Annual Report

CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE

2004

many perspectives, one source

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Canadian Biotechnology Advisory Committee (CBAC)
235 Queen Street
Ottawa, Ontario K1A 0H5

Toll free: 1 866 748-CBAC (2222)
TTY: 1 866 835-5380
Telephone: (613) 954-7059
Fax: (613) 946-2847
Web: **www.cbac-cccb.ca**
E-mail: **info@cbac-cccb.ca**

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Message from the Chair

Over the past five years, the Canadian Biotechnology Advisory Committee (CBAC) has considered the challenges and opportunities for Canada arising from biotechnology and its applications. New frontiers have emerged in health, food production, the environment and sustainable industrial development. Governments around the world are re-energizing their efforts to use biotechnology for social and economic objectives. The Government of Canada's stated goal for our country's strategy on biotechnology is "*to enhance the quality of life of Canadians – in terms of health, safety, the environment and social and economic development – by positioning Canada as a responsible world leader in biotechnology.*"

While Canada's international standing is favourable by some measures – 1st in research and development investments per employee, 2nd to the U.S. in number of biotechnology firms and 3rd behind the U.S. and U.K. in revenues – we must not overlook or under-estimate the impact of this technology on Canada's competitiveness globally. Nor can we ignore the views of Canadians on the development and use of biotechnology. Public engagement is key and access to information designed to inform and support dialogue and public participation must be a priority.

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Early in our mandate, our focus was on the adequacy of existing policy, instruments and operations (e.g. regulatory systems) to deal effectively with biotechnology developments. More recently, we have also turned our attention to the broader impacts of biotechnology on complex and dynamic systems, such as the health system. Our work has led us to develop a suite of products and activities that can be customized to meet the needs of Government in an often rapidly changing scientific and social context.

This fifth annual report, covering the year 2004, describes CBAC's program of work and highlights our recommendations to the Government of Canada and its partners. It also profiles our Committee's efforts to build linkages, exchange information and engage stakeholders in dialogue around current and emerging policy issues.

In particular this year, CBAC focused on biotechnology and health under the theme of *Biotechnology and Canadian Society*. The result of our work – a comprehensive report entitled *Biotechnology and the Health of Canadians*, sets out the potential role of biotechnology in relation to the wide range of factors that influence health, discusses the social and ethical considerations, and recommends actions necessary to equip our systems to meet the challenges that the unfolding era of modern biotechnology will present.

Staying abreast of the fast pace of scientific discovery and responding with appropriate policies and regulations that fully integrate the health, ethical, social, regulatory, economic, scientific and environmental dimensions of biotechnology is a daunting challenge. CBAC's strength is its ability to provide expertise and advice from many perspectives and from one source. I wish to thank the dedicated members of the Committee who are helping Government to meet the challenges of biotechnology with solid evidence and sound advice.

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WHO WE ARE

Our mandate, structure, and the ways we work make the Canadian Biotechnology Advisory Committee (CBAC) unique among advisory bodies in Canada and abroad. Membership consists of experts drawn from diverse fields – science, medicine, agriculture, environment, industry, ethics, economics, and communications – and reflects the breadth of areas that biotechnology and its applications impact in our society. Members are appointed on the basis of individual attributes, not as representatives of particular interests. They are appointed by the Government of Canada's Biotechnology Ministerial Coordinating Committee (BMCC). This group of seven Ministers – from Agriculture and Agri-Food, Environment, Fisheries and Oceans, Health, Industry, International Trade and Natural Resources – oversees *The Canadian Biotechnology Strategy*. As well, their portfolios include a range of biotechnology-related priorities.

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Montréal, Quebec

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Université Laval
Québec, Quebec

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Associate Professor
Environmental Science Department
Acadia University
Wolfville, Nova Scotia
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Cranbrook, British Columbia

CBAC members serve on a volunteer basis. The CBAC Chair receives a per diem (to a maximum number of days of work per year) commensurate with the demands of the position.

WHAT WE DO

CBAC provides the Government of Canada with comprehensive advice on current and emerging policy issues associated with the health, ethical, social, regulatory, economic, scientific and environmental aspects of biotechnology and its applications. This broad mandate reflects the reality of biotechnology, the challenges and opportunities it presents, and the fact that it cuts across the lines of government departments and, increasingly, demands the integration of diverse perspectives to develop coherent policy.

