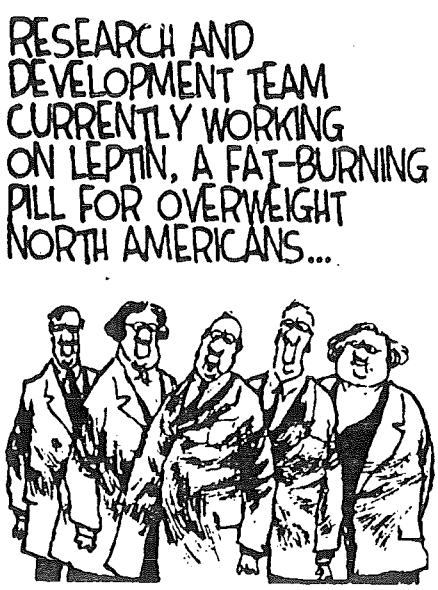
295

MANIPULATING LIFE:

Patenting Lifeforms and Biotechnology Development in Canada Today



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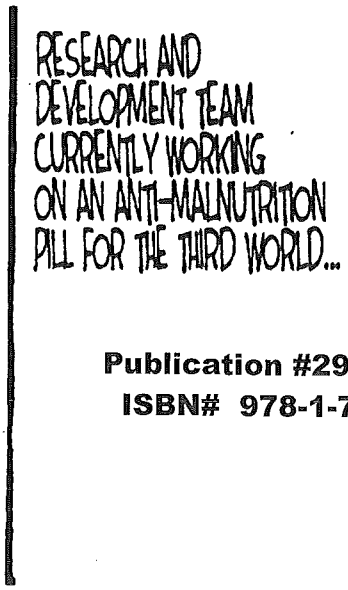

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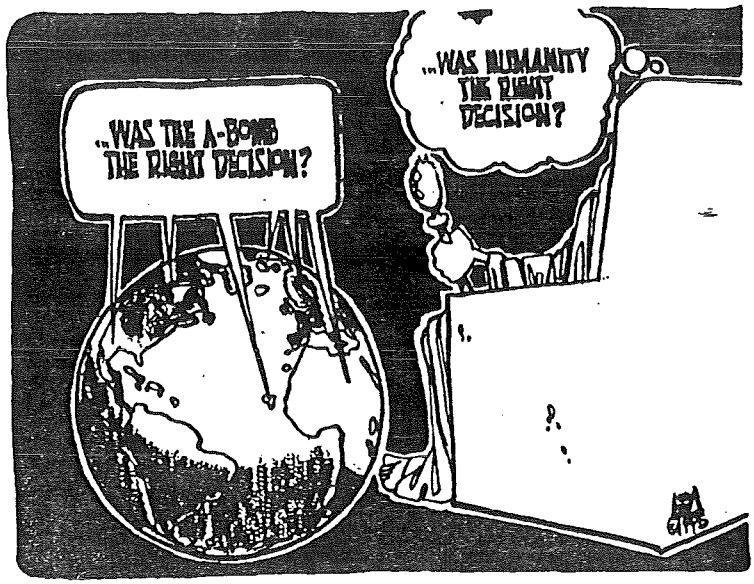

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Table of Contents

This document has been prepared by Ken Traynor of the Canadian Environmental Law Association (CELA) with the assistance of EYC summer student David Oppenheim. The material is based on discussions and work done in a small ad hoc working group on the development of biotechnology policy in Ontario and Canada. The informal name used by the group was Biojest or Biogest as you please. The other active members of the group were Elizabeth Abergel, Fiona Miller, Maureen Press-Merkur, Mark Winfield, Brewster Kneen, Rod MacRae, Laura Sky, Andrea Maenza, Stephanie Brown, Michelle Swenarchuk and Lisa Mills.

INTRODUCTION

The commercialisation of genetic engineering techniques will have profound social, environmental and ethical implications and requires careful public scrutiny and debate. Just as computer technology has brought computers into homes, offices and our daily lives in ways unimaginable as little as ten years ago, biotechnology may also have profound consequences for how we live, what we eat, our natural environment and what reproductive choices are available to us.

Unlike other technologies which alter how we work and relate to each other, biotechnology modifies the very structure of life-material itself. As Leon Kass has put it

> biomedical engineering circumvents the human context of speech and meaning, bypasses choice, and goes directly to work to modify the human material itself."[1]

These new technologies and the accompanying attempts to patent lifeforms raise fundamental questions about how we value life. Should anyone have a right to patent a life? On what grounds, if any, should someone be able to create new organisms? If these technologies are used what limits are put on the kinds of organisms that can be created? On what terms can new organisms be released into the environment? Who will decide, and how?

These questions are well known to people actively following developments surrounding these technologies but a number of recent events in Canada are generating active public interest in genetic engineering, its advocates and its implications. These include:

- The controversies surrounding the Royal Commission on New Reproductive Technologies and the inadequate response from the Minister of Health with her recent call for a voluntary moratorium on the use of nine specific technologies.

- The widespread opposition to the possible approval of recombinant bovine growth hormone (RBGH) for use in Canada.

- The release for commercial scale production of the first genetically modified herbicide resistant canola varieties in Saskatchewan and Alberta even though regulations governing the release have yet to be fully promulgated under the relevant statutes.

- The recent apparent decision (information can not be made public without approval from the applicant) by the Canadian Intellectual Property Office not to grant the patent claim on the "Harvard" or Onco mouse in Canada. This would have been the first Canadian patent on a multi-cellular lifeform.

- Concern over the development of an international biosafety protocol and apparent Canadian government acceptance of the U.S. government position calling for voluntary guidelines rather than a binding protocol.

- The recommendation by the Parliamentary Committee on Environment and Sustainable Development for a new and separate part of the *Canadian Environmental Protection Act* to cover the environmental release of genetically modified organisms.

It is important to note that these developments are occurring at a time when recent public surveys commissioned by Industry Canada (see information on the Optima and FNACQ surveys) have documented growing public scepticism about who benefits most from these technologies and concerns about the role of the federal government as regulator.

A long time observer and commentator on technology issues, Sheldon Krimsky argues that the reason for public apprehension concerning the commercialization of genetics -- compared, for example to computers, microelectronics and robotics -- is more than simply public sensitivity over biological issues. It is because concurrent with the genetics revolution, there have arisen challenges to traditional ways of promoting and regulating industrialization.[2]

It is clear that a significant portion of the Canadian public believes that biotechnology, especially in its applications to plant, animal and human genetic science, requires our collective examination and analysis. It is our belief that shared and democratic process must inform the formulation and implementation of government policy and regulation.

