OISS FORM 53 (12/80)

CONGRESSIONAL RECORD
PROCEEDINGS AND DEBATES OF THE 97TH CONGRESS

EXTENSION OF REMARKS

BILL	DATE	PAGE(S)
H.R. 6444	Aug. 10, 1982	E3771

REMARKS:

by Mr. Gore.

AN UNWARRANTED PATENT STRETCH

HON. ALBERT GORE, JR.

OF TENNESSEE

IN THE HOUSE OF REPRESENTATIVES

Tuesday, August 10, 1982

● Mr. GORE. Mr. Speaker, the following editorial from the New York Times of August 7, 1982, provides a forceful argument against H.R. 6444, the patent-term extension legislation. I commend it to the attention of my colleagues in the House.

AN UNWARRANTED PATENT STRETCH

The pharmaceutical industry is about to receive an extraordinary favor from Congress: the right to extend the patent protection of new drugs up to seven years beyond the conventional period of 17. Congress has let itself be persuaded, after a hasty review, that the extension is fair and will foster innovation. But the drug industry's case is dubious.

Its chief premise is that extension will restore the time unfairly lost from patent life by having to prove to the Government that new drugs are safe and effective. But the testing of drugs in animal and clinical trials is something that any responsible company would wish to do anyway.

Besides, the complaints gloss over the common practice of "evergreening"—filing a patent application early, so as to beat any rival, but then filing new applications that modify or extend the original to postpone the time at which patent life actually starts.

For example, the original patent for the tranquilizer Valium was first filed in 1959 and gained the Food and Drug administration's market approval in 1963. But because of a series of renewed applications, as well as a rival claim, the patent was not issued until 1968. When it expires in 1985, the drug will have enjoyed 22 years of protection.

The eight best-selling drugs in the United States in 1980 enjoyed an exceedingly healthy average patent life of 15.1 years, according to statistics kept at the Office of Technology Assessment. Even when a brand-name drug comes off patent, companies can still protect its market share by advertising; one study of off-patent drugs showed that half retained a 97 percent market share against companies selling the identical chemical under different names

The industry contends that effective patent life time has been dropping, from 14 years for pre-1965 patents to 10 years or less for those now being issued. But the law did not intend to guarantee every inventor a clear 17 years of market monopoly. Many inventions, not just drugs, enjoy less patent protection because of obstacles on the path to market. The drug companies complain that Government delays hold them back. But the bills that have passed both Senate and House committees grant an extension that goes far beyond any delay attributable to Government review.

The companies also contend that reduced patent life has discouraged investment in research and development. But figures from the technology assessment office show that the industry's investment in R & D has increased every year from 1965 to 1978, and has remained a strikingly constant percentage of sales. There is no proof that the windfall profits from a patent extension would in fact be plowed back into research. Even if research were in decline, Congress has many other means, like tax incentives to reverse it.

The pharmaceutical industry is efficient, profitable and healthy. It has no demonstrable need for any special break. The patent system as a whole may need reform, but that is a different issue. Monopoly rights should not be doled out to anyone with a hard-luck story, as Congress seems to believe. The proposed extension is unjustified, unsuited to the stated purpose of increasing research and offensive to the basic principle of a free economy.●