

TP248.195

.C2

C3

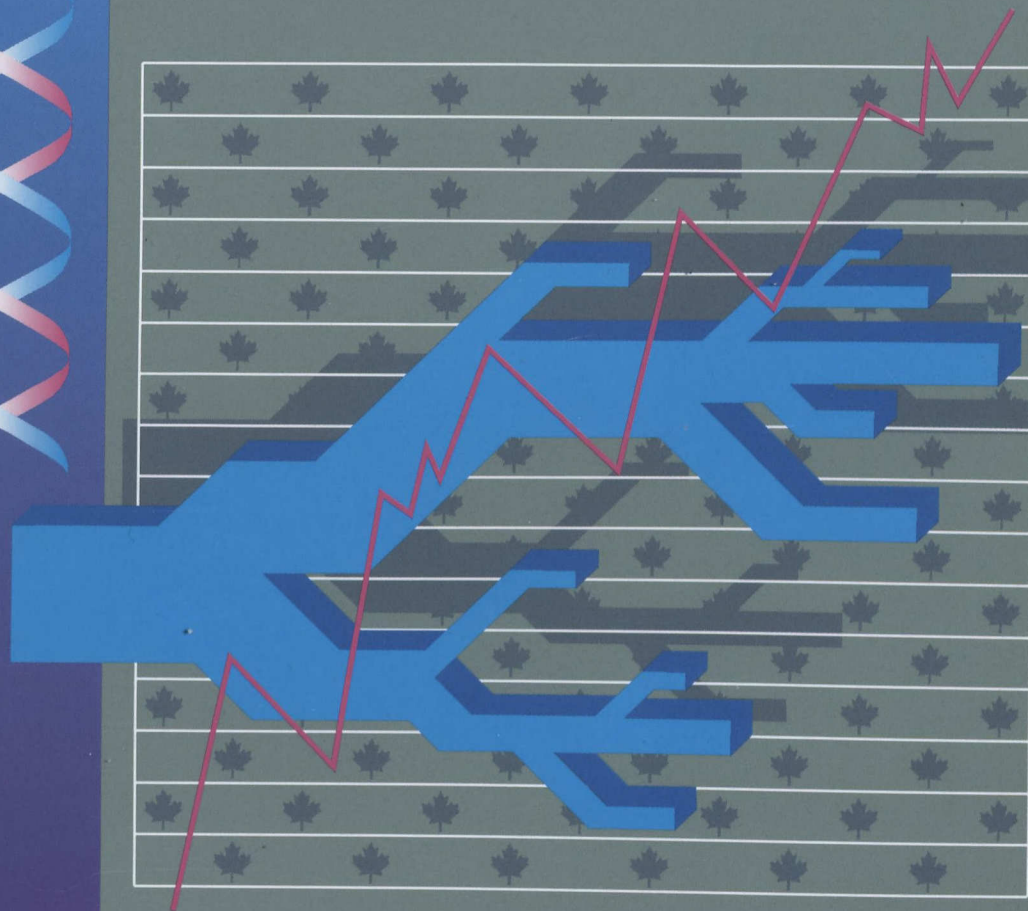
1991

Fifth  
Report

1991

# National Biotechnology Business Strategy

Capturing  
Competitive  
Advantage  
for Canada



Canada

Fifth  
Report

1991

**National  
Biotechnology  
Advisory  
Committee**

---

■ **NATIONAL BIOTECHNOLOGY BUSINESS STRATEGY:  
CAPTURING COMPETITIVE ADVANTAGE FOR CANADA**

---

INDUSTRY, SCIENCE AND  
TECHNOLOGY CANADA  
LIBRARY

DEC 11 1991  
BBQC  
BIBLIOTHÈQUE  
INDUSTRIE, SCIENCES ET  
TECHNOLOGIE CANADA

© Ministry of Supply and Services Canada 1991  
Cat. No C2-188/1991  
ISBN 0-662-58642-5

PU 0245-91-03

*Printed on  
recycled paper*



*Imprimé sur du  
papier recyclé*

---

## ■ Chairperson's Transmittal Letter and Statement

The Honourable William C. Winegard  
Minister for Science  
House of Commons  
Ottawa, Canada

Dear Minister:

*On behalf of the National Biotechnology Advisory Committee, I am pleased to transmit this report containing a recommended National Business Strategy for Biotechnology in Canada.*

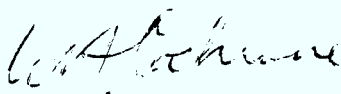
*Biotechnology consists of a number of enabling technologies which can form the basis for competitiveness in many industrial sectors, and can improve the health of Canadians and their environment. Consequently government, academic and industry efforts have focused on the research and development of biotechnologies for application in the many industrial sectors where Canadian industries have traditionally enjoyed competitive advantages. While important scientific breakthroughs and developments in the field continue to be made, attention should now be directed at transforming the science into business opportunities and improving the capabilities of Canadian industry to compete in international markets.*

*Despite important advances, a significant number of Canada's large resource sector companies has yet to adopt biotechnologies. Their competitors, on the other hand, are already using these technologies in order to strengthen their positions in the world marketplace. Moreover, many Canadian biotechnology companies remain small and may be only marginally profitable, or are still in a research phase. The opportunity to examine these issues in detail has resulted in this report.*

*The National Biotechnology Advisory Committee has consulted with interested parties across the country and undertaken studies to identify opportunities that are most promising in relation to Canadian expertise and industry needs. In this report, the Committee recommends steps that must be taken if Canada is to benefit from these opportunities. The nature and scope of the background work that has gone into the development of the present strategy is summarized in our 1989-90 Report of Activities, submitted to you in May 1991. On the basis of the Committee's findings, it is clear that if biotechnology is to contribute to the competitiveness of the economy, Canada must take a determined approach to reduce existing structural barriers which are holding back necessary investments and having a negative effect on the successful commercial exploitation of biological technologies.*

*It is important for me to stress that the market opportunities and recommendations contained in this report are addressed to both the public and private sectors in Canada. Concerted and well-focused actions are essential to succeed in the next stage in the development of biotechnology, specifically, the commercial exploitation stage.*

*Committee members plan to play an active role in bringing the identified market opportunities to the attention of the Canadian business community. We also stand ready to assist you in bringing about the necessary changes in public policy which we are recommending.*



**William A. Cochrane**  
Chairperson

November 1991



**National Biotechnology Advisory Committee Members  
1990-1991**

Dr. William Cochrane (Chairperson)  
President  
W.A. Cochrane & Associates Inc.  
CALGARY, Alta.

Dr. Henri Rothschild (Secretary)  
Director General  
Technology Policy Branch  
Industry, Science and Technology  
Canada  
OTTAWA, Ont.

Dr. Lorne Babiuk  
Director of Research and  
Development  
Veterinary Infectious Disease  
Organization  
SASKATOON, Sask.

Dr. Guy Bellemare  
Professor  
Department of Biochemistry  
Faculty of Science and Engineering  
Laval University  
STE-FOY, Que.

Dr. Chesley M. Blackwood\*  
President and CEO  
Clarenville Ocean Products  
ST. JOHN'S, Nfld.

Michael Brown  
President  
Ventures West Management Inc.  
VANCOUVER, B.C.

John Chappell  
Manager, Corunna Operations  
Petrochemical Division  
Novacor Chemicals (Canada) Ltd.  
SARNIA, Ont.

Dr. Michel Chrétien  
Scientific Director and Chief  
Executive Officer  
Institut de recherches cliniques de  
Montréal  
MONTREAL, Que.

Dian Cohen  
President  
Dian Cohen Productions Ltd.  
AYERS CLIFF, Que.

Jean-Claude Desrochers\*  
Vice-President  
Fresh Produce and Food  
Services  
Dellix Inc.  
MONTREAL, Que.

Dr. James (Jim) Friesen  
Director  
Hospital for Sick Children Research  
Institute  
TORONTO, Ont.

Brian Gray  
Partner  
Blake, Cassels & Graydon  
Barristers & Solicitors  
TORONTO, Ont.

Nigel G.H. Guilford\*  
President  
Laidlaw Waste Systems Ltd.  
BURLINGTON, Ont.

Dr. William (Jeff) Jeffery  
Executive Director  
Mining Industry Technology Council  
of Canada  
OTTAWA, Ont.

Dr. Susan Jensen  
Associate Professor  
Department of Microbiology  
University of Alberta  
EDMONTON, Alta.

Dr. Julia Levy  
Interim President and CEO  
Quadra Logic Technologies Inc.  
VANCOUVER, B.C.

Arthur Meyer, P. Eng.  
Executive Vice-President and  
Director  
Mohawk Oil Canada Ltd.  
BURNABY, B.C.

Gerry Moore  
President  
G.W. Moore Agribusiness Corp.  
STONEWALL, Man.

Dr. Kelvin Ogilvie  
Vice-President, Academic  
Acadia University  
WOLFFVILLE, N.S.

Deanna Rosenswig  
Senior Vice-President  
Corporate Electronic Banking  
Services  
Bank of Montreal  
TORONTO, Ont.

Kimberley (Kim) Stone\*\*  
Vice-President  
Chemicals and Packaging  
Operations  
Diashowa Forest Products Ltd.  
TORONTO, Ont.

Graham Strachan  
President  
Allelix Biopharmaceuticals  
MISSISSAUGA, Ont.

---

\* Resigned in 1990.

\*\* Resigned in 1991.

---

## ■ *Table of Contents*

<b>Chairperson's Transmittal Letter and Statement.....</b>	<b>i</b>
<b>List of Members .....</b>	<b>iii</b>
<b>Executive Summary .....</b>	<b>1</b>
<b>List of Recommendations .....</b>	<b>5</b>
<b>Introduction .....</b>	<b>11</b>
<b>The Nature of Biotechnology .....</b>	<b>11</b>
<b>The International Competitive Environment.....</b>	<b>12</b>
<b>The Essential Ingredients for Commercial Success .....</b>	<b>15</b>
<b>The Application of Biotechnology in Canada: Sector Opportunities .....</b>	<b>29</b>
<b>Appendices</b>	
<b>Appendix I:</b>	
National Biotechnology Advisory Committee Terms of Reference and Mission Statement .....	39
<b>Appendix II:</b>	
List of Studies Commissioned by the Committee .....	41
<b>Appendix III:</b>	
List of Recommendations from the Report of the National Advisory Board on Science and Technology Committee on the Financing of Industrial Innovation .....	43



---

## ■ **Executive Summary**

During the 1980s, Canada made significant progress in the field of biotechnology. Canadian scientists are among the world's leaders in the many basic research disciplines which underpin biotechnology. Well over 200 companies are now actively involved in research and development (R&D) to develop new products and processes based on biotechnology. These products and processes, as they become commercially available, will sustain and enhance the health of Canadians and our environment, as well as the international competitiveness of Canadian industry.