Various activities are undertaken with a view to providing comprehensive and practical advice to the Government. Our agenda is developed in two ways: based on the policy gaps and emerging issues that members identify, given their expertise in particular fields; and, from direct referrals from federal departments and agencies seeking advice on specific issues.

CBAC also uses a variety of mechanisms to advise Ministers and to communicate to stakeholders and the public through comprehensive reports, brief written commentaries, participation in workshops and conferences, our website, meetings with policy-makers, and interviews with the media. CBAC's advice to Government, our reports and background research are all public documents.

Due to the scope and complexity of our topics, we employ a number of different tools that support our analyses and create ongoing mechanisms for linkage and exchange. For example, CBAC: consults with stakeholders; commissions background studies, research and analysis; convenes round-table discussions; conducts workshops; and, establishes expert working parties.

CBAC's Achievements 2004

Recommendations to Government

Throughout 2004, CBAC advised the federal government on a range of current and emerging issues and, in doing so, put in place the foundations on which to build a dynamic policy agenda that supports and guides Canada's efforts to deliver the benefits of biotechnology to Canadians, and ensures that the risks are effectively anticipated and managed.

In 2004, CBAC tackled: the issue of our health systems' readiness to assess and adopt beneficial biotechnology-based innovations; the challenges around privacy protection in the age of genetic information; the pressing need to fill gaps in our regulatory system that currently risk impeding Canada's competitiveness; and, the urgency for the Government of Canada to bring clarity to the question of patenting higher life forms.

In particular this year, CBAC focused on biotechnology and health under the theme of Biotechnology and Canadian Society.

Making the most of
BIOTECHNOLOGY-BASED HEALTH INNOVATIONS

Advances in health and medicine from biotechnology, from antibiotics and vaccines to organ transplantation and gene-based medicines, play a major role in improving Canadians' health. In the 21st century, some predict they will fundamentally transform the way the health system is organized and managed, and how health services are delivered.

As exciting and promising as biotechnology-based health innovation (or BHI) may be, they create pressures – some economic, others social and political – that reflect the rapidly evolving scientific and social contexts that characterize this area. Government decision makers need strategies that both foster and regulate the use of BHIs to maximize their potential health benefits for Canadians while minimizing the risks.

CBAC's report, *Biotechnology and the Health of Canadians* is the product of extensive research and analysis, synthesis of findings, consultation with experts, and debate among CBAC members themselves. Central to the work was a focus on Canada's capacity to make evidence-based decisions on the adoption of biotechnology-based health innovations, as well as identifying policy actions that would achieve the following objectives:

- increase access by Canadians to the health and quality of life benefits of BHI in a cost-effective and efficient way;
- create mechanisms to address and manage the potential challenges, risks and hazards that may be associated with BHI;
- ensure the responsible and ethical development and use of biotechnology in the health care system; and,
- strengthen scientific and management capacity to generate, adapt and assimilate beneficial BHI.

Biotechnology and the Health of Canadians offers Government recommendations on how to equip decision-makers to make the choices they will confront as biotechnology-based innovations increasingly enter the marketplace. It underlines the need to create a body to set standards and to accredit organizations and institutions that are responsible for storing biological specimens used for research purposes, such as biobanks, which would collect and store genetic information gathered from individuals for research purposes. It also draws attention to the necessity of setting guidelines to make sure the benefits of genetic research, including any commercial benefits, are shared with the communities that provide the genetic material.

The report specifically recommends that Government:

- Strengthen coordination among the agencies that assess health technologies in Canada and work with international partners to reduce duplication of effort and share expertise.

- Enhance the approach used to assess health technologies to take in analysis of their potential impacts on the health system, including ethical and social considerations.

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- Modernize Canada's regulatory regime to make it more responsive to the rapid rate of innovation and to provide a more coherent government-wide approach that ensures high standards of protection for health, safety and the environment.

- Clarify the current confusion over the patenting of higher life forms and strike an appropriate balance between the interests of innovators, developers and the public seeking access to the benefits of BHI.

- Create the foundation for improving Canada's ability to adopt beneficial BHIs by making the ongoing assessment of Canada's performance in this regard the responsibility of a high level federal-provincial-territorial body.