We believe, therefore, that these technologies must be analyzed, regulated, monitored and controlled with the health and social needs of Canadians as the top priority. Independent information, discussion and

debate, and community decision-making must be brought in from the margins of public process. Public process must be structured and integrated into government decision-making in the development of science and technology policy, and the biotechnology industries.

Beginning in the early 1980s the Canadian government became a major biotechnology industry promoter in the apparent belief that biotechnology is a significant growth area for the Canadian economy. The Canadian government appears to accept as fact industry assertions that biotechnology offers risk-free solutions to many disease and agricultural problems. In fact the director of one multi-stakeholder, biotechnology "communications network" has said that he told Federal government representatives directly that they have squandered their opportunity to mediate between public and private interests in this area because they are no longer seen as neutral but as biotechnology promoters. And Canadian governments have become significant promoters of the commercialization of biotechnology applications.

Over the past decade more than $1.8 billion of public funds have flowed into biotech research and development while the indirect public subsidy in areas such as tax credits, university research and development, and guaranteed loans amount to much more. University and government research labs are increasingly involved in "partnership" arrangements with biotech companies. In 1991, Agriculture Canada field-tested more genetically-engineered crops than private industry tested.[3]

Despite this tremendous expenditure of resources it is apparent that the right questions about these emerging technologies are seldom addressed.

> A distinguishing characteristic of democratic institutions is that their acceptability is determined as much by how they make decisions (process) as by the nature of the decisions they produce (outcome). At least as important as the outcome of policy decisions about patenting higher life forms is the process by which the decisions are reached. Indeed, democracy is largely <u>about</u> process...[4]

The above quote comes from the authors of an Industry Canada commissioned paper <u>Ethical Issues Associated with the Patenting of Higher Life Forms</u> but it applies equally to all government policy on the applications of biotechnology. In their recommendations the authors suggest that a special committee of Parliament be struck to openly promote debate in order to develop effective public policy in this area. If the government acts on the suggestions included in this thorough review of the ethical issues related to biotechnology, it would be a useful advance over the ineffectual internal scattered consultation exercises to date.

The central problem of traditional systems of technology assessment is that it is an "expert"-centred process. Christine Massey, feminist sociologist, explains

> When clinicians, government policy-makers, and researchers continue to make decisions about research priorities, and what constitutes (scientific and/or medical) evidence, patients (or citizens) remain in a secondary, recipient role... Currently when decision-makers are faced with having to formulate policy on complex scientific or medical matters, they turn to recognized experts for their opinions--researchers, scientists, clinicians. The patterns of decision-making on science and technology issues have traditionally not been ones that encourage or even envisage a role for the public.[5]

Inherent in this discussion of technology assessment are two questions: <u>who</u> gets to decide and on what basis do they decide?

The Industry Canada ethics paper raises the central question that informs the regulatory process.

> How should societies and governments make choices about technologies that are unfamiliar and incompletely understood? One approach is to leave such decisions up to the experts: those who "know best". However, democratic societies appear increasingly unwilling to do this with respect to choices involving science and technology...[6]

Using the example of germ line modification, the Ethics paper quotes Krimsky again about this difficult but essential aspect:

> The implications of genetically modifying germ cells are far from understood. Many agree that there are profound consequences associated with initiating such experiments, but few can even begin to anticipate the scope of these consequences. Therefore, to begin such a process without understanding its broader implications, without a reasonable idea about whether it is possible to

> control the process once it has been done, and without a strong consensus from an informed electorate would be socially irresponsible.[7]

The Canadian government is haltingly attempting to address the complex social and ethical implications of these new technologies. This document outlines the current processes in order to stimulate and facilitate more active public involvement in these crucial decisions. It is an attempt to outline the host of domestic political pressures and international developments which affect these issues and hopefully to provide an avenue for people to enter the debate actively.

The material collected here has emerged from the discussions of a number of individuals who have met regularly over the past year in an informal working group to discuss issues arising from emerging applications of biotechnology in Ontario.

We came together in 1994 in response to a totally inadequate public consultation exercise ($621 out of a $400,000 budget were used to consult the public) carried out by the Biotechnology Council of Ontario (BCO). Created for this purpose, the Council had arranged a contract with the Ontario Government to prepare a report requesting increased financial and other support to develop the industry.

Following that frustrating experience, which unfortunately represents the norm rather than the exception for anyone questioning the boosterism pushing biotechnology solutions, we collaborated in a process, coordinated by the Canadian Institute for Environmental Law and Policy (CIELAP), that produced a wide-ranging critique of the BCO report for the Ontario government. This included identifying all the major issues which were left out of the document. (see appendix 2 for Table of Contents)

The material is intended to highlight the processes and decision points under each topic, not to produce exhaustive information on the issues themselves. We have tried to keep the explanations brief and to the point and provide further useful background material through contact organizations.

We have chosen not to offer a detailed overarching prescription to the complexity of issues which biotechnology engenders although many creative ideas and alternative approaches are included here and many more have been proposed elsewhere. The issue is not Can we do things better than we are? We can and must. Whether we have faith that existing social institutions are up to the job of crafting that better approach is a question much more difficult to answer positively.

We hope that this document will stimulate and facilitate a more active discussion amongst the broad array of people and organizations concerned about the uncritical embrace of biotechnology. In this way, we hope to contribute to greater public involvement in the crucial decisions which are now being made and to push our system of governance to address the full range of key questions raised by the commercialization of these technologies.

This document is divided into two separate streams - a Life Patents Stream and a Regulatory stream - which address the different decision making processes regarding issues surrounding biotechnology. Within each stream there are both domestic and international aspects to these activities. Recent articles of interest are included as appendices 1 through 10 and a number of contact organizations and information sources are included in appendix 11. This political process primer can be seen as a companion document to the recently released *Citizen's Guide to Biotechnology,* produced by the Canadian Institute for Environmental Law and Policy (see appendix 1 for details).

A. PATENTING LIFEFORMS

1. Canadian Intellectual Property Office Initiatives - Rejecting the Rush to Patent Life

At this time the Canadian *Patent Act* does not explicitly exclude lifeforms from patentability. Prior to 1982, Canadian Patent Office practice was to refuse patents for lifeforms a position common in other countries. With the arrival of commercial biotechnology, the filing of applications compelled patent offices to face the issue of patenting lifeforms.[8]

Current practice in the Canadian Patent Office is to grant patents for single-cell organisms, but not for higher lifeforms, ie., plants and animals (although the *Plant Breeders Rights Act* offers plant breeders patent-like rights over plant varieties).

Despite this stated policy the Patent Office has received a number of applications for patents on higher lifeforms. The first such patent claim, to reach a decision, a claim on the Onco-mouse (sometimes called the "Harvard mouse" which has been "engineered to be susceptible to cancer"), was rejected by the original examiner who reviewed the file. This ruling was appealed by the applicant. A decision on that appeal was made in early August, 1995.

