March 25, 1985 letter to Patent and Trademark Office from Congressman Robert W. Kastenmeier and Congressman Henry A. Waxman, House of Representatives

[Congress of the United States, House of Representatives letterhead]

March 25, 1985

Assistant Secretary of Commerce
Commissioner of Patents and Trademarks
Patent and Trademark Office
Washington, D.C. 20231

Dear Commissioner:

We are writing you as the Members of the House of Representatives most actively involved in the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) because of our concerns about the implementation of the Act. It has come to our attention that several patent term extension applications have been filed which do not meet the statutory criteria for an extension. These applications fall into two categories, and for the reasons set

forth below, we believe fall outside the ambit of the Act. We, therefore, urge you to reject these applications and take appropriate steps to prevent these possible abuses from occurring in the future.

The applications which concern us fall into two groups. In the first group are at least three applications which seek patent extension based on the Food and Drug Administration's (FDA) approval of a drug which contains an active ingredient that is also contained in another approved drug.[1] In the second group are four applications which request extensions based on FDA regulatory review periods which ended prior to enactment of the Act.[2]

The first group of applications listed above does not meet the statutory criteria for extension under the Act. The Act, in section 156(a)(5) of title 35, provides that a patent may be extended if the "product," which is the subject of the patent, has received its "first permitted commercial marketing or use." Sections 156(f)(1) and (2) define "product," in the case of a human drug, to be "the active ingredient of a new drug, antibiotic drug or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." When the definition of "product" is read in the context of section 156(a)(5), the section provides that a patent may be extended if the active ingredient in the human drug has received its first permitted commercial marketing or use. If there are two active ingredients in the drug, so that each is "in combination with another active ingredient,"

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1. As of December 7, 1984, these applications include: (1) an application by Merck for Indocin suppositories (Patent No. 3,849,549); (2) an application by Fisons for Opticom (Patent No. 3,975,536); and (3) an application by Squibb for Capozide (Patent No. 4,217,347).

2. As of December 7, 1984, this set of applications includes: (1) an application by Glaxo for Labetalol (Patent No. 4,012,444); (2) an application by Sterling for Amrinone (Patent No. 4,072,746); (3) an application by Merck for Indocin suppositories (Patent No. 3,849,549); and (4) an application by Hoechst for Trental Pentoxyfylline (Patent No. 3,737,433).

then each ingredient must have received its first permitted commercial marketing or use. Thus, extension is available only if each active ingredient in the drug was receiving its first approval. Because active ingredients in all these drugs had been previously approved, there can be no eligibility for extension.[3]

In addition to the pertinent statutory language, the legislative history of the Act clearly provides ample evidence that these applications should be denied. The foundation of the arguments for passage of any patent term bill for the last two Congresses has been allegations that new chemical entities suffered from excessive regulatory delay resulting in loss of effective patent life.[4] Thus, when Congress responded to this problem it

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3. For example, Indocin was first approved in 1965 and had an effective patent life of 16.5 years.

4. *Patent Term Extension and Pharmaceutical Innovation: Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 2d Sess. (1982) (testimony of Louis Engman on behalf of the PMA at 123, 126, 137–8, 158–60, 189; testimony of the FDA at 55; testimony of OTA at 24–26). *Patent Term Restoration Act of 1981: Hearings on H.R. 1937, H.R. 6444, and S. 255 Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the House Comm. on the Judiciary*, 97th Cong., 1st Sess. (1981) (testimony of L. Engman on behalf of the PMA at 88). *Patent Term Restoration Act of 1981: Hearing on S. 255 Before the Senate Comm. on the Judiciary*, 97th Cong., 1st Sess. (1981) (testimony of PMA at 29). *Health and the Environment Miscellaneous—Part 2: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 97th Cong., 1st Sess. (1981) (testimony of the PMA at 364, 367; testimony of Merck at 316, 330, 338). *Industrial Innovation and Patent and Copyright Law Amendments: Hearings on H.R. 6033, H.R. 6937, H.R. 3806 and H.R. 2414 Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the House Comm. on the Judiciary*, 96th Cong., 2d Sess. (1980) (testimony of Merck at 11). NATIONAL RESEARCH COUNCIL, THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY 66, 80 (1983). NATIONAL RESEARCH COUNCIL, THE IMPACT OF REGULATION ON INDUSTRIAL INNOVATION 16, 17 (1979). OFFICE OF TECHNOLOGY ASSESSMENT, CONGRESS OF THE UNITED STATES, PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY 12–15, 26, 29–31, 42, 59–69 (1981).

