major part of the patentee's right to exclude others. As clearly seen from the Bolar opinion itself, the infinger Bolar was attempting to effectively cut off two years of exclusive marketing by the patent owner.

2. The Right to Exclude is All the Patentee is Given

At first blush, one may wonder whether elimination of a patentee's right to exclude others in the final two years of his patent is a substantial encroachment on his patent right. To understand whether this is a substantial encroachment or not, one must go to the essence of what constitutes "patent property".

There is nothing other than the exclusionary right that exists. There is only the right to exclude others that is given by a patent. Nothing more.

Accordingly, taking away the patent owner's right to exclude strikes at the very heart of the patentee's right.

The June 26, 1984, Supreme Court opinion in Ruckelshaus v. Monsanto Co., __ U.S. ___, 52 LW 4886 (1984), follows more than a century of case law which confirms the exclusionary nature of an intellectual property right:

> The right to exclude others is generally "one of the most essential sticks in the bundle of rights that are commonly characterized as property." Kaiser Aetna [v. United States], 444 U.S. [164], at 176 [(1979)] With respect to a trade secret, the right to exclude others is central to the very definition of the property interest.

While Monsanto deals with trade secrets and not patents, the Supreme Court has recognized the fundamental exclusionary nature of the patent right for more than a full century. The early case law is summarized by one pronouncement nearly 75 years ago, Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 425 (1908), quoting with approval from Bloomer v. McQuewan, 14 How. 539, 549:

> The franchise which the patent grants consists altogether in the right to exclude every one from making, using, or vending the thing patented, without the permission of the patentee. This is all that he obtains by the patent.

The Monsanto determination of a property right has generated some surprise; the surprise is this reaction, and hardly the

decision itself, which is nothing more than hornbook law going back more than a century. The Supreme Court in James v. Campbell, 104 U.S. 356 (1882), noted the "exclusive property in [a] patented invention" and that it:

> cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser ****

Later, in Hollister v. Benedict Manufacturing Co., 113 U.S. 59 (1884), the Court reiterated its James pronouncement in the context of the Fifth Amendment "taking" issue:

> It was authoritatively declared in James v. Campbell, 104 U.S. 356, that the right of the patentee *** was exclusive *** and stood on the footing of all other property, the right to which was secured, as against the government, by the constitutional guaranty which prohibits the taking of private property for public use without compensation,*** [113 U.S. 59 at 67; emphasis supplied]

D. Constitutional Questions in the Revision of the Patent Law

1. Prospective Reversal, Unwise but Surely Constitutional

In a period of nearly two full centuries, Congress has consistently chosen to draft a broad patent law, operating under the Constitutional mandate of Article I, Section 8, Clause 8, which empowers Congress to pass laws which Promote the Progress of the Useful Arts. It did so first in 1790, borrowing in turn from the broad definition of a patentable invention of the 1624 Statute of Monopolies.

Whether Congress should now prospectively enact a statutory exception to the scope of the patent right as a matter of public policy may be seriously questioned on that ground, but not on Constitutional grounds. Thus, Article I of the Constitution gives Congress the power to enact, or even refrain from enacting, a patent law, if that is what Congress wishes to do. As seen from the 1978 environmental law changes considered in Monsanto, a prospective limitation of intellectual property rights is clearly constitutional and not in violation of the Fifth Amendment "taking" clause.

2. Retroactive Reversal, Both Unwise and Unconstitutional

Drugs now on the market after years of regulatory testing that are protected by existing patents quite clearly were put on the market based upon the expectation that the United States would maintain the broad patent rights mandated by Title 35 of the United States Code.

All that the patentee is given by the grant of letters patent is the right to exclude others; taking away that exclusionary right is taking away the heart of the patentee's right. The Monsanto case clearly governs this situation and graphically illustrates why retroactively narrowing the patent right would be just as much a Fifth Amendment "taking" as if the government permitted a third party, without compensation, to put a railroad through one's private pastureland.

IV. INFRINGEMENT BY FILING A PIECE OF PAPER

The second numbered paragraph of Section 202, proposed 35 USC §271(e)(2) creates infringement-by-filing-a-piece-of-paper. This proposal does serious damage to the integrity of the American patent system, with far ranging domestic and international implications.

A. More than Three Centuries of Common Law Traditions

Infringement-by-filing-a-piece-of-paper is a radical departure from more than three full centuries of our common law patent jurisprudence. Our Anglo-American patent system dating back more than three full centuries has consistently defined the patent right as a property right, which consists entirely of the right to exclude others from making, using or selling an invention. Other systems, notably Japan, have similar definitions but also include the act of importation of a patented invention.

B. A Legal Non Sequitur

The proposed infringement-by-filing-a-piece-of-paper would make the act of filing a regulatory application with the government an act of infringement of a private patent.

But, the total right under a patent is a private right of property, which consists entirely of the right to exclude others. Surely, no private party can exclude a third party from filing a government report. And, indeed, the legal fiction is confirmed by the final paragraph of Section 202, proposed 35 USC §271(e)(4), which would bar any right of recovery, injunctive or monetary damages, from the act of infringement-by-filing-a-piece-of-paper.

C. An Advisory Opinion Procedure Should not be Fostered

The totality of the patent right is the right to exclude others, as seen from a long line of nineteenth century Supreme Court precedent, summarized in Continental Paper Bag Company v. Eastern Paper Bag Company, 210 U.S. 405, 425 (1908). But, 35 USC §271(e)(4) would eliminate this right. The object of the second and fourth paragraphs of Section 202 is clear: Advisory opinions on the validity of a patent are desired.

The Constitutional perils associated with an advisory opinion stem from the earliest days. In the patent field, courts have strictly refused to entertain jurisdiction of patent cases in the absence of a clear actual controversy. There may well be an actual controversy in the sense of existing patent jurisprudence when a completed ANDA is filed, based upon the same type of infringing activity as exemplified in the Bolar case. If so, then surely a patentee can sue for patent infringement at the time a completed ANDA is lodged by the would-be generic manufacturer.

V. THE THIRD PARAGRAPH OF SECTION 202

Undoubtedly the most curious and redundant provision of H.R. 3605 is the third provision of Section 202, which provides a new 35 USC §271(e)(3) which eliminates a patentee's relief from actions under the first portion, 35 USC §271(e)(1). But, that first portion of Section 202 excludes certain acts from the category of patent infringement.

If something is not an act of patent infringement under §271(e)(1), then why is a separate paragraph needed to say that the patentee shall not have relief for acts by a third party that are under that paragraph?

The same constitutional objections that apply to the Bolar case in terms of retroactivity apply with equal force under this portion as well.

VI. AMERICAN RIGHTS ABROAD

While the American automobile, machinery and other industries have faced international setbacks, the American domestic pharmaceutical industry maintains its top worldwide position for pioneer drugs.

A. Stimulating American Sales Abroad Helps America

Maintaining this position may be considered far more important than maintenance of our leadership position in some

other areas. While Americans as exporters contribute to the flow of cash to our shores and provide employment for our citizens, in the healthcare field, the American worldwide initiative has two further benefits:

First, the revenue earned from foreign sales of pioneer drugs pours money for investments in new drugs back into our laboratories in the United States. The increased profits that American pioneers make abroad permit further research into new chemical entities here, all to the benefit of the American consumer.

Second, it is quite natural that each pioneer pharmaceutical manufacturer is most familiar with his own "home market", and that his first country of choice for regulatory testing of a drug, absent special circumstances, will be that home market. To the extent that the pharmaceutical industry is focused upon the American R&D community, this means that it is more likely that a new drug will appear here, at home, before it appears in Europe or Japan, when all other factors are equal.

B. America and the Diplomatic Conferences on Patents

Americans anchor their foreign patent rights on a document now over a century old, the historic Paris Convention of 1883, which has been amended only on a handful of occasions, most recently by the 1967 Stockholm Revision.

While the first 80 years of the Paris Convention were an era of progress and protection of patent rights, America in the most recent time has faced a difficult struggle against dilution of its rights abroad. We are now in the midst of ongoing sessions of a Paris Convention revision that has met periodically over the past five years in Geneva and Nairobi. Since Stockholm, the Paris Convention has been administered by the United Nations, and the one country-one vote problem has led to a rearguard action to sustain the Stockholm text.

Our State and Commerce Departments have been fighting the good fight, and so far have met with remarkable success in stopping the possibility of retrogressive treaty enactments. At the heart of the third world position for treaty "reform" has been the dilution of exclusive rights, and in particular the creation of an exclusive compulsory license of foreign (i.e., American) rights. It would be the height of irony for America, after having successfully fought off the international pressure of a weighted third world majority, to now unilaterally and domestically create a far worse example of the taking of property rights, as would be the overuling of Bolar.

C. The American Patent Law as a Model in the Past

It is not just the developing countries that have studied the American model. In the pharmaceutical field a generation ago, neither Germany nor Japan had strong "compound protection" for pharmaceuticals. (At that time, a pharmaceutical compound was unpatentable; the only recourse that a pioneer had was through an "analogy process" claim.)

The Germans in 1967 and the Japanese in 1975 passed progressive legislation to strengthen their domestic pharmaceutical industries by repeal of their respective bans on compound claims. The express purpose of the 1975 Japanese code revision was to strengthen the incentives for pioneer drug research.

D. The U.S. "Imprimatur" for ANDA-Like Foreign Approvals

Grant of an abbreviated new drug application (ANDA) in the United States quite clearly can have benefit in foreign countries. To the extent that an American manufacturer can tell a foreign government that his ANDA drug is approved here in the United States, it may be expected that foreign governments will more readily grant approvals there, in the foreign market.

The earlier the ANDA here, therefore, the earlier the possibility of foreign market erosion. As Americans are the leaders in the export of pioneer pharmaceuticals, it is the American export sales which are dealt the damage by this change in the law.

E. Avoidance of a Negative Role Model

If modern, industrialized countries such as Germany and Japan revise their codes to copy positive examples of American law to provide incentives for their pioneer industries, imagine the opposite side of the coin in countries totally devoid of any pioneer industry.

What happens when America, with a pioneer industry, sharply restructures its own code to the derogation of that pioneer industry? Undoubtedly, the message will be sure and swift. More than likely, the code revisions in third world countries would be far more extensive, and go beyond the pharmaceutical industry: If Americans, with their pioneer industries, are willing to look to the short range consumer interest at the expense of research incentives, then why should a totally consuming society not jump on the bandwagon?

F. America Immediately Risks a $585,000,000.00 Annual Market

Former PTO Commissioner William E. Schuyler's prepared statement succinctly summarizes some of the genuine concerns for loss of American rights abroad, particularly in areas of the world without patent protection. Commissioner Schuyler points out that American drug companies make some $585,000,000.00 per year in foreign sales only in these countries without patent protection. (see page 12 of his testimony before this subcommittee on June 27, 1984).

Commissioner Schuyler points out that:

> The bill strikes two blows against American companies. First, it deprives American companies of trade secrets obtained at great cost (often measured in tens of millions of dollars). Second, it deprives American companies of the ability to make first use of these costly data to obtain approval overseas, thereby hurting their ability to compete effectively in those foreign markets, with adverse effects on the balance of trade and domestic employment.

* * *

Again, I wish to emphasize my support for the objectives of the bill insofar as Congress would permit easy generic access to off-patent drugs. The public deserves no less. As these objectives can be fully met, all without doing violence to the patent system, we would do well to give the public these generic drugs now, but without the intricacies of the bill that are totally unnecessary and a step backward.

Very truly yours,

Harold C. Wegner

HCW40:tb

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WRITER'S DIRECT DIAL NO.

July 9, 1984

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil
Liberties and the Administration of Justice
House of Representatives
Congress of The United States
Rayburn House Office Building
Washington, D.C. 200515

RE: H.R. 3605, Abbreviated New Drug Applications
and Patent Term Extension (Senate Bill S 2748)

Dear Mr. Chairman:

The following comments are submitted in opposition to certain portions of H.R. 3605, which I respectfully submit has serious defects and should not be enacted as it presently stands.

I am a partner in the Washington, D.C. law firm of Cushman, Darby & Cushman which specializes in the practice of intellectual properties law, including patent law, both in the United States and internationally. I have been an active practitioner in this area of law since 1950 or for over thirty-four years. During that period of time I have been engaged professionally in all aspects of patent practice including obtaining and enforcing patents as well as defending against patents. I have also been involved in many patent interference proceedings as well as proceedings concerned with trade secrets

and unfair competition. A great deal of my time has been expended in the pharmaceuticals patent area both in support of and in opposition to patents in that field.

Based on my experience I do not believe that the present H.R. 3605 is a fair and equitable bill which adequately protects the public as well as private interests. I further question the wisdom of the legislation which creates what I believe is an arbitrary, unfair and unworkable system. My comments are directed to both Title I and Title II of the bill.

TITLE I--ABBREVIATED NEW DRUG APPLICATIONS (ANDA)

Section 101 provides for abbreviated new drug applications (ANDA) wherein a party may make application certifying that, in the applicant's opinion, a relevant and infringed patent is invalid. The applicant is required to give notice to the patentee who then has forty-five days after notice to bring an action for patent infringement. Approval is immediate if no infringement action is filed by the patentee. However, if an action is filed, approval of the ANDA application is made effective eighteen months after the filing of the action or after such shorter or longer period as the Court may order depending on whether or not any party fails to reasonably cooperate in expediting the action.

I believe the indicated proposals, which will of necessity lead to the filing of many patent infringement actions which might otherwise be avoided, are fundamentally unsound, unfair and inappropriate. They clearly represent a significant departure from existing law in that, for all intents and purposes, they force a patentee to bring an infringement action at a grossly premature time. The patentees may in fact be required to file larger numbers of suits to protect their position because, for example, it is conceivable that a non-patenting party may make numerous applications for approval to sell a whole series of patented products in the hope that one or more of such applications will "slip by" and not result in the bringing of an infringement action with consequent early approval of the ANDA. The patentee is faced with the apparent need to bring early actions against all non-licensed applications lest silence somehow be found in one way or another to constitute approval of the application. The possibility of a great increase in patent litigation, at a stage too early to tell whether the litigation is economically warranted, is manifest.

Under existing law a patentee cannot be forced to litigate patent rights. The patentee is left to determine if and when infringement action is warranted. This is an important and substantive right of a patentee, particularly one who may have

limited resources. As noted, however, under the bill, the patentee loses the freedom of choice to litigate and must bring action within forty-five days or be prepared to suffer any consequences resulting from the failure to do so.

Furthermore, the periods of time for action as proposed in the bill are arbitrary and unreasonable, and give unfair advantage to admitted patent infringers. As presently drafted, an infringer has unlimited time to prepare for litigation prior to submission of an ANDA. The patentee, on the other hand, has only forty-five days to decide whether or not to institute litigation and to prepare for it. Given the complexity of the technology involved and the further complexity of patent litigation, in my opinion, litigation cannot be reasonably started in forty-five days and terminated in eighteen months even if both parties reasonably cooperate in expediting the action. The proposed time limits obviously place an impossible burden upon patentees and on the United States courts. The hearings in the House and the Senate brought out the fact that the indicated periods of time were selected totally arbitrary and not based on any principle of fairness. Furthermore, with approval of the ANDA application automatic after the eighteen month period of expedited litigation, the admitted infringer can then finance the litigation through sales of the infringing drug while the

patentee loses the profits unfairly reaped by the infringer. In my opinion, the bill should be amended to condition the approval of the ANDA application upon the termination of expedited litigation regardless of the time involved in completing the litigation and, of course, dependent on which party prevails. The bill should also eliminate the time constraint for filing suit and should, in any case, make it clear that failure to file an infringement action pending ANDA approval does not constitute a waiver of any of the patentee's rights to bring and maintain a subsequent infringement action.

Section 104 is also a highly objectionable feature of the bill and may in fact be the most unfair aspect of the proposed legislation. This section provides that safety and effectiveness data and information which have been submitted to the FDA by the initial registrant and not previously disclosed to the public, shall be made available to the public upon request unless extraordinary circumstances are shown. Such disclosure is contrary to all precedents and clearly goes against important public and private interests in the United States. It calls for an unfair and unnecessary surrender of valuable information, accumulated at very substantial cost to the initial registrant. In addition, such information is irrelevant and unnecessary to filing an ANDA for approval. Furthermore, foreign manufacturers

will be able to use the disclosed information abroad without regard to United States interests and in direct prejudice thereto. Experience has dramatically shown that cottage industries, aided by the Freedom of Information Act, have sprung up to sell data released by the U.S. Government. Thus persons not even related or connected with the drug industry will reap a profit by selling data abroad. In view of the recent Supreme court decision in Ruckelshaus v. Monsanto Co., decided June 26, 1984, 52 L.W. 4886, valuable rights in proprietary information may not be summarily given away.

The language of Section 104 is quite confusing, particularly since it is not clear if subsection (1)(5) is considered to be an extraordinary circumstance. However, it appears that (1)(5) makes available all previously non-disclosed information on approval of an ANDA. If so, two serious anomalies arise under Section 104. Firstly, if an infringement suit is not decided by the Court within the proposed 18-month period and ANDA approval is granted, the information referred to above would apparently be published, even though the patent is subsequently found to be valid and infringed. Information once published cannot be unpublished. Secondly, if a patent grant is delayed, e.g., through a patent interference proceeding, and a product falling within the finally granted claims is marketed before the

patent is issued, it appeast that the patentee's FDA information would be published even though a valid patent may eventually issue. Clearly disclosure of the patentee's FDA information in either of the indicated situations is not appropriate.

The relevancy of Section 104 to ANDA and Patent Term Restoration is not apparent. The information in question is not published now in respect of an ANDA. The Section was introduced only in a late draft of the bill and has not been discussed thoroughly. On its face it appears to be totally irrelevant to the subject of the bill.

In my opinion the bill should be amended to eliminate the provisions for public disclosure of information. Accordingly Section 104 should be deleted in its entirety.

TITLE II--PATENT TERM RESTORATION

Section 201 provides that the patent term may be extended under certain circumstance if application is made within sixty days after approval of the new drug application. Such a requirement is totally impractical and wasteful of both the patentee's resources and the Government's resources. No one can safely predict at the time of approval whether a patented drug will really be of sufficient importance to warrant seeking patent extension. The drug may well be rendered obsolete and replaced

by an improved drug. Yet, under the bill, the patentee and the Government have no choice but to deal with extension requests filed within sixty days of FDA approval of the drug involved. It is clearly premature to request extension at this stage. Costly and complicated extension procedures must be undertaken immediately for every patent involved even though the ultimate facts may moot the desirability of any extension. Further, under the bill, only one patent term may be extended. It is impossible to foresee which patent should be extended. The proposed time frame for requesting extension is, therefore, totally unrealistic, unnecessary and unfair. It takes away the patentee's freedom of choice to seek an extension and arbitrarily subjects the patentee to another layer of government proceedings. Furthermore, the proposal is highly detrimental to the public because it could result in the unnecessary extension of patents which would otherwise be open to free use by the public. Thus, the proposal serves no public interest and in fact is detrimental to it. In my opinion, it would be far better to allow the application for extension to be filed, upon proper showing of need by the patentee, at a time nearer the end of the regular patent term.

Section 201 of the bill also provides that patent term extension is limited to the first patent which discloses or

claims the patented drug. Such a requirement is also arbitrary, unfair and totally contrary to the patent system, particularly since a patent may disclose several inventions but claim only one, the others being claimed in separate divisionals or continuing applications as provided by law. Surely patents issued on the other applications should be entitled to appropriate extension if the facts justify. For example, a patentee may obtain a patent on a single compound A even though the patent discloses compounds A and B. The patentee may file a divisional on B and obtain a second patent thereon. Under Section 201, if the patentee obtained an extension of the A patent, he could not extend the life of the B patent even though B might prove to be, in the long run, the more significant drug. This does not seem at all fair. In fact, Section 201 is contrary to the intent of 35 U.S.C. 121, which gives the Commissioner of Patents the authority to require the inventor to file divisional applications in the case of an application disclosing independent and distinct inventions and to ultimately obtain two or more separate and distinct patents on all of the disclosed inventions. The inventor is thus penalized for being too inventive. Extensions should be available for the patents as to any of these inventions.

Section 201 also does not provide for extensions in the case of later patents on narrow improvement or selection inventions which might fall within the scope of a broader, dominating patent owned by the same party. No valid reason is seen for this sort of discrimination. The present law recognizes that improvements on basic inventions are patentable and patents on such improvements, whether they relate to improved methods of use, improved preparation methods or improved formulations, should have the opportunity for extension just like patents on more basic inventions. In fact, it is often times the case that an improvement is of much more consequence in terms of the public good than a basic invention.

Clearly the indicated provisions in the bill are not in the public interest and are contrary to the Constitution, Article 1, Section 8, Clause 8, which provides:

> "The Congress shall have the power ... To promote the progress of science and useful arts, by securing for limited times to ... inventors the exclusive right to ... discoveries."

In addition to the discrimination as to multiple inventions, the bill, in its transitory provisions, arbitrarily discriminates as to all improvement type inventions, as noted, by denying patent term extension as to those inventions which would cover, for example, new and patentable formulations, dosages, and

uses. It cannot be stressed enough that the bill arbitrarily and unwarrantedly discriminates against a whole host of admittedly patentable inventions. This is an undisputed fact and not speculation. As such it is not in the best interests of the public or inventors.

Finally Section 202 provides that it shall not be an act of patent infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under Federal Law which regulates the manufacture, use or sale of drugs. The hearings brought out the fact that this was a deal made among certain private interests solely to nulify 200 years of patent precedent, as exemplified in the recent decision in Roche Prod. Inc. v. Bolar Pharmaceutical Co., 221 USPQ 937 (CAFC 1984). The hearings in the Senate also brought out the fact that the deal was made in private without input from all interested parties. Strong and substantial criticism of this provision was justifiably offered at the hearings. The first United States Patent Act of 1790 provided:

> "Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled ...
>
> That if any person ... shall devise, make, construct, use, employ or vend ... any art, manufacture, engine, machine, or device, or any invention or improvement upon ... without consent of the patentee ... every person so offending shall

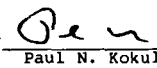
> forfeit and pay to the said patentee ... damages ... and moreover shall forfeit to the person aggrieved, the thing or things so devised, made, constructed, used, employed, or vended..."

The law of 1790 remains true today after almost 200 years. The unauthorized acts of making, using and selling a patented invention were prohibited then and are prohibited now, 35 U.S.C. 271. The present bill admittedly seeks to overthrow this nearly 200 years of sound legal precedent. For nearly 200 years the unauthorized act of making, using or selling has been deemed an unlawful patent infringement. The acknowledged deal reached by certain private interests should not be legalized by this Congress in the face of nearly 200 years of contrary Congressional action. In my opinion this Congress should not change what other Congresses have consistently upheld for nearly 200 years.

The question was raised at the House hearings whether the criticism of the present legislation was attributable to "patent purists," implying that such "purists" were obstacles to progress, or whether the criticism came from "true accommodators," implying that criticism from true accommodators was or would be entitled to some merit. Please be assured that my criticism is submitted not to oppose sound legislation. There are very serious problems in the present bill as brought forth in

the hearings and the written statements of Commissioner of Mossinghoff and former Commissioner Schuyler. I urge Congress to enact a bill that is fair and equitable to both private and public interests. The present bill, for the above stated reasons, falls short of these goals. If anything, the bill would lead to a much greater burden on our courts, our government agencies and those who provide for the research which results in the patentable inventions which improve our standards of living. The benefits hoped for from the bill do not justify this burden.

Respectfully submitted,

By 

PNK:pk

Paul N. Kokulis
Attorney-At-Law
Suite 800, 1801 K Street, N.W.
Washington, D.C. 20006
(202) 861-3000

cc: All House Subcommittee Members
All Senate Committee Members
Committee on Labor & Human Resources, Senate Bill 2748
Senator Charles McC Mathias, Jr.
Ralph Onau, Esq.

This is a true copy of a resolution as passed by the Section of Patent, Trademark and Copyright Law Section of the American Bar Association on August 4, 1984.

RESOLVED, that the Section of Patent, Trademark and Copyright Law reaffirms its support in principle to granting to a patent owner an extended patent term without unfair limitations on such extension, when the ability to exploit commercially a patented invention has been delayed, during the original term of the patent involved and through no fault of the patent owner, by governmental authorities, statutes or regulations; and Specifically, the Section continues to support Bills similar to S. 2892 (Bayh) 96th Congress, namely, in the 98th Congress, Synar H.R. 3502, Glickman H.R. 5529 and Mathias S. 1306, but opposes Title II - PATENT EXTENSION of Waxman H.R. 3605 (as amended by the House Committee on Energy and Commerce on June 12, 1984) and of Hatch S. 2748.

Charlotte M. Emmons

Mrs. Charlotte Emmons, Court Reporter

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JUN - 6 1984

HON ROBERT KASTENMEIER
HOUSE OFFICE BUILDING
WASHINGTON DC 20515

I WANT YOU TO KNOW THAT THE SERVICE EMPLOYEES INTERNATIONAL UNION, WHICH REPRESENTS THOUSANDS OF MEMBERS BENEFITING FROM GENERIC DRUGS, IS IN FAVOR OF THE ANDA PATENT TERM COMPROMISE BILL. WE HOPE THAT YOU WILL ACT SPEEDILY AND FAVORABLY ON THIS LEGISLATION. IT IS THE PRODUCT OF A HARD-FOUGHT COMPROMISE THAT WE SUPPORT.

SINCERELY,

JOHN J. SWEENEY
SEIU INTERNATIONAL PRESIDENT

22:52 EST

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5241 (R 7/82)

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June 26, 1984

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Philadelphia, Pa.

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Houston, Texas

Dear Representative:

On Wednesday, June 27th, the Judiciary Committee will consider H.R. 3506, the ANDA-Patent Term Extension bill. AFSCME urges you to adopt this compromise bill.

The bill that you will consider is a carefully designed compromise. We believe that this bill is needed to place less expensive generic drugs on the market. The bill will be of great benefit to all consumers -- and particularly to senior citizens -- in the years ahead. FDA has estimated the consumer savings to be $1 billion over the next decade. There will be increased competition in government contracts and there will therefore be a savings to the Federal and state governments in the delivery of health care.