It appears that the original examiners ruling was upheld and the applicant now has six months, until early February, 1996, to file an appeal to the Federal Court of Canada. As with the appeal of the 1989 *Pioneer Hi-Bred* case it will likely go to the Supreme Court of Canada. The decision would provide the precedent setting Canadian legal interpretation, unless the Act is changed by parliament, which would serve as the basis for subsequent decisions on the many other lifeform patent applications currently pending within the system. As of October 1995, 40 animal patents and 140 plant patents were pending.

As it stands, the situation in Canada, is in marked contrast to that in the United States and Europe. Patent claims on the Onco-mouse were granted in the U.S. in 1988, and in Europe in 1992. The European patent is being challenged by a third party, an opportunity that is

Animals and Ethics

The ultimate decision on whether Canada will allow the patenting of lifeforms has yet to be made, but it is important to highlight that a significant number of animals are already being utilized in biotech research. Animals are being "engineered" with "knock-out genes" for research purposes and animals are being bred to produce organs for experimental transplantation to humans. Performance enhancing drugs, such as rBGH, focus on animals as "factories" and are being pushed to market despite serious concerns about their animal health impacts.

Biotechnology, with or without the added incentive provided by patenting, has far-reaching implications for animals. Research and applications that are presently being employed not only create direct animal welfare concerns, they also challenge our entire moral framework regarding human exploitation of non-human animal species.

Animals are an integral part of biotechnology, yet are often invisible in any discussions surrounding the ethical implications of this technology. In our society animals are relegated to the status of a commodity. It is essential for industry to maintain the idea that animals do not warrant ethical consideration, in order to avoid the issue of animal sentience. Society's failure to acknowledge the intrinsic rights and interests of animals has allowed industry to push ethical boundaries and further institutionalize the notion of animals as inanimate objects - as tools.

Biotechnology offers the possibility for the recombination of genes of differing species dissolving previously impenetrable barriers. With an existing moral framework that has proven incapable of addressing current ethical dilemmas, even condoning the abuse and exploitation of animals, we cannot expect that it will accommodate new concerns arising from the transgression of genetic integrity.

Biotech applications currently being researched, introduced and heralded, emphasise short-term financial "benefits" with little regard for the biological or psychological health of the animals affected. There are already concerns which are not addressed by our current moral framework, making it especially difficult to address the ramifications of biotechnology on animals. Not only must the ethics of the science be examined but the very moral framework itself must be challenged. (See Appendix 9 for a more detailed debate.)

unavailable in the U.S. or Canada. (For more detailed information on the situation in the U.S. and Europe see the International section below.)

Under Canadian law a patentable invention is defined under section 2 of the Act as:

> ... any new and useful art, process, machine, manufacture or composition of matter: or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

This definition derives from and is essentially the same as that found in U.S. legislation. The first applicant to file a patent application is entitled to the patent. If the application is rejected by the examiner, as occurred with the first application to patent a microorganism and the Onco-mouse application, the applicant can request a review of the examiner's decision by the Commissioner of Patents who may convene a Patent Appeal Board to advise him. The Commissioner either upholds the decision or directs the original examiner to reexamine the claim in light of the boards decision. Only the applicant has the right to appeal the decision of the Commissioner to the Federal Court.

The first lifeform patent claim, granted in 1982, to the Abitibi Co. for a patent to a modified microbial culture that was capable of digesting spent sulphite liquor from pulp plants was first rejected by the examiner as not proper subject matter under the definition of invention in the Act. In the successful appeal of this decision, the Patent Appeal Board reviewed the approach taken in a number of other countries, including the Chakrabarty decision in the U.S.. The board concluded that the practice of countries such as the U.S., U.K. Australia, and Japan of granting patents on microorganisms cast doubt on the correctness of the then Canadian practice of refusing patents for living matter per se.[9]

Industry Canada staff have suggested that the only real options available to Canada are whether to adopt the U.S. approach of wide-open patenting of lifeforms or the European approach where the European Patent Office (EPO) has adopted a more restrained attitude where morality is assessed "mainly on the careful weighing of the suffering of the animals and possible risks to the environment on the one hand and the invention's usefulness to mankind on the other". Under this approach the patent claim for the cancer mouse was accepted by the EPO, but one for research on hairloss was rejected. Further developments in Europe have widened this divide, in March, 1995, the European Parliament rejected the European Commission directive supporting the patenting of lifeforms (see International Section).

Legal commentators in Canada[10] suggest that the Supreme Court of Canada has distinguished between what it calls genetic engineering via the process of hybridization (human intervention in the reproductive cycle only) and genetic engineering where there is a direct alteration of the genetic code that affects the hereditary material (such as recombinant DNA technology). In the Pioneer Hi-bred Case the court ruled the traditional hybridization approach was not patentable, being still largely an act of nature. The Court went on to note in order to accept genetic engineering which involved the more interventionist approach as patentable it would have to decide whether there is a conclusive difference between the two types of genetic engineering based on the nature and extent of human intervention which takes place. The Onco-mouse case may offer an opportunity to address this question.

At this time there is no avenue for the public to get information about the status of the ONCO-Mouse claim except at the discretion of the applicant. If the case is appealed then the court documents will become part of the public record. Any public interest intervention in the case would be at the discretion of the Federal Court.

2. Industry Canada - Developing Canada's Patent Policy

Both legal and political dynamics are driving the development of Canadian policy on the patenting of life. The principle force is the upcoming decision on the Onco-Mouse patent application most likely by the Supreme Court of Canada. Internationally, the GATT - TRIPS agreement, and the United Nations Convention on the Conservation of Biological Diversity, both contain provisions relating to the patenting of life forms.

The federal government of Canada (led by the Intellectual Property Policy Directorate of Industry Canada) has begun to gather information relating to the patenting of biotechnological subject matter. However, the outcome of this process is in question. With resources being cut, it is unclear whether Industry Canada places a high priority on creating a public

process to help develop policy on the patenting of lifeforms. Furthermore, it appears that until information about the Onco-Mouse decision enters the public domain and generates public responses, Industry Canada sees itself under little pressure to formulate a public process (personal communication, ISTC, September 1, 1995).

While contracts were issued for a number of papers (in areas of ethics, law and economics), it is unclear whether any formal mechanism for distribution or discussion of the papers has been developed. Links to other government processes, however, (National Biotechnology Strategy Working Group on Ethics, Biotechnology Forum Steering Committee on the Societal Implications of Biotechnology) are being explored. Whether or not a new process is created to deal with issues of patenting remains to be seen.