Our analysis and resulting recommendations were developed in four areas where policy initiatives are clearly and urgently required to expand capacities and to remove barriers to optimal performance: research and development; regulation and commercialization; technology assessment; and, health system adoption. Recommendations in each area are summarized (see sidebar starting on page 4).

Further, CBAC's report suggested that policies and regulations, in and of themselves, will not result in increased health benefits from BHIs. These must be complemented and enabled by general strategies that build and enhance collaboration, capacity development, public participation, public and professional education, and support for evidence-based decision making.

CBAC recognized that the adoption of biotechnology-based health innovations by the health system is a complex process, strongly influenced by the internal dynamics of health care systems, on the one hand, and health practitioners and consumers on the other. Health system managers face difficult choices in regard to the adoption and funding of BHIs because of their technical complexity and "disruptive" effects (eg. costs and impacts on organizational structures, professional roles) and, in some instances, because of their ethical and social implications.

protecting the privacy
OF GENETIC INFORMATION

While the public recognizes the potential benefits of genetic research, they are concerned about how and where personal data is stored and who will have access to it. Canadians fear that the inappropriate use of genetic information could result in discrimination – whether rejection for employment or insurance, or ineligibility for pensions for people with disabilities.

CBAC has focused attention on the consideration of policy actions required to facilitate access to genetic information for health research while ensuring that the rights of Canadians to privacy and confidentiality are respected.

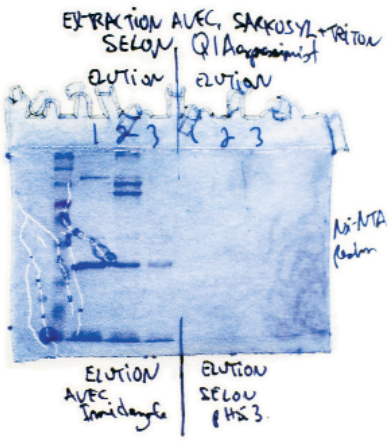
Protecting Privacy in the Age of Genetic Information brings together in one volume, the work that CBAC commissioned in this area. The first paper, "Of Volume, Depth and Speed: The Challenges of Genetic Information," explores a wide range of possible uses of genetic information, from improving health to use in law enforcement. The second paper "Genetics, Privacy and Discrimination" examines whether genetic information is adequately protected from misuse and notes that the benefits of genetic research could be lost if Canadians are not confident that their genetic information is handled appropriately. Finally, "Population Biobanking in Canada: Ethical, Legal and Social Issues", synthesizes the work of a team of legal experts, ethicists and researchers studying the implications of the development and use of "biobanks."

CBAC believes there are some specific issues that should be addressed before any population biobanks are established. Population biobanks must be designed from the very beginning to ensure that this is the type of research Canadians want and that the genetic information collected from Canadians will be handled, stored and used with appropriate safeguards, data encryption and security systems to ensure that privacy and confidentiality are protected. The principles of "informed consent" must be redesigned to account for future uses of the genetic information in a way that balances the needs of the researchers and the rights of the research volunteer. Current laws and policies will also need to be reviewed to ensure they can accommodate the new issues raised by biobanks.

completing the regulatory system

SMART REGULATION

Just as Canadian industry is a leader in the development of many new products of biotechnology, so too should we lead the way in developing and implementing appropriate regulation. The lack of a comprehensive and functional regulatory system for products of biotechnology is impeding the development of industries in Canada and consequently the potential for consumer and economic benefit. Gaps in Canada's regulatory system pose a problem not only for policy makers but also for industry and consumers.



This is the message that CBAC communicated in our advice to Ministers – "*Completing the Biotechnology Regulatory Framework*". CBAC called on the federal government to: reaffirm its commitment to the scientifically based regulatory framework for genetically modified (GM) foods and other novel foods and feeds; implement CBAC's previous recommendations on measures to strengthen and support the regulation of GM foods and feeds; extend the biotechnology regulatory framework to transgenic animals and fish, cloned animals, functional foods and nutraceuticals, and novel protein production systems; and, ensure that the expertise and capacity is in place to support these actions.

The importance of urgent action to develop a comprehensive biotechnology regulatory system was highlighted in the 2004 report of the External Advisory Committee on Smart Regulation (http://www.smartregulation.gc.ca).

