8.1 INTRODUCTION

Biological drugs make up one of the fastest-growing sectors of the pharmaceutical and biotechnology industry (IMS, 2010). For example, in 2010, spending on global biologics totaled about $138 billion. The spending of biosimilars has grown rapidly in the past few years. It is expected that spending on biologics will roar to over $200 billion beyond 2015 (see, e.g., Figure 8.1). This has given the pharmaceutical and biotechnology industry the opportunity to develop biosimilars when the innovative biologics go off patent protection.

Because of the high costs involved in the production and consumption of many drug products, regulatory regimes have been created to balance the intellectual property interests (patent protection) and investment made by innovative (originator) companies, with the need for wider patient access through generic forms of the drugs. In the United States, for the traditional chemical (small-molecule) drug market, such a regime was created by the Hatch–Waxman Act. This Act added

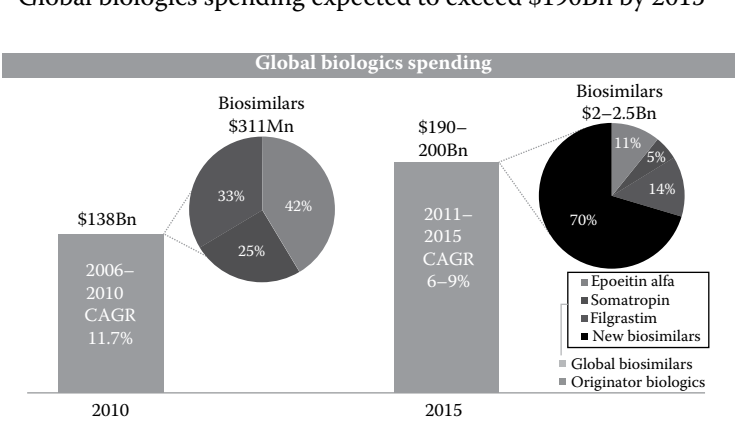

FIGURE 8.1 **(See color insert.)** Global biologics spending (in billion dollars). (IMS, Multinational integrated data analysis system (MIDAS). IMS Institute for Healthcare and Informatics, Danbury, CT, 2010.)