While the process (if it continues) has yet to "fail" it is important that it be monitored to ensure an open and adequate discussion takes place. The recent experience of the CEN Biotech Caucus with the consultation process (see letter to Lloyd Axworthy and reply in Appendix 6) suggests the problem of conflicts in various parts of the government between the promoters and those who regulate will be ongoing.

3. Genetics and the Law Conference - Lawyers and Gene Jockeys Respond

Though the Canadian Government has yet to develop any effective, inclusive process to address the issues surrounding the patenting of lifeforms the complexity and urgency of the task should come as no surprise. For example, in 1992, the Canadian part of the international Human Genome Project received $22 million for genetic research in this country. Recognizing the importance of addressing more than just the science of the issues, the grant stipulated that 7.5% of the funds must go towards ethical and legal research.[11]

The Genetics and the Law Conference program outlined below represents a portion of this requirement. Sponsored by a number of legal bodies, law firms and the Hospital for Sick Children the wide-ranging nature of the topics identified serves to highlight the magnitude of the potential impacts. It also acts as a useful comparator to the limited perspective shown in proposals currently circulating within the government from bodies such as the Western Economic Diversification Fund which chairs the Biotechnology Forum Steering Committee on the Societal Implications of Biotechnology.

GENETICS AND THE LAW
October 21, 1995.

PROGRAMME

MORNING:

Objectives and Purposes of this Study

- Preparing studies for reference by legislators in both levels of government
- Why the Bar must prepare for the gene era
- The fields in law which will be affected by advances in human genetics research; criminal law, insurance law, patent law, health law, labour and employment law
- Why the Human Genome Project will generate new demands on the law
- The role of the Bar in evolving regulatory policy
- Summary of noteworthy foreign genetics/DNA testing legislation
- The importance of educating the Bar and the judges
- Considerations of ethics in gene research and the law

Introduction to Genetics

- Overview of the Human Genome Project in Canada and around the world
- Recent discoveries and directions in research
- Gene therapies now in use and on the horizon
- Privately and publicly-funded research
- The degree of certainty available in genetic testing and the impact on criminal cases, physician's duty of care, etc.
- New ethical considerations in professional duties

Luncheon Speakers: Distinguished scientists, including:
Dr. Ronald G. Worton, Geneticist in Chief the Hospital for Sick Children

AFTERNOON: IN-DEPTH PANELS

Health Law

- The effect of rapidly growing genetic knowledge on the physician's duty of care; duty to perform all tests available at the time
- Threshold risk factors for routine testing
- Legal parameters for abortion
- Physician's duty to patient and to third party (foetus)
- Effect of emerging knowledge on medical defense, damages, i.e. damages in - "wrongful life" claims
- DNA evidence of probable life expectancy in awards for damages
- Genetic defect causing existing disability vs. probability of disease in later life; disclosure issues
- Legislative perspective: initiatives in health, employment standards

Patents

- Basis on which gene-related patents have been granted/refused to date
- Which living things are or should be patentable: plants, animals, human, plant or animal cells, human, plant or animal parts, genetically altered life forms - where, how, and by whom is the line to be drawn "Discovery" vs. "invention" in patenting genetic material
- Processing and challenging patents in the gene exploration field
- Patenting genetics-related testing procedures, equipment, etc.
- Canada's future patent policy in light of obligations under the intellectual property rights section of the GATT
- The impact of an unpredictable patent environment on Canada's growing biotechnology industry
- Sharing knowledge vs. the scientist's incentive

Insurance

- Adverse selection
- Right to reject risks vs. human rights legislation re discrimination between persons
- The insurer's obligation re disclosure/confidentiality of information
- Custody of genetic information by insurers
- Public policy limitation on an insurer's liability
- Insurability and the probability of future disease
- Widespread genetic screening/scanning and the insurability of the population: Will state insurance be necessary for the uninsurable?
- The state of the art in genetic scanning and screening for insurance purposes.

Criminal Law

- Analysis of amendments to the Criminal Code
- Identity testing under present law; proposed changes
- Expectation of privacy vs. unreasonable search and seizure where samples are collected from discarded tissues, licked envelopes, etc.
- Police powers: access to private and state DNA data banks by investigative authorities
- The state of the art in forensic DNA analysis: reliability, degree of certainty
- Admissibility of DNA evidence, historically and in the future
- The case for a DNA "fingerprint" bank
- Use of DNA profiles of convicted criminals
- Advocacy issues: how to present DNA evidence at trial; how to cross-examine an expert on DNA

Labour and Employment

- Genetic monitoring for hazardous substances in the workplace
- Limits on mandatory testing, i.e., information relevant to job performance; termination on genetic grounds
- Denying employment on basis of test results
- Independence of lab performing test

Ethics and Public Policy

- Infliction of emotional harm in reveal test results
- Preconception genetic testing and counselling: should there be selective access
- Abortion for personal preference of sex, height, intelligence, etc.
- Custodial duty re test results vs. actual sample
- Right to access to information by the individual
- Mandatory screening
- Possible misuse of genetic information
- Privacy vs. freedom of information in the public interest
- If human health is improved as a result of genetic advances and information, how should public policy-makers prepare
- Should we legislate against "genetic irresponsibility"
- Which questions should be the subject of new or revised legislation, and which should be decided on a case-by-case basis

International Influences

1. GATT Chapter on Trade Related Intellectual Property Rights (TRIPS)

The Uruguay Round agreement of the General Agreement on Tariffs and Trade (GATT) is the first GATT agreement to include intellectual property (IP) rights. The so-called TRIPS agreement has three fundamental principles.

1. General GATT Principles. The agreement applies general GATT principles to the area of IPRs. This is particularly important under national treatment provisions (where nationals of a foreign country must be accorded the same rights and privileges as nationals of one's own country).

2. Tie-in with existing Treaties. The signatories of the agreement on TRIPS will be bound by the provisions of the already existing IPR treaties making the agreement extremely complicated.

3. Minimum protection. The agreement on TRIPS will form a minimum level of protection for IPRs.[12]

Intellectual property has been protected by a number of international treaties since 1883. The World Intellectual Property Organization (WIPO) was established to oversee the most important of these treaties in 1967. WIPO became a specialised agency in the UN System in 1974. It has two objectives: to "promote the protection of intellectual property throughout the world" and to ensure administrative co-operation among the various intellectual property unions. In 1993 the WIPO had 135 members (more than GATT).

Much of the backbone of the agreement on TRIPS is provided by the already existing treaties that are covered by the WIPO. The TRIPS agreement continually refers back to these treaties and takes pains to point out that nothing in the TRIPS agreement detracts from commitments already made under these existing agreements. Many developing countries argued that the TRIPS agreement should be part of the WIPO system and not under the GATT system. The USA, in particular, wanted IPRs to be included in the governance of GATT.