RATIONALIZING
PATENT LAW

When biotechnological research leads to the invention of a new product or process, the inventors or their sponsors seek intellectual property protection, arguing that such protection is essential if biomedical discoveries are to be commercialized. However, patenting biological material – whether from microorganisms, plants, animals or humans – can raise complex social and ethical challenges.

In CBAC's June 2002 report, *Patenting of Higher Life Forms*, we recommended that Canada, like all its major trading partners, should permit plants and animals to be patented (provided certain safeguards were in place). In December 2002, however, the Supreme Court of Canada ruled that animals do not fall within the definition of "invention" in the *Patent Act* and are, therefore, not patentable in Canada[1].

In a later case, the Supreme Court ruled in a 5-4 decision that, even though plants are not patentable in Canada, a patent on a plant cell or modified gene within a cell still gives the patent-holder the right to control use of the plant because each individual cell in the plant contains the modified gene. The minority judges took the view that this ruling contradicts the conclusion in the Harvard mouse case[1] (also a 5-4 decision), making the earlier decision meaningless in practice, if not in law. They said that patent claims must be interpreted in the context of existing patent law; i.e., that plants are not patentable. They would therefore have limited the patent claims to prevent other seed companies from creating a competing seed using the modified genes and cells, but not to prevent farmers from growing plants containing them.

Consequently, in *Rationalizing Patent Law in the Age of Biotechnology*, CBAC again called on Parliament to decide whether, and to what degree, patent rights ought to extend to plants and animals.

We reiterated our June 2002 advice that the application of patent law to biological inventions should not be decided by patent office administrators or courts, as it has to date, in Canada and other countries as well.

Canada has an unprecedented opportunity to be the first country to ensure that the special characteristics of biological inventions are taken into account throughout the *Patent Act* and not only in the definition of "invention."

[1] The "Harvard Onco-Mouse," case, in which a mouse had been genetically modified for use in cancer research.

CBAC project in the works

FOSTERING INNOVATION AND DELIVERING HEALTH CARE

Intellectual Property Protection for Human Genetic Material and the Health Sector

In 2004, CBAC was asked by the federal departments of Industry and Health to examine the potential health-sector implications of having Canada's intellectual property regime applied to human genetic materials. The request was prompted by concerns that the current intellectual property regime, and particularly, the granting of patents on human genetic material, could result in barriers to health research and possibly impede the access to, and affordability of, new genetic tests.

Due to the nature of this project, and the need to mobilize significant technical expertise and experience, CBAC struck an Expert Working Party that includes participants from industry, public policy, the health system, intellectual property law, and economics. A comprehensive program of research and a consultation process has been designed to develop a "state-of-the-art" analysis of the issues and their impacts. Expert roundtables of health researchers, clinicians and clinician scientists, intellectual property experts, economists, entrepreneurs, health system administrators, and provincial/territorial governments are essential inputs into the Working Party's work. The process will conclude with a multi-stakeholder dialogue to validate and test recommendations. When completed, the Working Party will have identified and analyzed the issues and their current impacts, assessed trends, compared Canada to other countries, and determined if policy change or new policy is required to meet the dual objectives of encouraging Canadian innovation and providing access to new health products arising from human genetic material.

CBAC expert round-table mobilizes significant technical expertise:

- health researchers
- clinicians and clinician scientists
- intellectual property experts
- economists
- entrepreneurs
- health system administrators
- provincial/territorial governments.

Reaching Out

CBAC employs various tools to listen to, talk with and inform Canadians. For example, the Committee and its working groups host consultations to garner input from experts and interested individuals on a variety of topics. It also provides information products targeted to a cross-section of audiences to support the release of CBAC reports and other advice to Government. These audiences include Members of Parliament, particularly Ministers of the *Biotechnology Ministerial Coordinating Committee*, relevant Parliamentary Committees, as well as senior bureaucrats in federal and provincial governments.

Communications and consultation activities are also geared to the academic and research communities, non-governmental organizations advocating to government on issues related to biotechnology, members of the media and the general public.

