of scale in production, however, it might be conceivable that the ethical drugs industry could approximate to the condition of pure competition.

Patent protection is available in the drug field for process improvements and for the development of new products. Although a product patent cannot be obtained without an accompanying process patent, this is no obstacle to product patents. "Patent medicines" are by no means peculiar to the proprietary drugs field. Unrestricted patent privileges on drug products are, however, virtually peculiar to the United States. Most countries do not award product patents for drugs. Only 28 of the 77 countries for which the Senate Subcommittee could obtain patent law data granted pharmaceutical product patents. Twenty-five of these countries have provisions for compulsory licensing. Only Panama, Belgium, and the United States are without any such limitations.[12] In the United States, the definition of a patentable drug has been broadened in recent years. Prior to 1946, naturally occurring substances could not be patented; product patents on cortisone and hydrocortisone, for example, were impossible to obtain. In 1946 a patent was obtained on the antibiotic streptomycin, on the grounds that, although it was a product of nature, it was transitory in nature, had never been isolated, and its therapeutic use was unknown.[13] In 1955 a patent was issued for tetracycline, even though this compound was jointly produced in the yields from the process for making chlortetracycline, a previously patented drug, and even though tetracycline had previously been marketed by another firm (which did not receive a patent).[14] Patents, therefore, are becoming increasingly easy to obtain in the ethical drugs industry. Trademarks, in the drug industry as elsewhere, may be employed to extend a privileged market position for a larger period of time than the term of the relevant patent. A good example is the case of the barbiturate phenobarbital, which the patent holder sold as "Luminal", at $9.80 per ounce. After the patents expired in the 1930's, competitors produced phenobarbital for sale at $.85 to $.90 per ounce, but for years "Luminal" continued to sell at $9.80.[15]

The Food and Drug Administration has numerous responsibilities with regard to ethical drugs, chief among which are the control of the composition and quality of ethical drugs, the investigation of the safety of new drugs, the certification of antibiotics and insulin, and the prevention of the illegal distribution of prescription drugs. The laws are very complex. For the purposes of this paper, it may be sufficient to note that the purely economic impact of such regulation is, first, to supplement the quality control of individual firms through the authority of the Food and Drug Administration to inspect samples of ethical drugs (and its more limited authority to inspect production facilities) and, second, to prevent the marketing of dangerously lethal new drugs.[16] Violative samples of drugs may be simply confiscated and destroyed, or legal proceedings may be instituted, and civil and criminal penalties may be imposed by the court, including fines large enough to put a small firm out of business. The certification of new drugs, if done with proper regard for the standards necessary to insure drug safety, can be a time-consuming process. Economically, the consequences of regulation are therefore to provide an additional guarantee to the consumer that all drugs on the market are of acceptable quality and to delay the introduction of new drugs in the interests of safety.

II. DRUG INDUSTRY RESPONSE TO THE SPECIFIC ECONOMIC FRAMEWORK

The ethical drug industry's response to the given economic framework may be interpreted as a successful strategy to exploit the monopolistic potentialities inherent in trademarks, the patent privilege, and the great inelasticity of market, in such a way as to overcome the potential for competition implicit in the absence of economies of scale and, to a lesser extent, in the presence of governmental inspection to insure the safety of all drugs placed on the market.

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[12] The vast majority of European drug discoveries have been made in countries where no patent protection was available. Germany, Switzerland, Sweden, Austria, the Netherlands, and Italy are without product patents. France had none until 1959. Great Britain allows product patents on new drugs, but not on combinations of known drugs, and all such patents are subject to compulsory licensing at reasonable royalties. Subcomm. Report 105–6.

[13] *Id.*, at 141.

[14] *Id.* at 146.

[15] Hearings on Administered Prices, pt. 18, at 10433.

[16] Testimony of Food and Drug Administration Commissioner G. P. Larrick, *id.*, pt. 22, at 12110–36.