Although a high price has been paid for this bill, we believe that it will be of great benefit to the consumer and hope you will favorably report it.

Sincerely,

William B. Welsh
Director of Legislation

WBW:mlm

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JUL 10 1984
JUDICIARY COMMITTEE

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
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AUG 09 1984

Honorable Edward R. Madigan
Subcommittee on Health and the Environment
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Ed:

This letter sets forth the Administration's views on H.R. 3605, the "Drug Price Competition and Patent Term Restoration Act of 1984," which is scheduled to be voted on soon by the House of Representatives.

As more and more drugs from the post-1962 era come off patent, an abbreviated drug approval system, as contained in H.R. 3605, would increase competition, lower drug costs, and save American consumers hundreds of millions of dollars in the years ahead. H.R. 3605 could also result in significant savings to federal programs if cheaper, generic drugs were made available.

The Administration supports the basic thrust of H.R. 3605, but urges that two technical amendments be made to title II which deals with patent term restoration.

First, section 202 of title II should be amended to permit experimental use of a drug by a non-patentee only during the period in which the affected patent is in the restoration period. Existing patentees have relied upon accepted legal doctrine indicating that use of a patented invention for the purpose of obtaining regulatory approval infringes that patent. Upsetting expectations of this sort could only inhibit future innovation and investment, which depend upon the integrity of the patent laws. Such a change in law also raises a serious question under the "takings clause" of the fifth amendment of the Constitution, and could subject the United States to substantial compensation liability under the Tucker Act.

Second, section 201 of title II should be amended to simplify the procedures designed to prevent undue extension of patent protection by those who obtain several patents relating to the same pharmaceutical product. In place of the procedures now in section 201, which would place excessive demands upon the Patent and Trademark Office, we favor a simple limit on the time for which a patent term extension could be granted, to no more than 25 years from the date of the first application for a patent in a series of related patents stemming from that application.

I urge prompt and favorable consideration of H.R. 3605, with these technical amendments, by the Congress.

Sincerely,

David A. Stockman
Director

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER

1775 K STREET, N.W.

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*ADMITTED TO A BAR OTHER THAN D.C.

July 31, 1984

David Beier, Assistant Counsel
Subcommittee on Courts, Civil
Liberties and the Administration
of Justice
Rayburn House Office Building
Room 2137B

U R G E N T

Dear Mr. Beier:

I am enclosing a statement of Division 14 (Patent, Trademark and Copyright Law) of the District of Columbia Bar regarding the Patent Term Restoration Bill.

I understand that the Committee on the Judiciary is currently meeting on this legislation. Because of the complexity of the legislation and the traveling schedule of the steering committee members of Division 14, the enclosed statement could not be completed earlier. Nevertheless, considerable thought and effort went into it, and we hope that it can be considered.

Respectfully submitted,

Allen M. Sokal

AMS:ar

Allen M. Sokal
Chairman, Division 14

Enc.

STATEMENT ON BEHALF OF DIVISION 14 PATENT, TRADEMARK AND COPYRIGHT LAW DISTRICT OF COLUMBIA BAR* REGARDING THE PATENT TERM RESTORATION BILL

To The Subcommittee on Courts,
Civil Liberties And the
Administration of Justice On HR 3605

Prepared By:

Charles L. Gholz
Barry L. Grossman
Helen M. McCarthy
Joseph M. Potenza
Edward M. Prince
Watson T. Scott
Robert G. Weilacher

*MANDATORY DISCLAIMER

The views exposed herein represent only those of Division 14 (Patent Trademark and Copyright Law) of the District of Columbia Bar and not those of the D. C. Bar or of its Board of Governors.

STATEMENT ON BEHALF OF DIVISION 14
PATENT, TRADEMARK AND COPYRIGHT LAW
DISTRICT OF COLUMBIA BAR REGARDING
THE PATENT TERM RESTORATION BILL

The District of Columbia Bar, Division of Patent, Trademark and Copyright Law (Division 14), is pleased to submit its comments on H.R. 3605, "The Drug Price Competition and Patent Term Restoration Act of 1984". In summary, we support the overall objectives of this legislation but have serious reservations over whether the bill, as written, will achieve those objectives. We appreciate the fact that this bill represents a compromise between allegedly conflicting interests within different segments of the pharmaceutical industry. With respect to the patent and data provisions of H.R. 3605, however, the compromise reached distorts traditional and, we believe, desirable concepts of law.

The District of Columbia Bar, Division of Patent, Trademark and Copyright Law, has a membership of over 900 persons who specialize in intellectual property law, including many who reside and practice in other states. We will limit our comments on H.R. 3605 to the areas within our expertise, intellectual property, including patents and proprietary information.

The District of Columbia Bar supports the general concept of patent term restoration. If the seventeen-year term of a patent is effectively diminished as a result of required premarket federal regulatory reviews, it is both equitable and consistent with overall public policies supporting the patent system that the term of that patent should be extended so that the patent holder has the opportunity to enjoy the full seventeen-year term which Congress intended. While the problem of diminution of effective patent terms due to federal regulations is

certainly not limited to drug patents, it is most acute in that field. Patent term restoration is a concept which, we believe, will encourage research and development of new drugs.

H.R. 3605 embraces the general concept of patent term restoration, but Section 156 of the bill unduly limits its application by imposing artificial constraints on the patents and patentees eligible for patent term restoration. These limitations are unnecessary and will, in many instances, defeat the desirable objectives of this bill. In our view, each patent for which patent term is sought should be treated independently.

Under Section 121 of Title 35, each patent defines a separate and distinct invention. Any technological development may have within it several patentable aspects, each one of which would support a patent. For example, a product is patentable separately from the method of making the product. They are separately patentable because the patent law treats each as a separate invention. Additionally, in many cases various aspects of the technological development are submitted to the Patent and Trademark Office in a single patent application. The Patent and Trademark Office may require the applicant to divide the initial applications into separate applications for each distinct invention. The bill, however, draws distinctions based, in part, upon separate inventions disclosed in earlier issued patents. The law governing this aspect of patent law is complex and the subtle distinctions which this bill attempts to draw to deny extension to certain patents will be difficult at best to implement. We believe that the desirable objectives of the bill can be better effectuated by treating all patents and patentees independently.

The bill would obligate the Patent and Trademark Office to become involved in determining issues analogous to infringement. The Patent and Trademark Office has neither the expertise nor the resources to become involved in such considerations. In addition, the time periods for extension in the bill seem somewhat arbitrary.

We oppose Section 202 of the bill, which would overrule the Roche Products v. Bolar Pharmaceutical Co., Inc. case decided by the Court of Appeals for the Federal Circuit on April 23, 1984. In this case, the Court held that the use of a patented drug product prior to the expiration date of the patent for the purpose of conducting experiments required to obtain FDA approval for the commercial sale of the drug after the patent expired constituted patent infringement. The patent grant bestows upon the patent holder the right to exclude others from making, using, or selling the patented invention. While there is a well-recognized "experimental use" exception to the right to exclude bestowed by a patent, as the CAFC recognized in Roche, that exception has always been more narrowly construed than it would be under Section 202. We believe that it would be undesirable to expand the "experimental use" exception in the manner proposed in Section 202.

H.R. 3605 would impose undesirable and artificial constraints on patent enforcement. It would force patent holders to sue abbreviated new drug application (ANDA) applicants within an arbitrary 45 days after being notified that an ANDA has been submitted for a drug which infringes the patent. If the patent holder sues the ANDA applicant, ANDA approval is delayed until the litigation is resolved, but no more than 18 months. In effect, this provision makes the mere

submission of an ANDA an act of infringement for which the patentee can sue. In our view, mere submission of an ANDA should not itself be an act of infringement. If an ANDA applicant would infringe a patent in order to develop the data or information required in an ANDA, the patentee may bring an infringement action under current law, as exemplified by Roche. We see no reason to spur premature litigation and thus recommend against changing the current law.

Since our Division is concerned with the legal rights affecting all intellectual property, including trade secrets, we feel obligated to voice our objection to the provisions of H.R. 3605 which require disclosure of confidential trade secret data. This data is among the most valuable property rights owned by a company. To confiscate this property right by forcing new drug applicants to disclose their trade secret data is a certain way to diminish the incentives to undertake expensive research and development of new drugs. It will also reveal to foreign competitors valuable and practical research information of our most innovative companies. Consequently, we urge that these provisions of H.R. 3605 be amended to require the FDA to make a detailed summary of safety and effectiveness data, but not the complete raw data.

We appreciate the opportunity to present our views on the patent aspect of H.R. 3605. It is important legislation. The concerns noted above are merely representative of other numerous questions raised by the bill. We believe full hearings should be held before the bill is reported out of Committee. With further consideration and hearings, we are certain the bill will achieve its purpose and help to ensure the continued leadership of the United States in the development and production of new pharmaceutical products.

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CONGRESSMAN PETER W RODINO JR
2462 RAYBURN HOUSE OFFICE BLDG
WASHINGTON DC 20515

3

AS SENIOR VICE PRESIDENT OF THE HOFFMAN LAROCHE FACILITY AT RARITAN NEW JERSEY, I AM WRITING TO YOU TO EXRESS MY CONCERNS REGARDING H. R. 3605, THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984.

WE UNDERSTAND THAT REPRESENTATIVE KASTENMEIER HAS REQUESTED JURISDICTION OVER THE SUBJECT LEGISLATION THROUGH AT LEAST AUGUST 1, 1984 TO CONDUCT HEARINGS AND TO FULLY REVIEW H. R. 3605. REPRESENTATIVE KASTENMEIER'S REQUEST IS CONSISTENT WITH THE MAGNITUDE AND COMPLEXITY OF THE ISSUES IN THIS LEGISLATION, WHICH WILL HAVE CONSIDERABLE IMPACT ON THE NEW JERSEY RESEARCH-BASED PHARMACEUTICAL INDUSTRY.

WE BELIEVE THAT IS ESSENTIAL FOR CONSUMERS, HEALTH CARE PROVIDERS, AND PHARMACEUTICAL COMPANIES TO BE HEARD IN ORDER TO PROVIDE INPUT ON THIS MOST IMPORTANT LEGISLATION. TO DATE, THIS OPPORTUNITY HAS NOT BEEN PROVIDED IN THE HOUSE OF REPRESENTATIVES. THESE HEARINGS PLANNED BY REPRESENTATIVE KASTENMEIER WOULD DO A GREAT DEAL TO REMEDY THIS CIRCUMSTANCE.

WE RESPECTFULLY URGE THAT YOU GRANT REPRESENTATIVE KASTENMEIER'S REQUEST
PHILIP MAMMI

15:59 EST

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5241 (R 7/82)

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REPRESENTATIVE PETER W RODINO
HOUSE OF REPRESENTATIVES
WASHINGTON DC 20515

3

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JUN 19 1984
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DEAR CONGRESSMAN RODINO,

UNDERSTAND THAT REPRESENTATIVE KASTENMEIER HAS REQUESTED AN ADEQUATE OPPORTUNITY, THROUGH AT LEAST AUGUST 1, 1984, TO CONDUCT HEARINGS AND OTHERWISE FULLY REVIEW HR3605, THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984, RECENTLY ORDERED REPORTED BY ENERGY AND COMMERCE COMMITTEE.

WE URGE YOU TO GRANT THIS REQUEST WHICH IS CONSISTENT WITH THE MAGNITUDE AND THE COMPLEXITY OF THE ISSUES CONTAINED IN THIS LANDMARK LEGISLATION AND ESPECIALLY THE CRITICAL JUDICIARY COMMITTEE ISSUES RAISED THEREIN. WE BELIEVE IT IS ESSENTIAL FOR CONSUMERS, HEALTH CARE PROVIDERS AND PHARMACEUTICAL MANUFACTURERS (GENERIC AND RESEARCH BASED) THAT HR 3605, AS AMENDED BY THE ENERGY AND COMMERCE COMMITTEE, BE FULLY STUDIED AND UNDERSTOOD. TO DATE, THIS OPPORTUNITY HAS NOT BEEN PROVIDED. THE HEARING WHICH REPRESENTATIVE KASTENMEIER PLANS TO CONDUCT WOULD DO A GREAT DEAL TO REMEDY THIS CIRCUMSTANCE.

PLEASE KNOW WE WOULD WELCOME AN OPPORTUNITY FOR OUR COMPANY TO APPEAR BEFORE THE SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND ADMINISTRATION OF JUSTICE FOR THE PURPOSE OF EXPRESSING OUR VIEWS ON WHAT MIGHT BE DONE TO MAKE HR 3605 MORE EQUITABLE LEGISLATION.

WE BELIEVE PATENT TERM RESTORATION/ANDA LEGISLATION CAN BE ACHIEVED IN THIS CONGRESS, BUT THIS SHOULD NOT OCCUR AT THE EXPENSE OF A FULL AIRING OF ALL PERTINENT ISSUES OR RISK CREATING A SYSTEM WHICH WOULD NOT ADEQUATELY ADDRESS LEGITIMATE PUBLIC POLICY CONCERNS OF MANY RESEARCH BASED PHARMACEUTICAL COMPANIES. THANK YOU.

RICHARD M FURLAUD, CHAIRMAN AND CHIEF EXECUTIVE OFFICER SQUIBB CORP
VERN WILLAMAN, EXECUTIVE COMMITTEE JOHNSON AND JOHNSON
IRWIN LERNER, PRESIDENT AND CHIEF EXECUTIVE OFFICER HOFFMANN-LAROCHE
RICHARD J KOGAN, EXECUTIVE VICE PRESIDENT, PHARMACEUTICAL OPERATIONS SCHERING-PLOUGH CORP
WAYNE DAVIDSON GROUP VICE PRESIDENT BRISTOL MYERS
JOHN R STAFFORD, PRESIDENT OF AMERICAN HOME PRODUCTS
JOHN KOLBAS, PRESIDENT NORWICH EATON PHARMACEUTICALS A PROCTER AND GAMBLE CO
JOHN J HORAN CHAIRMAN AND CHIEF EXECUTIVE OFFICER, MERCK AND CO

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THE HONORABLE PETER W RODINO
CAPITOL ONE DC

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JUDICIARY COMMITTEE

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July 19, 1984

The Honorable Peter W. Rodino, Jr.
Chairman, Committee on the Judiciary
2137 Rayburn House Office Building
House of Representatives
Washington, DC 20515

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JUDICIARY COMMITTEE

RE: H.R. 3605 (Waxman)

Dear Congressman Rodino:

I am writing because of my great concern that H.R. 3605 (the counterpart of S. 2748), dealing with drug price competition and patent term restoration, will be enacted without further hearings.

I disclaim any expertise in the subject matter of Part I of H.R. 3605 that deals with new drug approval procedures before the FDA and, therefore, will not comment on Part I other than to deplore the totally unnecessary and divisive compromises that have been made in an effort to obtain passage of the patent term restoration legislation. I criticize the pressure blocs on both sides of the controversy, as I believe they have done a great mischief to the public by proposing unnecessarily complex solutions that will only serve to decrease innovative incentives.

The subject of Part II - the patent term restoration proposal - is a concept I highly favor. However, speaking as a lawyer concerned with a broad spectrum of patent matters for the past thirty years, I question many of the provisions therein, as I believe they discriminate against those patentees whose inventions are not concerned with drugs.

Commissioner Mossinghoff recently testified in connection with H.R. 3605 on the serious impact this bill would have on the Patent and Trademark Office's operation; I will not comment on his statement other than to endorse it wholeheartedly.

H.R. 3605 will, inter alia, reverse Roche v. Bolar Pharmaceutical (a recent decision of the Court of Appeals for the Federal Circuit on the use of a patented product during the term - which I believe to be sound law) and I, like many other active practitioners, am of the view that if enacted, the bill would have an

unconstitutional retroactive impact; however, I will not argue this point but will confine my discussion to an aspect which has not been previously covered.

I am particularly concerned that H.R. 3605 covers only those patents where the invention is subject to certain specified federal regulatory enactments. The bill does not reach any and all federal legislation that shortens the patent term by precluding commercialization until approval of federal authorities has been obtained. Under H.R. 3605, term loss relief is only given to products that are subject to premarketing regulation under enumerated statutes: the Federal Food, Drug and Cosmetic Act; the Public Health Act; the Virus, Serum and Toxin Act; and the Analogous Products provisions of the Act of Congress of March 4, 1913.

There are other federal regulations - Section 7 of the Plant Quarantine Act (7 U.S.C. §160) and the Plant Pest Act (7 U.S.C. §150ee), both administered by the Department of Agriculture; standards and regulations promulgated by the National Highway Traffic Safety Administration of the Department of Transportation; the Federal Insecticide, Fungicide and Rodenticide Act; and the Toxic Substances Control Act, just to name a few - that can also adversely impact on the effective term of a patented invention. No relief is given to patentees when these acts adversely impact on the patent term.

The problem is not unique to drug and drug-related patents. I have personally encountered situations in which the quarantine regulations of the Department of Agriculture and the safety standards of the Department of Transportation have adversely impacted on the terms of patents; yet as far as I can determine, these regulations have not been discussed in hearings before either the House or the Senate in any of the patent term restoration bills previously considered. There is no sound reason why all patentees should not be equally accorded the benefits of patent term restoration where federal premarketing regulations adversely impact on the useful life of their patents.

The enactment of H.R. 3605 as it now reads will, in my opinion, be extremely unwise. I strongly urge that there be further hearings by the House so that amendments can be considered to render the patent term restoration legislation operable for the Patent and Trademark Office and equitable to all patentees, and to eliminate the many other overly complicated, inconsistent and controversial provisions contained therein.

Yours very truly,

William H. Elliott, Jr.

WHE,Jr./ml

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July 11, 1984

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The Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts
Civil Liberties and the
Administration of Justice
U.S. House of Representatives
2232 Rayburn House Office Building
Washington, D.C. 20515

RE: Patent Term Restoration
(H.R. 3605)

Dear Mr. Chairman:

The American Intellectual Property Law Association (AIPLA) is a national bar association of more than 4800 attorneys engaged in the practice of patent, trademark, copyright, licensing, and related fields of law affecting intellectual property.

AIPLA supports the enactment of patent term restoration legislation because we believe it will serve the public interest. Our belief is not based on an analysis of the impact of the Federal regulatory process on those industries or American Industry in general. Rather, we believe history teaches that an effective patent system, premised on a commercially viable 17-year patent grant, has been of immense direct benefit to our country since the patent laws were enacted by the First Congress in 1790.

However, we are opposed to the enactment of H.R. 3605 with the inclusion of Section 202 which makes exceptions to fundamental, long standing, and important principles of patent law. In our opinion Section 202 (1) presents a constitutional issue which raises significant financial and public policy questions and (2) represents a significant negative precedent to the development of both United States and international patent laws. These points are discussed below. We also offer for your consideration an approach to eliminate the problem so the H.R. 3605 can go forward towards enactment.

(1) Section 202 raises a serious constitutional issue. When the Food and Drug Administration prevents a patent owner from selling a drug to the public until the drug is approved it does not interfere with rights conferred by the patent.

A patent bestows no right to sell but only to exclude others from practicing the invention. In Bloomer vs. McQuewan, 14 Howard 539 (1852) Chief Justice Taney said:

> "The franchise which the patent grants consists altogether in the right to exclude everyone from making, using, or vending the thing patented without the permission of the patentee. This is all that he obtains by the patent".

It is equally well settled that "patents are property and entitled to the same rights and sanctions as other property". Continental Paper Bag Company vs. Eastern Paper Bag Company, 210 U.S. 405 (1908).

However, new Sections 271 (e) (1) and 271 (e) (3) proposed in Section 202 deprive owners of existing patents of the right to exclude others from making, using, or selling their patented drug under certain circumstances. The Supreme Court in James v. Campbell, 104 U.S. 356 (1881) said:

> That the government of the United States when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt.

The Court elaborated in Hollister v. Benedict Manufacturing, 113 U.S. 59 (1885):

> It was authoritatively declared in James v. Campbell, 104 U.S. 356, that the right of the patentee, under letters patent for an invention granted by the United States, was exclusive of the government of the United States as well as of all others, and stood on the footing of all other property, the right to which was secured, as against the government, by the constitutional quaranty which prohibits the taking of private property for public use without compensation.

The patent owner's rights are not wholly extinguished by Section 202. However, "property is taken in the constitutional sense when inroads are made upon an owners use of it..." United States v. Dickinson, 331 U.S. 745 (1947). Also Acts of Congress, like actions of the Executive Branch, cannot by retroactive effect deprive persons of existing property rights without compensation. Lynch v. United States, 292 U.S. 571 (1934).

Section 202 is intended to reverse the April 23, 1984, decision of the Court of Appeals for the Federal Circuit in Roche Products, Inc. v. Bolar Pharmaceutical Co., 221 U.S.P.Q. 937 (Fed. Cir. 1984). Roche sued to enjoin Bolar from making federally mandated premarketing tests of a drug for which Roche held the patent. Roche maintained this use infringed their patent. Bolar argued that their use of the patented drug fell within the "experimental use" defense to infringment. While the CAFC recognized the validity of that defense which originated in Whittemore v. Cutter, 29 F. Cas 1120, 1121 (C.C.D. Mass. 1813), it found that Bolar had infringed the Roche patent. The court said:

> Bolar may intend to perform "experiments", but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention.

Therefore, if Section 202 is enacted the law will work a government taking of the exclusive property rights of patent owners specifically recognized in this fact situation by the Court in the Roche case.

HR 3605 is silent as to how owners of existing patents will be compensated for the property taken from them. The Supreme Court in Ruckelshaus v. Monsanto, ___U.S.___(1984) held that the Tucker Act, 28 U.S.C. 1491, is available as a remedy for the uncompensated taking of property (trade secrets) by the operation of the Federal Insecticide, Fungicide, and Rodenticide Act even though when that Act was passed Congress did not "mention or provide for [such] recourse against the Government..." In light of the Courts' ruling, the Tucker Act may provide a mechanism for providing just compensation which would make Section 202 of the bill constitutionally valid. If not, the Section is almost certainly not valid.

Just compensation in the constitutional sense "means the full and perfect equivalent in money of the property taken, United States v. Miller, 369 U.S. 369, 373 (1943). As the Court in the Roche case noted, by enjoining the use of its patented drug for FDA mandated testing, patent owners "gain for themselves ... upwards of two years" during which they are free from the competition of generic manufacturers sales. We do not have the financial data necessary to estimate the magnitude of the dollar losses to the owners of the scores of patented drugs now being sold when these products are deprived of "upwards of two years" of sales in exclusive marketing positions. However, the liability of the Government to pay money damages will certainly run into many tens of millions of dollars each year for many years to come.

While Congress may be willing to pay enormous sums to hasten the availability of lower cost drugs to the public, we seriously question the wisdom of the public policy which directly and substantially subsidizes generic drug manufacturers. The valuable rights obtained by this industry will be paid for by the Government with public funds.

(2) Section 202 amends Section 271 of title 35 which defines patent infringement. Proposed Section 271 (e) (1) and 271 (e) (3) create an unprecedented "commercial use" exception to basic patent rights for the purpose of solving special problems involving a certain industry. The specific problem addressed is caused by other federal laws and regulations.

Proposed Section 271 (e) (2) is also an unprecedented departure from United States and foreign patent laws. That Section provides that it shall be an act of infringement "to submit an application under 505 (j) of the Federal Food, Drug and Cosmetic Act for a drug claimed in a patent or the use of which is claimed in a patent." In the United States, and as defined specifically in 35 USC 271 (a), the manufacture or use or sale of a patented product constitutes an act of patent infringement. In most foreign countries, the act of manufacture or use or sale or importation constitutes patent infringement.

Property rights in patents granted by the United States or other countries have no extraterritorial reach. An American inventor who wishes to prevent the making, using, or selling of his invention outside the United States must obtain a patent in each and every country where he desires protection. Under proposed 35 USC 271 (e) (2), the United States would add as a fourth act of patent infringement the mere filing of a paper with a government agency which may be based upon acts of use engaged in outside of the United States. If a person tests the patented drug of another in a foreign country without authorization, the U.S. patent owner may or may not have a cause of action in that country depending on his patent rights there. To project U.S. patent rights beyond American borders amounts to the creation of a legal fiction resting only on a jurisdictional ground.

These two departures from conventional principles of patent law represent very unfortunate precedents for the future development of patent law in the United States. But these negative proposals have broader ramifications. During the past four years the United States has assumed a prominent role in the diplomatic conferences on the revision of the Paris Convention in urging the developing countries to adopt and use strong and effective patent laws. We point with pride to our patent system. We believe, and have tried to convince these countries to believe, that the clear protection of patent rights is in their best interest. We have urged them not to adopt local

weakening exceptions to that protection. Of course, strong local protection of U.S. owned technology we would like to export to developing countries is also in our interest.

Should the Congress enact Section 202, the world patent community would learn that the United States accepts expedient special exceptions which erode fundamental principles of our own patent system.

* * * *

We fully understand that HR 3605 requires that a number of legitimate interests be reconciled. Therefore, to that end, we recommend that you consider that the bill be redrafted so that clinical trials in anticipation of an ANDA filing after a drug goes off patent be allowed only during the patent term restored by HR 3605. This bill envisions that, in the future, patented drugs approved by the PDA will be entitled to some period of restored term after the original patent has expired. The bill should provide that when a patent owner petitions to gain that extension he thereby consents to allow testing in anticipation of ANDA filings by others. Having the owners consent will overcome the problems generated by the Constitution. This approach also greatly ameliorates the negative precedent of creating a commercial use exception to patent rights because the granted patent will have expired before the exception can apply. This approach would also allow the abandonment of the proposal of infringement by filing a paper as is found in 271 (e) (2).

HR 3605 does not extend the patent term of drugs already approved and on the market. The owners of those patents will never recover any patent time lost to them by regulatory delay. The approach we recommend makes this bill prospective for all parties. The copyists will not receive the time benefits which accrue with the reversal of Roche v. Bolar, as they do under HR 3605 as to drugs already patented and on the market. However, such result is equitable since the time the copyists would gain by having the bill retroactive in its effect would be considerably less than the time lost by the inventor of the drug due to regulatory delay.

Thank you for considering our views.