Given its growing impacts on society and the economy, there is increasing interest in the fast-changing biotechnology sector. *BiotechWatch*, a newsletter introduced by CBAC in the fall of 2004, is aimed at both the Canadian public and public policy makers who must consider the many aspects and impact of biotechnology. The newsletter is intended to provide an overview of those biotechnology issues on which CBAC is offering advice to Government. The newsletter is distributed broadly to both government and stakeholder audiences and is available online at: www.cbac-cccb.ca

CBAC's communications products and services include:

- *BiotechWatch* newsletter
- news releases
- backgrounders
- briefings
- presentations
- correspondence
- exhibits
- CBAC's public, committee member and working group Web sites.

Encouraging Constructive Debate

THE DIALOGUE TOOL

Public policy makers are faced with the task of understanding and reconciling competing interests, widely divergent perspectives and often polarized views on the correct course of action. Add to this landscape the accelerating pace of biotechnological innovation in our society, and the challenges are evident. To facilitate productive discussion, CBAC supported the development of a framework for dialogue that would help Canadians discuss contentious biotechnology issues. An Exploratory Committee, comprised of people with backgrounds in the environment, public health, industry, the food supply chain (farmers, producers, retailers), as well as consumers and members of faith groups, embarked on pioneering work to design and test an approach that would enable dialogue among those with widely divergent perspectives. Because the members of the Exploratory Committee themselves brought different perspectives to the discussion, the result met expectations.

A made-in-Canada "Dialogue Tool" was developed to stimulate debate about all the relevant issues – not only the science involved, but also the potential social, economic, ethical and broader societal impacts of biotechnology innovations, such as the sensitive issue of genetically-modified food and feed products. A "spectrum" was developed to gauge whether the introduction of a new product of biotechnology would be acceptable, acceptable with certain conditions, unacceptable at the present time or until more is known, or not acceptable under any circumstances. The *Dialogue Tool* enables stakeholders to assess whether a biotechnology application is likely to deliver positive, negative or neutral outcomes for Canadians.

The Dialogue Tool and accompanying documents, including a user guide, will be posted on CBAC's website early summer 2005 (www.cbac-cccb.ca). The tool is available to any organization wishing to encourage constructive discussion about biotechnology issues and to ensure different points of view are considered. It can be used by policy-makers, industry leaders, not-for-profit groups and academics. As much as it can help to inform public policy, it is also a valuable educational resource.

THE NEED FOR PUBLIC ENGAGEMENT: GENETICALLY MODIFIED (GM) FOODS

At one CBAC event during the year, Lord Robert May, President of the Royal Society of the United Kingdom, spoke about the public policy implications of GM plants in the U.K. He pointed to the lack of public engagement resulting in public resistance to the introduction of GM foods and how the GM agenda in the 1980s benefited agri-business and the farmer, but not necessarily the consumer.

The Royal Society's advice then, as now, was to engage the public in discussions about new technology so they can make informed choices. As the second generation of GM food crops deliver clearer consumer benefits and address environmental concerns, Lord May said he expects the public will judge the technology on a case-by-case basis and look at the risk/benefit ratio for themselves and their families – an attitude similar to that applied to biotechnology health products.

CBAC participation
IN BIOTECHNOLOGY-RELATED EVENTS

DEVELOPING CANADIAN POLICY FOR ACCESS AND BENEFIT SHARING OF GENETIC RESOURCES, DECEMBER 1 & 2, 2004

CBAC member Linda Lusby took part in this workshop, which aimed to: raise awareness of access and benefit sharing policy amongst the Canadian science and technology community; gather information about managing and developing genetic resources in order to guide domestic policy development; and share lessons learned on key issues.

BIONORTH, OTTAWA, NOVEMBER 29, 30, DECEMBER 1, 2004

Canada's 11th annual International Biotechnology and Life Sciences Conference and Exhibition, BioNorth, took place at the Ottawa Congress Centre. The focus of the conference and exhibition was "*Commercialization: The Business of Science and the Science of Business.*" CBAC participated as an exhibitor to build awareness among industry audiences of its role in providing comprehensive advice to Government on the many aspects of biotechnology and to showcase the Committee's work during 2004. At the BioNorth Panel discussion on Health Innovation, CBAC's report "Biotechnology and Health Innovation" was profiled.

PHARMING THE GENOME, OTTAWA, NOVEMBER 4, 2004

CBAC Chair, Dr. Arnold Naimark, was a speaker at the conference, which attracted members of government, industry and the research community from Canada, the U.S. and U.K. Participants explored public policy issues associated with the commercial applications of pharmacogenomics, the implications for human health and the economy, and social and ethical challenges surrounding this field of study.

