H.R. 1937

3/22/82

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On page 1, delete lines 21 and 22 and insert in lieu thereof the following:

(2)(A) The term of the patent shall be extended by the time equal to the regulatory review period for such product or method for the period up to 10 years after the date of filing of the earliest application for the patent and the time equal to one-half the regulatory review period for the period between 10 and 20 years from the filing date of the earliest patent application. If the term that the patent would be extended is less than one year, no extension shall be granted.

(B) In no event shall the term of any patent be extended for more than seven years, nor shall any extension exceed 27 years from the date of filing of the earliest patent application for the patent.

(C) In no event shall more than one patent be extended for the same regulatory review period for the product or method."

On page 3, line 12, after "applicable" insert the following:

"; the date of filing of the earliest application for the patent,"

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On page 3, line 14, delete the period and insert the following in lieu thereof:

"; and state that no other patent has been extended for the regulatory review period for the product or method."

On page 5, after line 2 insert the following:

"(3) The term "earliest application for the patent" means the patent application providing the earliest benefit of filing date to the patent and includes patent applications under Sections 119 and 120."

On page 5, lines 3 and 7, delete "(3)" and "(4)" and insert respectively "(4)" and "(5)".

EXPLANATION

This amendment is designed to provide limitations on the maximum term of restoration more restrictive than the 7 year maximum provided in the bill as introduced. In addition it provides that where more than one product patent has been obtained on a particular pharmaceutical or chemical product, that only one patent may be extended.

These additional limitations on term of extension are summarized briefly as follows.

No patent may extend more than 27 years from the first

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application anywhere in the world. Under H.R. 1937 as introduced a patentee might have a term which would exceed 27 years from first application if he experienced 7 years or more of regulatory review and took more than 3 years to process the patent application in the U.S. Patent and Trademark Office from the point in time he first applied for patent protection either in the U.S. or elsewhere. Because any period involved in processing a patent application which exceeds 3 years would normally be the result of actions on the part of the patent applicant himself, the amendment would deny the patentee extension of patent term based on such a delay.

In addition the amendment provides an incentive to developers of patents to take the steps necessary to securing regulatory review as early as possible after filing their patent applications. This is accomplished by granting full year for year extension only for regulatory delay experienced within the first 10 years after the filing of the patent application. Any regulatory delay suffered due to regulatory activity experienced more than 10 years after the patent application would be compensated at a rate of only 6 months for every year.

This amendment not only provides an incentive to all patent developers to put resources into the development of patents more rapidly than under present law, it also removes a windfall, which some foreign companies would reap under the bill as introduced. This windfall under the present bill would result where a pharmaceutical patent application was filed first abroad, tested and processed through premarket regulatory review abroad and only then seriously submitted for FDA clearance in the United States.

Under the bill as introduced a developer in this situation would be able to wait up to 18 months pursuant to the Paris Convention on Industrial Property before filing a patent

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application and then to drag out the issuance of the patent here while at the same time testing the possible efficacy and marketability of the product abroad. If the tests and market results abroad indicated a potentially lucrative market in the U.S., he could then move to perfect his patent application at a relatively late date here and have the benefit of the full 17 year term plus an extension of up to 7 years. In such circumstances his market protection in the U.S. would last far longer than abroad and give him a competitive advantage over U.S. developers. In most of the world outside the U.S. patent term is 20 years from date of application. Also, full ownership rights accrue from the moment of application. Only in the U.S. does patent term start running after examination.

The amendment also responds to a major criticism of the generic pharmaceutical industry in that it discourages companies from artificially manipulating both the patent application period and regulatory testing period to maximize the period of market control of a product. During hearings before the subcommittee this had been raised as a major concern by generic industry representatives.