the creation of the Abbreviated New Drug Applications (ANDAs). Prior to 1984, companies interested in marketing a generic version of a prescription drug were required to provide the same level of studies as the original manufacturer of the medicine in question, including animal safety studies, bioavailability studies, and human clinical trials. At the same time, generic manufacturer would not have the benefit of patent protection afforded to the "innovator" companies, making it more difficult for generic companies to recoup the substantial investments required to bring a drug to market. Under the provisions of the Hatch–Waxman Act, generic drugs could be approved for marketing based on the "innovator's" clinical and safety data. Bioequivalence studies designed to demonstrate that the generic drug provided the same bioavailability as the marketed equivalent replaced the time-consuming and expensive efficacy and safety trials, significantly lowering the cost of market entry.

Changes to the patent law and market exclusivity rules were also put into place in order to support both the "innovator" manufacturers and generic manufacturers in an effort to provide a balanced playing field for both. A "safe harbor" clause was included in the legislation that allowed generic drug companies to manufacture and study patented drugs as part of an effort to generate data necessary for an ANDA submission. In the absence of this "safe harbor" clause, generic companies could have been sued for patent infringement if their efforts to generate a generic copy of a drug occurred during the lifetime of a patent. This change coupled with the law's allowance for lawsuits by generic companies seeking to invalidate drug patents, created significant openings in the prescription drug market that have been exploited by generic drug companies. Those interested in the details of generic market entry based on lawsuits to invalidate drug patent are encourage to consult paragraph four of 35 U.S.C. 271 for additional information.

Measures to protect the "innovator" companies were also put into place, as it had become widely realized that a significant portion of a drug's patent life was being consumed by clinical trials and the FDA approval process. These processes were dramatically shortening the useful patent life of potential new drugs, thus increasing their overall cost. The ANDA provisions of the Hatch–Waxman Act threatened to further erode the useful patent life of new therapeutic agents if enacted alone. In recognition of this possible negative outcome for "innovator" companies, provisions were put in place for the extension of patent terms to compensate for time lost in both clinical trials and the approval process. In general, the length of patent protection for any drug was increased by 50% of the time spent in clinical trials and 100% of the time spent in the NDA approval process. The law also created a new class of drugs, those directed towards "orphan indications" or diseases with fewer than 200,000 patients. Companies