AUSTRALIA'S GENE TECHNOLOGY REGULATOR

CBAC took part this year, in a Canadian Biotechnology Secretariat briefing for Dr Sue Meek, Australia's Gene Technology Regulator. Dr. Meek is responsible for administering and enforcing the Australian national regulatory system for the development and use of gene technology. Her interest was in Canada's strategy for biotechnology and CBAC's role in providing advice to Government on biotechnology-related policy issues.

A world view

GENES AND INGENUITY: GENE PATENTING AND HUMAN HEALTH (AUSTRALIA)

In December 2002, the Australian federal Attorney-General requested the Australian Law Reform Commission (ALRC) to examine the laws and practices governing intellectual property rights over genetic materials and related technologies, with a particular focus on human health issues. *Genes and Ingenuity* is the culmination of this review. The report makes 50 important recommendations for reform to customize the current system to accommodate scientific breakthroughs, but the report does not suggest any radical overhaul of the patent system.

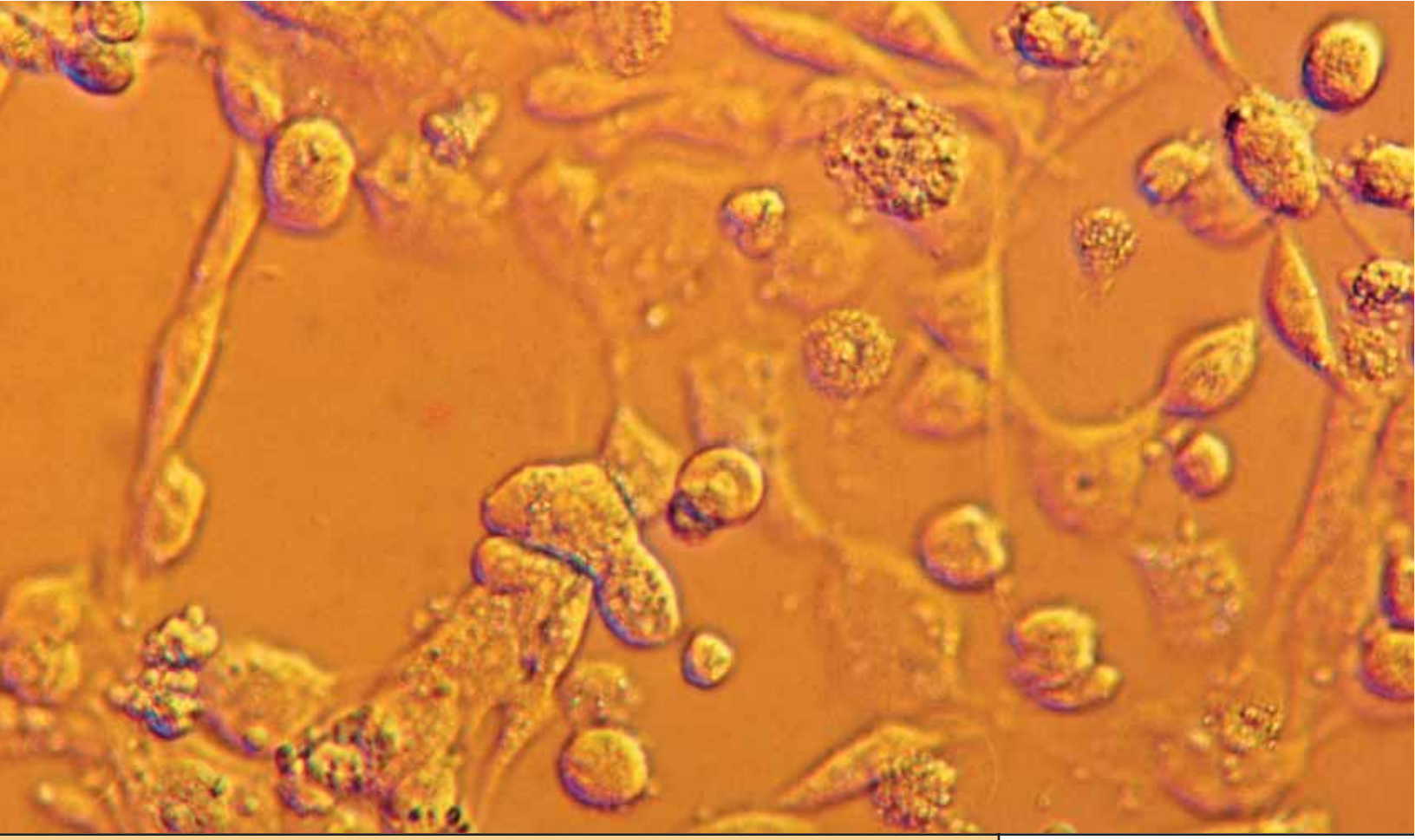
The report was prepared by the Australian Law Reform Commission, Sydney. ALRC, 2004 (http://www.austlii.edu.au/au/other/alrc/publications/reports/99/).