Rapid technological change, brought about by biotechnology, presents both opportunities and economic threats to Canada. Opportunities lie in the potential to use these technologies to strengthen the economy, particularly in the resource industries. As well, biotechnology provides an alternative to synthetic chemical technologies which can have negative impacts on the health of humans and the environment. However, there is a clear and present threat that Canada will be left behind other nations, which have already focused their national efforts to gain new competitive advantages through the use of biotechnology.

As a result of extensive study and consultation with stakeholders in this field, the National Biotechnology Advisory Committee (NBAC) has identified urgently needed changes in private sector decision-making and public policy, which together would greatly enhance the likelihood that Canadians will be in a competitive position to realize the economic potential of these technologies.

Seven specific issues have been identified. While acknowledging the importance of all seven, this report focuses on the first five where there is a pressing need for the private and public sectors to work in close partnership on an accelerated timetable to remove the structural barriers.

This report also identifies significant market opportunities in areas matched by Canadian strengths in biotechnology and recommends strategies for developing industrial capabilities to realize these opportunities. These areas are waste management, forestry, food and agriculture, and human biopharmaceuticals. The Committee recognizes that other industrial sectors such as aquaculture, energy, mining, diagnostics and vaccines -- areas that are of strategic importance to Canada -- are also benefiting from the application of biotechnology. The exclusion of a discussion of opportunities in these sectors reflects the Committee's concentration of endeavours. In the past two years, it has searched for solutions to structural barriers that are constraining the rapid adoption of biotechnology in Canada.

### **The Issues**

1. **Financial Resources for Growing Companies:** There is a lack of equity financing in Canada to support new businesses and the significant costs of taking technologies and new products through to market. This situation is inhibiting commercial development and exposing Canadian companies to takeovers by better financed foreign competitors.

2. **Human Resources:** Canada is currently experiencing significant shortfalls in highly qualified personnel skilled in the managerial and regulatory aspects of the commercial development of biotechnology. In addition, given the present intense international activity in biotechnology, shortfalls of highly qualified production and research personnel required by industry and universities are expected. In order to remain competitive, firms and countries will need to move people across borders as freely and quickly as they do products and information. Major challenges of the 1990s will be to develop education and immigration policies to meet the needs of economic competitiveness.
3. **Regulations:** Federal regulations are a critical determinant of the cost and time required to bring a new biotechnology product to market. Current delays and regulatory uncertainties are discouraging new research and investments in commercial facilities, driving up the costs of innovation and undermining public confidence.
4. **Intellectual Property Protection:** The present patent system is a significant cause of uncertainty and delay in translating scientific discoveries into commercial successes. In addition, Canada's slowness to develop regulations pursuant to the new *Plant Breeders' Rights Act* has constrained the commercial application of new biotechnologies for use in the agriculture and forest industries.
5. **Infrastructure for Scientific Research:** Funding to support infrastructure maintenance and upgrading for university research, critical to the generation of new knowledge in the basic sciences which underpin biotechnology, is being eroded. As a result, Canada is increasingly losing its best graduate students to better equipped facilities outside Canada and is failing to attract sufficient students to the life sciences.
6. **Public Perception and Market Acceptance:** When introducing the products of new technologies, a balance must be struck between regulation and promotion, equity and efficiency, protection of the public and the environment, as well as the furtherance of private interests and economic growth. These are complex issues which the Committee plans to examine more extensively.

At the present time, the Committee recognizes the importance of public perception of the risks and benefits associated with specific commercial applications of new biotechnologies to the overall success of this pursuit in Canada. It is planned that the general public will be included, as an important stakeholder, in deliberations which lead to the implementation of the recommendations contained in this report.

7. **Strong Voice for Industry:** Canadian companies involved in biotechnology require a strong, credible voice and a supporting infrastructure in order to play an advocacy role on generic issues such as intellectual property protection and regulatory requirements for the

products and processes of biotechnology. Moreover, this voice must be recognized both nationally and internationally as a key component in the long-term growth and sustainability of the Canadian biotechnology industry. The Committee, therefore, supports efforts to ensure that Canada continues to develop such a respected voice.

In conclusion, it is clear that biotechnology is changing the basis of competition in numerous industries which are important to the Canadian economy. Because biotechnology represents a major shift from the technologies which provided economic growth in the past, Canada, along with other countries, is passing through a period of transition which must be managed carefully if the full potential of the technology is to be translated successfully into benefits for all Canadians.

Governments and the private sector have important roles to play in accelerating the development and diffusion of biotechnology. Companies must take the initiative to make investments in biotechnology an integral part of their corporate business strategies. Governments must maintain a business climate which is attractive for innovation and foreign investment, and act to remove the barriers within their jurisdictions, that are inhibiting the commercialization of biotechnology research. In some areas, such as financing, human resource development and the exploitation of opportunities in agriculture and forestry, where government laboratories have a major research role, joint private and public sector actions are required.

The NBAC recognizes that successful commercialization of biotechnology requires not only development of world-competitive technologies which have applications in product areas with market potential, but also key adjustments in institutional structures. The changes, urgently required if biotechnology is to be integrated successfully into the industrial fabric of Canada, must be achieved through active partnership with the financial, legal, regulatory, educational and research communities, and with the public at large.



### **Financial Resources**

To address the critical need for adequate funding to finance the commercialization of biotechnology in Canada, it is recommended that:

- ☐ the Government of Canada give high priority to implementing the recommendations of the National Advisory Board on Science and Technology (NABST) Committee on the Financing of Industrial Innovation (see Appendix III), with particular priority to implementation of recommendations one and three, concerning capital gains tax and the establishment of a risk-sharing fund;
- ☐ the biotechnology community, with the support of Industry, Science and Technology Canada (ISTC), consult with the financial community concerning public and private policy changes required to create an environment which would generate pools of \$30 to \$50 million to be invested in smaller companies involved in biotechnology; and
- ☐ the Council of Science and Technology Ministers, as part of its national action plan, encourage the establishment of provincial Biotechnology Development Funds, as joint ventures among provincial governments and private sectors; the purpose of such funds would be to assist companies in the development phase of commercialization activities.

### **Human Resources**

To satisfy the need for qualified managers to develop new businesses based on biotechnology, the Committee recommends that:

- ☐ private industry and ISTC identify mechanisms whereby companies involved in biotechnology can upgrade their management skills; such mechanisms might include special courses and/or pairing new entrepreneurs or companies with experienced managers from more established companies;
- ☐ the Association of Universities and Colleges of Canada review the curricula of business schools and institute a process of change to increase the emphasis on the management of high technology companies, particularly small, start-up and emerging companies, and the management of technology in companies of all types; and,
- ☐ universities enhance science and engineering courses by including business, environmental and regulatory issues that specifically relate to a given discipline.

To provide an adequate number of highly skilled scientists and managers required by universities and industries involved in biotechnology, the Committee recommends that:

- ☐ universities, government and industry strive to maintain an attractive career environment for scientists in Canada; and,
- ☐ Employment and Immigration Canada change its procedures to ensure fast and ready entry into Canada by individuals with specialized skills, who are identified by Canadian industry and universities as a high priority for the development of their biotechnology activities, as well as fast and simple entry into Canada by the members of the immediate families of such personnel.

To satisfy the need for increasing numbers of people skilled in bioprocessing, the Committee recommends that:

- ☐ existing institutions such as the National Research Council's (NRC) Biotechnology Research Institute and the Alberta Research Council, develop training programs for technicians in fermentation technology and downstream processing in collaboration with a university or community college, as well as private companies involved in biotechnology, in order to provide generally recognized certification.

## **Regulations**

To reduce expenses and industrial personnel commitments required by a case-by-case regulatory approval system, the Committee recommends that:

- ☐ new products based on the use of biological organisms and/or processes, especially those directed to the protection of the environment, be regulated on the basis of the category of risk the product might pose to humans and the environment, rather than on an assumption that every biologically-based product or process automatically poses a risk.

To eliminate delays in the approval process for new biopharmaceutical products, the Committee recommends that:

- ☐ Health and Welfare Canada give urgent priority to increasing the number of professional and technical personnel committed to assessing new biopharmaceuticals.

To develop necessary regulations, as well as process increasing numbers of submissions, the Committee recommends that:

- ☐ Agriculture Canada be empowered to augment the number of permanent staff with the necessary expertise to undertake essential regulatory research and to process biotechnology-related submissions in an expeditious manner.

To ensure that a regulatory environment is developed which is conducive to commercial investment in research, development and production facilities in Canada, and that there is consistency among federal, provincial and municipal approaches to the regulation of the products of biotechnology, the Committee recommends that:

- ☐ federal, provincial and municipal agencies with responsibility for regulating production and use of biotechnology products and processes, work toward harmonization of regulatory requirements, evaluation procedures and the mutual recognition of approval systems with those of the U.S. and Europe. A report on progress towards harmonization of Canadian regulatory requirements with the U.S. and Europe should be made public on an annual basis by the agencies involved.

## **Intellectual Property Protection**

To put Canadian biotechnology inventors on an equal footing with competitors in other nations, the Committee recommends that:

- ☐ the Minister of Consumer and Corporate Affairs work with industry to continue the progress made under Bill C-22 to harmonize Canadian patent laws with those of other developed countries, within the context of increasing research and development efforts in Canada; and,
- ☐ the Minister of Consumer and Corporate Affairs table, without further delay, an amendment to the *Patent Act*, that will allow for the deposit of unicellular life forms in support of patent applications in Canada and follow this step by ratifying the Budapest Treaty.

To reduce the time needed to process biotechnology patents in Canada, the Committee recommends that:

- ☐ the federal Government proceed as a matter of urgency, to enable the patent office to become an independently operated agency and to recruit adequate staff to process applications for intellectual property protection without undue delay.

In order that simple, timely regulations under the *Plant Breeders' Rights Act* that expedite the granting of protection for improved forest trees be developed as soon as possible, the Committee recommends that:

- ❑ Agriculture Canada and Forestry Canada give high priority to the promulgation of descriptors and characteristics for regulation under the *Plant Breeders' Rights Act* for tree species, grains and oilseeds of economic importance to industry.

### **Infrastructure for Scientific Research**

In order that the research results from the national Networks of Centres of Excellence are translated into the development of Canadian companies and commercial benefits, the Committee recommends that:

- ❑ the Natural Sciences and Engineering Research Council, together with ISTC, review the extent of linkages and collaborations among biotechnology-related Networks of Centres of Excellence and Canadian industry, to ensure that the most effective steps are being taken to translate new research into commercial applications, in keeping with the original intent of the program.

To support the scientific base for commercial biotechnology, the Committee recommends that:

- ❑ the federal and provincial governments, as well as private industry, provide for the indirect costs of research supported by the federal granting councils, at a rate to be established through consultation with the institutions involved.

