

sicians, which effectively eliminates any possible competitive threat posed by the generically labeled output of the small firms. Trade names supplement patent monopoly where it exists and substitute for it where it does not.

Thus the large drug firms have used two devices, patents and trade names, to eliminate virtually all tendencies toward price competition. They have led to a different sort of competition—one in which the consumer comes up a loser. Not forgetting the contribution to better health and longer life made by the industry, there has emerged in it a new competition—one that rewards molecule manipulation, questionable patent tactics, excessive promotional claims, and oftentimes a product inadequately tested or cautioned. Such abuses are part of the industry's record, and have generated an increasing surveillance and regulation by the Food and Drug Administration.

Inevitably we come to the matter of public policy in regard to this situation. Specifically, the question as I see it is how to improve the market performance of the industry while not impairing and hopefully even improving its product performance, as I have used those terms. Stated in perhaps a more meaningful way, the question is: How can public policy restore effective competition to the manufacture and sale of ethical drug preparations and thereby make their prices more reasonable, while preserving sufficient incentives for the discovery and development of new and better products?

First, there is the matter of standards of drug patentability. Higher standards than those now prevailing are necessary to halt the routine issuance of patents whose validity is not substantiable in court. Higher standards of patentability will continue to reward true accomplishment and even induce more of it by affording it more protection than is now possible; patents for insignificant or substantial coattail developments or modifications would be eliminated. Such a change would greatly limit the financial gains available from molecule manipulation, but increase the gains from significant discovery, thus redirecting research and development funds away from imitative into innovational channels.

This is the context in which I suggested this commission of experts to assist the Patent Office. I believe they could provide a good deal of influence on this higher standard of patentability for drug patents.

Several years ago the Federal Trade Commission found that the tetracycline monopoly was built on patents obtained with "unclean hands and bad faith." Both the ability to acquire patents in such a manner and the economic motivation to do so must give way. My first specific recommendation, then, is that a special group, representing knowledgeable legal and medical expertise, serve as consultants to the Commissioner of Patents in reviewing and determining drug patent applications.

My second proposal also deals with patents, but is further reaching in its impact. This recommendation focuses on the duration and scope of drug patents, especially pertinent in view of the monopolizing effect of such patents. It is my view that in duration as well as scope, drug patents provide excessive protection from competition, to the detriment of consumers. Accordingly, I offer two alternative plans for making