



HealthPolCom Case Study

Patent Law Reform Initiatives

Situation 1: The pharmaceutical industry needed to build an analytical case for increasing incentives for pharmaceutical research and development by updating US patent laws. (It was believed that the tremendous growth of generic pharmaceuticals usage had undermined the original intent of the 1984 Drug Price Competition and Patent Term Restoration Act for using patent term restoration to increase incentives for pharmaceutical innovation.)

Actions: Managed the development and writing of a Boston Consulting Group (BCG) study about the effects of the 1984 Hatch-Waxman Act.

Coordinated input from 12 companies, the industry's trade association and academic experts into the BCG team drafting the report.

Organized and coordinated meetings of participating company representatives and the BCG team during the drafting of the study.

Edited drafts of the BCG report and coordinated industry input into the drafts.

Worked with BCG staff on final production of the study and its presentation at a Congressional hearing.

Outcome: "Sustaining Innovation in U.S. Pharmaceuticals: Intellectual Property Protection and the Role of Patents," was published by the Boston Consulting Group in January 1996. The study showed that the effective patent life of an innovator medicine had declined from about 13 years before the 1984 Hatch-Waxman Act to about 12.5 years in 1995 because the patent term restoration time was insufficient to make up for the immediate and almost complete loss of market share to generic copies upon patent expiration.

Situation 2: The BCG study's results were questioned by industry critics because it was industry-funded, and Members of Congress requested that the Congressional Budget Office (CBO) conduct an analysis similar to the BCG study.

Actions: Coordinated industry input into the CBO study and subsequent efforts to enact Federal legislative improvements to intellectual property protection for innovative pharmaceuticals using the quantitative conclusions of the BCG and CBO studies.

Outcome: The CBO published "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" in July 1998. This study found that "the patent extensions available under the Hatch-Waxman Act were not sufficient to fully preserve the returns from marketing new brand-name drugs. The present discounted value of those returns has declined by about 12 percent because of the rise in generic competition. However, that rise has resulted from a variety of demand-side factors as well as from changes in the act itself."