### **Forestry**

To obtain the involvement and commitment of major forest products companies to re-establish forest crops on harvested lands, the Committee recommends that:

- ❑ the Minister of Forestry, provincial counterparts and the forest industry, review present policies concerning the extension of forest-leasing rights and make appropriate changes that will make it commercially attractive for forest companies to use genetically improved trees for forest regeneration.



To accelerate the commercial evaluation and introduction of improved trees by means of somatic embryogenesis technologies, the Committee recommends that:

- ☐ Forestry Canada organize a presentation of its technologies and their commercial potential to the Committee of Deputies of the Canadian Council of Forest Ministers for the purpose of developing joint federal-provincial plans for two pilot scale operational demonstrations of new forest regeneration techniques, one in New Brunswick and one in British Columbia; and
- ☐ on a province-by-province basis, starting with British Columbia and New Brunswick, a task force involving Forestry Canada, the provincial forestry departments and the forest industry, be established to develop amendments to existing legislation and/or enabling legislation, which would accelerate the implementation of somatic embryogenesis related to forest regeneration.

To stimulate the development of a world class Canadian industry based on the production of biological controls for forest pests, the Committee recommends that:

- ☐ Forestry Canada, in collaboration with ISTC and private industry, promote efforts to commercialize advanced research in biological controls for forest pests.

## **Waste Treatment**

To co-ordinate Canadian efforts to support the commercial development of biotechnologies for the treatment of municipal and industrial waste water, the Committee recommends that:

- ☐ a research network, based on the concept of the national Networks of Centres of Excellence, be established with the Wastewater Treatment Centre, Burlington, Ontario, as the national focal point and primary centre of expertise for the demonstration of the application of biotechnology to waste water treatment;
- ☐ in addition to normal operating funds, Environment Canada provide \$3 million annually to the Wastewater Treatment Centre for a period of five years for the development and demonstration of biotechnology applications in industrial and municipal waste water treatment;
- ☐ an advisory board drawn from industry, government and universities be appointed to advise the centre and the NRC on research priorities and projects necessary to accelerate the industrial applications of biotechnology to waste water treatment; and,

- ❑ a federal interdepartmental committee, chaired by the centre, be established, with a mandate to co-ordinate the R&D activities of federal government laboratories working in this field.

## **Agriculture and Food**

To rationalize, co-ordinate and concentrate the research efforts of both government and university laboratories, in those areas that offer the greatest long-term opportunities for commercial success necessary for the development of a strong industrial base for the Canadian agriculture industry, the Committee recommends that:

- ❑ Agriculture Canada, as the lead department with responsibility for research and development in agriculture and food research, in consultation with representatives from industry, undertake an immediate assessment of public sector and Canadian university research to determine how ongoing programs could be co-ordinated to eliminate duplication, and set priorities in relation to areas identified as having high commercial potential for biotechnology in the agriculture and food processing industries.

To stimulate the commercial development of probiotics for use in Canada and for export, the Committee recommends that:

- ❑ Agriculture Canada, together with all parties engaged or interested in the use of probiotics, pursue a co-ordinated approach to develop the science further in order that it can be commercialized.

## **Human Biopharmaceuticals**

In order to stimulate the development of a Good Manufacturing Practice (GMP) facility in Canada for the production of biopharmaceutical drugs, the Committee recommends that:

- ❑ the Industrial Biotechnology Association of Canada take the initiative to bring together a consortium of private companies to establish, with support from federal and provincial governments, a jointly-owned and -managed GMP fermentation facility.

---

## **■ Introduction**

In an address delivered to the National Advisory Board on Science and Technology (NABST) in 1989, Prime Minister Brian Mulroney stated:

The goal is an economy that can compete with the best in the world, producing stimulating new jobs and new opportunities for future generations of Canadians . . . Science and technology are the keys to a modern competitive economy. It is clear that our traditional manufacturing and resource-based industries will no longer assure us a strong position in the global economy if we don't complement them with modern technology.

The National Biotechnology Advisory Committee (NBAC) has reviewed reports prepared by NABST and, within that context, this document emphasizes the role of biotechnology in achieving the goal outlined by the Prime Minister. It has been prepared in accordance with the NBAC's Terms of Reference (Appendix I), as well as with a request from the Minister for Science, contained in the mission statement, adopted by the Committee at its meeting with the Minister in May 1989. It reads:

The National Biotechnology Advisory Committee will recommend to the Minister for Science, policies and focused strategies for the continued economic growth of Canada, by enhancing the international competitiveness of Canadian industry through the development, application and commercialization of biotechnology.

### **The Nature of Biotechnology**

Biotechnology is the use of living organisms, or parts thereof, for the production of goods and services. Since earliest times, humans have modified the characteristics of plants and animals through progressive selection for desired traits and have used micro-organisms to produce foods such as bread and beer.

A biotechnology revolution began in the 1970s and 1980s, when scientists learned how to precisely alter the genetic structure of living organisms. With this discovery, biology was moved from an observation-based science to an interventionist science. As a result of the development of powerful biological techniques, it is now possible to produce therapeutic drugs and scarce human biopharmaceutical proteins in sufficient quantities to treat large numbers of patients. Furthermore, gene transfer techniques applied to plants permit the development of disease resistant crops, as well as crops that require fewer applications of pesticides, grow better under stress conditions and have more favourable dietary characteristics.

The application of new biological technologies to animal cells has led to the production of monoclonal antibodies for diagnostic purposes, improved human and animal vaccines and the culture of skin and other organs.

Outside the laboratory, the use of biotechnology is changing the way we evaluate the possibilities for growth in the aquaculture, agriculture, food and beverage, mining, energy, chemical and forest industries. Biotechnology holds significant promise for protecting our natural environment in many areas. Applications include bioremediation of contaminated sites, conversion of waste materials to energy, manufacture of chemicals and pulp and paper with minimal environmental impact, and the development of forest and agricultural crops to reduce the need for fertilizers and pesticides.

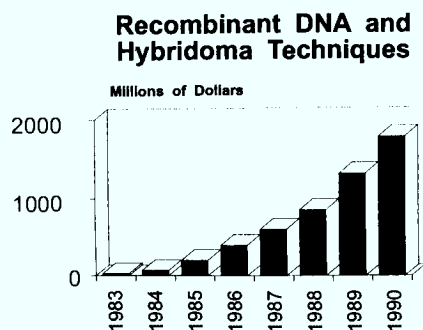
This rapid technological change created by biotechnology presents both opportunities and economic threats to Canada. Opportunities lie in the potential to use these technologies to strengthen the economy, particularly in the resource industries. As well, biotechnology provides an alternative to synthetic chemical technologies which can have negative impacts on the health of humans and the environment. There is, however, a clear and present threat that Canada will be left behind by other nations, which have focused their national efforts to gain competitive advantages through the use of biotechnology.

## The International Competitive Environment

Biotechnology has become of such strategic importance for key sectors of a modern economy that neither companies nor sovereign states can afford to ignore it. Consequently, many governments are now developing integrated policies and programs for biotechnology to ensure that they obtain its full benefits in the form of industrial regeneration, new job creation and social progress.

In creating a business environment conducive to the commercial exploitation of biotechnology, national governments have focused on four priorities:

- ☐ support of basic research to provide a continuous flow of expertise and technology;
- ☐ assistance to industry for pre-competitive research and development;
- ☐ protection of intellectual property; and
- ☐ development of a national regulatory environment that encourages biotechnology companies to make investments within their national boundaries.



U.S. sales of biotechnology products, 1983 to 1990.

Source: Office of Science and Technology Policy. Reprinted with permission of the President's Council on Competitiveness.

In regulating the development of biotechnology products, governments have learned that an unclear or unnecessarily restrictive regulatory regime, that is out of step with those of other national governments, will lead to investments in research, development and commercial production, being made in countries other than their own. In the U.S., biotechnology is being

## **INTERNATIONAL ACTIVITY**

### **In the United States:**

- some 1 100 companies are engaged in some aspect of biotechnology;
- 1990 sales were double those of 1989 and four times 1988;
- revenues from product sales in 1990 were \$2.9 billion and are expected to more than double in two years;
- biotechnology sales in 10 years are projected to be 20 times today's levels; and
- current export sales of biotechnology products total around \$600 million, or 19 percent of total sales.

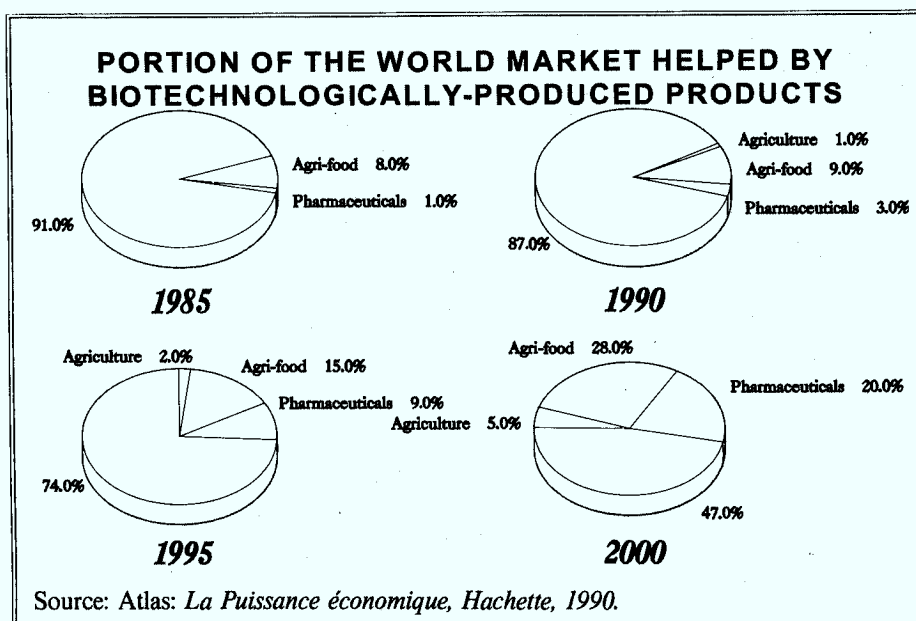
The U.S. President's Council on Competitiveness recently published a report on a National Biotechnology Policy, which identified four critical policy areas: support for science and technology; risk-based regulation for the protection of public health and safety; access to capital and financial resources; and, protection of intellectual property rights.

### **In Japan**

- expenditures on life sciences research in 1989 were approximately US\$8.9 billion with industry accounting for 51 percent of expenditures, universities, 35.3 percent and government research institutes, 13.7 percent;
- major research categories were medicine, biomechanisms and functions, environmental protection, and food resources;
- In April 1992, the Ministry of International Trade and Industry will inaugurate a \$72-million, seven-year program to develop micro-organisms to decompose pollutants.