is not too surprising that the response was limited to extensions for new chemical entities. This point is reinforced by the language of the Committee report from the House Committee on Energy and Commerce, which said:

> "[t]he Committee's bill requires extensions be based on the first approval of a product because the only evidence available to Congress showing that patent time has been lost is data on so-called class I, new Chemical Entity drugs." House Report 98-857, Part 1, at 38 (1984).

The clarity of the legislation on this point is further enforced by the fact that after the Committee on Energy and Commerce reported the bill a number of witnesses, including the Commissioner of Patents,[5] testified that the bill was too restrictive because it limited extensions to new chemical entities. This criticism was, however, rejected by the Committee on Judiciary in the House, and ultimately by the Congress.

The inapplicability of the Act to the patent extension applications in the first group is clear. Each of the three drugs contain either (1) a combination of one new active ingredient and one previously approved active ingredient, or (2) a previously approved active ingredient which has been approved for a new route of administration or a new use. None of these drugs meet the Act's requirements. Each of these applications seeks to expand the law beyond Congressional intent as well as explicit and clear statutory language. The approval of these applications would be unlawful and would render meaningless one of the most important and well-discussed rules of the Act—the NCE rule.

The applications in the second group also are not eligible for extension. They are based on FDA regulatory review periods

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5. *Innovation and Patent Law Reform: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the House Comm. on the Judiciary*, 98th Cong., 2d Sess. 6 (1984) (testimony of Commissioner Gerald Mossinghoff of the PTO).

which ended prior to enactment of the Act. It is obvious that Congress did not intend this inappropriate result. A fair reading of the statute rules out any extension for the applications in this second group.

Section 156(g)(1)(A) states that extensions are based on regulatory review periods "to which the limitations described in paragraph (4) applies." Because the limitations of paragraph (4) do not apply to these drugs there has been no regulatory review and they are not eligible for an extension.

It is our understanding that the Patent and Trademark Office intends to make decisions on the applications in these two groups on a case-by-case basis. We believe that approach is insufficient under the circumstances, especially for the type of applications in group one which will continue to be submitted until the PTO rules otherwise.

To assure that no additional applications seeking illegal patent extensions are filed, and to avoid the resulting unnecessary drain on the PTO's and the FDA's resources, we believe that the PTO should take several steps. First, the PTO should revise its "Guidelines for Extension of Patent Term under 35 U.S.C. 156" to specify that applications of the type we have discussed are not approvable. Second, the PTO should rule immediately that the applications in question are ineligible for patent extension. Notice of determination should be published in the Official Gazette. Third, the PTO should revise its application form so that an applicant is required to specify (1) that each of the active ingredients in the approved drug has never been approved before, and (2) whether the five-year limit of section 156(g)(4)(A) or (B) or the two-year limit of section 156(g)(4)(C) applies. With such an application form an applicant can determine whether its drug is eligible and the PTO can easily determine whether an application should receive further processing.

As Members involved in the passage of the Act, we expect to monitor closely its implementation. We would like you to

advise us of your interpretation of the Act regarding the issues raised in this letter and whether you will take the requested action. Because this matter is urgent, we would like to hear from you during the next two weeks.

Sincerely,

s/ _____
ROBERT W. KASTENMEIER,
Chairman
Subcommittee on Courts, Civil Liberties and the Administration of Justice of the House Committee on the Judiciary

s/ _____
HENRY A. WAXMAN, Chairman
Subcommittee on Health and the Environment of the House Committee on Energy and Commerce