Sincerely,

B. R. Pravel

B. R. Pravel
President

cc: Honorable Carlos J. Moorhead
Honorable Jack Brooks
Honorable Romano L. Mazzoli
Honorable Mike Synar
Honorable Patricia Schroeder
Honorable Dan Glickman
Honorable Bruce A. Morrison
Honorable Barney Frank
Honorable Howard L. Berman
Honorable Henry J. Hyde
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Honorable Harold S. Sawyer
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PATENT, TRADEMARK AND COPYRIGHT LAW SECTION
THE BAR ASSOCIATION
OF THE DISTRICT OF COLUMBIA
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July 16, 1984

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil
Liberties and the Administration of Justice
House of Representatives
Congress of The United States
Rayburn House Office Building
Washington, D.C. 200515

Subject: H.R. 3605, Abbreviated New Drug Applications and Patent Term Extension

Dear Mr. Chairman:

The following comments on H.R. 3605 are submitted on behalf of the Patent, Trademark and Copyright (PTC) Section of the Bar Association of the District of Columbia. In summary we oppose certain provisions of H.R. 3605 and urge that these provisions be deleted.

The PTC Section consists of over 300 lawyers who practice patent law before the United States Patent and Trademark Office as well as before the Federal Courts. These members seek patents on behalf of clients, enforce patents, as well as defend against patents. The members of the PTC Section also regularly deal with trade secrets as well as international patent matters. The Section members represent a wide range of inventors and corporations including those engaged in original pharmaceutical research as well as producers of generic drugs.

One of the goals of the PTC Section is to support a uniform system of patent law where all inventors and inventions are judged equally. As pointed out by Commissioner Mossinghoff in his written statement, H.R. 3605 does not apply to all inventions and all fields of inventive activity. Assuming patent term restoration is desirable, the PTC Section believes that it should apply to all inventions and not just a choosen few, as discussed in more detail infra. As pointed out in the Senate Hearings, Congress has heard from only a few special interests as regards this legislation. The bill, as presently drafted, accomodates only those few special interests and creates a special arbitrary class of patents.

TITLE I - ABBREVIATED NEW DRUG APPLICATIONS (ANDA)

The bill provides for abbreviated new drug applications (ANDA). The PTC Section expresses no opinion as to such matters per se as they are outside the scope of the law practice of the Section members. However, the bill goes on to provide that the ANDA application may contain a certification that in the opinion of the applicant the patent covering the drug is invalid and that a notice of invalidity has been given to the patentee. In that event ANDA approval shall be made effective immediately unless the patentee brings an action for patent infringement within 45

days from the date the notice is received. Further, if the parties to the patent infringement action reasonably cooperate in expediting the action, ANDA approval shall be effective upon the expiration of an eighteen month period beginning on the date of receipt of the notice.

These two periods of 45 days and 18 months directly affect patentees and as such are of serious concern to the PTC Section members. It is totally unrealistic to expect that complex patent litigation can be completed in 18 months from the date of notice. It is also totally unfair to the patentee to give unlimited time to the infringer to prepare for litigation and give only 45 days to the patentee. More importantly however, the bill forces the patentee into litigation, a radical departure from the concepts of our present system and contrary to the efforts of the federal judiciary to promote conflict resolution by means other than litigation. Congress has never before forced the patentee to resolve questions of infringement solely by litigation. The patentee has always had the freedom of choice whether or not to sue. A patentee of limited resources is unfairly penalized by this legislation.

Title I of the bill also provides that safety and effectiveness data and information which have been submitted to the FDA shall be made available to the public upon request unless extraordinary circumstances are shown. This provision affects

trade secrets which may be more valuable than patent rights. It is beyond question that the submitters of the information have a property interest protected by the Fifth Amendment's taking clause, see Ruckelshaus v. Monsanto Co., 52 USLW 4886, 4889 (U.S. 1984). This property interest is cognizable as a trade secret property right under state law. Monsanto, supra, 52 USLW at 4890. The Supreme Court stated, 52 USLW at 4892.

> "Thus, it is the fact that operation of the data-consideration or data-disclosure provisions will allow a competitor to register more easily its product or to use the disclosed data to improve its own technology that may constitute a taking."

The Supreme Court expressly noted that presumably an applicant would forego registration in the United States where the data is more valuable than the right to sell in the United States, 52 USLW at 4891, fn. 11. This Congress should not pass legislation which forces the owners of such information to make it available to the public.

TITLE II - PATENT TERM RESTORATION

The bill provides for patent term restoration to a few types of inventions in certain speciality fields. It does not cover each invention whose entry into the market has been delayed because of governmental requirements. Former Commissioner Schuyler's written statement to the Subcommittee clearly shows

that the legislation denies extensions to worthy inventions and acts to discourage research. If an invention is clearly worthy of a patent then it should be entitled to an extension on the same terms and conditions as other patents. This legislation unwisely creates different classes of patents, something no Congress has ever done.

It also actually discriminates against pioneer inventions. In Section 201 an extension is provided for a product which was not identically disclosed or described in an earlier patent if the holder of the patent seeking extension and the holder of the earlier patent are not the same. This means that the inventor of a pioneer drug who files and receives a patent cannot ever apply for an extension on an improvement even though no extension was ever applied for on the earlier patent. However a competitor - who is not the holder of the earlier patent - may receive an extension. The competitor may begin where the pioneer left off and ultimately received the first extension. This is manifestly unfair.

In addition, Section 201 wholly fails to consider the effect on what are called"divisional" patent applications. The PTO may, and frequently does, require a division or separation of an original patent application into a number of separate patent applications to facilitate examination. These "divisional" applications, under the terms of Section 201, would not be

entitled to retension of the term even though they arise out of the original patent document.

There is no justification for penalizing the inventor by excluding patents based on divisional applications from patent term extension when the divisional process is necessitated by PTO examination procedures.

The bill also provides that an application for an extension must be submitted within sixty days after approval of marketing. This is premature and wasteful of both the patentee's resources and the government. It cannot be predicted which patents will later prove worthy of an extension based on economical success. There should be no limit on when application should be made. Commissioner Mossinghoff additionally pointed out that the procedure provided in the legislation is confusing, difficult and unnecessary. The PTC Section agrees with Commissioner Mossinghoff's statement.

The bill also provides that it shall not be an act of infringement to make, use or sell a patentable invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs.

This is a drastic departure from existing law, contrary to Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d

858, 221 USPQ 937 (CAFC 1984). See also Pfizer, Inc. v. International Rectifier Corp., 217 USPQ 157 (D.C. Cal. 1982).

In Roche, Bolar obtained from a foreign manufacture 5 kilograms to use in generating data for a new drug application. The Court noted, "It is beyond argument that performance of only one of the three enumerated activities [makes, uses or sells, 35 U.S.C. 271] is patent infringement." 733 F.2d at 861, 221 USPQ at 939. See also Aro Manufacturing Co. v. Convertible Top Replacement Co., 377 U.S. 476, 484 (U.S. 1964). The Court in Roche concluded, 733 F.3d at 863, 221 USPQ at 941:

> "Bolar's intended experimental use is solely for business reasons... Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the '053 patent."

Bolar argued that the patent laws should apply differently to drugs and the Court refused, 733 F.2d at 864, 221 USPQ at 942.

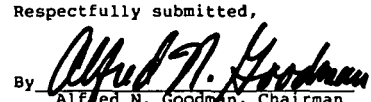
The Courts have long held that the right of the patentee to exclude others from making, using or selling is:

> "exclusive of the Government of the United States as well as of all others, and stood on the footing of all other property, the right to which was secured, as against the Government, by the constitutional guaranty which prohibits the taking of private property for public use without compensation;" Hollister v. Benedict, 113 U.S. 59, 67 (U.S. 1885), and James v. Campbell, 104 U.S. 356 (U.S. 1877).

Section 202 of the bill, which amends 35 U.S.C. 271, states that patentees no longer have the property right to sue for acts of patent infringement as regards drugs and submission of information under Federal Law. This is an outright taking of private property for public use without compensation, contrary to the above authorities.

The PTC Section of the Bar Association of the District of Columbia favors balanced and uniform legislation. As pointed out above, the present legislation falls short and should not be passed in its present form.

Respectfully submitted,

By 

Alfred N. Goodman, Chairman
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AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
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July 11, 1984

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The Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts
Civil Liberties and the
Administration of Justice
U.S. House of Representative
2232 Rayburn House Office Building
Washington, D.C. 20515

RE: Patent Term Restoration
(H.R. 3605)

Dear Mr. Chairman:

The American Intellectual Property Law Association (AIPLA) is a national bar association of more than 4800 attorneys engaged in the practice of patent, trademark, copyright, licensing, and related fields of law affecting intellectual property.

AIPLA supports the enactment of patent term restoration legislation because we believe it will serve the public interest. Our belief is not based on an analysis of the impact of the Federal regulatory process on those industries or American Industry in general. Rather, we believe history teaches that an effective patent system, premised on a commercially viable 17-year patent grant, has been of immense direct benefit to our country since the patent laws were enacted by the First Congress in 1790.

However, we are opposed to the enactment of H.R. 3605 with the inclusion of Section 202 which makes exceptions to fundamental, long standing, and important principles of patent law. In our opinion Section 202 (1) presents a constitutional issue which raises significant financial and public policy questions and (2) represents a significant negative precedent to the development of both United States and international patent laws. These points are discussed below. We also offer for your consideration an approach to eliminate the problem so the H.R. 3605 can go forward towards enactment.

(1) Section 202 raises a serious constitutional issue. When the Food and Drug Administration prevents a patent owner from selling a drug to the public until the drug is approved it does not interfere with rights conferred by the patent.

A patent bestows no right to sell but only to exclude others from practicing the invention. In Bloomer vs. McQuewan, 14 Howard 539 (1852) Chief Justice Taney said:

> "The franchise which the patent grants consists altogether in the right to exclude everyone from making, using, or vending the thing patented without the permission of the patentee. This is all that he obtains by the patent".

It is equally well settled that "patents are property and entitled to the same rights and sanctions as other property". Continental Paper Bag Company vs. Eastern Paper Bag Company, 210 U.S. 405 (1908).

However, new Sections 271 (e) (1) and 271 (e) (3) proposed in Section 202 deprive owners of existing patents of the right to exclude others from making, using, or selling their patented drug under certain circumstances. The Supreme Court in James v. Campbell, 104 U.S. 356 (1881) said:

> That the government of the United States when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt.

The Court elaborated in Hollister v. Benedict Manufacturing, 113 U.S. 59 (1885):

> It was authoritatively declared in James v. Campbell, 104 U.S. 356, that the right of the patentee, under letters patent for an invention granted by the United States, was exclusive of the government of the United States as well as of all others, and stood on the footing of all other property, the right to which was secured, as against the government, by the constitutional guaranty which prohibits the taking of private property for public use without compensation.

The patent owner's rights are not wholly extinguished by Section 202. However, "property is taken in the constitutional sense when inroads are made upon an owners use of it..." United States v. Dickinson, 331 U.S. 745 (1947). Also, Acts of Congress, like actions of the Executive Branch, cannot by retroactive effect deprive persons of existing property rights without compensation. Lynch v. United States, 292 U.S. 571 (1934).

Section 202 is intended to reverse the April 23, 1984, decision of the Court of Appeals for the Federal Circuit in Roche Products, Inc. v. Bolar Pharmaceutical Co., 221 U.S.P.Q. 937 (Fed. Cir. 1984). Roche sued to enjoin Bolar from making federally mandated premarketing tests of a drug for which Roche held the patent. Roche maintained this use infringed their patent. Bolar argued that their use of the patented drug fell within the "experimental use" defense to infringment. While the CAFC recognized the validity of that defense which originated in Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813), it found that Bolar had infringed the Roche patent. The court said:

> Bolar may intend to perform "experiments", but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention.

Therefore, if Section 202 is enacted the law will work a government taking of the exclusive property rights of patent owners specifically recognized in this fact situation by the Court in the Roche case.

H.R. 3605 is silent as to how owners of existing patents will be compensated for the property taken from them. The Supreme Court in Ruckelshaus v. Monsanto, ___U.S.___ (1984) held that the Tucker Act, 28 U.S.C. 1491, is available as a remedy for the uncompensated taking of property (trade secrets) by the operation of the Federal Insecticide, Fungicide, and Rodenticide Act even though when that Act was passed Congress did not "mention or provide for [such] recourse against the Government..." In light of the Courts' ruling, the Tucker Act may provide a mechanism for providing just compensation which would make Section 202 of the bill constitutionally valid. If not, the Section is almost certainly not valid.

Just compensation in the constitutional sense "means the full and perfect equivalent in money of the property taken, United States v. Miller, 369 U.S. 369, 373 (1943). As the Court in the Roche case noted, by enjoining the use of its patented drug for FDA mandated testing, patent owners "gain for themselves ... upwards of two years" during which they are free from the competition of generic manufacturers sales. We do not have the financial data necessary to estimate the magnitude of the dollar losses to the owners of the scores of patented drugs now being sold when these products are deprived of "upwards of two years" of sales in exclusive marketing positions. However, the liability of the Government to pay money damages will certainly run into many tens of millions of dollars each year for many years to come.

While Congress may be willing to pay enormous sums to hasten the availability of lower cost drugs to the public, we seriously question the wisdom of the public policy which directly and substantially subsidizes generic drug manufacturers. The valuable rights obtained by this industry will be paid for by the Government with public funds.

(2) Section 202 amends Section 271 of title 35 which defines patent infringement. Proposed Section 271 (e) (1) and 271 (e) (3) create an unprecedented "commerical use" exception to basic patent rights for the purpose of solving special problems involving a certain industry. The specific problem addressed is caused by other federal laws and regulations.

Proposed Section 271 (e) (2) is also an unprecedented departure from United States and foreign patent laws. That Section provides that it shall be an act of infringement "to submit an application under 505 (j) of the Federal Food, Drug and Cosmetic Act for a drug claimed in a patent or the use of which is claimed in a patent." In the United States, and as defined specifically in 35 USC 271 (a), the manufacture or use or sale of a patented product constitutes an act of patent infringement. In most foreign countries, the act of manufacture or use or sale or importation constitutes patent infringement.

Property rights in patents granted by the United States or other countries have no extraterritorial reach. An American inventor who wishes to prevent the making, using, or selling of his invention outside the United States must obtain a patent in each and every country where he desires protection. Under proposed 35 USC 271 (e) (2), the United States would add as a fourth act of patent infringement the mere filing of a paper with a government agency which may be based upon acts of use engaged in outside of the United States. If a person tests the patented drug of another in a foreign country without authorization, the U.S. patent owner may or may not have a cause of action in that country depending on his patent rights there. To project U.S. patent rights beyond American borders amounts to the creation of a legal fiction resting only on a jurisdictional ground.

These two departures from conventional principles of patent law represent very unfortunate precedents for the future development of patent law in the United States. But these negative proposals have broader ramifications. During the past four years the United States has assumed a prominent role in the diplomatic conferences on the revision of the Paris Convention in urging the developing countries to adopt and use strong and effective patent laws. We point with pride to our patent system. We believe, and have tried to convince these countries to believe, that the clear protection of patent rights is in their best interest. We have urged them not to adopt local

weakening exceptions to that protection. Of course, strong local protection of U.S. owned technology we would like to export to developing countries is also in our interest.

Should the Congress enact Section 202, the world patent community would learn that the United States accepts expedient special exceptions which erode fundamental principles of our own patent system.

* * * *

We fully understand that H.R. 3605 requires that a number of legitimate interests be reconciled. Therefore, to that end, we recommend that you consider that the bill be redrafted so that clinical trials in anticipation of an ANDA filing after a drug goes off patent be allowed only during the patent term restored by H.R. 3605. This bill envisions that, in the future, patented drugs approved by the FDA will be entitled to some period of restored term after the original patent has expired. The bill should provide that when a patent owner petitions to gain that extension he thereby consents to allow testing in anticipation of ANDA filings by others. Having the owners consent will overcome the problems generated by the Constitution. This approach also greatly ameliorates the negative precedent of creating a commercial use exception to patent rights because the granted patent will have expired before the exception can apply. This approach would also allow the abandonment of the proposal of infringement by filing a paper as is found in 271 (e) (2).

H.R. 3605 does not extend the patent term of drugs already approved and on the market. The owners of those patents will never recover any patent time lost to them by regulatory delay. The approach we recommend makes this bill prospective for all parties. The copyists will not receive the time benefits which accrue with the reversal of Roche v. Bolar, as they do under H.R. 3605 as to drugs already patented and on the market. However, such result is equitable since the time the copyist would gain by having the bill retroactive in its effect would be considerably less than the time lost by the inventor of the drug due to regulatory delay.

Thank you for considering our views.

Sincerely,

B. R. Pravel

B. R. Pravel
President

cc: Honorable Carlos J. Moorhead
Honorable Jack Brooks
Honorable Romano L. Mazzoli
Honorable Mike Synar
Honorable Patricia Schroeder
Honorable Dan Glickman
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July 19, 1984

David Beier, Esq.
Assistant Counsel
Subcommittee on Courts, Civil
Liberties and the Administration
of Justice
House Committee on the Judiciary
2137 Rayburn Office Building
Washington, D.C. 20515

Dear Mr. Beier:

With the permission of Howard Bremer, Patent Counsel of the Wisconsin Alumni Research Foundation, we are forwarding to you and the other members of the Committee on Courts, Civil Liberties and the Administration of Justice a letter from the Wisconsin Alumni Research Foundation to Chairman Kastenmeier on the pending Patent Term Restoration bill H.R. 3605.

The letter of the Research Foundation raises fundamental questions as to the effect of the proposed legislation on this country's patent system -- particularly on the long term effect of the bill on our position in international trade.

As you are aware from previous correspondence, the coalition of research based pharmaceutical companies whom we represent believes that the bill should be amended. The concerns voiced by the Research Foundation with regard to the constitutional issues, the long term impact on our international position in the development of technology, and the potentially chilling effect on innovation, underscore the necessity for seriously considering such amendments.

Sincerely,

Jack Lipson mps

Jack Lipson

Enclosure

WISCONSIN ALUMNI RESEARCH FOUNDATION

Dear Howard -

DAVID - please respond 7/19/84

July 16, 1984

The Honorable Robert W. Kastenmeier
House of Representatives
2232 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Kastenmeier:

We have had an opportunity to review H.R. 3605 relating to proposed amendments to the Drug Price Competition and Patent Term Restoration Act of 1984 and we are writing to you to indicate our concern that this bill, as well as the companion bill in the Senate, S. 2748, may be passed without a full hearing and sequential referral. From review of testimony given and a reading of the bill it is evident to us that the bill is complicated, contains many provisions which will be difficult to administer and raises substantial questions of unconstitutionality in the taking of property without compensation. In addition the bill, as a compromise measure, appears to trade off valuable patent protection for accommodations under the Food, Drug and Cosmetic Act and it does little to spur innovation in this country at a time when technology and its transfer has become a currency of high value in the conduct of foreign affairs.

The various aspects of the bill reflect in our mind the short term philosophy which has come to so dominate the business outlook in this country as to put it at a disadvantage with foreign nations and companies, particularly Japan, where long term planning and profitability is a greater consideration. It would seem that the premise of the bill arises from dissatisfaction with the length of time that is required for a generic drug manufacturer to be able to market drugs because of FDA regulatory requirements. The generic companies have, of course, coupled with this the emotionally appealing emphasis of being able to make the drug available at a lower price in the marketplace, with a projected, but not established, equivalent degree of safety and effectiveness as a patent-protected drug. This, of course, completely disregards the effort needed to transfer a new chemical identity into a publicly accepted pharmaceutical product and the necessity to offer some inducement for the private sector to commit the high risk money necessary to accomplish that transition.

In this circumstance, it would appear that we are again facing a situation where science is being made subservient to politics and that, upon analysis, some of the provisions of this bill would in fact weaken our patent system as we now know it. In today's technology transfer atmosphere the protection afforded by the intellectual property right for the heavy investment required in development is more necessary than ever since the lead time given by exclusive knowledge or patents is shorter than ever

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before. If that lead time disappears through the weakening of the ability to extend exclusive rights to intellectural property or through further weakening of the patent system it may become economically sound to be second in the field. It is such a result that we see being stimulated by some of the terms and provisions of this piece of legislation.

To our eyes the content of this bill evinces that that second-place philosophy already exists in the medical field and we see it philosophically leading to a second place attitude in U.S. industry broadly and as the almost predictable next step, of a willingness to become a second place nation.

The university community through its basic research generates new chemical entitites which prospectively can become curative drugs. Other investigations of the application of these various new chemical entities to different disease states is also an ongoing activity at many universities, as is the design of new processes for producing such entitites. We are, therefore, concerned with any piece of legislation which adversely affects technology transfer capability and innovation but are particularly concerned with any effort to hastily pass legislation as an accommodation that would affect the patent laws which represent the basis and incentive for effective technology transfer and the strength of this country.

Very truly yours,

Howard

Howard W. Bremer
Patent Counsel

HWB:rw

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AMERICAN SOCIETY OF HOSPITAL PHARMACISTS

4630 Montgomery Avenue/Bethesda, Maryland 20814/(301) 657-3000

July 6, 1984

The Honorable Peter Rodino, Chairman
House Committee on the Judiciary
2462 Rayburn House Office Building
Washington, DC 20515

Re: H.R. 3605, Drug Price Competition Act of 1983

Dear Mr. Chairman:

The American Society of Hospital Pharmacists, the national professional society of pharmacists practicing in hospitals and other settings of organized health care, is writing to urge speedy consideration of the above referenced legislation.

Our members have a strong interest in this legislation: they wish to see an increased rate of development of new drug products and new forms of drug delivery and they also wish to see the cost of drugs reduced. H.R. 3605 accomplishes this by providing patent term extension to newly developed drugs and by permitting post-1962 drugs, already shown to be safe and effective, to he marketed without duplicitous clinical testing. Although we do not know what the pharmaceutical industry will do with this new incentive for research, we do know that well over 100 drugs will be available for the new approval process; consumer savings and reduced health care costs will be the result.

We urge you to move expeditiously on this matter.

Sincerely,

Joseph A. Oddis

Joseph A. Oddis, Sc.D.
Executive Vice President

JAO/ln/062202

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JUL 9 1984
JUDICIARY COMMITTEE

3

Johnson & Johnson

1667 K STREET, N.W.
SUITE 410
WASHINGTON, D.C. 20006

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The Honorable Peter W. Rodino, Jr.
Room 2462, Rayburn House Office Bldg.
U. S. House of Representatives
Washington, DC 20515

Dear Congressman Rodino:

The House Judiciary Committee will be taking up HR 3605 (Waxman) in markup tomorrow, July 31. This bill was reported by the Energy and Commerce Committee on June 12, the same day it was introduced. It was reported by the Courts Subcommittee on July 25 without significant changes.

Supporters of the legislation are resisting any and all amendments on grounds that the bill is the product of private negotiations involving several major interests, including manufacturers of generic drugs. However this legislation has been sharply and publicly criticized by the FDA, the Patent Office and a number of leading pharmaceutical manufacturers who specialize in breakthrough drug research.

Amendments will be offered at markup that will correct some of the more blatant problems in this bill. I hope you will consider these proposed changes and support them. A description is attached. With the amendments the bill would enjoy broad support throughout our industry.

If passed, HR 3605 would constitute the most drastic change in U.S. patent policy and drug approval policy in over 20 years. It deserves thoughtful scrutiny by all members of the full Committee.

Sincerely,

Nicholas L. Ruggieri
Manager, Washington Affairs

907A/g
Attachment

Amendemnts to HR 3605

On Tuesday, July 31, 1984 the Judiciary Committee will meet to consider the Drug Price Competition and Patent Term Restoration Act of 1984 (HR 3605, Waxman).

The legislation is designed to accomplish two objectives:

> Permit expedited access to market for generic drugs and to extend patent life for new drugs subject to regulatory approval.

At the markup four amendments will be introduced. Two of these amendments are originating from the Patent and Trademark Office, which has strongly criticized the bill in its present form:

1. The first involves the reversal of the Bolar decision. This amendment will be introduced at the request of the Patent Office. The bill would overturn the principle affirmed in the recent Bolar case affecting prescription drugs which prevents a competitor from carrying out commercial premarket testing before a patent expires. This principle applies to all patents. The bill should be modified so reversal of the principle would apply only to drug products whose patents have benefited from extension.

2. The second involves the types of patents eligible for restoration. This is another Patent Office amendment. The bill prevents extension of a patent specifically claiming a particular compound if that compound had been claimed or disclosed generically under a prior patent. The bill also prevents extension of a patent on claims covering a second FDA-approved drug where one patent covers two approved drugs. In both instances, patent restoration is denied unfairly. Firms often cannot determine during patent application what drug or drugs eventually will be tested successfully and marketed. They also can expend considerable resources in developing each FDA-approved drug, but only one restoration would be allowed. These punitive provisions should be deleted, and replaced by an overall year cap on total patent life for any given product, taking extension into account.

3. Under the third proposed amendment marketing of a generic drug in situations where the originator's patent is being challenged, should not be permitted until at least a lower court judgment has been rendered on patent validity. In its present form the bill technically would allow generic manufacturers to market a drug before patent litigation has been resolved.

4. The fourth proposed amendment deals with the timeliness of patent challenges. The bill could force a firm to defend its patent much sooner than would be the case under present law. A change is needed to require that the generic competitor's required notice to the patent holder take place only after the FDA has determined that the generic applicant has filed a complete abbreviated application rather than triggering a patent challenge merely on submission of a preliminary, possibly incomplete application to the FDA.

Eleven of the nation's largest research-based pharmaceutical companies is supporting these amendments to HR 3605. While the companies endorse the concepts contained in the legislation, they feel that the amendments are necessary to make the legislation equitable and to assure incentives for long-term pharmaceutical research. Their adoption would greatly improve the legislation without affecting the essence of the compromise between generic industry interests and the manufacturers of pioneer new drugs.

891A/g
7/30/84



AMERICAN ASSOCIATION OF RETIRED PERSONS

26 YEARS OF SERVICE

RECEIVED

JUN 27 1984

June 26, 1984

The Honorable Peter W. Rodino, Jr.
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Rodino:

The American Association of Retired Persons would like to express its support for the ANDA - Patent Term Extension bill. Because the bill facilitates the availability of low-cost generic drugs to consumers, we are able to endorse this compromise legislation.