In the European Community (EC), a policy strategy containing recommendations aimed at promoting the competitiveness of biotechnology-based industrial activities within the EC has been prepared. The EC regards insufficient patent protection, fragmentation of the community market, and a poor image of biotechnology, as the greatest threats to future competitiveness. The new policy includes a commitment to eliminate all overlap between sectoral and horizontal regulation, and recommends an improved overall legal framework.

used by companies to develop new products in a number of sectors. Most are in the biopharmaceuticals and diagnostics sectors. However, some U.S. agricultural chemical companies have established large biotechnology efforts to develop genetically-engineered plants and new companies are being created to develop and exploit bioremediation technologies for application in the growing waste treatment/management market.



The Japanese have traditionally viewed research with a long-term perspective, and research and development in biotechnology have been no exception. Moreover, while the Japanese government is an active supporter of research in biotechnology, much industrial biotechnology research is funded by the private sector, including well known companies from the Japanese steel, electronics and banking sectors, that recognize opportunities for growth.

Research in Western Europe is following similar patterns to those in the U.S., with emphasis on development of human biopharmaceuticals, improved crop varieties and biological pest control methods. The use of advanced biological technologies to produce superior forests has advanced rapidly in Scandinavian countries and will pose a competitive challenge to the Canadian forest industry.

Problems have been created by longer-than-anticipated development times, obtaining registration for novel biotechnology products and uncertainties related to protection of intellectual property. Internationally, the number of companies which have developed products that yield significant returns on their investments, is still relatively small, compared with the total number of active biotechnology companies. However, as increasing numbers



of biotechnology products are nearing the end of regulatory approval processes, commercialization of biotechnology seems poised for the long-predicted, rapid growth phase. It is, therefore, imperative that the right climate be established in Canada to ensure that industry is well placed to compete in the international marketplace.

## **The Essential Ingredients for Commercial Success**

Five areas for public and private action in Canada have been identified by the NBAC as priorities. As well as these areas (discussed below), the Committee recognizes that Canadian industries involved in efforts to commercialize biotechnology have other needs, including the need for a strong voice in an advocacy role on generic issues such as intellectual property protection and regulatory requirements, nationally and internationally. These other needs have not been addressed in this phase of the Committee's work.

## **Financial Resources**

Essential to the success of a commercial venture is the ability to bring a product or idea from the initial concept stage through to the market and to distribute that product successfully. Such capability can be developed outright by a company or through joint ventures but, in either situation, it is dependent upon adequate financial resources. The NABST Committee on the Financing of Industrial Innovation addressed this issue in its report, presented to the Prime Minister in 1990.

The NBAC supports the NABST's recommendations (Appendix III) and urges that action be taken on these recommendations as a matter of priority. In addition, the Committee has identified issues related to financing, specific to the commercialization of biotechnology. This section contains a discussion of these issues and the Committee's recommendation for action.

Compared to other major industrialized countries that are encouraging the development of a strong national focus on biotechnology, Canada is at a significant disadvantage. By virtue of its industrial history and its reliance on resource industries for economic growth, Canada's largest conglomerates are concentrated in cyclical resource-based industries, where profits derive mainly from low-margin, high-volume, commodity products. Failing to recognize that their future competitiveness depends upon leading-edge research, many of these companies have not invested, to a significant extent, in the development of new technologies. In contrast, companies in countries such as Japan, the U.S., France and the United Kingdom, with more diversified product lines, or with a portfolio of high-value products, such as pharmaceutical chemicals, have a stronger financial base from which to fund long-term research in biotechnology and other products.

Although Canadian research and development efforts are not backed by the financial resources that are available in the U.S. or Japan, some

technology being developed is at the leading edge in its field. However, few Canadian companies involved in biotechnology have gone public with stock market offerings, and most have inadequate funds to develop their own technology and/or technology developed in universities and other research institutes, to a commercially successful product. For their long-term survival or expansion, many Canadian companies have been forced to sell a portion of their proprietary technology, or an equity share, to foreign investors and have thus lost control of their technologies or companies.

A number of small to medium-sized Canadian companies involved in biotechnology has been established either with venture capital investments alone, or with a combination of government assistance for specific projects and commercial venture capital. Performance of these companies has been mixed. Consequently, when seeking second- or third-round financing, they have achieved varying degrees of success. High risks and long-time scales to the successful launch of products are inhibiting the willingness of venture capital companies to invest in biotechnology, and it has become almost impossible for small companies to access these funds in Canada.

### **CHASING CAPITAL**

**Research by a U.S.-based multinational identified a significant opportunity for commercialization. A separate Canadian company with two Canadian partners was established with the Canadians agreeing to supply capital investment. The U.S. firm pulled out leaving a shortfall in initial investment.**

**The partners attracted a C\$1 million contribution from the NRC but no additional funds through contacts in Canada. Three attempts to raise money from Canadian venture capital funds failed. European investment was sought with two possibilities advanced, but no deal was closed. With initial capital investment largely consumed, the original partners hired a U.S. investment firm to raise capital. All possible Canadian sources were investigated. No interest was expressed. Five foreign organizations (three from Europe, two from the U.S.) were interested, but no suitable deals resulted.**

**The partners then decided to sell the company. The investment firm brought one serious offer (U.S.) which foundered because the bidding company itself was sold. Finally, the partners re-organized, down-scaled activities and reduced staff. Research was more focused as they adopted the approach of a research service organization. The re-organization had allowed for revenue generation based on contracts worth US\$1 million. This led to another unsuccessful try for support from the Canadian government. Contract revenues fell short of expenses. A second investment firm, asked to evaluate the company, reported an excellent business opportunity if investment was increased. But no Canadian investors were found.**

**After five years, the company CEO has spent more than 50 percent of his time seeking new sources of capital.**



The venture capital industry in Canada has shifted its attention away from early-stage high technology deals, to less risky later-stage financing. Moreover, venture capital managers lack the staff necessary to adequately manage investments in early-stage companies involved in biotechnology. In contrast, there are at least 60 venture capital companies in the U.S. which have already invested in companies concentrating on the development of biotechnology products. Those that have made investments in the initial stages of such businesses have expressed the most satisfaction with the results. Difficulties in accessing domestic capital are forcing Canadian biotechnology companies to seek foreign financing sources, thereby exposing themselves to future takeovers. While consolidation among companies involved in this field is to be expected, as it is in other countries, it would be unfortunate if the process in Canada is driven primarily by a lack of capital from Canadian sources.

In order to address the critical need for adequate funding to finance the commercialization of biotechnology in Canada, it is recommended that:

- ☐ the Government of Canada give a high priority to implementing the recommendations of the National Advisory Board on Science and Technology (NABST) Committee on the Financing of Industrial Innovation (see Appendix III), with particular priority to implementation of recommendations one and three, concerning capital gains tax and the establishment of a risk-sharing fund;
- ☐ the biotechnology community, with the support of Industry, Science and Technology Canada (ISTC), consult with the financial community concerning public and private policy changes required to create an environment which would generate pools of \$30 to \$50 million, to be invested in smaller companies involved in biotechnology; and,
- ☐ the Council of Science and Technology Ministers, as part of its national action plan, encourage the establishment of provincial Biotechnology Development Funds, as joint ventures among provincial governments and private sectors; the purpose of such funds would be to assist companies in the development phase of commercialization activities.

## **Human Resources**

The road to success for a company involved in biotechnology is similar in many aspects to that for most companies in other advanced technology areas. Once first-round financing is in place, the company must develop a sound business plan, focus its efforts on developing and marketing first-round products and develop a strategy to husband its capital resources. However, because the time between concept and product-launch is longer for products of biotechnology than for those of many other advanced technologies, it is essential that officers of these companies plan many years ahead and develop strategies for second-round financing long before it is needed.

Another important difference is the regulatory situation relevant to the products and processes of biotechnology. Companies must plan carefully for the financial implications of the various phases and uncertainties involved in the existing regulatory process.

Many scientist-entrepreneurs starting up a biotechnology-based business for the first time have neither the experience nor training to prepare them for these management tasks which are critical to success. As a result, their companies may pursue business strategies that are inappropriate for biotechnology. This lack of management ability also leads to difficulties in accessing capital. North American venture capital companies are no longer willing to invest in a start-up company that is based on an excellent researcher and good research. Management teams are essential to gain investor confidence as well as for financial control, market development and the other functions required to turn new ideas into profitable products.

In order to satisfy the need for qualified managers to develop new businesses based on biotechnology, the NBAC recommends that:

- ☐ private industry and ISTC identify mechanisms whereby companies involved in biotechnology can upgrade their management skills; such mechanisms might include special courses and/or pairing new entrepreneurs or companies with experienced managers from more established companies;
- ☐ the Association of Universities and Colleges of Canada review the curricula of business schools across Canada and institute a process of change to increase the emphasis on the management of high technology companies, particularly small, start-up and emerging companies, and the management of technology in companies of all types; and,
- ☐ universities enhance science and engineering courses by including business, environmental and regulatory issues that relate specifically to a given discipline.

As with other advanced technologies, the development of biotechnology in Canada depends upon the availability of well-qualified professional, regulatory and technical personnel. In the early 1980s, new research groups and small biotechnology companies were forced to look outside Canada for the scientific expertise they needed. Scientists, including repatriated Canadians, were drawn from all parts of the world.

The provision of an adequate number of trained researchers for industry, regulatory agencies and universities is closely tied to the quality of the research environment. Recent studies indicate that a shortfall in qualified scientists and engineers in Canada, the U.S., Britain and Western Europe, is to be expected in the coming decade. In order to remain competitive, firms and countries need to move people across borders as freely and quickly as they do products and information.

How countries and companies choose to deal with this phenomenon will affect their ability to compete in the new world economy. One solution lies in strengthening the Canadian research environment in order to convince young Canadians to make a commitment to science careers. However, Canada is currently unable to retain sufficient numbers of biomedical scientists, in particular, to meet the needs of our universities. Furthermore, companies involved in biotechnology are in need of skilled production and technical managers. Consequently, a challenge of the 1990s is to develop immigration policies to meet the needs of economic competitiveness and facilitate the immigration of highly qualified scientists and managers needed by Canadian companies and universities involved in biotechnology.

