

## Industry Analysis

# Biotechnology Development

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### Industry Overview

Biotechnology was first used between 4,000 and 2,000 B.C.E. to leaven bread and ferment beer with yeast. It was not until the 1970s, however, that it gained significant popularity after American biochemists Stanley Cohen and Herbert Boyer perfected a new recombinant DNA technique using enzymes and ligases to reproduce new DNA in bacteria. When Scotland’s Roslin Institute introduced Dolly the sheep to the world as the first animal to be cloned from an adult cell in 1997, biotechnology was further propelled into the spotlight. In the decade since Dolly’s birth, the biotechnology development industry has cloned many other species and witnessed many other innovations: the U.S. Food and Drug Administration (FDA) approved the breast cancer drug Herceptin® in 1998; the Human Genome Project was completed, providing information on the locations and sequence of human genes on all 46 chromosomes in 2003; the U.S. Environmental Protection Agency (EPA) approved the first transgenic rootworm-resistant corn also in 2003; the draft corn genome sequence was completed in 2008; and a nervous-system controlled bionic leg was used to climb the Chicago Willis Tower in 2012.

Biotechnology has four major applications – medical, agricultural, environmental and industrial. The industry is in the business of generating solutions for diseases that previously had no cure; developing high-yielding and disease-resistant varieties of crops; engineering microorganisms needed to find sustainable ways to clean up contaminated environments; and coming up with applications that lead to cleaner processes and produce less waste in the chemicals, textiles, energy and many other sectors.

According to the Biotechnology Industry Association (BIO), the industry has created over 200 new therapies and vaccines that include products to treat autoimmune disorders, cancer, diabetes and HIV. Another 400 biotech drug products and vaccines are in clinical trials. Data from International Service for the Acquisition of Agri-Biotech Applications (ISAAA) also shows that the U.S. has the largest area planted to biotech crops with 64 million hectares devoted to biotech alfalfa, canola, cotton, maize, papaya, soybean, squash and sugarbeet. It is the largest grower of biotech maize in the world.

The industry is faced with a highly regulated environment. Oversight is provided by the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (USDA-APHIS), the U.S. EPA and the Department of Health and Human Services’ Food and Drug Administration (FDA) under the oversight of the Department of Commerce. In regulating this industry, a major consideration is that new biotechnology products are safe for human and animal health and the environment.

Patent protection plays a key role in this industry. With companies investing millions in R&D investments at risk that may eventually be sold in the market can be protected from being copied. According to BIO, recent trends in a number of countries undermine the biotechnology innovation.

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