For many years AARP has promoted the use of generic drugs which provide the identical therapy of brand name prescription drugs, often at a fraction of the cost. Older Americans, many of whom require multiple medication to insure their continued health, must pay these costs out of pocket as Medicare generally does not pay for prescription drugs. Generics therefore, are especially important to the elderly who often live on small fixed incomes.

Unfortunately, current FDA drug approval policy, which requires duplication of expensive safety and efficacy tests as a prerequisite for approval of generic versions of pioneer drugs first approved after 1962, essentially denies the availability of those generics to consumers. This policy has the effect of insulating brand name manufacturers from competition from generic products long after their patents have expired. Reversal of this FDA policy is a welcome step.

The Association has opposed industry efforts to gain patent term extensions for their products, as this would only serve to prolong the period during which consumers are forced to pay high prices for prescription products. The compromise bill does provide for limited patent term extension which is of some concern to the Association. On balance however, we feel that the positive aspects of the bill make it worthy of support.

The broad range of support for this compromise bill is encouraging. Apparently, however, some efforts are being made to obstruct or water down this legislation. To allow these efforts to succeed would be to put special interests above the needs of consumers. Should the pro-competitive aspects of the bill be eroded — through further patent term extension or by raising obstacles to generic drug approval — AARP would be forced to reconsider and most likely withdraw its support for the bill.

We urge support and swift approval of the ANDA - Patent Term Extension bill in its present form so that consumers will be able to reap the benefits of lower drug prices and increased competition.

Sincerely,

Peter W. Hughes
Legislative Counsel

American Federation of Labor and Congress of Industrial Organizations

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June 14, 1984

Honorable Peter Rodino, Jr., Chairman
Committee on Judiciary
2137 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Rodino:

Earlier this week, the Energy and Commerce Committee reported out the Abbreviated New Drug Application (ANDA)-Patent Term Extension compromise. It is our understanding that this compromise bill will come before the Judiciary Committee early next week. The AFL-CIO urges support for this legislation which would resolve the long-standing problem of making generic drugs available to all Americans at low cost while dealing fairly with the patent rights of drug manufacturers.

Organized labor strongly supports this legislation which would make as many as 125 prescription drugs available to consumers in generic form and save purchasers $1 billion over the next 12 years. Although the AFL-CIO has had deep reservations about the issue of patent extension, we are pleased that the sponsors of this legislation were able to develop a compromise that would expedite the approval of generic drugs and allow manufacturers to make up time lost on their patents as a result of pre-market approval, without extending the current 17 year time limit.

Employers who are faced with health insurance premiums rising at annual rates of 25 to 40 percent are pressuring their employees' unions to accept reductions in collectively bargained health care benefits. There has been pressure on unions at the bargaining table to drop drug coverage, discontinue payment for eyeglasses and cut back on preventive care services. The AFL-CIO has been working with its affiliated international unions to develop initiatives which will reduce health care costs without reducing benefits. These initiatives include providing coverage in contracts for preadmission testing, preadmission certification, mandatory second surgical opinion, preventive care and early diagnosis and treatment. Unions which have made, or are in the process of making, a provision in their contracts to cover the cost of generic drugs, often find that many of the most frequently prescribed drugs do not yet have approved generic substitutes on the market.

By allowing manufacturers of generic drugs to file a scaled-down drug application, called an ANDA, this legislation would remove the duplicative testing requirements that prevent a generic drug from coming on the market for up to 3-5 years after the patent of an equivalent brand name drug expires. This delay works to the disadvantage of the consumer by perpetuating the monopoly the original manufacturer has had on a brand name drug and giving the manufacturer leeway to keep prices high.

The AFL-CIO believes that if the Food and Drug Administration certifies that generics are chemically and therapeutically equivalent to brand name drugs which have already been approved they ought not to be required to perform additional and costly tests before being available to consumers.

We are encouraged that the majority of the Pharmaceutical Manufacturers Association (PMA) has endorsed this bill. In the past, organized labor has taken the position that patent term extension legislation is anti-competitive, forces consumers to pay top dollar for prescription drugs and prevents lower cost substitutes from coming on the market. We are prepared, however, to support the provisions of this bill which would allow manufacturers whose drugs were approved prior to their product coming onto the market to make up for time lost on their patent in exchange for shortening the approval process for generic drugs. However, if the patent term provisions are expanded in any way, we would be forced to reevaluate our support for this legislation.

We therefore urge support of the ANDA-Patent Term Extension compromise and opposition to any weakening amendments.

Sincerely,

Ray Denison

Ray Denison, Director
DEPARTMENT OF LEGISLATION

c: Members of the House Judiciary Committee

NAPM

National Association of Pharmaceutical Manufacturers

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8 May 1984

David Byer
House Judiciary Committee
Subcommittee on Courts, Civil Liberties
and the Administration Of Justice
U.S. House of Representatives
Washington, D.C. 20515

Dear David:

As a follow-up to our telephone call of May 7, please keep NAPM in mind should Chairman Kastenmeier decide to hold hearings this spring on the post-1962 ANDA/patent extension legislation.

As the primary representative of U.S. generic drug manufacturers and distributors since 1955, NAPM has been actively pursuing the goal of making high quality, low-priced generic medicines available to the public. Most recently, NAPM filed a lawsuit in New York City seeking to require that FDA accept post-1962 ANDAs without further delay. That lawsuit, which is still pending in federal court, was in large part the impetus for the introduction in Congress of H.R. 3605, the "Drug Price Competition Act."

The members of NAPM include the largest firms in the generic drug industry as well as the smaller companies. Through our newly-established Washington office, we have closely monitored the developments of the "compromise" legislation that soon will come before your subcommittee.

The letter is intended to inform you of our great interest in participating in any hearings that might be held on the "Drug Price Competition Act;" however, please also consider it as a signal of our desire to assist you and the members of the subcommittee in any way you may deem appropriate.

Sincerely,

Tom Goodwin

Thomas G. Goodwin
Director of Government Affairs

NATIONAL ASSOCIATION of
PHARMACEUTICAL MANUFACTURERS

AMERICAN SOCIETY OF HOSPITAL PHARMACISTS

4630 Montgomery Avenue / Bethesda, Maryland 20814 / (301) 657-3000

July 6, 1984

The Honorable Peter Rodino, Chairman
House Committee on the Judiciary
2462 Rayburn House Office Building
Washington, DC 20515

Re: H.R. 3605, Drug Price Competition Act of 1983

Dear Mr. Chairman:

The American Society of Hospital Pharmacists, the national professional society of pharmacists practicing in hospitals and other settings of organized health care, is writing to urge speedy consideration of the above referenced legislation.

Our members have a strong interest in this legislation: they wish to see an increased rate of development of new drug products and new forms of drug delivery and they also wish to see the cost of drugs reduced. H.R. 3605 accomplishes this by providing patent term extension to newly developed drugs and by permitting post-1962 drugs, already shown to be safe and effective, to be marketed without duplicitous clinical testing. Although we do not know what the pharmaceutical industry will do with this new incentive for research, we do know that well over 100 drugs will be available for the new approval process; consumer savings and reduced health care costs will be the result.

We urge you to move expeditiously on this matter.

Sincerely,

Joseph A. Oddis

Joseph A. Oddis, Sc.D.
Executive Vice President

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June 20, 1984

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JUN 22 1984

The Honorable Peter W. Rodino, Jr.
Chairman, Subcommittee on Monopolies
and Commercial Law
U.S. House of Representatives
2462 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Rodino:

As you know, the National Council of Senior Citizens has long been opposed to any legislation extending the patent period for prescription drugs. We have pointed out the impact it will have on elderly consumers and questioned the Pharmaceutical Manufacturers Association's contention that higher profits automatically mean more research. On the other hand, we have actively supported Representative Waxman's legislation to accelerate the approval process for bringing generic drugs to market. It has been estimated that consumers stand to save $1 billion over the next 12 years should this legislation be enacted and senior citizens make up a large percentage of these consumers.

We now know that a compromise on these two issues has been reached which combines elements of both legislative proposals. After a careful review of the compromise, NCSC has determined that it is in the best interest of our members to support it. We do so with some reluctance, and the hope that drug companies benefiting from a longer patent period will invest their higher profits in drug research.

Senior citizens do stand to benefit greatly from an abbreviated new drug application process. One-half of the top ten selling drugs, many of which are consumed by the elderly, could soon be available in generic form. Examples include: INDERAL for cardiac conditions, DYAZIDE and LASIX for high blood pressure and INDOCIN for arthritis.

Therefore, on behalf of our 4,500 clubs and the 4,000,000 seniors we represent, I urge you to support the ANDA/Patent Term Extension bill as is. Any attempt to amend the legislation will not only jeopardize our support, but also undermine the entire compromise package.

Thank you.

Sincerely,

Jacob Clayman

Jacob Clayman
President

JC/S/lc4

First Vice President, Dr. Mary C. Mulvey, Providence, Rhode Island • Second Vice President, George J. Kourpias, Washington, D.C.
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INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE & AGRICULTURAL IMPLEMENT WORKERS OF AMERICA—UAW

OWEN F. BIEBER, PRESIDENT RAYMOND E. MAJERUS, SECRETARY-TREASURER

VICE PRESIDENTS

BILL CASSTEVENS • DONALD F. EPHLIN • ODESSA KOMER • MARC STEPP • ROBERT WHITE • STEPHEN P. YOKICH

IN REPLY REFER TO
1757 N STREET, N.W.
WASHINGTON, D.C. 20036
TELEPHONE: (202) 828-8500

August 2, 1984

Dear Representative:

It is our understanding that the House may take up the Abbreviated New Drug Applications (ANDA) - Patent Term Extension legislation next week. The UAW believes this bill represents a reasonable compromise, which will provide significant benefits both to consumers and to drug manufacturers. The UAW therefore urges you to support this important, bipartisan legislation, and to oppose any weakening amendments.

The legislation would accomplish two basic objectives. First, the ANDA provisions would extend the procedures which are currently used to approve generic copies of pre-1962 drugs to post-1962 drugs. Currently there are no procedures for approving generic copies of post-1962 drugs. This has greatly inhibited the development of generic equivalents for many of the most popular drugs on the market. Under the proposed legislation, generic copies could immediately be developed on over 150 drugs that have been approved since 1962, at a savings to consumers of approximately $1 billion over twelve years.

The UAW has long been a supporter of measures which would increase the availability of generic drugs. We believe the ANDA provisions would greatly expand the availability of generics, and thus provide substantial saving to all consumers, and especially to the elderly who often must spend a large portion of their limited resources on drugs.

Second, the patent term extension provisions would extend the patents which manufacturers have on various drugs. However, the bill places outer limits on the permissible patent extensions, as well as the total period of time a drug may be under patent. With these safeguards, the legislation, in our judgment, strikes a reasonable balance between the needs of the drugs manufacturers and consumers.

Opponents of the ANDA-Patent Term Extension legislation may attempt to offer a number of amendments on the House floor. These amendments would have the effect of delaying or restricting the availability of generic drugs, and thus would wind up imposing increased costs on all consumers. In our judgment, this would undermine the carefully constructed compromise between the interests of consumers and drug manufacturers which has been embodied in the ANDA-Patent Term Extension legislation. The UAW therefore urges you to oppose all amendments and to vote for the bill.

Your consideration of our views on this important legislation will be appreciated. Thank you.

Sincerely,

Dick Warden

Dick Warden
Legislative Director

AFSCME®
American Federation of State, County and Municipal Employees
1625 L Street, N.W., Washington, D.C. 20036
Telephone (202) 429-1000
Telex 89-2376

August 2, 1984

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Dear Representative:

Next week the House will consider H.R. 3506, the ANDA-Patent Term Extension bill. AFSCME urges you to support this bill without any weakening amendments.

The bill that you will consider is a carefully designed compromise. We believe that this bill is needed to place less expensive generic drugs on the market. The bill will be of great benefit to all consumers -- and particularly to senior citizens -- in the years ahead. FDA has estimated the consumer savings to be $1 billion over the next decade. There will be increased competition in government contracts and there will therefore be a savings to the Federal and state governments in the delivery of health care.

The passage of any amendments to this bill could negate a very delicate compromise in the present bill. We urge you to vote against any amendments and for final passage.

Sincerely,

William B. Welsh
Director of Legislation

WBW:mlm

in the public service



AMERICAN
ASSOCIATION
OF RETIRED
PERSONS

26 YEARS OF SERVICE

AUG 3 1984

August 2, 1984

The Honorable Robert W. Kastenmeier
2232 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Kastermeier:

The American Association of Retired Persons would like to thank you for your efforts on behalf of H.R. 3605, the Drug Price Competition Act.

Because this bill will facilitate the availability of low priced generic drugs to consumers, AARP has endorsed this compromise legislation. Our position has been that since H.R. 3605 is already a compromise, we would oppose any efforts to weaken it through amendment by either creating obstacles to approval of generic drugs or by insulating brand name companies from competition with additional patent extension. You are to be commended for your leadership in opposition to such amendments in the Judiciary Committee.

We are hopeful for quick passage of H.R. 3605 on the House floor as reported out of the Committee, and are confident that we can rely on your continued support. Once again, your thoughtful attention to this matter is appreciated.

Sincerely,

Peter W. Hughes

Peter W. Hughes
Legislative Counsel



AMERICAN
ASSOCIATION
OF RETIRED
PERSONS

26 YEARS OF SERVICE

August 3, 1984

The Honorable Robert W. Kastenmeier
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Kastenmeier:

The American Association of Retired Persons would like to express its support for the Drug Price Competition Act, H.R. 3605 and urges that you approve this bill as reported by the Judiciary Committee without further amendments.

H.R. 3605 represents a carefully crafted compromise on an issue of great importance to the nation's elderly. It has the support of the majority of the pharmaceutical industry, both brand name and generic, as well as consumer and aging organizations. Because it will facilitate the availability of low cost generic drugs to consumers, AARP has endorsed this legislation.

It is our understanding that the bill will go to the House floor next week, and we strongly urge that you oppose any amendments offered at that time. While it may be suggested that the proposed amendments are innocuous or intended to simplify, the fact is that they will effect significant substantive changes on this delicately balanced legislation. Adoption of these amendments will serve to further delay the opportunity for consumers to purchase low cost generic drugs. This is of particular concern to the elderly, many of whom spend a great deal out of pocket each year for prescription drug products. Since Medicare generally does not pay for prescription drugs, it would be most unfair to deny older Americans the ability to save money by purchasing needed prescription medication in generic form.

To permit H.R. 3605 to be weakened by approval of the proposed amendments would put special interests above the needs of consumers who already must contend with the continually increasing cost of health care. Concessions have already been made so that a compromise could be reached. Further modification would destroy this compromise and would be most unfortunate.

The American Association of Retired Persons would like to thank you for your attention to this matter and to encourage swift approval of the Drug Price Competition Act in its present form.

Sincerely,

Cyril F. Brickfield

Timely & helpful !!

The American Institute of Chemists, Inc.
7315 Wisconsin Avenue, Bethesda, Maryland 20814 / 301-652-2447

Dr. Willard Marcy, FAIC
President 1984-85
3 Priory Lane
Pelham, NY 10803
(914) 738-4341

September 14, 1984

Hon. Robert W. Kastenmeier
Chairman of the Subcommittee on Courts, Civil Liberties
and Administration of Justice
2137 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Kastenmeier:

The American Institute of Chemists (AIC) is a national, nonprofit organization of 4800 members whose function is to improve public recognition of the chemical profession. The AIC engages in a broad program of professional enhancement through its prestigious Fellow membership category, its national certification program in chemistry and chemical engineering, and its activity in the areas of awards, student recognition, and governmental legislation and administrative matters.

In connection with its function and programs, the AIC would like to record its support of the principle of the patent term restoration bill relating to pharmaceuticals that recently passed the Congress, namely Senate bill S.2926 and House bill HR 3605.

The AIC would also like to record its support of the principle of patent term restoration with respect to agricultural chemicals, and urges that a suitable compromise be worked out with respect to the current Senate bill S.2950 and House bill HR 6034 with respect to agricultural chemicals.

Sincerely yours,

Willard Marcy

WM/jcdp

united fresh fruit and vegetable association
NORTH WASHINGTON AT MADISON, ALEXANDRIA, VIRGINIA 22314, 703/836-3410, Cable: UNIFRESH

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the fresh approach

20 September, 1983

The Honorable Robert W. Kastenmeier
U. S. House of Representatives
Washington, D.C. 20515

Re: Patent Term Restoration Act of 1983 (HR 3502)

Dear Chairman Kastenmeier:

On behalf of United and its 2500 member companies I am writing in support of the "Patent Term Restoration Act of 1983 (HR 3502), which has been referred to your Courts, Civil Liberties, and The Administration of Justice subcommittee of the House Committee of The Judiciary. Because this legislation will restore valuable patent life lost on products subject to federally-mandated testing and review, such as agricultural pesticides, United fully supports this legislation.

The members of United produce and market more than 80 percent of the fresh fruits and vegetables in the United States. The availability of a wide variety of high quality fresh produce is related to the safe and proper use of federally-approved agricultural chemicals. Under federal law, chemical manufacturers spend five to seven years fulfilling the data requirements of the Enviromental Protection Agency in seeking its approval to market their agrichemical products. During this elaborate testing and review process, the seventeen year patent protection period is dwindling. Consequently, a significant portion of the patent term on newly registered agrichemicals is lost. By contrast, unregulated products cannot experience similar abbreviated patent terms as a result of government testing and review requirements.

The adoption of HR 3502 will restore equal protection to all inventions and discoveries which result in new products, will provide investment incentives to engage in the expensive research and development which results in new products, and will result in better and less expensive products.

Accordingly, United fully supports the Patent Term Restoration legislation and respectfully urges its prompt and favorable consideration by your subcommittee.

Sincerely,

J. Patrick Boyle
Government Affairs Counsel

THE UNITED STATES HISPANIC CHAMBER OF COMMERCE

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Past President
Nelson Rodriguez

August 6, 1983

National Director
Salvador Gomez

The Honorable Peter W. Rodino, Jr.
2462 RHOB
Rayburn House Office Bldg.
Independence & New Jersey Avenues, SE
Washington, D.C. 20510

Dear Representative Rodino:

The United States Hispanic Chamber of Commerce enthusiastically supports and endorses your House bill S1306 the Patent Term Restoration Act now pending before the Congress. You are to be commended for your vision and foresight in leading the fight to correct a situation with grave implications for this nation's high technology pharmaceutical and chemical industries.

The Act would provide more equitable patent protection for investment in the research and development of products such as drugs and chemicals.

Restored research incentives would stimulate the flow of new and improved therapies publically. Better medicines would obviate the need for more costly forms of therapy, such as surgery or hospitalization. Furthermore, the competition fostered by the flow of new products would result in lower prices for existing products.

Our Hispanic business, and community as a whole, depend upon readily available and reasonably priced products affected by this Act.

The pharmaceutical industry has been the most successful high technology industry in the world economy, leader in therapeutic innovation through its ability to discover and develop new drug products.

This has permitted the creation of new employment and our Hispanic community is well represented in these ranks. Your efforts in support of this Act will permit us to further increase our work force in this high technology industry in an effort to reduce our above national level underemployment.

Your support will turn the tide in the declining U.S. position in innovation and decreasing market share for the U.S.-based companies in the future.

Thank you very much for considering our views of the United States Hispanic Chamber of Commerce, its chapters throughout this nation and Puerto Rico, and its over 30,000 member business community.

Sincerely,

Hector Barreto
President

October 15, 1983

The Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts
Judiciary Committee
U. S. House of Representatives
2137 Rayburn House Office Building
Washington, D.C. 20515

RE: Drug Patent Reform

Dear Congressman Kastenmeier:

The Executive Committee of the Association's Board of Trustees has recently completed a review of the particulars with regard to H.R. 1937, your bill to amend U.S. Patent Law and restore to the term of a patent grant the period of time which non-patient regulatory requirements prevent the marketing of a patented product or method. While we are well aware that the measure and its companion S. 255, were not enacted, please be advised that the National Medical Association will actively support the passage of similar legislation whenever such is introduced in Congress.

Please keep us advised on any developments in this area and feel free to call on us when you feel that we can be of assistance.

Very truly yours,

Edward A.R. Lord, M.D.
Chairman
Board of Trustees

1012 Tenth Street, Northwest • Washington, D.C. 20001 • (202) 347-1895



National Association
of Manufacturers

H. RICHARD SEIBERT, Jr.
Vice President
Resources and Technology Department

File Patent Team

October 4, 1983

The Honorable Robert Kastenmeier
U.S. House of Representatives
2232 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Kastenmeier:

The National Association of Manufacturers notes with great interest the recent introduction of the Patent Term Restoration Act, S. 1306/H.R. 3502, by Senator Mathias and Congressman Synar.

The patent system provides important incentives for innovation. The patent right to exclude others for a limited time is widely recognized as fostering, and often essential to, the large investments of time, talent and money required for research.

In recent years, concern for the environment and health has created extensive pre-market testing and review requirements for several classes of products. Stringent regulations coupled with increasingly sophisticated testing procedures have made these review requirements complex and time-consuming.

This federal regulatory review process now often takes up a significant part of the 17-year period of patent protection on a particular product or process. During the pre-approval period no commercialization is possible. In such cases the federal review policy acts as a disincentive to innovative efforts.

The National Association of Manufacturers supports legislation which would restore the normal patent life by extending the patent term to compensate for the time lost due to testing and review requirements. Specifically, the NAM supports S. 1306 and H.R. 3502, which would provide this relief to a broad range of affected products and processes. The NAM would oppose any efforts to reduce the scope of coverage of patent term restoration to only a few products.

We urge you to act promptly on this legislation.

Sincerely,

HRS:sa
Encl.

1776 F Street, N.W.
Washington, D.C. 20006
(202) 626-3700

file: Patent Term

AACOM

Chicago College of Osteopathic Medicine
College of Osteopathic Medicine of the Pacific
The College of Osteopathic Medicine at The University of Health Sciences
Kirksville College of Osteopathic Medicine
College of Osteopathic Medicine Michigan State University
New England College of Osteopathic Medicine
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Southeastern College of Osteopathic Medicine
University of Osteopathic Medicine and Health Sciences
West Virginia School of Osteopathic Medicine

American Association of Colleges of Osteopathic Medicine • 122 C Street, N.W., Suite 675, Washington, D.C. 20001 • (202) 783-7444
Office of Governmental Affairs

November 21, 1983

Robert W. Kastenmeier, Chairman
Subcommittee on Courts, Civil Liberties,
and the Administration of Justice
2137 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Kastenmeier:

The American Association of Colleges of Osteopathic Medicine, representing the fifteen institutions educating osteopathic physicians nationwide, wishes to express its support of H.R. 3502, "The Patent Term Restoration Act of 1983," and to convey to you our dismay at its lack of movement out of subcommmittee.

As you are no doubt aware, the profit motive has stimulated the development of numerous preventive and palliative agents which have proven significant aids to the reduction of disease and disability. The prospect that pharamaceutical companies may retrench in their research efforts is of great concern to medical educators, as the successful conduct of preventive and therapeutic activity depends to a considerable degree upon the development of new and better pharmaceutical products. In the case of medical schools holding patents on discoveries made in their laboratories, the restoration of patent life for an additional several years as proposed represents a greatly needed addition to institutional resources.

We urge you to report H.R. 3502 favorably to the full committee at the earliest opportunity, and to seek conclusive action before Congress adjourns for the year.

Sincerely,

Laura E. Levine, Director
Office of Governmental Affairs

LEL/wlb

UNIVERSITY OF WISCONSIN — MADISON



March 18, 1983

The Honorable Robert W. Kastenmeier
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Kastenmeier:

It was a pleasure to meet you, even though only briefly, at the Wisconsin Alumni Reception Tuesday, March 15. Formerly I enjoyed excellent contact with your office through Ms. Analoyce Clapp, but I have been remiss in not establishing contact with your current legislative aide for matters relating to health and education.

You asked my opinion regarding the orphan drug bill and on patent restoration. I think the orphan drug bill is excellent legislation and, indeed, evidence of its value is already developing. Patent restoration is a more complicated matter, however. I support this legislation because I firmly believe the incentive it provides is essential to foster innovation in drug discovery. In the future, drug delivery, that is, delivering the drug in the desired concentration directly to the organ or tissue to be affected, thus reducing general toxicity and unwanted side effects, will be as important as discovering new drug molecules. This type of research must be seeded if the longer-term benefits are to be realized.

On the other hand, patent restoration must not become a tool through which inordinate profits are generated. It seems to me that the important objective in stimulating innovation is that of providing assurance to the innovator that an adequate period to market the innovative product will exist. A bill to assure a reasonable period of patent protection after a product has been cleared for marketing by the FDA may thus be the best compromise possible.

I have taken the liberty of enclosing a data sheet on student financial aid prepared by the American Association of Colleges of Pharmacy for your information and files. Your interest in and support of the needs of pharmaceutical education are very much appreciated.

Sincerely,

August P. Lemberger
Dean

APL:bh
Enclosure

CENTER FOR HEALTH SCIENCES • SCHOOL OF PHARMACY
425 North Charter Street, Madison, Wisconsin 53706 Telephone: 608/262-1416

National Association
of Manufacturers

H. RICHARD SEIBERT, Jr.
Vice President
Resources and Technology Department

October 4, 1983

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The Honorable Peter W. Rodino
U.S. House of Representatives
2462 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Rodino:

The National Association of Manufacturers notes with great interest the recent introduction of the Patent Term Restoration Act, S. 1306/H.R. 3502, by Senator Mathias and Congressman Synar.

The patent system provides important incentives for innovation. The patent right to exclude others for a limited time is widely recognized as fostering, and often essential to, the large investments of time, talent and money required for research.

In recent years, concern for the environment and health has created extensive pre-market testing and review requirements for several classes of products. Stringent regulations coupled with increasingly sophisticated testing procedures have made these review requirements complex and time-consuming.

This federal regulatory review process now often takes up a significant part of the 17-year period of patent protection on a particular product or process. During the pre-approval period no commercialization is possible. In such cases the federal review policy acts as a disincentive to innovative efforts.

The National Association of Manufacturers supports legislation which would restore the normal patent life by extending the patent term to compensate for the time lost due to testing and review requirements. Specifically, the NAM supports S. 1306 and H.R. 3502, which would provide this relief to a broad range of affected products and processes. The NAM would oppose any efforts to reduce the scope of coverage of patent term restoration to only a few products.