### **THE TWO-YEAR SEARCH**

**A major Canadian biopharmaceutical company needed a vice-president, research and clinical development, to lead it from an R&D-based firm into commercialization. Candidates named through its network proved unsuccessful. It turned to an executive search firm. Preference would be given to Canadians, at home or abroad. During the next nine months, 15 candidates were interviewed, including several Canadians working in the U.S. pharmaceutical industry. None was interested, largely because of Canada's punitive tax system relative to that of the U.S. The non-Canadian candidates were either not suitable or not interested.**

**After nearly a year, two U.S. candidates were identified, interviewed and expressed serious interest. The position was then advertised nationwide in Canada. There were no responses. Both U.S. candidates wanted permanent residency status so their spouses could pursue their own careers, and they would have employment and residential security beyond the two years provided by a work permit.**

**But one candidate had a young child with a controlled disability. Employment and Immigration Canada (EIC) advised this could make permanent status difficult, if not impossible. The second candidate's application was hindered by relocation of the company's files to a new EIC office. EIC told the company that approval would require 12 months and was not guaranteed. Finally, EIC agreed to a two-year work permit acceptable to the candidate and ongoing arrangements with the company should permanent status not be obtained.**

**After another year of effort, the candidate joined the company, reported that he was cordially greeted by a Canadian Immigration official and entered the country without a problem!**

To provide an adequate number of highly skilled scientists and managers required by universities and industries involved in biotechnology, the Committee recommends that:

- ☐ universities, governments and industry strive to maintain an attractive career environment for scientists in Canada; and,

- ❑ Employment and Immigration Canada change its procedures to ensure fast and ready entry into Canada by individuals with specialized skills, who are identified by Canadian industry and universities as a high priority for the development of their biotechnology activities, as well as fast and simple entry into Canada by the members of the immediate families of such personnel.

Fermentation is a common production process in biotechnology. The process is very sensitive to operating conditions and trace contaminants and may be difficult to control requiring experienced technicians to oversee the operations. Although it is difficult to accurately predict the future demand for technicians with appropriate skills, it is estimated that approximately 10 per year are likely to find jobs in Canada over the next five years. The NRC's Biotechnology Research Institute is currently training employees of its client companies on an ad-hoc basis and the institute has expressed willingness to develop an appropriate training program, should there be sufficient demand. Ideally, such a training program would be certified in order that trainees achieve a recognized level of skill appropriate to the needs of industries involved in biotechnology. In addition, co-op education programs might be broadened to provide for on-the-job experience in commercial fermentation facilities in foreign countries.

To satisfy the need for increasing numbers of people skilled in bioprocessing, the Committee recommends that:

- ❑ universities, government and industry strive to maintain an attractive career environment for scientists in Canada; and
- ❑ existing institutions, such as the NRC Biotechnology Research Institute and the Alberta Research Council, develop training programs for technicians in fermentation technology and downstream processing, in collaboration with a university or community college, as well as private companies involved in biotechnology, in order to provide generally recognized certification.

## Regulations

In biotechnology, meeting regulatory requirements is a critical factor affecting the timeframe and cost of bringing a product to market. Companies involved in biotechnology recognize the necessity of regulations to ensure that the health and safety of workers, consumers and the environment are protected. The NBAC identified the critical nature of regulations to the commercial production and use of biotechnology products in its Third Report (1987-88). As indicated in that report, internationally viable biotechnology-based commercial activities require a regulatory system which engenders public confidence, makes economic sense, allows for long-term planning of development and commercialization, has international compatibility, is flexible to accommodate new developments, clarifies jurisdiction and avoids duplication, is based on

risk assessment principles, has defined responsibilities for risk management, and draws upon independent scientific advice.

In Canada, the regulatory requirements for most biotechnology products are administered by two federal departments -- Agriculture Canada and Health and Welfare Canada. These departments use existing legislation to regulate new biotechnology products in their areas of responsibility. In 1988, the *Canadian Environmental Protection Act* empowered Environment Canada to regulate those products of biotechnology not covered by other legislation. Environment Canada and Health and Welfare Canada are both developing regulatory requirements to accompany this Act. To date, two rounds of stakeholder consultations have been conducted concerning the proposed regulations.

Regarding the regulatory requirements, companies actively pursuing the commercialization of biotechnology in Canada have three major concerns:

- ☐ areas of responsibility of the regulatory departments should be clearly defined;
- ☐ new products should receive rapid and unequivocal processing; and
- ☐ clear testing protocols should be established.

Companies consulted noted that a major barrier to the commercialization of biotechnology products is that new products are regulated on a case-by-case basis. This means that for each new product a new protocol is required. For companies bringing a new product to market, this causes significant delays and expense, as well as substantial time commitments of company personnel.

To reduce expenses and industrial personnel commitments required by a case-by-case regulatory approval system, the Committee recommends that:

- ☐ new products based on the use of biological organisms and/or processes, especially those directed to the protection of the environment, be regulated on the basis of the category of risk the product might pose to humans and the environment, rather than on an assumption that every biologically-based product or process automatically poses a risk.

The largest number of new biotechnology products for which companies are seeking approval is human biopharmaceuticals. These are biological drugs, regulated by Health and Welfare Canada. Manufacturers must be licensed for the production of biopharmaceuticals, and must obtain a "Notice of Compliance" before such drugs can be sold in Canada. The manufacture of these drugs must be carried out in facilities that are built to "Good Manufacturing Practice" and inspected by officials from Health and Welfare Canada before manufacturing begins, and annually thereafter.

As biopharmaceuticals are complex biochemicals, their potency may vary. Therefore, each batch of a drug must be thoroughly tested. Furthermore, protocols for testing, because of the newness and complexity of biotechnology products and the resulting lack of a body of previous knowledge, are more complex than those for chemical pharmaceutical drugs and hence have heavy requirements for testing and reviews. As a result, increased demands have been placed on federal regulators and longer than normal delays are occurring in issuing "Notices of Compliance". This situation worsened as a result of staff cuts at Health and Welfare Canada in the spring of 1991. For new companies bringing their first biopharmaceutical products to market, long delays mean increased financial hardship and possible bankruptcy.

To eliminate delays in the approval process for new biopharmaceutical products, the Committee recommends that:

- ☐ Health and Welfare Canada give urgent priority to increasing the number of professional and technical personnel committed to assessing new biopharmaceuticals.

Agriculture Canada has the major federal responsibility for regulating agricultural biotechnology products. It is responsible for licensing new crops, biopesticides, feeds, vaccines and biologics for veterinary use. In 1988, the department processed 16 submissions for biotechnology products. By 1991 this number had grown to 160. Recent information from the department indicates that the number of permanent staff assigned to process these submissions is inadequate. Moreover, the resources allocated for regulation, in spite of the expressed willingness of companies to pay user fees, do not appear to recognize that scientific expertise is required in emerging areas such as transgenic animals and plants "making" biopharmaceuticals.

To develop necessary regulations, as well as to process increasing numbers of submissions, the Committee recommends that:

- ☐ Agriculture Canada be empowered to augment the number of permanent staff with the necessary expertise to undertake essential regulatory research and to process biotechnology-related submissions in an expeditious manner.

The responsibility for the co-ordination of Canadian federal, federal-provincial and international initiatives in the harmonization of regulations for biotechnology products, lies with the Interdepartmental Sub-Group on Safety and Regulations in Biotechnology. The sub-group reports to the Interdepartmental Committee on Biotechnology, chaired by ISTC.

To ensure that a regulatory environment is developed which is conducive to commercial investment in research, development and production facilities in Canada, and that there is consistency among federal, provincial and municipal



approaches to the regulation of the products of biotechnology, the Committee recommends that:

- federal, provincial and municipal agencies with responsibility for regulating production and use of biotechnology products and processes, work toward harmonization of regulatory requirements, evaluation procedures and the mutual recognition of approval systems, with those of the U.S. and Europe. A report on progress towards harmonization of Canadian regulatory requirements with the U.S. and Europe should be made public on an annual basis by the agencies involved.

### **Intellectual Property Protection**

The patenting of inventions has become an important issue for companies seeking to commercialize biotechnology. Many key patents granted to date have been for human therapeutic agents produced by genetically-engineered yeasts or bacteria, techniques for performing specific operations such as the ELISA monoclonal antibody assay, and for the isolation and use of enzymes or other chemicals for specific techniques or applications.

Internationally, patents have also been issued for bacteria, other single cell organisms and isolates of animal or plant cells that can produce specific biochemicals, or have been genetically engineered to produce a proprietary compound or a range of compounds.

In Canada, current patent office practice excludes the patenting of multicellular life forms. Moreover, the *Patent Act* does not allow for the deposition of any life form in support of a disclosure. Consequently, it is difficult to write a Canadian patent application that would be regarded as a complete disclosure of an invention relating to a micro-organism. Therefore, patent protection for such inventions is unavailable in Canada.

The patent office (the Intellectual Property Directorate, Patents, Trade-marks, Copyright and Industrial Design, of Consumer and Corporate Affairs Canada) expects to be in a position to correct this situation before the end of 1991, by proposing an amendment to the current Act which would allow for depositions of simple life forms. This amendment will open the way for Canada to become a signatory to the Budapest Treaty, an international treaty that recognizes the validity of such depositions in support of patent applications. Until Canada recognizes it, inventors wishing to protect novel micro-organisms by patent in Canada, are at a disadvantage with respect to their international competitors.

## **PATENT DELAYS**

**The tremendous backlog of cases at the Canadian patent office, unpublished and unexamined, presents great logistical difficulties for Canadian companies.**

**A Toronto biomedical company was left – primarily because of the delays in examination at the patent office – with the possibility of being held to ransom for a patent which had been abandoned in Europe, restricted in the U.S. and probably for which a Japanese company retained no interest in Japan.**

**The company had discovered a therapeutic use for an existing chemical. It thought the existing chemical should not be patentable per se. A search showed that patent applications for the chemical itself, not restricted by process of manufacture or use, had been filed by a Japanese company in Japan, Canada, the U.S. and Europe.**

**The U.S. case had issued but with narrow claims that did not affect the Canadian company's business. The European application had been published three years earlier and was subsequently abandoned. Because the Canadian system is so slow, no examination of the Canadian application had taken place and the Canadian application was still pending.**

**The Canadian company was left in a state of uncertainty. It did not know whether the Japanese company would abandon or severely narrow its Canadian case when it was examined. Claims published in Europe were broad and covered the chemical per se for all uses. Such claims were possibly unpatentable. The Japanese company seemed to have accepted this by abandoning the European case. The Canadian company could not be sure the Japanese company would not regain its interest in broad patent protection when the Canadian company published its new information. It did not seem wise to contact them and ask if they were still interested.**

To put Canadian biotechnology inventors on an equal footing with competitors in other nations, the Committee recommends that:

- ☐ the Minister of Consumer and Corporate Affairs work with industry to continue the progress made under Bill C-22 to harmonize Canadian patent laws with those of other developed countries, within the context of increasing research and development efforts in Canada; and,
- ☐ the Minister of Consumer and Corporate Affairs table, without further delay, an amendment to the *Patent Act*, that will allow for the deposit of unicellular life forms in support of patent applications in Canada and follow this step by ratifying the Budapest Treaty.



The time to process a biotechnology patent in Canada may be four years or longer. According to officials at the patent office, delays in the process are of similar magnitude to those experienced in the U.S. However, the U.S. is moving rapidly to shorten these delays by the hiring of many new examiners.