There were two main reasons put forward for this. Firstly, the USA was said to be unhappy with the working of WIPO, particularly in the area of enforcement. It is useful to note that the USA made little attempt to change the working of the WIPO system. Secondly, bringing IPRs into the GATT system would allow the USA to tie progress on IPRs to progress on other issues of concern to developing countries as well as allow the use of cross retaliation (use of trade sanctions on goods) against IPR infringers.

Both GATT and the Convention on Biological Diversity specifically protect the biotechnology industry: the GATT by obliging countries to pass intellectual property legislation over lifeforms; the Biodiversity Convention by stipulating that such legislation must be respected.

All GATT signatories must adopt (if they do not already have) intellectual property legislation which conforms to the GATT TRIPS provisions. Specifically, all signatories must provide patent coverage for microorganisms; they must have some form of sui generis (self generated) intellectual property legislation to cover plants; they may decide for themselves about intellectual property rights over animals. Whatever people in the South - including indigenous peoples - and others may feel about patenting lifeforms, it is being legislated for the world by the GATT. But there is a transitional grace period which governments may use to consider the most appropriate forms of intellectual property for their countries.

The relevant clauses from the GATT TRIPS Agreement are reproduced below.[13]

GATT TRIPS - Relevant Clauses

Section 5: Patents - Article 27 Patentable Subject Matter

1. ... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application. ... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions..... to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that the exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this paragraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 65 Transitional Agreements

1. ... no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.
2. A developing country Member is entitled to delay for a further period of four years the date of application.....
4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member.... it may delay the application of provisions on product patents .... to such areas of technology for an additional period of five years.

Article 66 Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members ..... such Members shall not be required to apply the provisions of this Agreement .... for a period of 10 years from the date of application..... The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. U.S. Update - U.S. Decisions Drive International Policy

In 1988 the Harvard mouse or Onco-Mouse became the first U.S patent on a living animal, marking a turning point in the debate over life-patents. The debate had started in 1974, with the application by microbiologist Ananda Chakrabarty on a genetically engineered bacterium capable of "digesting" crude oil.[14] The Supreme Court upheld the lower court decision by a five-to-four margin, stating that "the relevant distinction was not between living and inanimate things, but whether living products could be seen as human-made inventions".[15] Chakrabarty's microbe was deemed an invention and not a product of nature and therefore patentable material.

In 1985, the U.S Patent and Trademark Office (PTO) extended the Chakrabarty decision to include plants, seeds, and plant tissue. In 1987, the PTO ruled that all multicellular living organisms, including animals were patentable.

As of 1993, over 190 patent applications for genetically engineered animals, were pending in the United States[16], however, by late 1994, only three additional animal patents had been granted. This was likely due to either the reluctance of the PTO to set off the certain political controversy, or the result of a backlog of biotechnology patents in general.[17] By April, 1995, the number had grown to nine with 200+ in the pipeline.

According to Sheldon Krimsky, active in biotechnology and public policy for almost 20 years:

> The decision to patent a mammal brought many of the advocacy groups that opposed the patented bacterium into the latest policy fray. It also attracted another formidable constituency, animal rights groups. The concept of a patented animal signalled to these groups that society was regressing to an extreme Cartesian view of animals as soulless, unfeeling creatures that may be treated like machine parts".[18]

The concerns of these groups were heard by legislators before

the Onco-mouse patent was issued in 1988; subcommittee hearings of the House of Representatives Committee on the Judiciary held hearings on proposed legislation to impose a moratorium on the patenting of animals in both 1987 and 1989. However legislation failed to pass in both cases.

"Case Studies," adapted from the Citizen's Guide to Biotechnology by CIELAP)

In October of 1992, the American Patent Office set a precedent by granting a full species patent to the firm Agracetus Inc. for cotton. Sixteen months later, this same American company was granted a similar patent by the European Patent Office for soybeans. These patents gave Agracetus' parent company, the transnational chemical company W.R. Grace, full control over the techniques used to genetically alter these plants as well as all genetically-transformed cotton or soybean varieties. The significance of this is that all genetically altered cotton and soybean plants were considered the "intellectual property" of W.R. Grace. According to Dr. Geoffrey Hawtin, Director-General of the International Plant Genetic Resources Institute:

"The granting of patents covering all genetically engineered varieties of a species...puts in the hands of a single inventor the possibility to control what we grow on our farms and in our gardens. At a stroke of the pen the research of countless farmers and scientists has potentially been negated in a single, legal act of economic high jack."

As of December 1994, the American cotton patent was revoked although appeals are still pending. Various groups are fighting to have the soybean patent revoked in Europe as well.

The search for patents widened in 1988, when the Human Genome Organization was launched as a 15-year, internationally cooperative effort to map and decipher the 100,000 genes and 3 billion chemical compounds that form the complete genetic instructions for a human being. A detailed statement on the Human Genome Diversity Project by Indigenous Peoples representatives from the America's is included in Appendix 3.

Although no single product has yet come to the market from this research, patent claims on genes and gene fragments are being made at an astonishing rate. During 1991 and 1992, two researchers for the lead agency in the project, the US National Institutes of Health, filed for patents on nearly 7,000 partial DNA sequences for human genes. These patent claims, however, were rejected by the US Patent and Trademark Office for failing to meet the standard patent criteria; they were judged as not useful, not new and too obvious.

The US Patent Office had granted previous applications for patents on human genes, but only for those whose full sequences and functions were known. The NIH application, however, was for patents on only partially characterized genes, where no biological function had been identified. This ruling by the US Patent and Trademark Office is controversial and has not stopped private corporations from continuing to file for patents on partial sequences, although none have yet been granted.

3. European Update

EUROPEAN PARLIAMENT FOLLOWS GREEN LINE: NO PATENTS ON LIFE! - By Diana Johnstone

On March 1, 1995, in a surprise victory of ethical consideration over commercial profit, the European Parliament solidly rejected the joint text of the proposed European Union Directive on "the Legal Protection of Biotechnical Inventions", thereby answering with a resounding "no!" to industry's demand to be able to patent human genes, body parts, gene therapies, genetically altered animals and other forms of life.

In a rollcall vote, 188 Members of the European Parliament (MEPs) voted in favour of the draft legislation strongly backed by industry, but 240 voted against, with 23 abstentions. The vote effectively kills this Directive.[19]

This was a stunning victory for the Greens in the European Parliament, who have fought the Directive since its inception in 1988.