We urge you to act promptly on this legislation.

Sincerely,

HRS:sa
Encl.

1776 F Street, N.W.
Washington, D.C. 20006
(202) 626-3700

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Meet us in Chicago
49th Annual Scientific Assembly
October 23 -27
1983

July 5, 1983

RECEIVED
JUL 8 1983

The Honorable Peter W. Rodino, Jr., Chairman
House Judiciary Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Rodino:

The American College of Chest Physicians is a professional medical specialty society of more than 11,000 physicians, scientists, and educators, who specialize in the diseases of the heart, lungs, and circulatory system. As President of this organization, and as an individual who conducts pharmacologic research, I wish to express our support for H.R. 3502, "The Patent Term Restoration Act of 1983," which is now pending before the House Judiciary Committee.

Great strides have been made in combatting cardiopulmonary diseases in recent years. Promising new beta-blockers and other therapeutic agents are demonstrating that the death rate from cardiovascular diseases can be further reduced. In the pulmonary area, drug therapies are under development for debilitating chronic lung diseases, such as bronchitis and emphysema, which afflict 15 million Americans.

It is imperative that the Federal Government assure sufficient incentives for universities, pharmaceutical companies, and other research institutions to sustain and expand current efforts in research and development of new, more effective drugs, biologicals, and other health care products necessary for the prevention, treatment and control of these major health problems.

The original intent of the patent law was to provide incentives for American research and innovation in scientific fields. Over the last 20 years, the time between approval of patents on compounds and the actual approval of new therapeutic agents for use in patients has

grown significantly, effectively reducing from 17 to less than 10 years patent protection guaranteed to the innovator/researcher.

Concurrently, the costs of conducting research have grown substantially. We are pleased that FDA is currently implementing and considering changes in the IND and NDA processes which may expedite the approval process in a manner which will not compromise the rigorous safety and effectiveness standards required by law in considering new drug applications. However, until the time that such reforms are implemented, pharmaceutical manufacturers should be afforded adequate incentive for the conduct of the often time-consuming studies required for approval.

We believe that the availability of a "real" 17-year patent life, one which reflects the time required for approval of a drug, would provide such an incentive. Accordingly, we recommend that you, as a member of the House Judiciary Committee, support H.R. 3502.

On behalf of our membership and our millions of patients, we appreciate your attention to this important matter.

Sincerely,

W. Gerald Rainer

W. Gerald Rainer, M.D., F.C.C.P
President

American Flint Glass Workers Union AFL-CIO

INTERNATIONAL HEADQUARTERS
1440 SOUTH BYRNE RD.
TOLEDO, OHIO 43614
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Assistant Secretary

July 30, 1984

Mr. David W. Beier, III
Assistant Counsel, Subcommittee on Courts, Civil Liberties & the Administration of Justice
2137 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Beier:

In the last several years hundreds of thousands of good paying factory jobs have been lost in the steel, auto, electronic and many other American industries. Two of the major causes of this loss of American jobs have been low wage imports from abroad and obsolete American manufacturing capabilities in certain industries making it difficult for them to compete. In the American glass industry in recent years alone more than 50,000 jobs have been lost. Most of these jobs will never be recovered.

A third reason for the loss of American jobs has been the pirating of American technology by foreign nations and particularly by the Japanese. For example, not too many years ago there were thousands of Americans engaged in the production of color television sets, largely an American invention. Presently, most of these jobs have gone overseas and we are constantly engaged in a fight to maintain what is left of this great industry.

Our major hope for new jobs rests upon emerging new technologies here in America and their promise for the future. It is essential that this emerging new technology resulting from the expenditure of millions of dollars and the know-how of American engineers, scientists and workers, be protected if we are to have any promise of a future in manufacturing.

Virtually all commercial countries except America have laws which provide patent protection for products produced by patented processes. Without this protection U.S. companies employing American

workers are operating under a severe handicap particularly in high technical oriented manufacturing.

Certain American companies spend a tremendous sum on research and development, which leads to specialized and unique manufacturing processes. In many cases the new process does not produce a patentable product. Although the product may not be patentable, the process by which it is produced many be superior than any other existing throughout the world. Under present American law it is not an infringement of a U.S. process patent if that particular patented process is used outside of the United States and the resulting product is imported into this country. No U.S. manufacturer has any protection against foreign infringement upon his patents except through an action taken before the International Trade Commission. This relief, of course, is important but it is prolonged and inadequate. We feel it does not provide sufficient protection.

The Corning Glass Works employs thousands of members of our Union in its several plants across the nation. Corning is a leader in the glass industry and spends literally millions of dollars on research and development. At the turn of the century Corning, working with Thomas Edison, pioneered in the development of the incandescent lamp. Corning also led the world in the development of the color television picture tube. However, in spite of its pioneering in the research and development of television, it has now lost much of that market and our members have lost thousands of jobs. Much of the problem was the result of infringement by foreign producers upon some of Corning's process patents.

For many years the Corning Glass Works has been spending huge sums in developing "optical wave guides." This involves many new processes through which glass wire is manufactured and substituted for copper. It represents a revolution within the communication and telecommunication industries. Members of the American Flint Glass Workers Union working in the laboratories and plants of Corning have cooperated fully in the development of this new product. This new technology offers much for the future. Through it our members are hopeful of recovering some of the jobs they have lost.

Optical wave guides, however, are being produced outside of the U.S., and we are very concerned that without patent protection this new industry and improved processes, which both the company and our members have such a great investment in, will be usurped by others just as color television and others have been taken over.

It's unfair that American workers lose jobs because they eat hamburger instead of rice. It's even worse to have their opportunities and jobs literally "stolen away."

Presently there is legislation being considered by Congress that would be extremely helpful in protecting the potential of this and other great new American developments. The Corning Glass Works that developed the wave guide processes, its employees and the communities where it presently has plants located, deserve and need your help. We are referring to bill S1535 before the Senate and HR4526 before the House of Representatives. Any action that you might take to obtain passage of this fair and essential legislation will be greatly appreciated.

This appreciation will not come from the workers alone. It will also come from American companies dedicated to research that have invested tremendous sums in these wonderful new products and it will come from the American communities who will benefit from the new plants and improved economies that will result as more jobs are created. Attached is a recent clipping from the Wall Street Journal on Corning's plans to expand its Wilmington, N.C. plant.

Sincerely,

George M. Parker
International President

GMP/ls
Attachment

Corning Glass to Boost Optical-Fiber Output At Cost of $87 Million

By a WALL STREET JOURNAL *Staff Reporter*

CORNING, N.Y.—Corning Glass Works said it will commit $87 million to expand its manufacturing capacity of optical waveguide fibers.

The company said the expansion will occur over a two-year period. A spokesman said that 25% of its previously allocated funding will be spent on the expansion in the first year.

Optical waveguides are hair-thin silica fibers used to transmit voice, video and data signals by impulses of light.

The expansion will bring waveguide capacity to more than 700,000 miles, or one million kilometers, a year in 1986. A spokeswoman said the current capacity was "hundreds of thousands of kilometers," but she wouldn't elaborate.

Corning said it will construct a manufacturing facility for the fibers near its Wilmington, N.C., plant.

Founded 1914

Suite 1120
1001 Connecticut Avenue, NW
Washington, DC 20036

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

202/872-8110

July 22, 1983

The Honorable Robert W. Kastenmeier
U. S. House of Representatives
2232 Rayburn House Office Building
Washington, D. C. 20515

Dear Mr. Kastenmeier:

I am writing to you to urge your support and cosponsorship of H.R. 3502, the Patent Term Restoration Act of 1983, introduced by Congressman Mike Synar (D, OK). and 100 other cosponsors. A similar bill (S. 1306) was introduced in the Senate by Senator Charles Mathias (R, MD).

CSMA has a membership of nearly 400 firms engaged in the manufacture, formulation, distribution, and sale of insecticides; disinfectants and sanitizers; detergents and cleaning compounds; automotive chemicals; and waxes, polishes, and floor finishes for household, institutional, and industrial uses. A significant number of these products have pesticidal claims and are, therefore, subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Patent Term Restoration Act.

Because of federal agency registration requirements which must be met before a patented product can be brought into the market, the effective 17-year patent life of the product is greatly reduced. As a result, the ability of a company to recover its research and development expenditures and developmental costs, and stake out a share of the market, is likewise reduced.

In recent years and especially since the early 1960's, new federal laws and regulations of such agencies as EPA and FDA have led to a steady lengthening of the pre-market testing and clearance process. Recently, EPA estimated that patent life for chemical products has been reduced to about 12 years, including household products for the home, lawn and garden.

Substantially shortened patent terms provide insufficient time for companies to recover their investments. In a very real sense, the curtailment of incentives to pursue important technological advancements operates against the public interest by depriving people of important products in addition to the jobs required to produce them. Exacerbating the problem is the increased competition from foreign companies which threatens our country's traditional role as the world leader in innovation.

Legislation was introduced in the 96th and 97th Congresses to restore some of the patent life lost due to federal agency review requirements. While a bill passed the Senate in 1981 and had the support of almost two-thirds of the members

of the House in 1982, it died in the House Rules Committee during the final days of the 97th Congress.

The bill would restore up to a maximum of 7 years the patent life for chemical products regulated under the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, equal to the marketing period lost between the time that significant animal studies are commenced and the product is registered by the EPA or is lawfully permitted to be manufactured.

We at CSMA support H.R. 3502 because it would:

- o Restore some of the patent protection lost in the Federal regulatory process.
- o Sustain the incentive needed for our member companies to continue to invest long-term capital in research and development.
- o Enable U. S. chemical specialty companies to maintain their leadership position internationally.
- o Correct a present inequity in the system which denies appropriate protection to regulated products.
- o Especially benefit small businesses for which the contribution of innovation is proportionately greater than for large companies. Lengthened patent protection for them provides long-term stability to enhance cost recovery and outside financing opportunities and to make additional investments in capital and employment.

We believe that patent life should be restored for chem' :al specialties products which are lost due to federal agency pre-market testing and regulatory review requirements.

We respectfully urge your support and cosponsorship of H.R. 3502, and your assistance in moving this bill through the legislative process. We thank you for considering this important matter.

Sincerely,

Ralph Engel
President

RE:mk

napim
NATIONAL ASSOCIATION OF PRINTING INK MANUFACTURERS, INC.
550 Mamaroneck Avenue, Harrison, New York 10528 / 914-698-1004
JAMES E. RENSON, Executive Director

August 8, 1983

The Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil Liberties and the
Administration of Justice
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Kastenmeier:

The National Association of Printing Ink Manufacturers (NAPIM) would like to comment on H.R. 3502 the Patent Term Restoration Act of 1983 on behalf of the printing ink industry. NAPIM is a trade association representing small, medium and large printing ink manufacturers in the United States and accounting for nearly 90% of total U.S. printing ink production. There are about 213 ink companies in the United States and most of them are small, privately owned businesses.

We believe that legislation is necessary to grant a recovery period of up to seven years of patent life lost due to government mandated testing and review. The Toxic Substances Control Act requires that new chemical products undergo years of premarket testing and federal agency review before they can be marketed and during much of this time patents on these products are elapsing. NAPIM believes that this shortening of the marketable patent term seriously decreases incentive for investment in research and development on new products.

The printing ink industry is vitally dependent on new technology in such chemical products as pigments, resins and other specialty chemicals. While we strongly concur in the objectives of the Toxic Substances Control Act, it must be acknowedged that the premarket testing requirements of this Act do pose a deterrent to new developments which are vital to the printing ink industry. The loss of marketable patent terms resulting from the extensive testing requirement poses a further deterrent to research and development. For this reason, NAPIM believes that chemicasls subject to PMN under the Toxic Substances Control Act should be eligible for patent life recovery as proposed by H.R. 3502

Therefore, NAPIM asks for your support of H.R. 3502 and urges that every effort be made to enact this legislation.

Sincerely,

James E. Renson
Executive Director

NAPM

National Association of Pharmaceutical Manufacturers
747 Third Avenue, New York, New York 10017 • (212) 838-3720

BURTON GREENBLATT
President
•
MILTON A. BASS
General Counsel
•
GEORGE SCHWARTZ
Executive Director

THOMAS G. GOODWIN
Director of Government Affairs
Washington, D.C.
(202) 337-6276

22 August 1983

Michael J. Remington
Chief Counsel
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
U.S. House of Representatives
Washington, D.C. 20515

Dear Mike:

In anticipation of hearings later this year on "The Patent Term Restoration Act," the National Association of Pharmaceutical Manufacturers(NAPM) would like to request the opportunity to testify when such hearings are held.

NAPM represents small and medium-sized generic drug manufacturers, as well as the largest firms in that segment of the industry. We are opposed to the legislation as introduced in the House earlier this year by Rep. Synar D-Okla).

I have enclosed for your information a copy of the statement we filed with the Senate Judiciary Committee on Sen. Mathias'(R-Md.) version of this legislation.

To the extent that you think I may be of help in providing information during any future subcommittee and full committee deliberations on patent restoration legislation, please do not hesitate to contact me. You may recall that until recently, I was Capitol Hill Editor for "F-D-C Reports," the leading specialized publication in the pharmaceutical field. In that capacity as a reporter, I followed the debate concerning this legislation. My concerns about it, coupled with a strong interest in other health care issues involving generics, prompted me to assume NAPM's newly-created post of government affairs director in early July.

In the event hearings are scheduled, NAPM will of course provide a detailed statement for the subcommittee. In the meantime, for your information, our position in brief is that the brand-name pharmaceutical companies have failed to justify the extensions of marketing monopoly contained within the Synar legislation. Furthermore, we believe that existing barriers to the marketing of low-cost, safe and effective generic drugs mitigate strongly against enacting this far-reaching proposal to change existing U.S. patent laws.

When and if hearings are scheduled, please keep the NAPM in mind. In the meantime, I'd like to keep in touch with you as the House debate begins to unfold.

Thank you for your consideration.

Sincerely,

Tom Goodwin

Thomas G. Goodwin
Government Affairs Director

NATIONAL ASSOCIATION
of
PHARMACEUTICAL MANUFACTURERS

TGG/mcm
enc: NAPM statement to Senate record

The National Association of Pharmaceutical Manufacturers(NAPM), a nonprofit trade association representing a broad cross-section of U.S. generic drug manufacturers and distributors, submits the following statement for the record on "The Patent Term Restoration Act of 1983."

NAPM opposes this legislation.

As proposed by Sen. Charles Mathias(R-Md.), the legislation would extend the marketing monopolies of highly-profitable, brand-name drug companies, thus delaying the entry to the marketplace of generic competition which would result in dramatically reduced drug costs to our elderly and other consumers who need important pharmaceuticals.

The generic drug industry is not opposed to the U.S. patent system, which has provided necessary incentives to important research and development for well over 100 years.

However, NAPM cannot support this proposal to alter drastically the patent system because it flies in the face of stated U.S. national policy to bring our health care system under control through cost containment measures. Simply stated, patent extension legislation would perpetuate inflated drug prices to those members of our society who are least able to afford them.

NAPM believes that if Congress wishes to undertake such a major revision of existing patent law -- especially a revision that would provide continued profit windfalls to an already highly-successful special interest at the expense of consumers -- it must act on the basis of incontrovertible evidence that the brand-name pharmaceutical industry is in serious need of additional help to assure its continued viability.

Based on the evidence provided to the Senate panel reviewing this legislation, and that submitted to two House panels in 1982, NAPM believes there is overriding doubt as to the need for patent extension.

1. PATENT EXTENSION AS AN "EQUITY" OR "FAIRNESS" ISSUE

The generic drug industry has great difficulty in comprehending the "equity" and "fairness" issue as argued by supporters of patent extension.

The extent of the "inequity" -- the alleged loss of patent protection for high-priced brand-name pharmaceuticals -- often is equated with regulatory requirements imposed by the U.S. Food and Drug Administration.

NAPM points out that whatever the FDA requirements may be, the patent system does not guarantee to a patent holder the right to sell or market an invention. Rather, the patent system grants to an inventor the right only to exclude others from making, using or selling that invention.

Thus, even though a patent holder for a drug may be barred from marketing his product until such time as FDA approval has been granted, he has the same rights as other patent holders who are not required to seek pre-marketing approval from FDA: exclusive monopoly rights to make and use the product and to prevent others from doing so.

The "Mousetrap"

Supporters of patent extension are fond of referring to this legislation as a "fairness" and "equity" measure. They argue that it is unfair for the inventor of a better mousetrap to enjoy longer patent protection than the inventor of an important new drug.

NAPM does not understand the mousetrap analogy because inventors of new drugs do not compete in the same marketplace with inventors of better mousetraps; rather, they compete with other drug inventors, all of whom must play by the same rules of FDA approval. In addition, the patent laws do not guarantee -- and the mousetrap inventor does not receive -- specific marketing rights. As with the studies conducted by the drug inventor, the mousetrap inventor sees some patent protection eaten away by his need to obtain financing, conduct marketing and sales tests and establish manufacturing facilities.

With all due respect to the important contributions made by the brand-name research-intensive pharmaceutical

companies, NAPM believes that the performance of laboratory, animal and human clinical studies are, quite appropriately, the cost of doing business in the research segment of the pharmaceutical industry today -- the rewards for which cost are patent protection and the impressive profits and market share realized by that segment. In addition, the fact that a patent has expired does not mean that an innovator's market share is suddenly washed away. On the contrary, the heavy advertising and personal visits to physicians by the drug firms' sales forces tend to prolong the vast majority of market share well after patent expiration, for most major drugs.

The Patent System Works -- Very Well

A recent California court decision points up the fact that generic manufacturers face real "equity" and "fairness" issues under existing patent law. In the court's decision in Pfizer v. International Rectifier, a generic manufacturer was found to have infringed upon Pfizer's patent for a drug merely by making the drug for investigational purposes in order to obtain data for submission of an application for approval to FDA.

NAPM notes that, to the extent this case is upheld in other jurisdictions, it will provide a form of de facto patent extension to brand-name firms, by prohibiting generic companies from preparing the data necessary to obtain FDA approval until after a patent has expired.

If, in fact, a generic firm is precluded from conducting tests to gain marketing approval until after the patent on an original drug has expired, then the innovator will, in fact, enjoyed a continued marketing monopoly for the additional three or so years required for the generic firm to conduct tests and obtain approval of its lower-priced version.

Patent extension would, therefore, exist for a period of years beyond patent expiration even without this legislation.

2. THE LEGISLATION AS PROPOSED: "FAIRNESS"?

Even were it established beyond doubt that patent extension is reasonable approach to creating new research incentive -- which cannot be done -- the legislation as proposed goes far beyond the boundaries of "equity" and "fairness" and thus represents a special interest bill of outrageous proportions. NAPM herein addresses the two key provisions of the legislation now under consideration.

A. Amount of "Lost" Patent Life Eligible for Patent Extension

Developers of new drugs would receive up to seven years' reimbursement for patent life allegedly lost to FDA regulatory review requirements. The reimbursement would cover the time expended between the drug sponsor's initiation of a "major health or environmental effects test" and the date of FDA approval of the product.

Aside from being unsupportably vague, this provision gives to developers of new drugs carte blanche in determining the diligence with which they pursue FDA approval of their potential product.

"Due diligence" in pursuing FDA approval is an important point, NAPM believes, because sponsor delays easily could violate the spirit of the legislation, e.g., to provide compensation for patent life lost to FDA requirements.

For example, there are demonstrable instances in which a developer may find it beneficial to withhold from the market a new product that would compete with another of his own drugs already marketed.

Furthermore, and more importantly, the provision seems to imply that companies would market new drugs without conducting any testing at all, assuming the absence of the allegedly burdensome FDA requirements for which they seek compensation. It is, of course, absurd to assume that responsible research firms would rush to the marketplace without some testing, and NAPM does not draw any such inference here.

However, the ethical and moral obligations inherent in providing a safe and effective new remedy to the public requires some form of testing. With or without formal FDA regulations governing the approval of drugs, NAPM believes, extensive animal, laboratory and human testing is part and parcel of doing business in the research-intensive drug industry, and thus is not in and of itself a reason for extension of patent life.

To the extent that patent extension is justifiable in any respect, Congress must consider as eligible for reimbursement only that period of time required by FDA for review and approval of a new drug application (NDA).

Such a limitation would acknowledge the amount of testing that would be expected of any drug developer in the ab-

sence of any FDA controls, and would provide extension of patent life only for that period which is most out of the developer's control -- the NDA Review period.

Furthermore, Congress should refuse to provide any patent extension for delays in FDA's review process that are caused by the drug developer, and for any delays in the granting of a patent which are attributable to the drug developer.

B. Application of Patent Extension: Effective Date

As proposed, the legislation would apply to drug products already patented and under review by FDA at the time the legislation is enacted. NAPM strongly opposes this provision, since it goes well beyond any reasonable criterion of "equity" or "fairness."

Simply stated, there is no justifiable reason for extending patent life on a product already patented and under FDA review because no further incentive for research is needed for that product.

That this provision is the most controversial and unsupportable section of the legislation was well -recognized in 1982 by the House sponsor of patent extension at that time, Congressman Robert Kastenmeier(D-Wis.).

During consideration of the 1982 legislation by the House Judiciary Committee in July, 1982, Kastenmeier was successful in urging that patent extension be offered only

for drug products patented after the effective date of the legislation.

Kastenmeier explained his rationale in a May 28, 1982 letter to Judiciary Committee Chairman Peter Rodino(D-N.J.) in which he requested a delay in the consideration of his own bill:

> "You may know the legislation has been severely criticized by certain of our colleagues, consumer groups, organized labor and the generic industry as providing unjustified windfall to the pharmaceutical industry." In my view, this criticism was particularly justified with respect to the original bill. Under that legislation, extension of patent term would be granted to products which had already been patented.
>
> "Yet, the purpose of the legislation is to stimulate investment in new technology; in other words, to encourage investment in products yet to be patented."

Kastenmeier went on to explain to Rodino that he had been successful in amending the legislation to provide patent extension only to products patented after the effective date.

> "The amendment responded to the criticism of opponents (of the bill) because, although the incentive of a definite 17-year term for all new technology will be available to investors immediately upon enactment of the bill, generic pharmaceutical houses and therefore consumers will not experience any negative price impact for nearly 20 years. By that time, the advantages of the bill should have outweighed the negative consumer impact and the now fledgling generic industry should be in a strong competitive position."

It is well-recognized by both supporters and opponents of patent extension that Kastenmeier would have opposed his

own legislation had there been attempts to extend its coverage to drugs already patented.

3. THE REGULATORY "BURDEN": FDA REVIEW AND APPROVAL

The premise upon which patent extension legislation is based is that incentives for new research and development have decreased due to "lost" patent life stemming from FDA regulatory requirements.

To the extent this premise is true, NAPM urges Congress to abandon consideration of patent extension legislation in favor of assuring the continuation of FDA's recent progress in reviewing and approving new chemical entities.

Supporters of the legislation claim that it requires between seven and 10 years to clear FDA testing and review requirements before a new drug can be brought to market.

This claim is true only on the most superficial level.

If one takes as a given the ethical and moral obligation of new drug sponsors to conduct extensive drug testing even in the absence of FDA rules, then the only real regulatory "burden" is the length of time that FDA takes in reviewing and approving an NDA.

Supporters of this legislation are fond of citing the phenomenon known as "drug lag," which is a term referring to the delays of the U.S. FDA in approving drugs already marketed overseas.

Without going into the merits of the existence of a "drug lag," it is quite clear that the phenomenon no longer

applies. Indeed, the experiences of the U.S. in the thalidomide and Oraflex cases might indicate that a "drug lag" is not per se totally negative.

Furthermore, NAPM believes that the only "drug lag" in existence today applies to the refusal of FDA to permit clearance of safe and effective generic drugs which are equivalent to products no longer under patent.

In any event, FDA has undertaken a massive revision of its NDA requirements in order to facilitate the review and approval of new drugs.

Even though this revision is not yet totally complete, the results of FDA's activities are dramatic:

* As of March, 1982, the mean review time for drugs regarded by FDA's classification system as representing "important" or "modest" therapeutic gains stood at 11.9 months. This figure, representing 32 approvals granted between October 1, 1978 and March, 1982, compares with a mean of 17.5 months for the previous two-year period, 1976-1978.
* The mean approval time for the 27 new molecular entities approved in 1981 decreased to 30.7 months, down from 34.5 months in 1980 and 37.5 months in 1979.
* Overall, for the 96 NDAs approved in 1981, the mean review time was 24.4 months, down from the 33.6 months required for each of 94 NDAs approved in 1979 (mean review time).

Supporters of patent extension also argue that alleged delays in FDA's review process are resulting in the approval of fewer new drugs. This clearly is not true.

In 1982, FDA approved a record 27 new drug applications, surpassing by one the number of NDAs that received approval in 1981. FDA is doing a better, not worse, job of bringing important therapies to the marketplace.

NAPM would be willing to consider, even support, some form of patent extension if it could be shown, in real terms, that FDA's regulatory review is a true burden in the context of extending patent life. The data is just not there.

4. R&D DATA DO NOT INDICATE INNOVATION INCENTIVE "PROBLEMS"

According to supporters of patent extension, research and development expenditures are increasing because of inflation, but decreasing in terms of real dollars. It is said the R&D decrease is due in large part to a lack of incentive for new development caused by reduced patent life.

Aside from the fact that the inflation factor has in recent months decreased to its lowest point in years, there exists no data to show that R&D expenditures are decreasing, for whatever reason. Quite the contrary; there has been a steady increase in real dollar terms in drug R&D.

Rather than recite the existing data in detail here, NAPM refers Congress to the report published in 1981 by its own Office Of Technology Assessment("Patent Term Extension and the Pharmaceutical Industry," Library of Congress Number

81-600113). On page 12, the report shows a clear, unbroken steady increase in real R&D expenses, which more than doubled during the years 1975-1978.

Supporters of the legislation, notably the Pharmaceutical Manufacturers Association, argue that the OTA data is flawed and out-of-date. However, PMA has not provided any alternative data to the Congress.

As the representative of production-intensive drug manufacturers, who invest heavily in state-of-the-art manufacturing and quality control techniques, NAPM does not have access to R&D data.