There are many reasons for the present situation. Companies are conscious that in biotechnology, it is essential to have a patented proprietary position in a key technology. Consequently, many patents for new biotechnology processes and products are being filed. Although the Canadian patent office has added more officers, it is unable to respond fully to the needs of industry because of staffing restrictions. This situation exists even though the patent office actually generates profits from the work it performs and could cover the costs of additional examiners from its revenues. It is also important that more resources be devoted to publishing information about pending cases/open applications in order that Canadian companies can anticipate problems before biotechnology patents are granted.

The 1991 budget suggested the patent office become a government-owned, independently-operated company. Doubts exist whether this would allow it to recruit staff essential for the timely processing of applications to protect all forms of intellectual property, even though additional staff could be self-supporting.

### **50-YEAR BACKLOG**

**Statistics for biotechnology patents at the Canadian patent office as of March 21, 1990, show:**

- **2 500 cases were pending as of January 1, 1990;**
- **the oldest pending case dates to December 21, 1979, and the oldest unexamined case, to August 29, 1984;**
- **334 cases were issued between January 1979 and May 1988;**
- **an average of 35.15 cases are issued per year;**
- **an average of two cases are abandoned per year (based on 1989 abandonment rate of 5.8 percent); and**
- **37 applications, on the average, were dealt with per year between January 1979 and May 1988.**

**The time required to clear up the current backlog -- at 50 cases dealt with per year -- is 50 years.**

---

**Source: Consumer and Corporate Affairs Canada, the Intellectual Property Directorate, Patents, Trade-marks, Copyright and Industrial Design (the patent office).**

To reduce the time needed to process biotechnology patents in Canada, the Committee recommends that:

- ☐ the federal Government proceed as a matter of urgency, to enable the patent office to become an independently operated agency and to recruit adequate staff to process applications for intellectual property protection without undue delay.

In 1990, Canada proclaimed the *Plant Breeders' Rights Act*, which makes it possible for breeders of new plant varieties to hold exclusive rights and receive royalties when those varieties are sold in both Canada and other nations with similar rights. The NBAC commends the Government of Canada for this important piece of legislation, which should provide a significant stimulus to the commercial development of plant biotechnology in Canada.

In accordance with this legislation, Agriculture Canada has established a Plant Breeders' Rights Office and a Commissioner of Plant Breeders' Rights has been appointed, as well as an advisory committee, to assist in establishing the regulations required for implementation of the Act. To date, proposed regulations for canola, chrysanthemums, potatoes, roses, soya beans and wheat are being drafted.

As indicated in the forestry section of this report, biotechnology is enabling the development and propagation of superior conifers for use in replanting harvested forests. However, producers of such trees need to be assured that improved varieties can be protected under the Act before their production can be commercially successful.

In order that simple, timely regulations that expedite the granting of protection for improved forest trees be developed as soon as possible, the Committee recommends that:

- ☐ Agriculture Canada and Forestry Canada give high priority to the promulgation of descriptors and characteristics for regulation under the *Plant Breeders' Rights Act* for tree species, grains and oilseeds of economic importance to industry.

## **Infrastructure for Scientific Research**

On the basis of a competitive process and international peer review, the Canadian Government funded the establishment of a number of national Networks of Centres of Excellence, in conjunction with industrial collaborators. The fact that approximately 40 percent of the networks funded are involved in research related to the field of biotechnology is a significant indication of Canada's strength in this field. The NBAC commends the Government for this initiative and wishes to highlight the importance of these research networks for the development of commercial biotechnology in Canada.

## INADEQUATE FUNDING

### *No Space*

Researchers at the Hospital for Sick Children in Toronto had received awards in two Networks of Centres of Excellence. To accommodate the research, additional space was needed. None was available. Nor were there funds for renovation. Space was finally found in an abandoned animal-holding room with money extracted from the operating budget of the research institute involved. But that meant the purchase of an important piece of equipment, needed in another area, was not bought and the appointment of a new faculty member was cancelled.

### *Clerk Needed*

The Department of Medical Genetics at the University of Toronto needed a clerk to manage and audit grant finances. No money was available. Funds were found when a faculty member was fortunate enough to win partial salary support for a three-year period. When that award runs out, there will again be no money to pay a person to administer the grants, resulting in a real risk of faulty accounting of public funds.

### *Lost to U.S.*

A major piece of equipment used for the separation of cell types of the immune system reached the end of its functional life in a research institute connected with the University of Toronto. The replacement cost of \$200 000 was not available. Ultimately, the young investigator whose research depended on the instrument, had no choice but to look for a job elsewhere -- in the U.S. where funds were available for the machine.

In order that the research results from the national Networks of Centres of Excellence be translated into the development of Canadian companies and commercial benefits, the Committee recommends that:

- ☐ the Natural Sciences and Engineering Research Council, together with ISTC, review the extent of linkages and collaborations among biotechnology-related Networks of Centres of Excellence and Canadian industry, to ensure that the most effective steps are being taken to translate new research into commercial applications, in keeping with the original intent of the program.

A recent report, prepared on behalf of the Royal Society of Canada, indicates that the ability of universities to generate new knowledge is heavily dependent on the infrastructure which supports research. In recent years, because provincial funding has been below the rate of inflation, universities have been forced to reduce their expenditures on infrastructure. This has occurred at a time when the costs of both equipment and services have increased and standards for the work environment, animal care and other research-related activities have risen.

A study of indirect costs in Canada was carried out in 1982 by the Canadian Association of University Business Officers. Its research indicated that the indirect costs (equipment maintenance, special technical services, secretarial services for publication of results, etc.) associated with the conduct of scientific research, are 47 percent of the direct costs of the research (supplies, equipment, travel, technicians, etc.). This calculation of indirect costs, however, did not include capital depreciation for buildings and equipment or the cost of faculty time devoted to research. Inclusion of these costs raises the indirect cost of scientific research at Canadian universities to 89 percent of the direct costs.

To support the scientific base for commercial biotechnology, the Committee recommends that:

- ☐ the federal and provincial governments, as well as private industry, provide for the indirect costs of research supported by the federal granting councils, at a rate to be established through consultation with the institutions involved.

### **Strong Voice for Industry**

Although the public sector influences the climate for successful commercial exploitation of biotechnologies, private industry has a key role to play. This role requires a strong and united voice for Canadian interests both nationally and internationally. The NBAC urges industries with interests in the commercial exploitation of biotechnology-based products and services, to join together, in developing a strong advocacy position for the resolution of national issues. A forceful voice for the industry would have a positive influence on the commercial application of biotechnology in Canada.

## ■ ***The Application of Biotechnology in Canada: Sector Opportunities***

### **Introduction**

The following sections identify what the NBAC considers to be significant market opportunities in areas matched by Canadian expertise in biotechnology, as well as proposed strategies for developing industrial capabilities to exploit these opportunities.

### **Forestry**

The forests of Canada are its largest visible national asset, covering approximately 997 million hectares of its surface. Of this forested area, one quarter, or 244 million hectares, is harvestable; approximately one million hectares, or 0.4 percent are cut annually. The provinces own 87 percent of the forested land and lease parcels of it to harvesting companies for periods of time that vary from province to province. In 1989, the sales of products generated by the industry totalled \$40 billion; export sales generated a trade balance surplus in forestry products of nearly \$20 billion.

There are three important areas in this sector in which Canadian companies could profit significantly from the application of biotechnology -- the pulp and paper industry, regeneration of harvested forests and protection of existing and new forest resources.

In the past, the pulp and paper industry has relied upon the use of chemical bleaching methods to produce high-quality paper products. In recent years, chemical byproducts of this process have come under suspicion as harmful to both the natural environment and humans. New enzyme technology allows for the significant reduction of chemical bleaching agents in pulping operations and it appears that companies will be eventually obliged by an environmentally conscious public to adopt this technology. In addition, energy savings as a result of biological pre-treatment in mechanical pulping operations will make a significant contribution to enhancing the competitiveness of the final product.

Two research groups in Canada, and several other groups around the world, including Finnish, Japanese and American companies, have strong research efforts in this area.

Information concerning the application of biotechnology to industrial waste treatment problems, including those of the pulp and paper industry, is contained in the waste management section of this report. The biological treatment of industrial waste water is identified as an important opportunity for the commercial application of biotechnology.

Forests that provide raw materials for the sector are owned predominantly by the provinces. They are leased to companies for harvesting under conditions that may vary significantly from province to province. All provinces with major harvestable stands require companies to regenerate or

re-establish a forest crop on cut areas within a fixed time. However, only two provinces require lease-holders to bear the reforestation costs. Leases on forest tracts are frequently only for five years. Since it takes a minimum of 60 to 80 years for a softwood tree to grow from a seedling to a commercially harvestable size, it is understandable that the commitment of companies to reforestation has been lacking.

To obtain the involvement and commitment of major forest products companies to re-establish forest crops on harvested lands, the Committee recommends that:

- the Minister of Forestry, provincial counterparts and the forest industry review present policies concerning the extension of forest-leasing rights, and make appropriate changes that will make it commercially attractive for forest companies to use genetically improved trees for forest regeneration.

Research in techniques related to reforestation is being pursued vigorously in a number of laboratories across Canada. Scientists in both Canada and Sweden have successfully developed a technique called somatic embryogenesis to culture cells from trees that are selected for their all-round outstanding growth characteristics. With this technology, it is possible to rapidly produce thousands of genetically-improved trees for reforestation of cut areas. Work has commenced to develop technologies for the encapsulation of embryos developed in this process to produce true artificial seeds. The Canadian program in conifer cell culture is currently at the leading edge of world biotechnology research in this area.

Significant research efforts on different aspects of the tissue culture of forest tree species and their propagation in large numbers is currently under way at Forestry Canada, as well as at the NRC's Plant Biotechnology Research Institute, the British Columbia Research Institute and at a number of Canadian universities. As part of the development and commercialization of tissue culture techniques for forest species, it is important for the various groups involved to integrate their efforts to develop automated techniques that can reduce or eliminate many of the labour intensive steps in the propagation process. To achieve this goal, there is a need for a closely co-ordinated effort among Forestry Canada, the provincial Ministries responsible for forestry and the forest industry. However, despite the important breakthrough represented by the development of somatic embryogenesis, provincial agencies have yet to evaluate the technology and its potential to produce genetically-improved trees, to improved fibre yields and to assure necessary genetic diversity.



To accelerate the commercial evaluation and introduction of improved trees by means of somatic embryogenesis technologies, the Committee recommends that:

- ☐ Forestry Canada organize a presentation of its technologies and their commercial potential to the Committee of Deputies of the Canadian Council of Forest Ministers, for the purpose of developing joint federal-provincial plans for two pilot scale operational demonstrations of new forest regeneration techniques, one in New Brunswick and one in British Columbia; and,
- ☐ on a province-by-province basis, starting with British Columbia and New Brunswick, a task force involving Forestry Canada, the provincial forestry departments and the forest industry, be established to develop amendments to existing legislation and/or enabling legislation, which would accelerate the implementation of somatic embryogenesis related to forest regeneration.

