

## BIO-INDUSTRIES

Biotechnology, broadly defined, is the application of living organisms or their components to make or modify products, to improve plants or animals, or to develop micro-organisms or higher life forms for specific uses. This definition encompasses both the new biological tools of genetic engineering, cell fusion, and protein engineering, as well as traditional techniques of fermentation used in wine and beer production and classical breeding for selecting improved plants and livestock. A more narrow definition ("new" biotechnology) refers only to the use of more advanced applications based on recombinant DNA, monoclonal antibody and other modern bioprocessing techniques arising from applications of molecular cell biology.

In reality, biotechnology is not so much an industry but a broad enabling technology with applications across a wide range of industries such as health care, agriculture and agri-food, aquaculture, environment, forestry and mining. Since standard industrial classification codes do not exist for biotechnology products and because biotechnology is often broadly defined, consistent statistical data on sales, exports and employment are not generally available.

### Main Challenges

#### Company Size

The majority of Canadian biotechnology companies are very small firms with niche products or services. Typically, they have limited resources to gather market intelligence and promote their products and services abroad.

#### International Partnerships

Because intellectual property protection, legal matters and business culture differ throughout the world, firms need information on the business and legal framework in each country to avoid potential pitfalls and breach of contract lawsuits. Of particular importance is product liability information in the United States and knowledge of intellectual property protection and how to do business in the Far East, where business culture is radically different from that of North America.

### Regulations

The regulatory environment is a major factor affecting international competitiveness because of its impact on product costs, market access and investment decisions. Currently, there is no mutual acceptance of regulatory approvals, and the regulatory situation, particularly for agri-food products in Europe, is in flux. Canadian firms need a clear description of regulatory requirements in major markets, a list of appropriate contacts, and the tracking of progress toward harmonization. Knowledge of ISO certification, labelling and packaging requirements is also important.

### Non-tariff barriers

Several firms cited difficulties in getting their goods across the border due to the U.S. Food and Drug Administration (FDA), U.S. customs, and U.S. Department of Agriculture inspections. Similar delays were encountered on importing products into Canada. As of December 1995, the FDA required foreign manufacturers of medical devices (including in-vitro diagnostics) to have an agent residing in the U.S. list and register their products, which puts Canadian firms at a competitive disadvantage with U.S. domestic suppliers who list with the FDA directly.

### Investment

Over the last five years, the total private-sector investment into Canadian biotechnology companies has exceeded \$1 billion. Nevertheless, financing remains a challenge for early-stage companies. More established firms have also indicated that it is important to keep the U.S. investment community aware of Canadian developments. While alliances with multinational pharmaceutical firms may address to a large extent the needs of biotechnology companies in the health-care therapeutic and diagnostic fields, other sources of capital are still needed for companies in the agri-food, aquaculture, resource and environmental sectors.

### Promoting Canadian Capabilities

Efforts to promote Canadian bio-industries abroad have focussed mostly on helping firms find alliance partners in the United States and Western Europe. Awareness is low of Canadian capabilities in other important markets (e.g. the Asia-Pacific region and Latin America). A related issue is the need to increase trade officials' awareness of the strengths of Canadian biotechnology, which will enable them to better identify market opportunities on behalf of Canadian companies.

### Strategic Direction

#### International Marketing

- continue to focus on the United States, followed by the European Union (EU), as the major markets and source of foreign investment for most Canadian biotech companies;
- foster strategic alliances and provide market intelligence for biopharmaceutical companies, and promote Canadian biopharmaceutical capability to the investment community;
- promote Good Manufacturing Process (GMP) contract production of biotherapeutics in Canada for clinical-trial applications;
- promote the ability of U.S. diagnostic companies to have their products manufactured in Canada for offshore markets while waiting for FDA approval;
- foster alliances with small and medium-sized U.S.-based environmental engineering consulting firms that do not have in-house biological expertise and that are interested in partnering with Canadian bioremediation companies;
- promote exports of immunodiagnostics in the EU;
- provide information on opportunities in emerging markets in the Asia-Pacific region and Latin America for selected niche applications: Korea, China, Taiwan, and Malaysia (agri-food, veterinary vaccines, animal husbandry); Ecuador, Chile (aquaculture); and Mexico, Argentina, Brazil, Cuba, and Central America (veterinary vaccines, animal husbandry); and

- carefully screen and select promotional activities in Japan, given the difficulty that SMEs have in penetrating this market. Major opportunities are in aquaculture (exports) and therapeutics (exports; technology transfer).

### Regulatory

- provide information on the particular regulatory requirements and points of contact for each country in the EU for diagnostics and agri-food biotechnology products;
- provide information on U.S. FDA regulations in the area of biologics and biopharmaceuticals; and
- work with authorities in the EU and Japan for acceptance of agri-food products derived from biotechnology.

### Investment

- promote Canadian biotechnology as an investment success story;
- introduce early-stage companies to international alliance partners and sources of capital, focussing on the United States and Western Europe;
- develop a database on the agri-food biotechnology cluster to facilitate collaboration and investment opportunities; and
- promote foreign investment in Canada.

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