In the spirit of "fairness" and "equity," though, NAPM believes strongly that the Congress should not consider seriously any claims that existing data is flawed when alternative data is not forthcoming.

Finally, with regard to the question of incentive as it relates to R&D expenditures, NAPM points out that, in 1981, the Congress authorized a 25% tax CREDIT for R&D expenses; and in 1982, Congress provided further tax incentives for R&D in the critical "orphan drug" area.

5. PATENT EXTENSION AND PRESCRIPTION DRUG PRICES

Supporters of patent extension insist that it will result in lower prices to consumers, primarily by generating incentives to develop new therapies that may replace more costly surgery or hospital treatment.

This reduced-cost argument is false not only on its face, but also when considered in light of the evidence available.

Of all the arguments put forth with regard to patent extension, none is more true than the fact that the legislation will extend the marketing monopolies of research-oriented drug companies. NAPM notes that it is an equally-well accepted fact that a lack of competition, in any industry, does not tend to result in reduced prices for a given product.

In almost every instance, the availability of generic competition in any drug class has resulted in dramatic cost savings to consumers. It is not unusual for the cost difference to be on the order of several hundred percent.

Even the congressional Office of Technology Assessment, in its report on patent extension, found that under reasonable application of the legislation, consumer costs could be expected to be "one hundred forty percent of the cost without patent term extension."

A more specific, and more dramatic, example of the absurd reduced cost-through-less competition argument is found in the U.S. Defense Department's procurement of the drug metronidazole.

In 1980, the drug was supplied to the government by the brand-name manufacturer, G.D. Searle, for $53.24 per bottle. This price remained in effect until May, 1982, when a generic manufacturer, Zenith Laboratories, received approval for its own version of metronidazole and entered the marketplace. Zenith bid for the Defense Department contract with a price per bottle of $32, while Searle had increased its price to $69.74. In September, 1982, Zenith came in at $28, while Searle remained at $69.74. In February, Searle reduced its bid dramatically to $26.40, beating Zenith's bid of $26.60. In April, 1983, a new entry, Cord Laboratories, won the Defense Department contract with a low bid of $19.67.

As a clear result of generic competition, the government has saved $1.16 million over Searle's price -- from only one drug!

Aside from being totally unprovable, the argument that patent extension will reduce the cost of healthcare in the longterm ignores the plight of our elderly and poor populations now.

It is a fact that in 1982, prescription drug prices, as measured by the Department of Commerce, rose 12% -- a rate three times higher than the increase in the Consumer

Price Index for all items.

So far in 1983, prescription drug prices already have increased at an annual rate of 11.8% -- once again, more than three times the rate of increase in the Consumer Price Index.

However, during 1982, the cost-of-living increase for Social Security recipients amounted to only 7.4%, causing them to lose ground in their efforts to keep up with drug prices. In addition, the elderly will, in 1983, be subjected to a six-month delay in Social Security cost-of-living increases.

There is little doubt that one of the most important issues facing the U.S. today is the financial crisis in healthcare. Our stated national policy is to reduce the staggering increase of healthcare through programs of cost-containment.

Congress should not abet continued drug price increases, restraints to competition in the marketplace, and the denial to more and more patients of the medications they need. Those are the true implications of patent extension legislation.

6. THE PROFIT QUESTION

NAPM does not begrudge the legitimately-obtained profits of the research-intensive pharmaceutical industry. As with the need for some form of patent protection for inventors through the current laws, NAPM recognizes that a profit potential must exist in order for the research and development of new medical entities to continue.

However, NAPM questions the need for instituting a dramatic change in the patent laws to show "fairness" and "equity" to an industry as profitable as the brand-name manufacturers of prescription drugs.

According to figures published by the Department of Commerce, the pharmaceutical industry is the third most profitable in the U.S. It is not hurting in any known sense of the word.

Profit trends compiled by the Federal Trade Commission show a 24-year profit stability(1956-1980) that is not matched by any other industry. During those years, after-tax rates on return of equity ranged from a low of 16.7%(in 1961) to a high of 20.8%(first three quarters of 1980), with the rate holding at 18% or higher during the most recent years of the FTC data, 1976-1980.

In addition, figures developed by the Pharmaceutical Manufacturers Association show that drug industry revenues

have grown significantly since 1965, even on a constant-dollar basis.(PMA Office of Policy Analysis, report of April, 1981).

NAPM believes that such a solid track record does not exactly cry out for "equity" and "fairness" measures which would maintain and increase high profits and revenues, while at the same time preventing consumers from obtaining lower-cost safe and effective drugs.

As the trade representative of small-sized generic manufacturers as well as larger firms, NAPM well understands the significance of profits to business growth. Generic industry profits have increased in recent years, due in large part to the expiration of patents for a few important and widely-selling drugs.

NAPM believes that profitability is essential for this fledgling segment of the drug marketplace to continue to be able to offer lower-priced, safe and effective products manufactured under state-of-the art conditions. Some of that profitability also is going to research. As an example, several of the drug products identified by FDA as being potential "Orphan Drugs" are under development by generic firms.

Therefore, NAPM does not oppose the high profits now realized by brand-name firms. It merely notes that generic manufacturers, unlike their brand-name counterparts, are not

seeking rewards for their success in the form of new barriers to competition.

NAPM believes that, rather than correcting an allegedly wrongful situation, patent extension legislation will provide a bonus to an industry that does not need it, at the expense of consumers and our elderly -- and to the exclusion of other industries, none of whom realize the magical 17 years of patent protection. The legislation as proposed is, unfortunately, protectionist and anti-consumer.

As a final note, NAPM quotes the 1981 report on patent extension by the Office of Technology Assessment on the implications of this legislation:

> "Extension will be most beneficial to firms selling high income drugs and will therefore encourage research on drugs with potentially large markets.
>
> "However, it will not increase the attractiveness of research on drugs with smaller markets.
>
> "The bulk of revenues generated by patent extension will go to a relatively small number of firms who have a history of success in particular research areas.
>
> "The successes could increase their dominance in these areas and discourage other firms from conducting similar types of research."

Respectfully submitted,

NATIONAL ASSOCIATION OF
PHARMACEUTICAL MANUFACTURERS

PublicCitizen

Congress Watch • Critical Mass Energy Project • Health Research Group • Litigation Group • Tax Reform Group

July 18, 1983

Dear Representative:

On June 30th Representative Mike Synar introduced H.R. 3502, the Patent Term Restoration Act of 1983. This bill would extend the period of monopoly marketing of brand-name drugs for up to 7 years beyond the current 17 years of patent protection. The bill purports to be needed to correct an inequity in existing patent law. The patent system is intended to reward innovation and then to facilitate competition after patent expiration. Congress Watch supports the present patent system and finds no need for modification. The pharmaceutical industry is thriving under the current system. We urge you to refuse to co-sponsor or otherwise support this anti-consumer measure.

The patent system does not guarantee a 17-year marketing period--it only excludes competitors from profiting from the invention for that period.

The Pharmaceutical Manufacturers Association insists that there must be legislation in order to address what they claim has been a decline in "effective patent life," the period under patent during which the product is sold. While it is not uncommon for the period of drug sales under patent protection to be less than 17 years, pharmaceuticals need no patent extension. A patent is only a right to exclude competitors from selling the invention for up to 17 years, during which the innovator may research, test, develop and exclusively market the product. Because of the years ordinarily needed to bring a product to market, it is rare for a patent holder to receive a full 17 years of sales under patent protection. No guarantees are provided by the patent system that a product will ever be marketable--and any failure to market products for 17 years is not a problem that the patent system is designed to address. Products such as the television and the zipper took over 20 years to get from the drawing boards to the market, much longer than the time it takes drug manufacturers to get a product to the pharmacies.

Drug manufacturers are responsible for most of the delay between patent issuance and drug approval.

The Pharmaceutical Manufacturers Association claims that it takes an average of nine years to get a drug to the pharmacies. However, the FDA approval process took an average of 25 months in 1981 and 23 months in 1982. Drugs identified as important therapeutic advances were reviewed even more rapidly, taking an average of 11 months last year. Much of the lag complained of lies solely within the control of the manufacturers. Drug companies which decide for commercial reasons to delay tests or to abandon development of certain drugs or which submit

inadequate documentation of safety or efficacy, should not expect patent extentions. The Food & Drug Administration is not to blame for alleged reductions of sales time under patent.

Many brand-name drugs have far longer than 17 years of monopoly sales because of physicians' prescribing habits and FDA policy.

Even after the patent expires, many brand-name drugs face little or no competition from generics. This occurs because many physicians, in defiance of recently passed substitution laws, write prescriptions to prevent pharmacists from dispensing inexpensive generic drugs. In addition, the Food and Drug Administration has failed to issue regulations concerning expedited approval of generic versions of drugs marketed after 1962. As a result, approval of the generic version may well take a few years after the patent expiration of the brand-name drug. The effect is an inadvertant grant of several additional years of monopoly sales to the original patent holder.

Patent extension proponents have not provided independently verifiable evidence to buttress their allegation of a decline in pharmaceutical innovation.

The drug companies argue that without patent term extension, the incentives to do research and development of new pharmaceuticals will decline. Unfortunately, they have not provided evidence to support their claim that incentives for innovation have diminished. The fact is that R&D has increased, even when adjusted for inflation. Another measure of innovation, the number of new molecular entities approved by the Food and Drug Administration, also shows no reduction since the 1960s. The number of drug approvals which are considered important therapeutic gains has remained constant for the past 25 years, at about 3 annually.

The drug manufacturers already have more than adequate incentives to conduct R&D.

There are currently numerous and sufficient incentives for innovation in the pharmaceutical industry. Certainly a powerful reason to invest is the enviable 16.9 percent return on investment, second only to the banking industry last year. The 1981 ERTA 25% R&D tax credit also encourages such activities. Estimates of the 1981 tax credit by the National Science Foundation, Division of Policy Research and Analysis put the total at $57 million for the chemical industry and $45 million for the drug industry, 3rd and 4th of all industries benefitting from the credit. There are also tax deductions permitted for most R&D and a special 50% tax credit for research on orphan drugs. Thus it is understandable that Dow and DuPont are diversifying into the pharmaceutical industry. This is hardly an area of declining investment incentives.

H.R. 3592 would increase profits instead of encouraging innovation.

But even if there were a need to encourage R&D in this industry, patent extension legislation is an inapt method. This legislation will not induce innovation which otherwise would not occur. Instead, should this bill pass it would merely increase profits across the board for all new drugs. The Office of Technology Assessment's 1981 report concludes that there is no evidence that additional revenues derived from patent extension would increase the percentage of R&D activity. Indeed, because patent holders would be invulnerable from competition for longer, there is a possibility that innovation would decline because of a lessened need to use ingenuity in order to retain market dominance.

The high cost of prescription drugs will become exorbitant if generic competition is restricted still further.

American consumers cannot afford to give the pharmaceutical industry greater profits merely because the industry would like it. Drug prices currently are rising at about triple the Consumer Price Index. Even now many elderly and ill Americans are paying from 42 to 74 percent more for their prescriptions than they would if their doctors would prescribe generically, according to the FTC.

The arguments in favor of H.R. 3592 sound plausible enough. Many respected organizations including the American Association of Retired Persons, the Washington Post and the New York Times have bought the patent extension proponent's arguments only later to repudiate them. We believe that the bill requires the utmost scrutiny. In the final analysis, this bill amounts to an income transfer from chronically ill and elderly Americans to a few of our most profitable companies. We urge you in the interest of consumers, to refuse to co-sponsor or to otherwise endorse this measure.

Sincerely,

Nancy S Drabble
Nancy Drabble
Director

Janet Hathaway
Janet Hathaway
Staff Attorney

AFSCME®

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August 1, 1983

Honorable Robert Kastenmeier
2232 Rayburn House Office Building
Washington, D.C. 20515

RE: Drug Patent Extension Bill

Dear Mr. Kastenmeier:

I am writing to express the serious doubts of the Wisconsin AFSCME Councils concerning the Drug Patent Extension Bill, also known as H.R. 3502.

Such an extension is unwarranted and will certainly be detrimental to prescription drug users, many of whom are elderly or chronically ill. H.R. 3502 will prevent competition from low-cost generic drugs for as many as seven years beyond the adequately protective 17-year patent term. The result will be to extend the time during which lower-cost alternatives to "brand name" drugs will be unavailable to working people and the poor.

There is no provision in H.R. 3502 which would compel drug manufacturers to use the profits gained from this additional competition-free period to expand research and development of new drugs. In effect, this bill will create a windfall for an already highly profitable industry.

Please use your vote and your position as chairman of the Judiciary Subcommittee on Courts, Civil Liberties, and the Administration of Justice to oppose the Drug Patent Extension Bill. The pharmaceutical industry should not be allowed to increase its profits at the expense of the poor, the sick and the elderly.

Sincerely,

Dennis L. Boyer
Legislative Representative
Wisconsin AFSCME Councils

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY
100 BERGEN STREET / NEWARK, NEW JERSEY 07103

OFFICE OF THE PRESIDENT

August 30, 1983

Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
2137 Rayburn Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Kastenmeier:

The Patent Term Restoration Act, S. 1306 and H.R. 3926 in the 98th Congress, is legislation of great significance not only for the drug and chemical industries of our nation, but also for medical schools throughout the country.

As you know, the 17-year life of a patent is in itself a great incentive for individuals and corporations to invest their talents in discovering and improving pharmaceuticals and the chemical components thereof. Unfortunately, the effective life of the patent is greatly diminished because of the process of governmental review to which each drug is subject. This process, conducted in numerous stages, may last six to ten years, all of which time is charged against the 17-year patent. During this period of testing, neither the manufacturer nor the patent holder realizes a return on investment, and it was precisely this anticipation of profit which stimulated the research and development in the first place.

The University of Medicine and Dentistry of New Jersey does not dispute the need for appropriate examination of all pharmaceuticals available to the public; indeed, we support thorough pre-clinical and human testing of these products. These vital procedures, however, are now conducted at the expense of corporations who regularly invest an average of $70 million in research and development per drug as well as individuals in the forefront of medical research. Many of these individuals are on the faculty of medical schools, which stand to gain significantly from sales of products for which the institutions hold patents.

Although the Senate is expected to act shortly on this legislation, the House of Representatives has as yet shown no disposition to do so. As chairman of the Judiciary subcommittee with jurisdiction in this matter, and as the sponsor of similar legislation in the 97th Congress, you are in an excellent position to promote favorable consideration of the Patent Term Restoration Act in the current congress. I strongly encourage you to do so and will lend whatever support may be helpful to that end.

Medical advancement is tied to progress in pharmaceutical discovery, and the latter is linked to financial incentive. We believe that H.R. 3926 strikes a fair balance between medical progress and the profit motive, and I urge your support of this legislation.

I look forward to hearing from you and hope that you will contact me if I can be of assistance in any way.

Sincerely,

Stanley S. Bergen, Jr., M.D.
President, UMDNJ

Generic Pharmaceutical Industry Association

200 Madison Avenue, Suite 2404
New York, N.Y. 10016
(212) 683-1881

26 July 1983

Mr. David Beier
Committee on the Judiciary
2137 Rayburn House Office Bldg.
Washington, DC 20515

Dear Mr. Beier:

As you suggested, we asked our patent counsel for an analysis of the suggestion that the Patent Commissioner could use his rulemaking authority to extend the effective market life of pharmaceuticals.

The enclosed letter of July 22, 1983 from Alfred B. Engelberg cites several reasons why patent extension by regulation is contrary to the language and intent of the patent statute.

If you would like to discuss this issue further, please feel free to call Mr. Engelberg directly.

Sincerely,

Dee Fensterer
Director

DF/b
Encl.

cc: Alfred B. Engelberg

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July 22, 1983

Mr. William Haddad
General Pharmaceutical Industry
Association
Suite 2405
200 Madison Avenue
New York, New York 10016

Re: Patent Term Extension

Dear Bill:

Enclosed are the relevant pages of the article which appeared in the November, 1982 issue of the Journal of the Patent Office Society relating to the proposal by the Commissioner of Patents to explore the possibility of using his rule-making authority to extend the effective life of drug patents. You may recall the April 25, 1983 issue of the Pink Sheet reports on an exchange between Representative Kastenmeier and Patent Commissioner Mossinghoff on that subject and he was also questioned about it during the recent Senate hearings.

I thoroughly disagree with Commissioner Mossinghoff's suggestion that the enclosed article "was well-researched". In fact, it cites no meaningful authority for the proposition that the life of a patent can be extended by regulation and the idea appears to be contrary to both the language and intent of the patent statute.

I would call your attention to the following points which were completely overlooked by the author of the JPOS article:

1. The patent statute (Title 35, United States Code) compels the Commissioner to examine patent applications and to issue patents if the criteria for patentability are met (35 U.S.C. §131). The statute

also defines specific time periods for that purpose (35 U.S.C. §133). Accordingly, the Commissioner lacks the rule-making authority to refrain from actually examining a patent application to determine if it contains allowable subject matter.

2. 35 U.S.C. §151 contains the following language with respect to the issuance of a patent:

> "If it appears that applicant is entitled to a patent under the law, a written notice of allowance of the application shall be given or mailed to the applicant. The notice shall specify a sum, constituting the issue fee or a portion thereof, which shall be paid within three months thereafter.
>
> Upon payment of this sum the patent shall issue, but if payment is not timely made, the application shall be regarded as abandoned."

Under the foregoing provisions, the Commissioner is compelled to issue a patent within a defined time period if the application contains allowable subject matter. The Commissioner does not have the authority to make rules which contradict the statute.

3. Under 35 U.S.C. §181, the grant of a patent may be withheld when the head of an interested government agency demonstrates that the issuance of the patent might be detrimental to the national security. Since the only current exception to the immediate issuance of an allowable patent is based on a statute (rather than a rule), any subsequent exceptions should also be statutory. Patent Office rules permit limited suspensions of time for acting on patent applications in certain other circumstances but those rules do not contemplate a delay of several years in granting a patent. See 37 C.F.R. 1.103; Manual of Patent Examining Procedure, Section 703.

4. The fundamental public purpose of granting patents is to give the public the benefit of the disclosure contained in the patent. Accordingly, the withholding of a patent application from issuance would

be contrary to the basic legislative intent of the patent law. Indeed, by withholding patents from issue, the Patent Office would be depriving both itself and the public at large of a vital source of "prior art" which would normally be relied upon to prevent the issuance of subsequently filed patent applications for the same subject matter. The author of the JPOS article recognizes this problem and suggests that it can be overcome by a rule which would permit publication of patent applications immediately after allowance but prior to issuance. Such a rule would violate 35 U.S.C. §122 which requires that patent applications be kept in confidence.

5. The proposed regulation by the Commissioner would violate the spirit of the decision In Application of Anthony, 414 F.2d 1383 (C.C.P.A. 1969). In that case, the Patent Office had taken the position that patent applications covering therapeutic compositions could not be granted without proof that the claimed composition met the FDA standards with respect to safety and efficacy. That position was overruled by the highest patent court, The Court of Customs and Patent Appeals (now the C.A.F.C.), on the ground that an invention could be "useful" in the sense of the patent law, even though it might not be commercially saleable under other laws. The Anthony case clearly stands for the proposition that it is not proper for the Patent Office to base its actions on commercial considerations. Indeed, it is well recognized that many thousands of "paper patents", i.e., patents covering ideas which have never been reduced to practice, are granted each year.

6. The proposed patent extension legislation would result in an extension only if NDA approval is actually obtained and then only for a defined period of time. In contrast, the Commissioner of Patents would be granting the extension in advance and for an unlimited period of time. Moreover, the Commissioner obviously lacks the authority to make rules which would force an applicant to make available information to establish that it was acting with due diligence in pursuing FDA approval.

Please let me know if you have any questions concerning any of the foregoing comments.

Cordially,

AMSTER, ROTHSTEIN & ENGELBERG

Alfred B. Engelberg

ABE:mv
Encl.
cc: James Flug, Esq. (w/encls.)

PART THREE: POSSIBILITIES FOR NEW RULEMAKING

Part 1 of this article traced the history of Patent and Trademark Office rulemaking since 1836. Part 2 discussed the scope of the Commissioner's authority to make rules. It showed that the Commissioner's power to make legislative rules under the authority delegated by Congress in 35 U.S.C. 6(a) is very broad. It also showed that the Commissioner can issue interpretative rules.

The present, final part of this article explains several possibilities for future rulemaking by the PTO. Many of these come from proposals for patent legislation. Policymakers sometimes were incorrect in assuming legislation was necessary to implement the proposals. Although recently enacted legislation has preempted certain opportunities for rulemaking, a large number of opportunities still exist.

The rules discussed in this part are given as examples that are within the scope of the Commissioner's authority. No position is taken on whether it would be desirable to promulgate them.

I. Patent Term "Restoration"

The 97th Congress came close to passing legislation called the "Patent Term Restoration Act."[292] That legislation would have extended the length of the 17-year patent term to compensate patent owners for delays in obtaining approval from Federal regulatory agencies to market their inventions. The legislation would have provided extensions of patents for food additives, pharmaceuticals, medical devices and chemicals, upon a showing that regulatory delays had occurred.

Many patent owners encounter delays of several years in obtaining approval from agencies such as the Environ-

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292 S.255, 97th Congress, 1st Sess. (1981); H.R. 6444, 97th Congress, 2d Sess. (1982).

mental Protection Agency and the Food and Drug Administration.[293] Most people have assumed patent owners cannot be compensated for these regulatory delays without an act of Congress. In fact, the Commissioner possesses authority to provide relief through a rule that would defer the starting dates of the 17-year patent terms until patent owners obtain regulatory approval.

Nothing in the patent code says the Commissioner must issue a patent immediately after completing the examination and determining claims are allowable.[294] PTO procedures already provide for deferring the issuance of patents in a few circumstances.[294a]

A rule deferring the starting dates of patents to compensate for regulatory delays would be within the Commissioner's rulemaking power under 35 U.S.C. 6 because the timing of issuance of a patent is a part of "the conduct of proceedings in the Patent and Trademark Office." A reviewing court would be persuaded that deferring issuance to await regulatory clearance is reasonably related to the purposes of the law the PTO administers.[295] The patent code envisions that inventors will have a 17-year period of exclusivity. A rule deferring the issuance of the patent in order to give 17 years of effective protection would be viewed as consistent with the spirit as well as the letter of the law. The failure of the 97th Congress to enact patent term restoration legislation would not be taken to mean the Commissioner lacks rulemaking authority to accomplish a similar result.[296]

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293 U.S. Department of Commerce, *Advisory Committee on Industrial Innovation, Final Report*, Sept. 1979, p. 157, Proposal VI (advisory committee established as part of President's Domestic Policy Review of Industrial Innovation). *See generally* R.J. Anderson, Jr., "Patent Term Restoration", 8 APLA Quarterly Journal 340 (1980).

294 *But cf.* Sampson v. Banner, 466 F.Supp. 965, 201 USPQ 15 (D.D.C. 1978). There the court held, in an unusual fact situation, that when an inventor demanded issuance after the claims had been declared allowable, issuance could not be delayed. However, the procedure discussed in the text would delay issuance only at the applicant's request.

294a Manual of Patent Examining Procedure, Sections 1002.02(b) and 1308. *See* rule 1.313.

295 A "reasonably related" test was used by the Supreme Court in Mourning v. Family Publications Services, Inc., 411 U.S. 356, 369 (1973). See text accompanying note 189 *supra*.

The fact that the Commissioner has not asserted authority to make such a rule before does not mean he lacks authority.[297]

Probably the biggest drawback to the rulemaking approach, in the eyes of the proponents of the patent term restoration legislation, would be that rulemaking cannot provide any extension of patents already issued. Chairman Kastenmeier's bill in the House of Representatives in 1982, however, did not affect patents already issued either.[298] If the supporters of the legislation are willing to settle for extending the terms only of patents issued in the future, the rulemaking approach might be attractive.

In drafting rules to establish a system for deferring the issuance of patents, several policy considerations would have to be addressed. Most important, the technological information in the patent application would have to be disseminated without delay. This could be done by providing that the application would be published by the Office immediately after the examination was completed, even though the issuance of the patent would be deferred.[299] Several other details would have to worked out.[300]

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297 *See* text accompanying note 205 *supra*.

298 H.R. 6444, note 292 *supra*.

299 The entire patent disclosure could be published again when the patent issued. As a less expensive alternative, only a brief notice might be published, similar in format to certificates of correction published by the PTO under 35 U.S.C 254 and 255. The notice would be attached to the patent application published earlier. The published patent application could carry a seven-digit identifying number just as if it were a patent, but the document would be labeled "issuance deferred". An automated system could be designed to keep track of patents with deferred issuance. The PTO will be designing an automated system to keep track of patent maintenance fees that will be payable in a few years under Public Laws 96-517 and 97-247. The same system easily could provide information on which of the applications whose issuance was initially deferred had issued, and the dates of issuance.

300 A fee would need to be charged for deferring issuance, to cover the extra processing cost. Authority for such a fee exists under 35 U.S.C. 41(d), as amended. The benefits of the delayed term should not extend to generic claims which cover a group of related compounds only one of which is the product undergoing regulatory review. This problem might be overcome by allowing the applicant to file a divisional application. The rule would need to avoid compensating the applicant for an evaluation period prior to the regulatory review. *See* R.J. Anderson, Jr., note 293 *supra*. This might be accomplished by requiring the applicant to file a terminal disclaimer giving up the time period by which the delay in issuance exceeded the period of regulatory review. The rule should discourage dilatory action on the part of the patent applicant in getting the product tested and approved

II. Merging The Board Of Appeals And The Board Of Patent Interferences

S. 2255 and other patent reform bills proposed to merge the Board of Appeals and the Board of Patent Interferences into a single board with jurisdiction over both ex parte appeals from patent examiners and inter partes patent interference proceedings.[301] In fact, legislation is not needed to merge the two patent boards. Section 7 of the patent code contains specific provisions governing the makeup of the Board of Appeals. Section 135, however, does not mandate any particular structure for the Board of Patent Interferences. It does not even require that a Board of Patent Interferences exist as a discrete organizational unit.[302]

The enactment of Public Law 97-247 in 1982 paves the way for merging the boards, because it eliminates the limit of 15 permanent members of the Board of Appeals.[303] The Commissioner now can appoint as many permanent members of the Board of Appeals as he chooses, and assign panels of Board of Appeals members to act as a board of patent interferences pursuant to 35 U.S.C. 135 when they are deciding interference matters.[304]

The principal benefit that has been cited for combining the boards is that it would avoid piecemeal consideration of issues of patentability and priority of invention.[305] Merging

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for marketing. This might be done by imposing a limit on the amount of time issuance could be deferred.