The protection of existing and new forest resources from pests will be a critical factor in maintaining their ecological and economic viability. Such protection must be carried out in an environmentally responsible manner. Researchers at Forestry Canada are developing leading edge technologies for effective biological pest controls, as alternatives to synthetic chemical treatments. At the present time, negotiations are underway for a company specializing in production of biological pesticides to relocate from the U.S. to Sault Ste. Marie, Ontario, to take advantage of the technologies being developed by the local Forestry Canada research laboratory.

To stimulate the development of a world class Canadian industry based on the production of biological controls for forest pests, the Committee recommends that:

- ☐ Forestry Canada, in collaboration with ISTC and private industry, promote efforts to commercialize advanced research in biological controls for forest pests.

The development of improved conifer species and the use of natural and genetically-modified organisms in the forestry products industry will have a significant, positive impact on the entire sector. These developments underline the importance of the recommendations made in the Intellectual Property Section in this report on the patenting of micro-organisms, and the protection of improved forest species under the *Plant Breeders' Rights Act*.

## **Waste Treatment**

Based on the information presented to it, the Committee has concluded that, in its application to waste management, biotechnology will find its largest market in the treatment of waste water. Of the estimated US\$56 billion spent

on waste management in the U.S. in 1988, approximately 60 percent was spent on water pollution control measures. While up-to-date figures are not available for Canadian expenditures in this area, waste water treatment technologies can be applied in many jurisdictions. Expenditures on the use of biotechnology for waste treatment accounted for 17 percent (US\$8.5 billion) of the U.S. waste treatment costs, approximately 90 percent on waste water treatment.

As the populations of many countries become more environmentally aware, their demands for a cleaner, healthier environment have become more urgent, thereby pressuring politicians to pass legislation necessary to encourage the treatment of industrial waste water. In Canada, there is a major concern regarding the quality of waste water, which is managed largely by industry and municipalities. While legislation has moved quickly, the development of improved waste water treatment processes is lagging.

In Canada, when companies or municipalities are required to address a waste water treatment problem or are seeking technologies to enhance the operation of existing treatment facilities, they normally engage the services of a consulting engineering firm. About a dozen consulting engineering companies specialize in the design of waste water treatment facilities. Of these, only two or three have active in-house research programs. In addition, there is a similar number of companies and industrial associations that sponsor research seeking biological solutions to generic industrial pollution problems. Because novel treatment systems are mainly untried, consulting engineers have been reluctant to employ them and continue to recommend older, proven technology, at the expense of innovative new solutions.

Municipal authorities are also not normally active in the development of improved technologies for waste water treatment. They too rely on established technologies and the consulting engineering community.

Canada has two federally-funded research centres with programs oriented toward the use of biotechnology for the treatment of municipal or industrial waste water. At the Canada Centre for Inland Waters in Burlington, Ontario, the Wastewater Treatment Centre is active in this field and would like to expand its biotechnology program. At the NRC's Biotechnology Research Institute in Montreal, a research team exists with many years of experience in this field. The expertise gained by the NRC staff is, in some areas, complementary to that of the Wastewater Treatment Centre. But there appears to be a lack of program co-ordination between the two. As a result, there is a strong potential for the duplication of research activities and staff. In addition, both facilities are having difficulty obtaining funding to demonstrate new technologies on a commercial scale.

Committee members had extensive discussions with the staff at Wastewater Treatment Centre concerning the operation of this facility as a government-owned, company-operated (GOCO) institution. Under this initiative, the centre has a mandate to commercialize the technology and



expertise developed by its scientists. The NBAC strongly supports this initiative and urges the Government to do everything possible to ensure its success, as it could be an excellent model for the operation of certain government laboratories in the future.

It is important to note that an increased emphasis on biotechnologies for waste water treatment would not, initially, result in the generation of profits for the centre. Therefore, it is essential that it be provided with incremental financial support to pursue the development and demonstration of such technologies as a national objective.

The NBAC is convinced that Canada has talented people and first class facilities that should enable it to be a leader in this field. Furthermore, on the basis of its research, the Committee is confident that technology developed or enhanced in Canada will find a ready market worldwide, as environmental standards continue to become more stringent. The Committee has therefore developed a proposal to foster Canadian leadership in the development of commercial biotechnologies for application in the field of waste water treatment.

To co-ordinate Canadian efforts to support the commercial development of biotechnologies for the treatment of municipal and industrial waste water, the Committee recommends that:

- ☐ a research network, based on the concept of the national Networks of Centres of Excellence, be established with the Wastewater Treatment Centre, Burlington, Ontario, as the national focal point and primary centre of expertise for the demonstration of the application of biotechnology to waste water treatment;
- ☐ in addition to normal operating funds, Environment Canada provide \$3 million annually to the Wastewater Treatment Centre for a period of five years for the development and demonstration of biotechnology applications in industrial and municipal waste water treatment;
- ☐ an advisory board drawn from industry, government and universities be appointed to advise the centre and the NRC on research priorities and projects necessary to accelerate the industrial applications of biotechnology to waste water treatment; and
- ☐ a federal interdepartmental committee, chaired by the centre, be established, with a mandate to co-ordinate the R&D activities of federal government laboratories working in this field.

## **Agriculture and Food**

In 1988, agriculture and food production, processing and distribution alone constituted 4.5 percent of the Gross Domestic Product (GDP), with the value

of exports reaching \$10.2 billion. Among the major commodities exported are wheat, barley, oilseeds and meat.

Biotechnology in the agricultural sector has the potential to benefit virtually all aspects of crop and animal production. Genetic engineering techniques can effect many improvements to the normal growth characteristics of crop varieties. These include increased yields and resistance to disease, adaptation of crops to grow in a wider range of environmental conditions by improved drought and cold tolerance, increased resistance to pest attack, as well as the generation of new products produced by modified plants.

In fighting chronic cattle diseases, such as shipping fever and bovine virus diarrhoea, the use of biotechnology has already resulted in the production of new and more efficient vaccines. These developments will benefit farmers in Canada and around the world. They should also bring financial returns to the Canadian scientists and companies involved in their development.

Because of the importance of a strong agriculture sector to the overall competitiveness of the economy, and despite the global political manipulation of agricultural prices by the use of national subsidies, Canada cannot afford to fall behind its major international trading partners in the development and commercialization of new crop varieties, improvements to animal husbandry products and advances in food technology. It is important to recognize that it will be essential to the long-term national interests of Canada to undertake a significant amount of biotechnology research in agriculture to maintain an internationally competitive agricultural base. It is also important to acknowledge that for many crops, individual seed companies would not be able to obtain a profitable return on their research and development investments. This is the case, in particular, for high-volume, low unit-price crops such as feed barley, oats and similar grain crops, and low-volume specialty crops such as the pulses, which play an important role in crop rotations in many arable areas of Canada. In such situations, it is important for research in the public sector to be supported, with greater emphasis placed upon creating a critical mass of researchers and allocating funds to priority areas for crop development. In these areas, Agriculture Canada should be a leader and co-ordinator for long-term research needs, and avoid becoming a competitor of the commercial seed industry.

The Committee has identified encouraging prospects for the use of biotechnology to support medium- and long-term growth in Canadian agriculture, in a number of areas.

An example is the improved hardiness of winter wheat grown in the Prairie provinces. It has been estimated that with hardier winter wheat varieties, there could be up to an eight-fold increase in the acreage of winter wheat planted. Winter wheat offers a number of advantages, related to soil conservation, as well as drought and salination problems, over spring wheat,

which it would replace. The net incremental value to farmers of these advantages, assuming only a four-fold increase in the acreage of winter wheat, could be up to \$50 million annually. The seed industry would also benefit by increased revenues of \$1.5 to \$2 million annually. Another example is canola, a high-value (\$1.5 billion) high-quality oilseed crop where a large research effort is underway. To take advantage of opportunities such as these, it will be essential for all parties to closely co-ordinate their research efforts.

In past years, major advances in agricultural and food research in Canada have come from the research laboratories of Agriculture Canada, universities and other public sector research institutes such as the NRC's Plant Biotechnology Institute in Saskatoon. New crop variety development has traditionally been conducted by the universities or Agriculture Canada, which pass new varieties to the farmer through SeCan, an organization run by the Canadian Seed Trade Association, specifically to commercialize the results of research conducted by public sector laboratories. In the past, this method of disseminating new crop varieties, combined with the lack of plant breeders' rights in Canada, effectively inhibited the development of proprietary breeding programs by Canadian seed companies, with the result that there is not one Canadian-owned internationally competitive seed company.

In many countries, large private seed companies have become established as a result of their ability to develop and protect proprietary varieties. Their establishment has meant that most major crops have benefited over the years from the development of high yielding new varieties. The profits from the development and commercialization of these proprietary strains over a long period of time, have ensured a strong independent international seed industry which is now in a position to use biotechnology to produce an even wider range of new crop varieties.

The adverse economic and social consequences for Canada of not using biotechnology for the development of a wide range of commercially competitive advanced crop varieties tailored specifically to Canada's climatic conditions, will be severe. Without these continuing improvements, and the development of an industrial base capable of commercializing the results of public research, Canadian farmers will not be able to compete in the international markets of the future and will be forced to seek the best competitive products from abroad.

To rationalize, co-ordinate and concentrate the research efforts of both government and university laboratories, in those areas that offer the greatest long-term opportunities for commercial success necessary for the development of a strong industrial base for the Canadian agriculture industry, the Committee recommends that:

- ☐ Agriculture Canada, as the lead department with responsibility for research and development in agriculture and food research, in consultation with representatives from industry, undertake an immediate assessment of public sector and Canadian university research to

determine how ongoing programs could be co-ordinated to eliminate duplication, and set priorities in relation to areas identified as having high commercial potential for biotechnology in the agriculture and food processing industries.

The application of biotechnology to products for improved animal husbandry and health care offers numerous opportunities which would improve the welfare of agricultural livestock, maintain the profitability of Canadian dairy and livestock farmers, and produce significant commercial benefits for Canadian veterinary companies. Several strong research teams have been established in public sector and university research laboratories. This research is being translated into viable commercial products by Canadian companies. An independent study conducted for the Committee indicates that a major market potential for advanced bovine and porcine vaccines and other animal health care products exists in the U.S., with smaller markets in Western Europe and South America. These markets can be readily accessed by Canadian companies or their international marketing partners.

