

that provide new therapies for orphan indications were granted market exclusivity for 7 years, irrespective of the patent status. This provision was designed to provide an incentive for targeting rare and neglected diseases.

Overall, the laws created under the Hatch–Waxman Act of 1984 were generally regarded as successful, although there continues to be both ongoing litigation and debate regarding when and how generic drugs may be brought to market. “Innovator” companies and generic drug manufacturers will likely continue to battle each other over the rights to either maintain or eliminate patent protection for new drugs in an attempt to maintain their profit margins, much to the delight of patent lawyers around the world.

### Biologics Price Competition and Innovation Act of 2009<sup>132</sup>

When the Hatch–Waxman Act was being considered and eventually passed as a law, the biotechnological revolution had only just begun. Politicians concerned with the high cost of medication and health care were not aware of and did not account for the complexities of antibody therapeutics, recombinant proteins, or other macromolecular therapeutics. Their main concern at the time was the price of small molecule therapeutics and the creation of a more robust generic drug market that would lower overall health care costs. As such, generic biologics were not covered in the Hatch–Waxman Act, leaving generic drug companies without a regulatory pathway to gain approval of a generic equivalent of a macromolecular therapeutic. The high price of biologics, however, made it clear very quickly that this oversight needed to be addressed. A single year’s treatment with Herceptin, an antibody used in the treatment of breast cancer, for example, can cost over \$70,000.00.<sup>133</sup>

The substantial differences between small molecule and macromolecular therapeutics made it impractical to simply apply the rules for one to the other. While it would be a relatively simple matter, for example, to ensure that the identity of a small molecule is the same in a “branded” version versus the generic version, the same cannot be said of macromolecules. Under the guidelines for small molecules, a “generic” antibody possessing a 99.9% overlap in structure with the “branded” version, sharing the same function and mechanism of action of the original, and with the same safety features would not be allowed on the market under the provisions of the Hatch–Waxman Act. The Biologics Price Competition and Innovation Act of 2009 addresses these, as well as other issues that prevented generic drug manufacturers from marketing cheaper version of biological medicines. New rules set forth in this law removed the requirement that generic macromolecules had to be identical with their branded counterpart. Biosimilarity replaced the identity requirement with a “highly