301 S. 2255, 94th Cong., 2d Sess., §§5(c) (3), 105 and 136. That bill called the combined board the Board of Examiners-In-Chief. The Board would have consisted of up to 60 Examiners-In-Chief.

302 Section 135 states, "the question of priority of invention shall be determined by a board of patent interferences (consisting of three examiners of interferences) whose decision, if adverse to the claim of an applicant, shall constitute the final refusal by the Patent and Trademark Office of the claims involved. . . ."

303 Public Law 97-247 (1982). Section 4, amending 35 U.S.C. 3(a)

304 The merger of the two boards could be accomplished by administrative fiat of the Commissioner, without a rule change, by abolishing the Board of Patent Interferences as a separate organizational unit and assigning its duties to an expanded Board of Appeals. The combined board might be called the Board of Appeals, the Board of Examiners-In-Chief, the Board of Patent Appeals and Interferences, or the Patent Trial and Appeal Board. In order to integrate interference proceedings and patentability appeals smoothly, however, a number of existing rules would need to be redrafted.

305 In some cases an issue of patentability has been appealed to the Board of Appeals and subsequently the same issue in the context of an interference pro-

PATENT RESTORATION VIA *REGULATION* UNDER REVIEW BY PATENT OFFICE, HOUSE COURTS SUBCMTE. TOLD; REP. KASTENMEIER TAKING "WAIT AND SEE" APPROACH TO LEGISLATION

The Office of Patents & Trademarks is considering whether to extend the effective life of patents by *regulation,* Patents Commissioner Gerald Mossinghoff told Rep. Kastenmeier's (D-Wis.) House Judiciary/Courts Subcmte. at an April 20 oversight hearing.

During the hearing, Kastenmeier referred to an article in the November issue of the *Journal of the Patent Office Society,* which asserts that the patent commissioner has the authority to defer the starting date of patent life until after regulatory approval for a product is granted. "Is this viable, in your view?" Kastenmeier asked. Mossinghoff replied: "We are considering it...That article was well-researched. We have not reached a conclusion whether that would or would not be possible — although I tend to be persuaded by the arguments concerning the breadth of the commissioner's power."

> Mossinghoff added that his prime concern is the "delay of new technology," saying: "If by delaying the starting date of a patent, we were to delay the disclosure of new technologies, I probably would not be favorably disposed towards it."

The subcmte. chairman pressed Mossinghoff on the point, saying that "even if, theoretically, you were correct, wouldn't you agree that a change in policy of this magnitude ought to be a statutory change?" Mossinghoff replied: "We certainly have to take that into account."

The article referred to by Kastenmeier and Mossinghoff is a treatise on the legislative history of the Patent Office and the traditional powers of the commissioner. Author Herbert Walmsley, a former patent office official who is now the exec director of the Intellectual Property Owners Assn., wrote, in part: "For instance, the commissioner, by rule if he wished, could institute a system for the deferred examination of patent applications...[and could establish] a rule to extend the expiration dates of patents. A rule could establish a proposal similar to the one proposed in the 97th Congress in the patent term restoration bill."

Patent Office Strongly Supports Some Form Of Patent Restoration, Mossinghoff Says

Kastenmeier, who shepherded the patent restoration bill through the full Judiciary Cmte. last summer only to see it die in the House Rules Cmte. as time ran out in the last Congress, is taking a "wait and see" attitude on the legislation this year. In response to an inquiry from "The Pink Sheet," Kastenmeier said he has "not made any decision" whether to renew the effort. "I'm inclined to wait and see how the legislation fares in the Senate before deciding" whether to proceed in the House, he said. Sen. Mathias (R-Md.) has scheduled Senate hearings on patent restoration for June 22.

> Kastenmeier also suggested that the enactment of Rep. Waxman's (D-Calif.) Orphan Drug Act "may very well have slowed some of the drive behind patent restoration." He elaborated: "A great concern of the pharmaceuticals [industry] has been in R&D costs, and I think this bill may help out alot in this area."

In prepared testimony before the subcmte., Mossinghoff reiterated his strong support for some form of patent restoration, saying that "when the present systems of necessary regulatory screening are overlaid with the fixed 17-year patent term, the results discriminate against very important segments of our industry." The patent commissioner also told Kastenmeier that his office is "seeing progress" in its efforts to reduce patent application review time from an average of 27 months to 18 months.

Generic Pharmaceutical Industry Association

200 Madison Avenue, Suite 2404
New York, N.Y. 10016
(212) 683-1881

12 July 1983

Mr. David Beier
Judiciary Committee
2137 Rayburn House Office Bldg.
Washington, DC 20515

Dear Mr. Beier:

Per our discussion last Thursday, enclosed are:

(1) Supreme Court decision and transcript of Inwood v. Ives.

(2) Background and court decisions on FDA's Paper NDA Policy.

(3) GPIA analysis entitled "Patent Extension: An Expensive Solution to a Nonexistent Problem."

(4) Analysis of patent law and practice by GPIA counsel, Alfred B. Engelberg.

(5) The Eisman/Wardell study circulated last year. Note that "effective patent life" is measured from the first patent issued and that the authors conclude that 40% of decline in EPL is caused by increased time between patent filing and clinical testing and by a shorter pendency period in the patent office.

(6) New York Times report (2/4/82) of the OTA analysis for Gore showing that company delays, rather than the government regulatory process causes loss of monopoly life.

(7) Wall Street Journal article (4/25/83) quoting a former Searle officer that "the industry has to take a good deal of the rap for drug lag, because many drug applications are incompetent, poorly done and don't prove anything."

(8) American Home Products memorandum distributed to Congress in September 1982 indicating the strategy to amend the prospective Kastenmeier bill in conference to make it "consistent" with the retroactive Senate bill.

(9) Letters from consumer groups, unions, seniors and others urging defeat of drug patent extension.

(10) Recent articles on the sharp increase in R&D spending and the future for drug innovation.

Jim White of Gore's staff indicated that he would send you the hearing record, OTA's regression analysis, and Gore's 1981 letter request to the PMA for patent and FDA filing data. I am sure that Waxman's staffer, Bill Corr, who is thoroughly familiar with this issue, would also be glad to provide any additional information you might want.

Please don't hesitate to let us know--Bill, Jim or myself--whenever you have further questions.

Sincerely,

Dee Fensterer
Director

DF/b
Encl.

cc: Jim Flug

STANFORD, CALIFORNIA 94305

OFFICE OF THE PRESIDENT

March 9, 1982

James F. Flug, Esquire
Law Offices of Lobel, Novins & Lamont
1523 L Street, N.W.
Washington, D.C. 20005

Dear Mr. Flug:

You asked for my views on the Patent Extension Bill; I am happy to provide them as follows, with the understanding that you will communicate them to others in unchanged form, and only in their entirety.

I think that the proposed Patent Extension Bill is desirable in principle; indeed, when I was Commissioner of the Food and Drug Administration we argued, in connection with the Drug Regulation Reform Act of 1978, that changes in the patent laws should be considered as an accompaniment to proposed changes in the new drug approval process.

I believe, however, that the Bill should be passed only if the following conditions are met:

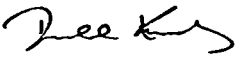
1. The amount of the extension should return to innovators only that protected patent time taken away by the government regulatory process. Even in the absence of the present new drug approval process, patentees would require substantial time to develop, test, and otherwise prepare for the widespread commercial sale of a new product. These steps are meant to occur within the patent period, and should not be deducted from it. Moreover, even when government requirements are being met, delays are often the responsibility of the manufacturer and not the Food and Drug Administration. Accordingly, extensions should only reflect time actually occupied by the government during the approval process.

2. Other barriers to vigorous post-patent competition should be removed. It was our intention, in proposing modifications of the new drug approval process when I was Commissioner, that extensions of the period of market exclusivity designed to compensate for government "regulatory time" would be

balanced by statutory changes to decrease certain barriers to entry now enjoyed by innovators in the post-patent marketing period. In considering patent extension legislation, therefore, Congress should also make clear that appearance is not protected, and that there are appropriate encouragements for the use of the non-proprietary name.

3. Finally, extensions should only be granted if there are changes in the new drug approval process that eliminate duplicate testing and other requirements that amount to surrogate barriers to entry against competitive products during the post-marketing period.

Sincerely yours,



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July 11, 1984

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil Liberties
and the Administration of Justice
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Re: H.R. 3605 - Drug Price Competition and
Patent Term Restoration Act of 1984

Dear Mr. Chairman:

I am patent counsel to the Generic Pharmeceutical Industry Association (GPIA) and am submitting this letter in response to the June 27, 1984 testimony of Gerald J. Mossinghoff, Assistant Secretary and Commissioner of Patents and Trademarks, on HR 3605.

In his testimony, the Commissioner suggested sweeping changes in the patent term extension provisions of the bill which would clearly upset the delicate balance on which the compromise embodied in H.R. 3605 is based. The Commissioner claims that these changes are necessary because HR 3605, is too complicated and would create an undue administrative burden on the Patent Office; and that the eligibility requirements for patent extension are too arbitrary and undermine principles of patent law which have existed for over 200 years. None of these arguments can withstand scrutiny.

At the hearing, the Commissioner used a chart of frightening dimensions to illustrate his allegation that HR 3605 would impose an inordinate administrative burden on the Patent Office. The appearance of this chart was so intimidating that it seemed on its face to prove the Commissioner's point and there was no opportunity at the hearing to examine its actual content. In fact, the chart is nothing more than a piece of advocacy which contains an overly complicated "computer age" breakdown of the provisions of HR 3605. It is not representative of the manner in which

applications for extensions would actually be processed despite its title. In actual practice, the Patent Office would most certainly require the use of a standardized form of Application for Extension. Similar forms are a normal part of current Patent Office practice. Such a form would obligate the patent holder to provide the necessary information to establish both the eligibility for and duration of a patent extension. I have prepared a model for such a form and it is attached to this letter. This simple, one page form contains the essence of the Commissioner's useless chart in a practical and usable manner and demonstrates that the "administrative burden" amounts to a few minutes of clerical time for each extension application.

HR 3605, expressly permits the Commissioner to rely upon representations made by the applicant for extension in determining whether or not the applicant meets the eligibility requirements for an extension. The proposed form takes advantage of that provision in a manner which is analogous to the manner in which the Commissioner now relies upon representations of an applicant for an original patent with respect to such matters as prior public use, prior publication or prior sale of an invention. Full disclosure by the applicant for an extension is assured by criminal penalties (18 U.S.C. Section 1001) as well as the possible loss of any patent extension. In addition, HR 3605 provides that the validity of an extension can be challenged in any patent infringement litigation just as the validity of an issued patent may now be challenged.

In view of the foregoing, it is hard to escape the conclusion that the Commissioner has unfairly characterized the administrative burden actually imposed by HR 3605.

HR 3605 would not make every patent eligible for extension and would limit the length of extensions. The Commissioner claims that these limitations are arbitrary, unduly restrictive and violate principles of patent law which are as old as the patent system. This is a meaningless and unfair criticism since the idea of patent extension itself is a radical departure from the basic principles of the patent system. As the Commissioner certainly knows, the issuance of a patent carries with it only the right to exclude others from the practice of an invention and was never intended to provide any guaranteed period of commercial exploitation to the patent owner. In fact, the patent owner's ability to derive profit from a patented invention has always depended on a variety of factors which are not relevant to the date on which a patent is granted. These include federal and state laws which might restrict or prohibit the use of a patented invention on safety, moral or

other grounds; the existence of an earlier-issued blocking patent; the time and money needed to commercialize an invention; the existence of a market; etc.

About 20 years ago, when the safety and efficacy requirements of the current food and drug law were first enacted, the Commissioner of Patents took the position that a patent covering a drug should not be granted unless and until the FDA had ruled that the drug was safe and efficacious. At that time, the highest patent court ruled to the contrary based, in part, on the argument made by research intensive drug companies that the issuance of patents for non-commercialized products would spur the investment necessary to develop these products. See Application of Anthony 414 F.2d 1383 (CCPA 1969). The issuance of a patent on a drug product at an embryonic stage of its development, is inconsistent with the argument that a patent should guarantee its owner 17 years of commercial exploitation. Yet, that has been the practice in recent years and it accounts for far more of the loss in commercial patent life than regulatory delay.

It is well-known that the impetus for patent term extension legislation came from the research intensive drug companies through the lobbying activities of the Pharmaceutical Manufacturers Association. PMA produced a mass of questionable statistics which were designed to support a claim that commercial patent life had shrunk to as low as 7 or 8 years. It heavily relied on that data to argue for legislation which would have extended the life of every patent for up to 7 years. In the course of legislative hearings on earlier versions of patent extension, it became apparent that the PMA statistics were misleading and that pre-marketing regulatory review was only one of many factors which had an effect on the length of a commerical monopoly. A large number of other significant factors, all of which are largely under the discretion and control of the patent owner, were identified. These factors include when a patent application is filed in relation to the actual state of development of the invention; how long the patent application remains pending in the Patent Office; the scope of the patent in relation to the commercial product which it seeks to dominate; the number and type of patents which may ultimately be granted to cover different aspects of the commercial development; the time at which clinical investigations are commenced in relation to the patent application and issue date; and the pace of development.

At the time HR 6444 was under active consideration by the House, PMA was still managing to successfully resist Congressman Gore's demand for the production of sufficient information with respect to NDA application and approval dates and the identification of all relevant patents so that an independent determination could be made with respect to the extent of the alleged problem of shrinking patent life.

Congressman Synar was finally able to pry that data loose from PMA in the latter part of 1983. It revealed that the arguments for shrinking patent life were based on the first patent to issue which covered a new chemical entity that had never before been used as a drug. When full consideration was given to the existence of other (later) patents and to the regulatory delays encountered by generic drug makers in bringing products to the market, the effective commercial monopoly life for the 50 top selling drugs turned out to be 15.5 years and for the 100 top selling drugs it was almost 14 years. Although the Commissioner continues to deny the existence of "evergreening", the data presented to Congressman Synar and analyzed by Congressman Waxman's staff established that there are numerous instances in which more than one patent must expire before there can be any competition. The most typical situation involves an early issued product patent followed by a later issued therapeutic use patent claiming the only FDA approved use.

HR 3605 incorporates the knowledge gleaned from the foregoing data and is therefore more restrictive than earlier versions of patent term extension legislation such as S. 255 and H.R. 6444. More specifically, the bill is based on the simple principle that only the earliest issued patent which either claims or fully discloses an approved drug product can be extended one time. That extension is for a maximum period of five years or for 14 years following the drug approval date whichever is shorter. These rules do not, prevent the research-intensive drug companies from continuing to apply for large numbers of related patents or to control the filing or issue dates of those patents in relation to the commercial development. Rather, they provide a reasonable period of extension for the only problem which the PMA companies have even alleged to exist -- shortened patent life for the first patent covering a new chemical entity -- while discouraging the use of patent extensions to slow down new developments or as a new tool for manipulating the patent system so as to unfairly lengthen patent monopolies.

The ultimate test of the fairness of the patent term extension provisions of HR 3605 is the endorsement of the bill by a 2 to 1 majority of PMA members. If PMA did not believe that the bill fairly addresses and solves the problem of shortened patent life it would not have endorsed this compromise. In view of that fact, it simply makes no sense for the Commissioner to attack those provisions as being too arbitrary or restrictive or to argue in favor of a more liberal patent extension policy.

The Commissioner's lack of appreciation for the problem which HR 3605 addresses and equitably solves is highlighted by his testimony with respect to the Bolar decision. GPIA and PMA were able to reach a compromise only because patent owners were assured of a longer commercial

monopoly period and generic drug manufacturers were assured of obtaining the necessary approval to engage in competition immediately after that well-defined monopoly period ended. The parties recognized that it was essential to this compromise that generic companies engage in the necessary steps required to obtain ANDA approval prior to the patent expiration date so that they could commence marketing immediately after the patent expired rather than 2 or 3 years later. The agreement to accomplish that result was reached without controversy because it was consistent with common industry practice extending back over many years and therefore did not infringe on any vested economic interest of drug patent owners. The Commissioner's disregard for the fairness of the compromise is demonstrated by the fact that he is anxious to provide patent owners with relief (in the form of patent extension) for the time which they lose in getting to market because of regulatory delay but is unwilling to give generic companies the same relief from the same problem at the end of the patent monopoly period.

Finally, it should be noted that throughout the course of the many hearings which have been held on the subject of patent term extension, the Commissioner has not come forward with any data whatsoever which would suggest that the commercial life of patented inventions in any field remotely approaches 17 years; that the commercial life of drug patents is materially shorter than the commercial life of patents in other fields; or that extending patent life in any field for any reason would stimulate investment in research or development. Rather, the Commissioner has consistently supported whatever proposal would lead to longer patents without regard for any demonstrated need for such a change in the patent law or the impact of such a change on the competitive environment or on consumers. Such an institutional bias is not surprising but it is disappointing that the Patent Office is unable to make a more constructive contribution to this compromise effort.

Respectfully submitted,

AMSTER, ROTHSTEIN & ENGELBERG

Alfred B. Engelberg

ABE:llk

APPLICATION FOR PATENT EXTENSION
(DRUG PRODUCT OR USE PATENT)

Extension Application Date: _____

Patent No. _____ Issue Date: _____ Expiration Date: _____

Patent Holder: _____ Assignment Recorded: Reel _____ Frame _____

NDA Approval Date: _____ NDA Submission Date: _____ IND Filing Date: _____

Active Ingredient(s) in Approved Product: _____

_____

Approved Uses: _____

Patent Claims Covering Approved Product or Use(s): _____

_____ declares that (s)he is the _____ [title] of the above-identified patent holder and is authorized to submit this application for extension of the above-identified patent pursuant to 35 U.S.C. §156. A copy of the patent for which extension is sought is enclosed.

I hereby declare the following with respect to this application:

1. The patent for which this extension is sought claims a product (method of using a product) which was subject to a regulatory review period under the Food, Drug and Cosmetic Act prior to its commercial marketing. The relevant dates of that regulatory review period are set forth above.

2. The patent for which this extension is sought has never been extended.

3. The patent for which this extension is sought does not claim a product (method of using a product) which received permission for commercial marketing under the Food, Drug and Cosmetic Act before the NDA Approval Date set forth above.

4. The active ingredient(s) in the approved product, including any salt or ester thereof, as a single entity or in combination with another active ingredient has never received permission for commercial marketing under the Food, Drug and Cosmetic Act before the NDA Approval Date set forth above.

5. The following patents have been identified in the application under Section 505(b) of the Food, Drug and Cosmetic Act for the above-identified approved product as patents for which a claim of patent infringement might reasonably be asserted in the event of the unlicensed manufacture, use or sale of the approved product:

   _____
   _____
   _____

6a. To the best of my knowledge, the approved product (method of using the product) is not claimed in another patent having an earlier issuance date or which was previously extended.

6b. The approved product is claimed in U.S. Patent No. _____ but it is not identically disclosed or described therein. U.S. Patent No. _____ has never been and will never be held by the patent holder herein and the patent for which extension is sought has never been and will never be held by the holder of U.S. Patent No. _____.

7. To the best of my knowledge, the approved product and the use approved for the approved product are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended.

An extension of _____ years, _____ months and _____ days until _____ [Date] is sought based upon the following calculation:

1/2 (NDA Submission Date - IND Filing Date)	=	_____yrs. _____mos. _____days
(NDA Approval Date - NDA Submission Date)	=	_____yrs. _____mos. _____days
Total	=	_____yrs. _____mos. _____days

The extension does not exceed five years and will not extend the expiration date of the patent for more than fourteen years from the NDA Approval Date.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent extension issued thereon.

_____
APPLICANT'S SIGNATURE DATE

_____
POST OFFICE ADDRESS

_____

ATTACHMENT

GENERIC DRUG TESTING AND APPROVAL
PRIOR TO EXPIRATION OF PATENT ON BRAND NAME DRUG

BRAND NAME DRUG (Generic Drug)	PIONEER FIRM Generic Firm	DOSE	APPLICATION SUBMISSION with test data	DATE OF APPROVAL	PATENT EXP.
LIBRIUH (Chlordi-azepoxide HCL)	ROCHE	5 mg	12/59	4/60	7/76
		10 mg	12/59	2/60	
		25 mg	12/59	5/60	
	Barr	10 mg	7/72	6/76	
	Zenith	5-10 mg	5/73	3/75	
	Parke Davis	5-10 mg	12/74	8/76	
	Mylan	10 mg	12/74	3/76	
DARVON (Propoxyphene HCL)	LILLY	32-65 mg	3/57	8/57	12/72
	Zenith		1/71	11/71	
	Leuerle		7/71	9/72	
	Danoury		2/72	8/72	
	Roxane		6/72	8/73	
	Cord		7/72	10/72	
	Bolar		7/72	12/72	
ORANASE (Tolbutamide)	UPJOHN		8/56	5/57	1/78
	Warner Lambert		9/77	11/79	
	Mylan		6/78	4/79	
	Chelsea		10/77	1/79	
	SKF		11/77	8/79	
	Cord		4/78	6/80	
	Zenith		7/79	3/80	
ALDACTAZIDE (Hydrochloro-thazide)	SEARLE		9/60	9/62	12/78
	Bolar		7/77	2/79	
	Chelsea		8/77	4/81	
	Mylan		7/78	8/79	
	Cord		1/79	7/80	
	Zenith		4/79	5/80	
	Darr		2/80	4/81	

HYGROTON (Clorthaliuone)	USV	100 mg	1/60	4/60	9/79
		50 mg	1/60	7/67	
		25 mg	12/77	9/79	
	Mylan	50 mg	1/79	2/81	
		25 mg	11/79	2/81	
	Bolar	25 mg	6/79	3/81	
		50 mg	5/79	3/81	
	Zenith	50 mg	10/79	4/81	
	Barr	25-50 mg	3/80	3/81	
PERSANTINE (Dipyridamole)	BOEHRINGER-INGELHEIM	25 mg	4/61	12/61	4/79
	Pharmadine		1/79	9/79	
	Preono		2/79	10/79	
	Cord		3/79	8/80	
	Bolar		4/79	9/79	
	Zenith		4/79	9/79	
	Chelsea		6/79	9/79	
	Bar		7/79	9/79	
NELLARILL (Thioridazine)	SANDOZ	10-25 mg	12/58	5/59	3/83
		100-150 mg			
		50 mg	12/58	6/70	
		200 mg	12/58	5/61	
	Mylan	10-25-50 mg	6/82	3/83	
	Cord	10-25-50 mg	9/82	8/83	
	Zenith	50 mg	11/82	4/83	
DIABINASE (Chlorpropanide)	PFIZER		8/58	10/58	10/84
	Premo		3/75	7/80	
	Chelsea		11/79	10/80	
	Pharmadine		2/80	11/80	
	Zenith		6/80	6/81	
	Par		10/82	2/84	
VIBRAMYCIN (doxycyline)	PFIZER	50 mg	6/66	12/67	8/82
		100 mg	6/66	8/68	
	Rachelle		2/73	7/73	
	Chelsea		8/78	8/81	
	Danbury		12/76	2/77	
	Lemmon		6/79	12/79	
	Barr		9/82	1/83	
	Mylan		10/81	3/82	
ALDOMET (methyldopa)	MERCK	125 mg	12/73	1/75	9/84
		250 mg	2/62	12/62	
	Cord	125 mg	1/83	6/84	
		250 mg	1/83	6/84	

AMSTER, ROTHSTEIN & ENGELBERG

MEMORANDUM

SECTION 202 OF H.R. 3605 IS NOT UNCONSTITUTIONAL

Section 202 of H.R. 3605, in pertinent part, reads as follows:

> It shall not be an act of infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs.

The purpose of the foregoing provision is to permit a generic drug manufacturer to engage in the limited experimental activities which are necessary to obtain FDA pre-marketing approval before a patent expires so that actual competition between the generic drug and the original drug can begin immediately after the patent covering the original drug expires. Section 202 does not authorize any activity which would deprive the patent owner of the sale of a single tablet during the life of a valid patent. In fact, the limited testing activity required to obtain FDA approval of a generic drug would not normally result in the use of even a single generic tablet for its therapeutic purpose during the life of a valid patent.

On January 27, 1984, Professor Norman Dorsen, testifying on behalf of a small group of dissident members of PMA, argued that Section 202 of H.R. 3605 violates the Fifth Amendment of the Constitution because it involves a "taking" of private property without just compensation. Professor Dorsen contends that patents are a form of property; that the right to exclusive use of a patented invention is an integral part of that property right; that Section

202, in overturning the decision in Roche v. Bolar, takes away part of that property right from the patent owner; and that this "taking" is an unconstitutional taking of property in violation of the Fifth Amendment. In order to arrive at this conclusion, Professor Dorsen is forced to stretch both the facts and law well beyond any reasonable breaking point.

No one disputes that patents are property, but a serious dispute does exist as to whether Congress ever vested a patent owner with a property right of such dimensions that it would prevent the experimental activity which Section 202 would now expressly permit. The Bolar decision is not, as Professor Dorsen would have us believe, an obvious reaffirmation of a 200-year old principle of patent law. Rather, it is the latest in a long line of case-by-case decisions by the courts which reaffirm that not every literal "use" of a patented invention constitutes an infringing "use" under Section 271 of the patent laws. Indeed, in the Bolar case itself, the Federal Circuit stated:

> Because Congress has never defined "use" its meaning has become a matter of judicial interpretation. Although few cases discuss the question of whether a particular use constitutes an infringing use of a patented invention, they nevertheless convincingly lead to the conclusion that the word "use" in Section 271(a) has never been taken to its utmost possible scope. (Emphasis added.)