The study also indicates that more efficient utilization of feed by hogs and cattle can provide significant financial returns to Canadian farmers. For example, a one percent increase in feed efficiency and carcass quality for beef cattle could result in a \$27 million profit improvement at the farm gate. Research has shown that bacterial inoculants for use with animal feed stuffs (called probiotics) can have a beneficial effect on animal health and hence animal growth rate. Co-ordinated research in this area could lead to significant benefits for farmers in terms of improved feed utilization and increased rates of weight gain. The commercialization of this research could also lead to exciting opportunities for Canadian veterinary and health care products companies. The study estimated the global market for hog and cattle probiotics is in the order of \$50 billion. When weighting factors were applied, that took into account all restrictions to market access, the potential size of the probiotics market accessible to Canadian companies is in the order of \$4.4 billion annually.

To stimulate the commercial development of probiotics for use in Canada and for export, the Committee recommends that:

- ☐ Agriculture Canada, together with all parties engaged or interested in the use of probiotics, pursue a co-ordinated approach to develop the science further in order that it can be commercialized.

Both nationally and internationally, the food industry is a high-volume, low-profit-margin industry. With few exceptions, major food companies have research and development strategies which emphasize a small research but a large development component. There are, however, a number of small and medium-sized Canadian companies which are developing small-volume products, normally based on proven enzyme or protein purification technology, to address specific niche market possibilities. As in the past, these companies continue to rely upon access to public sector or university laboratories to meet

their research and technology needs. Because most food companies have individual and often unique product development objectives, the long-term benefits to the food industry from biotechnology will most likely come from continued attention to well-directed basic and applied institutional research.

## **Human Biopharmaceuticals**

When the outlines for the National Biotechnology Strategy were developed in 1983, there was not a strong Canadian presence in the international pharmaceutical industry. This led to a conscious decision to concentrate national investments in biotechnology in other sectors. However, through the 1980s, this sector emerged as a significant factor within the Canadian biotechnology industry, primarily for two reasons: firstly, the strength of researchers in the biological sciences relating to health care; and secondly, the dramatic increases in R&D expenditures in Canada by international pharmaceutical companies, stimulated by improved patent protection in 1987.

According to the third annual report of the Patented Medicine Prices Review Board, R&D spending in 1990 by patent-holding drug companies totalled \$281.3 million or 8.8 percent of sales, almost triple the level of 1987. A significant amount of this expenditure is being targeted to the discovery and development of novel biopharmaceuticals and strategic alliances between established pharmaceutical companies and emerging Canadian biotechnology-based companies. It is apparent from the high level of research and development in the application of biotechnology to the international pharmaceutical sector, that future major advances in biotechnology will continue to come from this sector.

Many technological advances have resulted in key patents (for example, "polymerase chain reaction") and have driven the development of important products, such as Tissue Plasminogen Activator (TPA) and Erythropoietin (EPO). For now, Canada does not have a strong international presence in either conventional pharmaceuticals or in human biopharmaceuticals. However, there are some encouraging developments in the fledgling biopharmaceutical industry in which innovative pharmaceutical companies have capitalized on investments and forged successful alliances. It is noteworthy that the top six Canadian biotechnology companies, in terms of numbers of employees and revenues generated, are in the health care sector, as are all three publicly-traded companies.

Compelling arguments favour the continued encouragement of the development of an effective Canadian presence, especially in biopharmaceuticals. Investments in biotechnology in the global biopharmaceutical sector have outstripped growth in other sectoral applications, by several orders of magnitude. In view of the attractive returns on investment from the successful application of biotechnology to the human biopharmaceutical sector, it is anticipated that this international emphasis in investment and research is likely to continue. The absence of a Canadian presence in the international biopharmaceutical sector would have a



significant negative effect on long-term developments in other sectors of biotechnology application in Canada and could erode the existing professional scientific base. It is estimated that there are perhaps eight to 10 small to medium-size Canadian companies in the area of diagnostic kits or biopharmaceuticals development that are large enough to employ a "critical mass" of staff, including scientists involved in research. These companies typically have 50 to 100 employees. The number of smaller companies that may be thought of as being in an early "start-up" phase, with between five to 20 employees, is difficult to estimate accurately. Many Canadian companies which are commercializing kits for the diagnosis of various human disease conditions, already have products on the market. But none of the companies developing human biopharmaceuticals has yet marketed a product, although some are at the critical point of initiating clinical trials.

Apart from the significant costs (\$100 to \$200 million, depending on the product) involved in clinical trials for these products -- a significant hurdle -- none of the Canadian biopharmaceutical companies has built a fermentation facility for the production of these agents. It is estimated that the cost of building such a facility, designed to Good Manufacturing Practice (GMP), would be between \$5 to \$20 million.

To facilitate the registration of a biopharmaceutical drug, after clinical trials have been completed, the same facility should be used to produce the drug for both the clinical trials and the product launch. Companies are able to use the fermentation facilities at the NRC's Biotechnology Research Institute to produce trial lots of biopharmaceutical drugs. These facilities do not have a GMP certification from Health and Welfare Canada or the Food and Drug Administration in the U.S. Therefore, the products can only be used in pre-clinical trials. The institute is in the process of converting the facility to meet these exacting standards. When completed, it should be in a position to allow companies to use the facility on a contract basis to produce drugs for clinical trials. The extent of the demand for such a service is not yet known.

Several companies engaged in this type of research anticipate that they will need a GMP facility within the next 12 to 18 months, to allow for the production of biopharmaceutical drugs. Some think, for several reasons, it would be preferable if industry were to establish its own facilities, on a co-operative basis.

In order to stimulate the development of a GMP facility in Canada for the production of biopharmaceutical drugs, the Committee recommends that:

- ☐ the Industrial Biotechnology Association of Canada take the initiative to bring together a consortium of private companies to establish, with support from federal and provincial governments, a jointly-owned and -managed GMP fermentation facility.

## **National Biotechnology Advisory Committee**

### ***Terms of Reference***

1. The National Biotechnology Advisory Committee is appointed by, and provides advice to, the Minister for Science.
2. The Committee shall consist of a chairperson and not more than 24 other members.
3.
  - a) The Chairperson and other members of the Committee shall be appointed by the Minister to hold office for a term of three years, with the possibility of reappointment.
  - b) The Chairperson has supervision over, and direction of, the work of the Committee and of the persons appointed for the purpose of carrying out the work of the Committee.
4. The Committee will provide advice to the Minister on matters related to the creation and maintenance of an internationally competitive Canadian position in the development and application of biotechnology as well as those matters specifically referred to it by the Minister. Key areas for advice will include:
  - i) the development of strategic plans for the near and longer term incorporation of biotechnology in industry, which recognize and exploit the underpinning and transformative nature of the technology;
  - ii) the continued strengthening of the science and technology infrastructure to support the industrial development and application of biotechnology;
  - iii) approaches to biotechnology being pursued by other nations and the opportunities and appropriate mechanisms for Canada to consider in fostering international collaboration in this field; and
  - iv) programs, policies, regulations, and the like, which are, or are capable of, influencing the course of industrial and human resource development in biotechnology in Canada.
5. The Committee may advise the Minister whenever it deems it appropriate to do so, or when specifically requested by the Minister. In addition, a report of the work undertaken by the Committee shall be prepared and submitted shortly after the end of each fiscal year.



6. The Committee, through its Chairperson, shall consult annually with the Minister concerning its plan of work.
7. The Minister shall, subject to the appropriation of the necessary funds, set aside each year the funds required by the Committee to carry out its work.
8. The Committee shall meet as often as necessary to carry out its work, but no less than annually. Sub-committees may be established from its members on an ad hoc basis to carry out specific projects.
9. The Secretariat of the Committee shall be provided by the Technology Policy Branch of Industry, Science and Technology Canada.

### ***Mission Statement***

The National Biotechnology Advisory Committee will recommend, to the Minister for Science, policies and focused strategies for the continued economic growth of Canada by enhancing the international competitiveness of Canadian industry through the development, application and commercialization of biotechnology.

### **List of Studies Commissioned by the Committee**

- ☐ Strategic Industry Analysis: Biotechnology in the Waste Treatment Industry. Secor Inc., October 1989.
- ☐ Strategic Study of Opportunities for Canadian Biotechnology in Specialty Food Crops. Agri Studies Inc., March 1990.
- ☐ Strategic Study for Canadian Biotechnology in Animal Husbandry Products. Deloitte & Touche, March 1990.
- ☐ A Preliminary Identification of Strategic Opportunities for Development of Bio-Control and Inoculant Products in Canada. Deloitte & Touche, March 1990.
- ☐ Biotechnology in Forestry. A paper prepared for the NBAC by Forestry Canada, September 1990.
- ☐ Industry Profile: Biotechnology Applications and Trends in the Mineral and Energy Industries. Prepared for the NBAC by Dr. W. (Jeff) Jeffery, Executive Director, Mining Industry Technology Council of Canada, Ottawa, and member, NBAC, September 1990.
- ☐ Biotechnology in the Pulp and Paper Industry. Pulp and Paper Research Institute of Canada, December 1990.
- ☐ National Business Strategy for Biotechnology Phase I and II Reports. Peat Marwick Stevenson and Kellogg, August 1991.



**List of Recommendations from the Report of the NABST  
Committee on the Financing of Industrial Innovation**

**1. *Capital Gains***

The Committee recommends that the capital gains tax rules be modified so that gains from eligible equities held longer than three years are not included within personal income for the purposes of taxation.

**2. *Pensions***

The Committee recommends that a tax penalty be applied against the assets of pension funds which do not invest at least one percent of their assets in eligible small enterprises. Should a fund fail to invest any of that one percent in eligible firms, a penalty of 10 percent would be assessed on the amount not so invested. Eligible enterprises would include companies that perform substantial amounts of research and development or venture capital groups that specialize in the financing of technology-intensive firms.

**3. *Risk-Sharing Fund***

The Committee recommends the establishment of a national fund of up to \$1 billion, capitalized over time by government and/or by the penalty tax on pension funds (see recommendation two), administered at arm's length from government, for the purpose of sharing up to 50 percent of the industrial innovation costs for specific high-risk projects proposed by medium and large firms, the fund contribution to be repayable at premium rates from revenues generated by the eventual sales of the product developed and marketed.

**4. *Matching Investment Fund***

The Committee recommends the establishment, on a pilot basis, of a matching investment fund, which would provide contingently repayable government contributions directly to new and/or small innovation-based ventures of amounts up to 75 percent of equity funds raised by individual investors. Government would finance the creation of the fund. Funds would be "bonded" as to use (i.e. for innovation); provided the bond was in place and certain minimum criteria were met, funds would be made available without government review.

5. ***Industrial Innovation Merchant Bank***

The Committee recommends the establishment of a financial institution, the purpose of which would be to provide equity and debt investment for technology-intensive firms. Government(s) would contribute some part of the initial capitalization of this bank. The financial institution would endeavour to earn market rates of returns on its investments.

TP248.195/.C2/C3

Canada. National Biotechnol

Canada. National

**Biotechnology Advisory**

BBQC 1991

[illegible]

ISTC 1551 (2/90)

INDUSTRY CANADA/INDUSTRIE CANADA



136684