MR. RAILSBACK'S AMENDMENT TO H.R. 1937,

RELATING TO PROCESS PATENT

On page 2, line 3 after the word "product" add the following "subject to regulatory review," and on line 4 after the word "using" add "such" and on line 4 after the word "product" add "or a method for producing such a product,".

Page 2, line 2, strike "paragraph (2)" and insert in lieu thereof "paragraphs (2) and (3)" and on page 2 after line 22, insert the following new paragraph:

"(3) The term of a patent which encompasses within its scope a method for producing a product may not be extended under this section if--

(A) the owner of record of such patent is also the owner of record of another patent which encompasses within its scope the same product and

(B) such patent on such product has been extended under this section."

CONFORMING AMENDMENT

On page 4, line 1 strike "product or method for using a."

On page 4, line 5 after the word "use" add "or of producing."

On page 5, line 15 after "using" insert "or of producing." On line 18 after "using" insert "or of producing." On line 23 after "using" insert or of producing."

On page 6, line 1 after "using" insert "or of producing."

On page 8, line 7 after "using" insert "or of producing."

MR. RAILSBACK'S AMENDMENT
RELATING TO PROCESS PATENTS

PRODUCT, USE AND PROCESS PATENTS

Background

H.R. 1937 provides for the restoration of both patents covering a product (product patents) and patents covering a method for using a product (use patents) but does not cover a method for making a product (process patents). Product patents are more valuable and enforceable because competitive products are out in the marketplace and it is relatively easy for the patent owner to tell whether his product patent has been infringed and by whom. A use patent on the other hand is for a particular use of a product and is considered less valuable because to enforce such a patent an owner must sue the user, rather than his competitor which is inefficient and creates bad will. However, recently the U.S. Supreme Court, 448 U.S. 176 (1980), approved of enforcing a use patent by a contributory infringement suit against one's competitor.

The patent laws require (35 U.S.C. 112) that at least one process for making a product be disclosed in a patent application. As a result, if the process is patentable, the original process will be patented at about the same time as is the product. The patent owner is required by--35 U.S.C. 102 (b) to file for any process patent that was described in his application for a product patent within a year. From the owner's viewpoint, process patents are less desirable than product patents because they too, like use patents, are difficult to police. The infringing activity

covered by a process patent typically takes place in a competitor's plant rather than in the open market. Also, process patents do not necessarily grant their owners exclusive rights in a particular product line. There may be many processes for making a product and if so, competitors are free to use them.

H.R. 1937 does not restore process patents. For most products, that's no big deal because if you have a product patent there is usually a process which is part of the product patent but the problem arises when the inventor of a process is unable to obtain a patent on the product which is a result of a particular process. For example, gasoline. The product itself, gasoline, is not patentable because the patent law requires that an invention must be novel in order to be patentable and the product, gasoline is old. This is so even where important characteristics of the product were never before recognized. In such situations the inventor must settle for either a use or a process patent. Therefore, if all an inventor has is a process patent which had to go through several years of regulatory review, H.R. 1937 as written, makes no provision for restoring that patent.

The Genentech Case

Genentech is a small California company founded five years ago in the belief that genetic engineering technology could be made to produce practical benefits in the pharmaceutical and other fields. Today, three products of Genentech research are presently undergoing the human clinical testing that is required before marketing approval can be obtained, human insulin, human

growth hormone and interferon, all made by genetically engineered microorganisms.

The process for the biosynthetic production of human interferon using new gene-splicing techniques illustrates the problem. because human interferon has always existed, a product patent cannot be obtained because of lack of novelty. While the Patent and Trademark Office thus treats the product as old, the Food and Drug Administration has taken the position that when such a substance is made by genetically engineered microorganisms it will be treated as a new drug. Thus, because it is old in the eyes of the Patent and Trademark offices (therefore no product patent), but new in the eyes of the Food and Drug Administration, it will be subject to premarket approval, but not entitled to patent term restoration under the present version of H.R. 1937. My amendment would correct this inequity.

Please note that this is an extremely limited amendment: it would only apply in instances in which, because of a process by which a product is made, the product is required to undergo premarket approval. It would not apply, for example, in instances in which a product cannot immediately be marketed because of emission standards or environmental impact statements. Under my amendment, there must be a direct relationship between the process covered by the process patent and a requirement that a product made by that process undergo premarket approval. Otherwise stated, the amendment would apply in instances in which an "old" product must undergo federal premarketing approval because of the new process by which it is made. I understand that the

generic drug companies have argued that adoption of a process patent amendment would result in "evergreening" or "pyramiding" product patents. This is not correct. The patent laws require that at least one method of making a product be disclosed in a patent application. As a result, if the process is patentable, the original process will be patented at about the same time as is the product. If the process is not patentable, it becomes available immediately. Thus, both the product, such as a drug, and the original method of making it will become available to the public at about the time the product patent expires.

However, to completely assure that there can be no "pyramiding" my amendment also provides that an owner of record of a product patent cannot also apply for an extension of the process patent which it encompasses in the product patent.