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HR 1937	Oct. 7,1981	S11329

Action:

Remarks by Mr. Grassley

S. 255, THE PATENT TERM RESTORATION ACT (H.R. 1937)

● Mr. GRASSLEY. Mr. President, it has been brought to my attention that S. 255, the Patent Term Restoration Act (H.R. 1937), is presently being considered in the House of Representatives. A clarification is needed to help those patentholders subjected to invalid tests and litigation outside the normal regulatory review period covered in this legislation.

This class of patentholders would not receive the same equity as those who obtain their licenses in the normal course of business. Rather, they lose additional patentlife due to the exercise of their administrative/legal rights. I raised a preliminary question about this issue of "trigger provisions"/time extension at our Senate hearing on April 30, 1981, but not feel it was adequately answered.

In the course of applying for licenses, the regulatory agencies require patentholders to provide proof of efficacy and safety. They require patentholders to test their products and they also conduct their own agency research. Many times agencies contract out to private researchers because they lack in-house specialization or equipment. In the process, they remain fully aware of the time limitations placed on the patents of their applicant licensees.

Businesses normally try to obtain licenses at the beginning of their patentlife period, allowing for a full 17-year marketing cycle.

Since most applications are filed during the patent pending stage in the normal regulatory review period, only a few years of patent life are used. The right to patent usually comes along at the same time the license is approved. This is a normal and prudent business practice. However, when one has to exercise their administrative/legal rights due to agency fault, then most of the patent life is consumed as the licensees seek equity.

I strongly recommend that clarifying language with regard to such invalid agency tests from patent holders exercising their lawful administrative and legal rights be included in this legislation. That language, which I am now presenting to the Judiciary Committee of the House of Representatives, Subcommittee on Courts and Civil Liberties is to correct this gap.

A second problem is how to grant time equity for those applicants who came into the regulatory review period pipeline many years ago and are still engaged in the lawful exercise of their administrative/legal rights. If this legislation passes in its present form, they would only have a year or two of redress ~~and no~~ normal marketing period. This is not in conformity with the intent of this legislation.

I propose the effective date of this section be amended to add language allowing for an exception "that such additional time shall be granted to include that period of time lost from patent life due to agency fault." I feel these minor changes in S. 255—H.R.1937—would restore equity to this class of patent holders I feel are not presently covered. I will work with the final stages of this legislation to insure it is amended properly or clarified to my satisfaction.

I bring this to your attention because there have been numerous challenges to agency testing procedures through the years. They have had to be initiated by regulated licensees who sincerely felt and could prove the agency was at fault in denying them a license or conducting a test. I personally know of an Iowa firm which is involved with such a problem with invalid agency tests and are now losing most of their patent life as they pursue their lawful administrative/legal rights. I feel such people should be compensated and that this action would not be a windfall, but equity.●