

that Congressional attention has fostered and promoted this central goal of public policy, the examination of the ethical drug industry has been a worthwhile endeavor on its part.

To the economist concerned with the relationships among market structure, industry behavior, and economic performance, important findings have been added by these hearings and reports to his catalogue of knowledge. This knowledge serves him well, for it strengthens his understanding of the forces contributing to the desirable and undesirable aspects of market performance. Conclusions already suggested by other industry studies have gained additional substantiation; other tentative conclusions have been amended, qualified, or rejected in the face of new knowledge gained from these investigations. Most important, we have come closer to an understanding of the determinants of market performance and the manifestations of their influence in this industry.

This paper has as its frame of reference this economic approach. Its goals are two-fold: first, to evaluate the performance of the ethical drug industry on the basis of the material presented in the various hearings and other sources, and, second, to suggest how substantial improvement in this performance can be achieved through amendment of the patent laws applying to drugs.³ The thesis presented is that compulsory patent-licensing is essential for the needed improvement in the "market" performance of the industry (where market performance refers to those aspects of the industry's activities that determine the cost and profit elements covered by the prices consumers pay for finished products). It will also be argued that such a patent policy will not impair, and may even improve, the industry's product performance (where product performance refers to those aspects of the industry's activities that contribute to better health through the flow of new products to consumers as a result of research and development expenditures).

I. THE SALIENT STRUCTURAL AND BEHAVIOR FEATURES OF THE INDUSTRY

The ethical drug industry can trace its lineage back many decades and even centuries to the fields of chemistry, pharmacy, and medicine. Nonetheless, in its present form it is a young industry, arising out of our break in World War I with Germany, on whose sophisticated and knowledgeable chemicals industry we were then dependent for our drugs. Building on the foundation afforded by wartime successes in drug synthesis and manufacture, medical science and drug therapy began a co-operative effort that soon led to the discovery of insulin in 1921 and its commercial manufacture the next year. There followed discoveries and development of sex hormones; vitamins, first from natural sources and later by synthetic processes; barbiturates; germicides; intravenous anesthetics; improved forms of sulphanilamide; the commercial manufacture of penicillin; and then advances in the whole area of antibiotics. In the post World War II period, successes came more and more quickly: steroid hormones; tranquilizers, anti-depressants, and other mental drugs; oral antidiabetic drugs; polio and measles vaccines; oral contraceptives; and a host of other new types of drugs.

The development of new products has been the main source of the industry's growth. The rapid expansion of the industry's output, to a current domestic level of \$3 billion per year at the manufacturers' level, is one measure of the increasing success that the industry has had in its research and development activities and the applicability of its discoveries to an expanding range of illnesses and injuries. But of equal significance to its rate of growth of output are the characteristics which the industry has acquired as it has matured.

A. The emphasis on "specialties"

In the late 1940's and early 1950's the ethical drug industry faced serious problems. The discoveries of penicillin and streptomycin caught the attention of many firms. Penicillin, a so-called "product of nature," was unpatentable; the streptomycin patents were held by Rutgers University and freely licensed. As a result, markets for these products were easy to enter. The government encouraged the expansion of facilities, and new production methods greatly increased yields. The combined result of these factors was a large overcapacity in the pro-

³ It is important to note that drugs, which, technically, are the active chemical substances in drug products, are patentable, as are the processes in drug and drug-preparation manufacture. The finished products are not patentable per se, although the brand or tradenames under which they are sold are copyrighted.