The Greens had succeeded in introducing a certain number of safeguards into the draft Directive. But in the very last stretch, all seemed lost as the Conciliation Committee (made up of 15 MEPs and 15 Council representatives) accepted a "compromise" text that abandoned Parliament's earlier clearly-stated principles. In particular:

- The final text would have accepted industrial patenting of parts of the human body. In an absurd effort to overcome misgivings, the proviso was added that patenting would be excluded only for parts of the body "ascribed to a particular individual".

- The final text would have allowed patenting of highly controversial germ line gene therapy (which alters the genetic identity not only of the individual but of unborn generations.) To get the Parliamentarians to accept this, the Council proposed issuing a separate declaration that such therapy "is

not at the present time ethically acceptable" on humans, a statement which evaded the patenting question and would not have had the force of law.

- Even the strongly supported "farmers' rights" clause, ensuring that farmers would not have to pay licence fees for reproduction of patented plants or livestock, was dropped from the compromise. The Commission merely made a vague promise to propose some such derogation for farmers in subsequent animal-breeding legislation.

The fact that most of the MEPs on the Conciliation Committee accepted this text seemed to augur victory for the industrial lobbies. Greens decided to fight hard against it, but with slight hope of winning. At voting time, each Green MEP took the floor to denounce a particular aspect of the Directive for the record. Hiltrud Breyer (Saarland, Germany), the Parliament's rapporteur four years ago on "the human genome", warned that human life would be degraded into "biological raw material" for commercial purposes. Green Group President Claudia Roth called for rejection of the Directive in order to strengthen opposition to the US Government application for European patents on cell lines of indigenous peoples in the Solomon Islands and Papua-New Guinea. The Agriculture Committee's Green vice president, organic farmer Friedrich Wilhelm ("FriWi") Graefe zu Baringdorf, reminded his colleagues of the serious consequences of such a Directive for farmers, livestock and the environment.

Over the years, Greens had made resistance to patents on life "their" issue, exerting far more influence than their numbers would suggest: only 25 out of 627 MEPs. Austrian Green MEP Johannes Voggenhuber encouraged his colleagues by recounting his party's success in persuading the Austrian Parliament to vote unanimously against this legislation, thus forcing the Austrian government to oppose it in Council. On the eve of the vote, Greenpeace succeeded in draping a banner across the Parliament's Brussels headquarters calling on MEPs to reject the Directive. It was clear by then that the Left Group and the Radicals would vote with the Greens, while the vast majority of the large conservative group would support the Directive. The Socialist Group, the largest in the Parliament, was wavering. One of its members, Willi Rothley, was Parliament's rapporteur for the legislation and supported the final compromise. It was only at the last minute that a majority of the socialist Group defected from the Directive, notably other members of Rothley's own German Social Democratic Party.

Industry spokesmen were aghast at the outcome. The European Federation of Pharmaceutical Industry Associations issued a statement calling the vote a "severe blow to investments and job prospects within the European pharmaceutical industry". This statement was scarcely surprising: competitivity and jobs are the two arguments used constantly by industrial lobbies to get their way. Europeans have been hearing for years that their wages must be lowered and their regulations loosened in order to make the European industrial base more attractive to investment than the United States or Japan, and that this is the only way to create jobs. These arguments are losing their force as it becomes clearer to more and more people that the "competitivity" argument is bottomless and that the "jobs" argument is false, inasmuch as unemployment has mounted steadily through fifteen years of pro-business policies that were supposed to "create jobs".

Europe-based corporations still seek patents on life in countries that grant them, such as the United States, if they choose. However, so far the big demand for European patents on life comes from US companies, who will be on an equal footing with European companies in the European market.

The serious question that now arises is the status and function of scientific research. If research is totally privatized under the control of profit-oriented business, then the absence of patents may be a discouraging factor. This is scarcely tragic if it prevents development of a new monster barnyard of designer animals. The only valid objection concerns medical research. The real answer is to maintain a strong public sector of scientific research able to contribute to commercial product development without being totally dominated by it. In any case, the ethical and social implications of biotechnology need to be studied before rather than after its commercial development.

In 1987, the United States Patent and Trademark Office had granted the first patent on an animal, and major European corporations argued that their competitive position required a legal framework for extending intellectual property rights from mechanical inventions to the genetically engineered product of biotechnological research. In response, the Commission in Brussels in 1988 submitted a draft "Directive on Legal Protection for Biotechnological Inventions" to the European Parliament as the first step in the EC's complex legislative process.

At the same time, a worldwide movement was developing against "enclosure" of the "biological commons", or in other words in opposition to commercial privatization of the fruits of biological research. Working closely with public interest organizations and concerned researchers, the Greens set out to raise awareness of the complex ethical and social issues raised by the rapid development of genetic engineering. They argued that discoveries were being abusively labelled inventions, and that it was inappropriate to apply patent law, designed to protect mechanical inventions, to the identification and rearrangement of genetic materials.

In a series of conferences and brochures, the Greens warned that patenting life forms would:

- subject scientific research to commercial objectives, to the detriment of humanitarian and ethical considerations:

- create unknown risks for the environment by promoting large-scale releases of genetically modified organisms and development of herbicide-resistant plants;

- deepen Third World dependency and indebtedness;

- accelerate the erosion of genetic diversity in agriculture by favouring the trend to cultivation of relatively few high-yield strains;

- create strains of animals destined to suffer for productive or research purposes;

- undermine the reverence for life that is an essential foundation of social ethics.

The range of disturbing issues raised brought together an unusual coalition including farmers, animal welfare activists, Third World NGOs and religious organizations. This complex consciousness-raising campaign combined with parliamentary manoeuvres and legal briefs before the European Patent Office in Munich was coordinated by Green Group staff member Linda Bullard.

By raising objection after objection and using every parliamentary device available, the Greens delayed the adoption of this Direction for years, gaining time to spread public awareness of the implications. As it turned out, the delay also postponed the final vote until the Maastricht Treaty had given the Parliament the increased powers necessary to decisively reject the Directive.

As the Green Group's coordinator of genetic engineering issues, Texas-born Linda Bullard has led seminars in Rio de Janeiro and travelled to India to support the large Indian movement opposing the takeover of Southern genetic resources by Northern industrial corporation. In October 1993, as half a million farmers demonstrated to launch the campaign against "intellectual piracy", she announced the Greens' intention to file legal opposition to the patenting of the Neem Tree, symbol of the campaign. The tree's medicinal and other qualities have been used freely in India for millennia, before being patented in recent years in the United States by multinational corporations such as W.R. Grace and Cargill, for products including pesticides and toothpaste. The Greens are opposing applications for patent at the European Patent Office (EPO) in Munich.