Until the Bolar decision, the judicial construction of the term "use" has consistently upheld the public's right to "use" a patented invention for purposes which do not distrub a patent owner's economic enjoyment of the exclusive privileges while variously characterizing such non-infringing "uses," as de minimus, experi-

mental, outside the scope of the patent or in the public interest. Those interpretations are consistent with the Supreme Court's more practical definition of the patent property right as the "right to be free from competition in the practice of the invention." Mercoid Corp. v. Mid Continent Investment Co., 20 U.S. 661, 665 (1944).*

The totally unsettled nature of Professor Dorsen's alleged "property right" which, for the first time, was found to exist in the Bolar decision, is highlighted by several other significant factors as follows:

1. The lower court in Bolar found that Bolar's experimental activity was not an infringement and stated as follows (Memorandum and Order of October 11, 1983):

> . . . the Court cannot find a basis for holding that Bolar's limited experimental use of flurazepam HCL would constitute infringement. First, Bolar realizes no benefit during the term of the patent; its activities are in no way connected with current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the Patent Law. This Court will not act to protect the right or benefit that is without legal basis. Third, Roche can point to no substantial harm it will suffer from Bolar's FDA studies before the patent expires. Bolar's threatened activity is at best de minimus and will not support an action for infringement.

* The "experimental use" exception to patent infringement is closely analogous to the "fair use" doctrine of the copyright law which has recently received much attention from both Congress and the Courts in the Betamax home tape recording controversy. As noted by the Supreme Court in the Betamax case, the economic harm to the copyright owner is a paramount issue in determining whether a particular use is "fair" or "infringing."

2. The Bolar decision was the first of its kind relating to the status of the "experimental use" exception to patent infringement in the context of FDA testing.* No prior attempt had ever been made by a drug patent owner to prevent a generic company from engaging in pre-marketing tests required by the FDA before a patent expired despite the fact that such testing was a common and well-known practice in the drug industry.

3. In early 1984, the PMA Executive Board, including most of those companies which now oppose Section 202 on constitutional grounds, approved Congressman Waxman's proposal to incorporate Section 202 into H.R. 3605. At that time no one suggested that this was an unconstitutional "taking" of a settled or valuable property right. Indeed, such a suggestion would have been dismissed as ludicrous in view of past industry practice and the lower court decision in the Bolar case which had been rendered shortly before Congressman Waxman's proposal. Congressman Waxman obviously recognized that the Bolar litigation might drag on for years and, depending on its ultimate outcome, could upset the balance between longer patent life and faster generic drug approvals. Section 202 was designed to eliminate that possibility so that agreement could be reached on the overall compromise embodied in H.R. 3605 regardless of the Bolar result.

* About a year earlier in Pfizer Inc. v. International Rectifier Corp., 217 U.S.P.Q. 157 (C.D. Cal. 1982), a District Court had found that activities relating to obtaining FDA premarketing approval did not constitute an experimental use under the patent law. However, the defendant had previously engaged in commercial infringement of the same patent and was in contempt of a Court Order for engaging in any activity which violated the patent. The Pfizer case was disregarded by the Bolar Federal Circuit Court because of its unusual fact situation.

Professor Dorsen's hypothesis that an unconstitutional "taking" has occurred is critically dependent on the presumption that the alleged "property right" was so well established even prior to the Bolar decision that drug patent owners made their investment decisions based on a belief in its existence. That hypothesis not only ignores the facts which establish that the alleged right has never been enforced but is also based on a literal construction of the word "use" in Section 271 of the patent law -- a "permissible scope" of the word "use" which was even rejected in Bolar. Professor Dorsen demonstrates a significant unfamiliarity with fundamental principles of patent law in seeking to elevate the controversial and unprecedented decision in Bolar into an inalienable property right.

Ironically, if the Supreme Court, which has not yet ruled on the issue raised by the Bolar decision, agrees with the District Court decision in Bolar, Professor Dorsen's constitutionally inalienable "property right" would vanish just as quickly as it came into being. But, he most certainly would allow the courts such a free hand in construing the legislative intent of the patent laws without regard to whether such constructions had an economic impact on existing property rights. It makes no sense that Congress cannot express its actual intent on the same matter matter without facing a choice between compensation to patent owners or a 17-year delay in making its intent effective. The Constitution vested Congress, not the courts, with the exclusive power to establish the scope of the patent grant. If Professor Dorsen's view of the relative roles of Congress and the courts was correct, Congress would be rendered essentially powerless to clarify existing legislation and the

courts, for practical purposes, would control the right to amend the patent statute. Even the Bolar court disagrees with this view of the balance of power. In Bolar, the Federal Circuit Court of Appeals noted the pendency of H.R. 3605 and stated:

> It is the role of Congress to maximize public welfare through legislation. Congress is well aware of the economic and societal problems which the parties debate here, and has before it legislation with respect to these issues. [Citations omitted.] No matter how persuasive the policy arguments are for or against these proposed bills, this court is not the proper forum in which to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation." (Emphasis added.)

Professor Dorsen has correctly noted that the recent decision of the United States Supreme Court in Ruckelshaus v. Monsanto Co. reaffirms that (1) economic impact and (2) interference with reasonable investment-backed expectations are the two most important factors in evaluating whether or not a "taking" has occurred as a result of government action. However, he ignores the Supreme Court's express recognition that the determination of whether a "taking" has occurred in a particular case is an essentially "ad hoc, factual" inquiry. Instead, he demonstrates a complete misunderstanding of the fundamental differences between trade secrets and patents in attempting to analogize Section 202 and the fact situation considered by the Supreme Court in the Monsanto case.

A long line of cases define a "trade secret" as any technical or business information which is known and used in one's business which gives him an opportunity to obtain an advantage over

competitors who do not know or use it. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974). Thus, when the EPA made Monsanto's trade secrets available to Monsanto's competitors, it totally extinguished Monsanto's property right. Despite that fact, the Supreme Court found that the EPA's disclosure of Monsanto's trade secrets to third parties did not constitute an unconstitutional "taking" except for the brief period of time between 1972 and 1978 when the relevant statute explicitly created an expectation that trade secrets submitted to EPA would be protected. Indeed, as a general matter, the Monsanto Court found that it was an entirely appropriate act of a public character for the government to enact a law which was designed to get competitive products on the market more quickly even though it would cause Monsanto to lose its trade secrets. The policy underlying Section 202 is closely analogous to the public policy approved in the Monsanto case.

The Supreme Court's failure to find a "taking" in the Monsanto case (except for the limited 1972-78 exception) despite the rather complete devastation of the property right by EPA would lead a reasonable person to the conclusion that Section 202 does not involve any "taking." The limited "experimental use" permitted by Section 202 does not, in any way, impinge on the exclusive right of the patent owner to make, use and sell the patented invention for all commercial purposes during the life of the patent. The permitted experimental use would not result in competitive commercial activity until all valid patents expired. Accordingly, Section 202 has absolutely no economic impact during the life of a patent and does

not interfere with any reasonable investment-backed expectation of the patent owner that he will reap the full monopoly profits during the entire 17-year life of a patent free from any competition.* In attempting to analogize trade secrets to patents, Professor Dorsen has totally overlooked the fact that trade secrets have unlimited duration and cease to exist only when disclosed whereas patents are expressly granted for a limited time. Section 202 merely ensures that the time limitation on the life of a patent will be meaningful and that patent-like monopolies will not be inadvertently continued beyond the patent expiration date.

It is true, that the experimental use permitted by Section 202 may reduce or even eliminate the possibility that the patent owner's monopoly will extend beyond the patent expiration date. But the inadvertent monopoly extension which results from the fact that generic manufacturers must comply with FDA pre-marketing regulations is not a vested property right of patent owners and cannot properly form the basis of a reasonable investment-backed expectation. As stated in Upjohn Manufacturing Co. v. Schweiker, 681 F.2d 480, 484 (6th Cir. 1982):

> "The Federal Food, Drug and Cosmetic Act and the underlying regulations governing the approval for the marketing of new drugs were not intended to provide patent-like protection for a seller who has gained approval of a pioneer new drug application."

* It is of more than passing interest that in the Bolar case the Circuit Court noted that even Roche's lawyer candidly acknowledged that any monetary damage to Roche as a result of the experimental activity was nominal.

Moreover, a long line of Supreme Court cases including Scott Paper Co. v. Marcalus Co., 326 U.S. 249, 259 (1964) have held that:

> "Any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires whatever the legal device employed, runs counter to the policy and purpose of the patent laws."

Surely, a Congressional enactment such as Section 202, which does no more than ensure that this sound policy is not inadvertently disrupted by other federal laws such as the Food and Drug Law, cannot be reasonably construed as a "taking" of property.

Wholly apart from the foregoing, it is clear that drug patent owners had no expectation that the "experimental use" exception expressly set forth in Section 202 was not already part of the patent law. It was certainly well known to all current patent owners at the time they sought patent protection that the term "use" is not defined in the patent statute and that certain types of experimental, de minimus and other "uses" are not, or may not be, infringements as a matter of judicial interpretation. As previously noted, the Bolar decision was the first of its kind and was contrary to the common and previously unchallenged practice of testing prior to patent expiration in the drug industry which existed for many decades. No comparable legal or economic factors were remotely present in the Monsanto case but the Supreme Court nevertheless found that there was no "taking" except for the limited period of time when the EPA statute guaranteed that trade secrets would be protected.

In summary, Section 202 does not raise a constitutional question because it does not impinge on any vested property right and, even if it did, the trespass is so minor that it has no economic impact on patent owners.

ABE/fgl
7/13/84

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from Generic Proponents of HR 3605

CONSTITUTIONALITY OF §202 OF PATENT EXTENSION ACT

1. §202 falls within the Public Purpose Requirement.

In order to pass constitutional muster, a "taking" of property by a governmental entity must be done to further a "public purpose". At an elementary level, this has been said to prohibit the government from taking the property of A and giving it to B.[1] Yet, the fact that a given governmental act inures to the benefit of individuals — even identifiable persons -- does not, of necessity, mean that the act is purely private. So long as the legislature's judgment is not "palpably without reasonable foundation,"[2] the means it chooses to effectuate its judgment — even means that could be characterized as a private transfer -- will not serve to undermine its constitutionality.

The above was emphatically reaffirmed by a unanimous Supreme Court this term in Hawaii Housing Authority v. Midkiff, 52 U.S.L.W. 4673 (U.S. May 30, 1984). Midkiff involved the constitutionality under the "public use" requirement of a Hawaii law which operated to permit the state government to condemn privately owned land in order to transfer fee simple title to individual homeowners. The purpose of the law was "to reduce the perceived social and economic evils of a land oligopoly traceable to their (Hawaii's) monarch's." Id. at 4676. The original landowners argued and the court

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1. See, e.g. Hawaii Housing Authority v. Midkiff, 52 U.S.L.W. 4673, 4674 (U.S. May 30, 1984). See also Calder v. Bull, 3 U.S. (3 Dall.) 386, 388 (1978); Tribe, American Constitutional Law §9-2 (1978).

2. Midkiff, 52 U.S.L.W. at 4676 citing United States v. Gettysburg Electric R. Co., 160 U.S. 668, 680 (1896).

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of appeals held that the law was unconstitutional because it effectuated a private transfer. Id. at 4674.

In reversing, the Supreme Court held that the 'public use' requirement is "... coterminous with the scope of a Sovereign's police powers." Id. at 4676. Accordingly, the Court stated that its review role was the "extremely narrow one" of determining whether the governmental action is "rationally related to a conceivable public purpose ..." Id. (emphasis supplied). Further, with regard to the means chosen by Hawaii -- the private transfer to individual homeowners -- the Court stated:

> The mere fact that property taken outright by eminent domain is transferred in the first instance to private beneficiaries does not condemn that taking as having only a private purpose. The Court long ago rejected any literal requirement that condemned property be put into use for the general public. "It is not essential that the entire community, nor even any considerable portion ... directly enjoy or participate in any improvement in order [for it] to constitute a public use" ... . "What in its immediate aspect [is] only a private transaction may be raised by its class or character to a public affair".... The act advances its purposes without the State taking actual possession of the land. In such cases, government does not itself have to use property to legitimate the taking; it is only the taking's purpose, and not its mechanics, that must pass scrutiny under the public use clause.

Id. at 4677 (citations omitted)(emphasis supplied).

Given Midkiff, any argument that §202 is unconstitutional because it, at first, aids drug manufacturers rather than serving a public purpose would certainly fail. Sec. 202 not only falls within Congress' plenary authority under the Patent Clause but also serves to enhance the public benefits

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that patent legislation is designed to serve.

As has been noted by others, Article 1 §8 of the Constitution grants Congress broad authority to regulate patents in order to "promote the progress of Science and the Useful Arts." The patent laws effectuate this purpose by giving creators a limited exclusive control[1] for a definitely set period of time. In effect, the patent laws expand on the common law rights of inventors[2] by extending exclusive control. The latter scheme however was not designed to benefit the patentee but rather to benefit the public by (1) providing incentives for inventions; (2) promoting "disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires"; and (3) "to assure that ideas in the public domain remain there for the free use of the public." Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979).

If the present law is interpreted to prohibit "use" of patented drugs by drug manufacturers for the purpose of preparing an FDA application, the result is that the public is illegitimately deprived of the benefits of the patented article for at least two years after the expiration date -- a result contrary to the purposes of the patent laws. Stated otherwise the patent holder's "legal monopoly" is illegitimately extended beyond the expiration

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1. E.g. Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., No. 84-569 (Fed. Cir. April 23, 1984)(the word use "has never been taken to its utmost possible scope." Id. at 6.) See also, Deep South Packing Co. v. Laitram Corp., 406 U.S. 518 (1972). "... [W]e should not expand patent rights by overruling or modifying our prior cases construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language." Id. at 531.

2. E.g. Rawlings v. National Molasses Co., 394 F.2d 645 (9th Cir. 1968).

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date — a result not only contrary to Congress' bargain with the patent holder but also contrary to "this Nation's historical antipathy to monopoly and of repeated congressional efforts to preserve and foster competition." Deepsouth Packing Co. v. Laitrum Corp., 406 U.S. 518, 530 (1972).

Section 202 serves to cure the above result — a result caused inadvertantly by the operation of FDCA — towards the aim of assuring immediate public access to creations which are technically in the public domain upon the expiration of the patent. The latter is without question a public purpose. In fact, the Supreme Court in another case this term, Ruckelshaus v. Monsanto Corp., No. 83-196 (U.S. June 26, 1984), held that a provision of FIFRA strikingly similar to §202 was not invalid as effecting a private transfer. With regard to a provision permitting EPA to use and potentially disclose the trade secrets of some manufacturers to evaluate the applications of others, the Court stated:

> It is true that the most direct beneficiaries of EPA actions under the data-consideration provisions of FIFRA will be later applicants who will support their applications by Monsanto or some other original submitter... . This Court, however, has rejected the notion that a use is a public use only if property is put to use for the general public... .
>
> So long as the taking has a conceivable public character, "the means by which it will be attained is ... for Congress to determine." ... Congress believed that the provisions would eliminate costly duplication of research and streamline the registration process, making new end-use products available to consumers more quickly .... Such a procompetitive purpose is well within the police power of Congress.

Id. at 25-26 (citations omitted).

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The means chosen by Congress in §202, limited access to experimental quantities of a patented drug by other manufacturers for purposes of filing an FDA application, cannot under Midkiff and Monsanto serve to transform that public purpose to a private one, especially since those manufacturers will not be competing for profit in the marketplace until after expiration of the patent.

2. §202 is Not A Compensable Taking of Property

Not every governmental interference with private property constitutes a compensable taking under the Fifth Amendment. Rather, the Supreme Court has consistently distinguished noncompensable "regulation" and compensable takings. Although the distinction between regulations and takings involves a factual inquiry and is, thus, somewhat unpredictable,[1] the mere fact that the governmental action causes some diminution in value to the property holder will not transform it into a compensable taking. As Mr. Justice Holmes stated in Pennsylvania Coal Co. v. Mahon 260 U.S. 393 (1922):

> Government hardly could go in if to some extent values incident to property could not be diminished without paying for every such change in the general law. As long recognized, some values are enjoyed under an implied limitation and must yield to the police power. But obviously the implied limitation must have its limits, or the contract and due process clauses are gone. One fact for consideration is the extent of diminution.

Id. at 413 (emphasis supplied).

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1. E.g. Kaiser Aetna v. United States, 444 U.S. 164, 175 (1979)(no set formula exists for determining a "taking"; ad hoc factual inquiry conducted to determine what "justice and fairness" requires).

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Later cases indicate that even substantial diminution in value and in potential economic exploitation will not be deemed a taking short of complete destruction of any potential economic use.[1] Excepting cases involving overt permanent physical occupation of property,[2] recent decisions show that the Court will balance the following factors: (1) the character of the governmental action; (2) its economic impact, and (3) its interference with reasonable investment backed expectations. Pruneyard Shopping Center v. Robbins, 447 U.S. 74, 83 (1980).

Although some have implied that the exclusivity provisions of the patent laws weigh heavily in this inquiry,[3] in reality that fact, standing alone, is entitled to little weight in the determination of a "taking". Certainly it is true that existing law characterizes patents as property and extends an undefined right to exclusive control. Yet, exclusivity is an attribute of all private property and no one has proffered a persuasive reason why patents should be scrutinized more strictly than other forms of property.

Applying the factors stated above to the impact of §202 on patentees clearly indicates that it should not constitute a taking. As stated above,

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1. E.g. Andrus v. Allard, 444 U.S. 51 (1979)(upholding statute prohibiting most profitable use of property); Penn Central Transp. Co. v. New York City, 438 U.S. 104 (1978)(upholding state landmark law); Village of Euclid v. Ambler Realty Co., 272 U.S. 365 (1926)(diminution by 75% of property not a compensable taking).

2. E.g. Loretto v. Teleproimpter Manhattan CATV Corp., 458 U.S. 419 (1982). In Loretto the Court suggested that complete physical takeovers will always constitute a taking. Id. at 427.

3. Statement of Norman Dorsen at 15-16; statement of Henry Paul Monaghan at 8.

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§202 is an economic action designed to enhance the policies behind the extant patent laws, to increase competition in the pharmaceutical industry and to further the aim of decreasing health care costs to individuals. The section in no way results in a physical invasion, permanent deprivation or destruction of the patentees property or its commerical interest in the property. The character of the governmental action is a miniscule intrusion to further a substantial public benefit in an area of recognized plenary congressional authority.

With regard to the second factor, economic impact, certainly the benefit in terms of society at large is clear. Compared to this substantial public benefit, the economic impact on patentees is trifling. Sec. 202 does not affect a patentee's ability to commercially exploit its legal monopoly during the life of the patent. In terms of dollars and cen s, what §202 does prevent is the patentee's ability to maintain its monopoly control for a period of two years after expiration of the patent. Certainly, one would be hard put to argue that this does not impact the patentee's profits. Yet, it does such at a time when patentee has no statutory right to maintain a monopoly[1] — a time when the patentee is presently able under Roche v. Bolar to exploit for gain a product or process which is legitimately in the public domain and which Congress has said should be subject to competition.

The above leads to the factor which has so far been most relied upon by

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1. In fact in other contexts, the Court has held explicitly that attempts to "extended" patents beyond their term is contrary to the purposes of the patent laws and, hence, forbidden. E.g. Scott Paper Co. v. Marcalus Co., 326 U.S. 249 (1964).

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those objecting to §202: the "reasonable investment backed expectation" of the patentee. Basically a reasonable investment backed expectation constitutes a substantial benefit which is intended for the property holder. E.g. Webb's Fabulous Pharmacies v. Beckwith, 449 U.S. 155, 161 (1980). "A 'reasonable investment-backed expectation' must be more than a "unilateral expectation or an abstract need.'" Monsanto at 17 citing Id. In terms of "benefit" to the patentee, the only affect §202 has is to deprive the patentee of a de facto two year extension on its patent. Thus, assuming the correctness of Roche v. Bolar, the benefit or "competitive advantage" deprived the patentee is one to which, under the law, it is not entitled.

If this "benefit" did not exist, the only thing lost to the patentee under §202 is some vague, ephemeral right to exclusivity with little to no economic or commercial value. Thus even if allowing others access to patented material for the limited purpose of filing an NDA constitutes a "use" under the present law, its affect on the total patent rights of the patentee is de minimus. "At least where an owner possesses a full 'bundle' of property rights, the destruction of one 'strand' of the bundle is not a taking, because the aggregate must be viewed in its entirety" Andrus v. Allard, 444 U.S. 51, 65-66 (1979). Andrus v. Allard is particularly enlightening as a comparison to §202. Andrus involved the constitutionality under the Fifth Amendment of the Eagle Protection Act and the Migratory Bird Treaty Act, 16 U.S.C. §§608,703, which flatly prohibited any sale of products made from certain wildlife even if the products were manufactured prior to the date of the acts. The Supreme Court held this was not a taking despite the

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fact that the acts and regulations under them denied property owners the most profitable use." Id. at 66. The Court noted that the owners could still own and transport the products and thus a total deprivation did not exist. Id. "... [I]t is not clear that appellees will be unable to derive economic benefit from the artifacts ... . At any rate, loss of future profits — unaccompanied by any physical property restriction — provides a slender reed upon which to rest a takings claim. Prediction of profitability is essentially a matter of reasoned speculation that courts are not especially competent to perform. Further, perhaps because of its very uncertainty, the interest in anticipated gains has traditionally been viewed as less compelling than other property-related interest." Id. (citation omitted).[1]

Compared to the diminution in value incurred by the property holders in Andrus, that allegedly caused by §202 is pocket change. During the life of the patent, patentees will not be financially or competitively injured by §202. The only injury caused by §202 is the speculative anticipated gains patentees may receive because of the de facto and illegitimate extension of their patents because of regulatory delay.

Some have argued that the competitive advantage lost to the patentee is related in some vague way to the expenses incurred by the patentee in research and development costs and regulatory review.[2] Yet, certainly

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1. In Andrus, the Court also rejected the appellees argument that the Congressional purpose could be achieved by a less drastic means. "[E]ven if there were alternative ways to insure against statutory evasion, Congress was free to choose the method it found most efficacious and convenient." Id. at 58.

2. E.g. Statement of Norman Dorsen at 17; Statement of Henry Paul Monaghan at 7.

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the former costs factored into the original decision on the 17 year patent period as part of the incentive to inventors. Regulatory costs also are an insufficient basis on which to find that §202 interferes with investment backed expectations. Such costs constitute "a burden borne to secure 'the advantages of living and doing business in a civilized community"[1] and are not a justification for depriving the public of health care products at competitive prices.

Contrary to the suggestions by others, the Supreme Court's recent decision in Ruckelshaus v. Monsanto Co. does not alter the above analysis. Monsanto involved the issue of whether EPA use and potential disclosure of trade secrets was a taking under the Fifth Amendment. The Court held that a taking existed only for the period between October 22, 1972 to September 30, 1978 when statutory law explicitly guaranteed confidentiality. To the extent that the definition of "use" in 35 U.S.C. §271 encompasses the limited use of patented material provided in §202, a surface analogy can be made to the Monsanto holding. Yet, the Court in Monsanto did not purport to change the existing law of "takings", which, as mentioned before, served to sustain as a "regulation" a law which deprived property holders even of the most profitable use. See Andrus v Allard, 444 U.S. 51 (1979). Rather, obviously crucial to the Court's decision was the nature of the property at issue. "With respect to a trade secret, the right to exclude others is central to the very definition of the property interest. Once the data that

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1. Andrus v. Allard, 444 U.S. 51, 67 (1979) citing Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 422 (1922)(Brandeis, J., dissenting).

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constitutes a trade secret is disclosed to others, or others are allowed to use that data, the holder of the trade secret has lost his property interest in the data." Id. at 23. In effect, the governmental action in Monsanto resulted in a total deprivation of the attributes of the property at issue. In contrast, to the extent that §202 interferes with any property interest, it deprives a patentee exclusive control over a portion of its property with little if any legitimate economic value.

The Court in Monsanto also stated the existence of reasonable investment backed expectations should be determined as of the time the property holder knew the extent of his right to exclusive control. Id. at 19, 25 n17. Thus, with regard to the fact that the 1975 amendments to FIFRA which retroactively mandated nondisclosure of trade secrets to 1970, the Court stated that "the relevant consideration for our purposes is the nature of the expectations of the submitter at the time the data was submitted [to EPA]. Id. at 25n17. With regard to noncommercial use of patent information for applications to the FDA, patentees were not aware of this element of their exclusive control until the April 25, 1984 decision in the admitted test case of Roche v. Bolar. Although the court in Roche held that use for applications was "use" under §271 of the patent statute, it is undoubtedly true that Congress did not contemplate such a definition of "use" in 1952 when it enacted the patent law. As the Supreme Court has stated, "use" under 35 U.S.C. §271 means the "right to be free from competition in the practice of the invention", Mercoid Corp. v. Mid Continent Investment Co., 200 U.S. 661, 665 (1944), which clearly implies commercial use for profit.

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As stated above, §202 does not interfere with the latter. Until Roche, in fact, it was industry practice to use patented information for applications to the FDA. E.g. Wall Street Journal (cite)(FDA approval of Cort drug still on patent). The problem of substantial delay in getting FDA approval did not really occur until the Drug Amendments of 1962. See e.g. Roche at 12. Nothing in that law dealt with its effects on patentees. Pertinently, the court in Roche admitted that its interpretation of "use" was subject to revision by Congress. Id. at 15-16.[1]

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1. Professor Dorsen has argued that §202 is constitutionally invalid because there exists no "average reciprocity of advantage". It is true that in certain cases the Supreme Court has considered, as part of the total factual history before it, that a given statute contains some sort of reciprocal advantage. However, the Court has never elevated such to one of the factors, listed above, for analysis in takings cases; nor has the Court even intimated that such a fact is in any way determinative of a takings issue. To argue that the lack of such reciprocity forecloses the constitutionality of a given enactment is an interesting theory more suitable for a law review article than a discussion of the extant legal doctrine of the Fifth Amendment. In addition, those drug patentees who have under existing patent a truly innovative product or process — rather than a product or process which received a patent because of minor alterations or combinations — derive the advantage under H.R. 3605 of a 5 year extension on their term to make up for regulatory delay. Finally, assuming Professor Dorsen's argument is in anyway viable, to say that patentees are somehow entitled to a reciprocal advantage for a provision that causes them absolutely no legitimate economic or commercial disadvantage would be, as they say in law school, to exalt form over substance.