A PATENT SYSTEM FOR THE 21ST CENTURY (UNITED STATES)

The U.S. patent system is in an accelerating race with human ingenuity and investments in innovation. In many respects, the patent system has responded with flexibility, but the strain of continual technological change and the greater importance ascribed to patents in a knowledge economy are exposing weaknesses including questionable patent quality, rising transaction costs, impediments to the dissemination of information through patents, and international inconsistencies. A panel, including a mix of legal expertise, economists, technologists, and university and corporate officials, recommends significant changes in the way the patent system operates.

A Patent System for the 21st Century urges creation of a mechanism for post-grant challenges to newly issued patents, reinvigoration of the "non-obviousness standard to quality" for a patent, strengthening of the U.S. Patent and Trademark Office, simplified and less costly litigation, harmonization of the U.S., European, and Japanese examination process, and protection of some research from patent infringement liability.

This report was prepared by Stephen A. Merrill, Richard C. Levin, and Mark B. Myers, *Editors*, Committee on Intellectual Property Rights in the Knowledge-Based Economy, National Research Council (http://books.nap.edu/catalog/10976.html).



PATENTING HUMAN GENES AND STEM CELLS (DENMARK)

This report, prepared by the Danish Council of Ethics, contributes to a clearer public discussion about the ethical defensibility of patents on human genes and stem cells. As well, the report makes recommendations on how best to safeguard ethical considerations within the current rules and practices. With respect to gene patents, the Council recommended they be permitted, but only with narrow scope and practical utility and that patent rules not discourage research. The Danish Council of Ethics, Copenhagen, 2004 (http://www.etiskraad.dk/sw475.asp).

CONVERGING SCIENCE AND LEADERSHIP: THE KEY TO THE FUTURE

Technological progress in biotechnology has been profound. Life-saving biotech drugs and hardier agricultural crops are already in widespread use. Canada has been in the vanguard of these advances. However, rapid commercial and technological progress is beginning to stress the industry's human resources capacity. If Canada is to sustain its excellence in biotechnology, we must address this crucial issue. This report looks at current and future human resource (HR) issues and makes recommendations to help ensure that Canada has the people required to sustain and unlock the industry's potential.

This report was prepared for the Canadian Biotechnology Human Resources Council, 2004 (http://www.bhrc.ca).

Looking ahead

The demand for leading-edge research, solid evidence and sound advice from diverse perspectives will only grow in the years ahead.

Biotechnology is proving to be one of the most powerful tools the world has ever witnessed. Its applications to human and animal health, the environment, food and feed crops, international trade and the global economy are so widespread it's hard to find a sector of society that isn't directly affected by this growing body of rapidly-advancing knowledge. Consequently, the demand for leading-edge research, solid evidence and sound advice from diverse perspectives will only grow in the years ahead.

As its contribution to meeting this challenge, in addition to its work on human genetic materials and intellectual property rights, in 2005, CBAC will further its work under the theme of *Biotechnology and Canadian Society* by initiating a new project, *Biotechnology, Sustainable Development and Canada's Future Economy*. Through this major project, CBAC will provide guidance on the role of biotechnology in the sustainable development of Canada's economy in the 21st century. This project is expected to be complete by March 2006.

Given the escalating rate of scientific discovery, the need for oversight and strategic advice to Government has never been greater. There is a continuing need for a national strategy that embraces the economic, scientific, ethical, legal, social, regulatory, environmental and health aspects of this transformative technology. Canadians can continue to count on CBAC for guidance and expertise in these areas. As always, CBAC will provide many perspectives, one source.