Now that the EU Directive has been defeated, the front line of the battle against "patents on life" moves to the EPO, where the legal situation is unclear. The EPO operates according to a 1972 Treaty drafted before the issue arose. The EU Directive was an attempt to influence interpretations of that vague text in favour of industry. As it turns out, the defeat of the Directive will strengthen the arguments of Greens patents on animals, plants and genes by the Munich office.

The Greens also want to stimulate debate in the United States, where patenting life has been left to the executive and judicial branches. Patenting life has never come before Congress. The U.S. Patent Office has granted patents on living organisms by administrative decision, and the legal situation rests on a 1980 Supreme Court decision allowing the patenting of a bacterium.

The March 1 vote was the first time that the European Parliament has definitively rejected a Directive. The fact that the Greens were the main driving force behind his unique case of the Parliament using its teeth says something about the potential influence of a small but active group in a democratic system with proportional representation.

Certainly, such a victory hinged on the unique ethical aspects of the issue, which cut across party lines. But the ethical implications are also profoundly political, and create a powerful barrier to the free market trend that has swept everything out of its way for the past couple of decades. One significant political lesson is the necessity to maintain a strong public sector of scientific research that can be open to public scrutiny, notably in sensitive areas of biology. DNA cannot be left to commercial interests. The wave of privatization must stop at life itself.

4. Blue Mountain Declaration - International Organizing and Collaboration

The recent decision in Europe served to galvanise renewed opposition to life patents in the United States. In June, 1995 a number of activists from around the U.S. and from Canada, Europe and Brazil met to discuss active collaboration in opposing patents on life.

The meeting was organized and funded by the Council for Responsible Genetics in the United States an activist scientific organization which has been involved with these issues for ten years.

A number of the people from the United States are also active in the Biotechnology Working Group which is active on biotechnology issues pressuring within the United States and in international arenas for better United States biotechnology policy.

The following statement was issued at the end of the week-end discussions.

Blue Mountain Declaration June 3, 1995

The humans, animals, microorganisms and plants comprising life on earth are part of the natural world into which we were all born. The conversion of these life forms, their molecules or parts into corporate property through patent monopolies is counter to the interests of the peoples of the world.

No individual, institution, or corporation should be able to claim ownership over species or varieties of living organisms. Nor should they be able to hold patents on organs, cells, genes or proteins, whether naturally occurring, genetically altered or otherwise modified.

Indigenous peoples, their knowledge and resources are the primary target for the commodification of genetic resources. We call upon all individuals and organizations to recognize these peoples' sovereign rights to self-determination and territorial rights, and to support their efforts to protect themselves, their lands and genetic resources from commodification and manipulation.

Life patents are not necessary for the conduct of science and technology, and may in fact retard or limit any benefits which could result from new information, treatments or products.

Recent developments emphasize the importance of our common position:

♦ the European Parliament in March 1995 soundly rejected a bill to authorize patents on life in the European Union;

♦ three weeks later, the Indian Parliament refused a similar bill on life patents;

♦ in May 1995, a large coalition of religious leaders in the U.S. openly opposed patents on humans and animal life;

♦ a recent attempt by the US Department of Commerce to patent a human cell line from an Indigenous Guyami woman from Panama was opposed by a coalition of activists and withdrawn;

♦ following protests by citizen groups, governments and scientists, corporate "species-wide" patents on all transgenic crops have been revoked by the United States and India;

♦ in May, 1995 the Indigenous peoples of the South Pacific began drafting a treaty to declare the region a life form patent-free zone; other Indigenous peoples are working to enact similar treaties in their territories;

♦ in the last two years, the European Parliament decided to stop all public European Union funding for research associated with the Human Genome Diversity Project. Additionally, the European Parliament legislated that publicly funded research should not give rise to privately held patents.

As part of a world movement to protect our common living heritage, we call upon the world and the Congress of the United States to enact legislation to exclude living organisms and their component parts from the patent system. We encourage all peoples to oppose this attack on the value of life.

Participants in the Blue Mountain conference:

Alternative Agricultural Projects (AS-PTA) (Brazil)
The Canadian Environmental Law Association (Canada)
The Community Nutrition Institute (US)
The Council for Responsible Genetics (US)
The Cultural Conservancy (US)
Cultural Survival Canada
The Edmonds Institute (US)
The Feminist Alliance on New Reproductive Technology (Canada)
The Foundation on Economic Trends (US)
The Institute for Agriculture and Trade Policy (US)
The International Center for Technology Assessment (US)
Debra Harry, a Northern Paiute activist
Brewster Kneen, The Ram's Horn (Canada)
Rural Advancement Foundation International

B. REGULATING BIOTECHNOLOGY

1. Regulating Biotech in Canada - It should and can be done better

In the 1995 growing season the first genetically modified plants (a herbicide-resistant canola variety) were grown commercially in Canada in Saskatchewan and Alberta. Although thousands of field trials have been carried out this historic commercial release of a genetically modified organism, or (GMO) for short, comes while the regulations to govern these releases were still not in force because of an on-going debate between the Environment and Agriculture departments of the federal government. This state of flux represents the norm with regards to policy in this area.

Currently in Canada, most products of biotechnology are regulated under legislation other than the *Canadian Environmental Protection Act* (CEPA) even though CEPA is Canada's main federal environmental law. CEPA regulates only those biotechnology products that are *not* regulated under some other federal statutes. Most biotechnology products are therefore released into the environment without CEPA having any direct role.

The current piecemeal approach to regulating biotechnology, allowing for inconsistent screenings of biotechnology products, is the product of a specific Federal cabinet decision, announced in January, 1993, (see sidebar) which rejected the development of a separate act to regulate biotechnology and endorsed the utilization of existing acts, an approach very similar to that used in the United States. The stated rationale was that the primary responsibility would rest with the departments with the traditional expertise and experience related to the specific classes of products.

Biotechnology is defined in CEPA as "the application of science and engineering in the direct and indirect use of living organisms or parts or products of living organisms in their natural or modified forms." This definition has been recently incorporated in a number of other Federal Acts in an attempt to have them judged equivalent under CEPA for the purposes of regulating applications of biotechnology.

CEPA includes biotechnology products under Part II: Toxic Substances. Under Section 26, new biotechnology products, not regulated under other federal statutes, must be screened in a process similar to that used for new chemicals, before they can be imported or manufactured in Canada. If they are considered "toxic", as defined under CEPA, then the Minister of the Environment can impose conditions on their manufacture, use, release or importation.

Official Federal Government Announcement, in 1993, of its Regulatory Framework for Biotechnology

OTTAWA, Jan. 11, 1993. - Federal regulatory departments have agreed on principles for a more efficient and effective regulatory framework for Canadian biotechnology.

These principles will ensure the practical benefits of biotechnology products and processes are balanced against the need to protect the environment, human health and safety. They will be the basis of a federal regulatory framework for biotechnology that:

- maintains Canada's high standards for the protection of the health of workers, the general public and the environment;
- uses existing legislation and regulatory institutions to clarify responsibilities and avoid duplication;
- continues to develop clear guidelines for evaluation of products of biotechnology which are in harmony with national priorities and international standards;
- provides for a sound scientific database on which to assess risk and evaluate products;
- ensures that both the development and enforcement of Canadian biotechnology regulations are open and include consultations; and,
- contributes to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and adoption of sustainable Canadian biotechnology products and processes.

The goal of the regulatory framework is to minimize environmental risks while fostering competitiveness through timely introduction of biotechnology products to the marketplace.

However, the majority of biotechnology products are regulated under other federal statutes. Biological pesticides (which may include living organisms) are regulated under the *Pest Control Products Act,* transgenic crop varieties produced by rDNA technology are regulated under the *Seeds Act,* and soil inoculants for fertilizer enhancement under the *Fertilizers Act.* All of these Acts are administered by Agriculture and Agri-Food Canada. Pharmaceutical drugs produced as a result of

new biotechnological techniques are regulated under the *Food and Drugs Act* administered by Health Canada.

A limited number of federal biotechnology product regulations have been in place for some time, including those for pesticide products and some drug products. Additional regulations for the products of biotechnology are under development in various departments but have yet to be proclaimed. It appears that there are differences of opinion over the scope and depth of the environmental assessment required before products are approved for release into the environment.

Biotechnology products represent a number of unique risks to the environment and human health. Since many of the products include lifeforms, which can reproduce and spread, it may be difficult if not impossible to control them once they are released into the environment. The novelty of many of the techniques used in genetic engineering injects a great deal of uncertainty when these products are evaluated for potential environmental and health effects.

When the parliamentary committee on Environment and Sustainable Development undertook a public review of the CEPA, the Toxics caucus of the Canadian Environmental Network developed a detailed proposal (prepared by Canadian Institute for Environmental Law and Policy (CIELAP)) for more effective regulation of biotechnology products (see sidebar). Briefly CIELAP proposed that " If different laws continue to be applied to different biotechnology products, all biotechnology products released into the environment should be evaluated with the same criteria, same standards for public participation and available prevention options as in CEPA."

The committee's final report endorsed the overall approach suggested by CIELAP quoting extensively from it. Its recommendations 68 and 69 are specifically on biotechnology:

Recommendation 68

> The committee recommends that CEPA be amended to include a new Part to deal specifically with the products of biotechnology. This new Part will include minimum notification and assessment standards for all products of biotechnology released into the environment, including those regulated under other federal acts. Other federal statutes shall prevail over CEPA in regard to the environmental impact assessment of products of biotechnology only if their notification, assessment and regulatory standards are at least equivalent to those prescribed under CEPA.

Recommendation 69

> The Committee recommends that CEPA be amended to require the Governor-in-Council to publish a list of statutes considered to be at least equivalent to CEPA with respect to their assessment process for products of biotechnologies.

CEN Toxics Caucus CEPA Proposals

10.1 If different laws continue to be applied to different biotechnology products, all biotechnology products released into the environment should be evaluated with the same criteria, same standards for public participation and available prevention options as in CEPA.

10.2 All biotechnology products should be evaluated on the basis of:

(a) Their direct, indirect, long-term, and cumulative environmental and health effects, and their impact on biodiversity;
(b) their purpose;
(c) their efficacy;
(d) their biological and ecological characteristics;
(e) the availability and effectiveness of monitoring, preventing, and treating the waste associated with biotechnology products; and,
(f) the availability of alternatives to a proposed product.

10.3 The testing of biotechnology products in the open environment should only occur with specific approval of the Minister of the Environment. Any violations of the conditions of the approval should be prosecuted.

10.4 The public should have a greater role in decisions on biotechnology products, including the right to appeal decisions, the right to be informed of tests in their community, and the right to access the information used to evaluate the biotechnology product.

10.5 CEPA should require the Minister of the Environment to establish a publicly accessible database on all environmental releases of biotechnology products.

10.6 In addition, since many new biotechnology products are entering the market and many issues are arising, a Royal Commission on Biotechnology should be established to debate these issues in a broad and conclusive manner.

The Minister of the Environment must respond to the committee's recommendations by November 17th, 1995. Environment Canada's draft memorandum to cabinet has been prepared and circulated to other Ministries for comment. The draft apparently included provisions for a new section for biotechnology under the Act but included only references to direct environmental and health effects for evaluation. Once comments are in and a cabinet decision is taken, the drafting process for amendments to the legislation will begin. Recent leaked documents and press editorials suggest the recommendations are meeting significant internal and external opposition.

The recent announcement by the Minister of Health of her call for a voluntary moratorium on the use of NRTs and the continued push by the federal government in support of rBGH taken together with the intent of the *Regulatory Efficiency Act* suggest that the committee's recommendations on biotechnology will be challenged within the government as well as lobbied against by industry representatives.

2. Canadian Public Opinion - Sceptical of promises, concerned about risks

Two recent surveys, one by Optima Consultants (1994) and the other by the Fédération Nationale des Associations de consommateurs du Québec (FNACQ), (1994) have begun to shed some light on the significant differences between the opinions of industry and the public (including citizens and public interest groups) on various issues concerning biotechnology.

While the two studies differ in their choice of respondents, their findings point to the same conclusions; the public has significant scepticism about biotechnology and vastly different opinions to that of industry, on issues such as regulation, labelling and product development.

Two examples from the FNACQ study illustrate this divergence in opinion.

The first concerns the issue of regulation. According to the study, the senior executives of biotechnology companies are opposed to any distinct regulations for biotechnological products,[20] while public interest representatives requested strict regulation of biotechnologies with a specific law.[21] Further evidence is illustrated in the example of labelling. Respondents requested mandatory labelling of all the products of biotechnologies, more specifically, genetically-manipulated food products, whole or as ingredients. At the same time, companies did not want specific labelling for biotech products.[22]

Methodology

The Optima study was undertaken on behalf of a number of federal departments including Agriculture and Agri-Food Canada, Health Canada, Environment Canada and Industry Canada. The Consumer Policy Branch of Industry Canada had responsibility for the study.

The primary objective of the Optima study was to provide a benchmark of public attitudes and expectations about the role of the federal government in the diverse and emerging field of biotechnology, (Optima Consultants, 1994,1). Respondents were also questioned on such issues as patenting, genetic testing and privacy and food related issues.

Focus groups and questionnaires, and post-survey focus groups were used in a survey of public attitudes. A random sample of telephone households was used to generate 2,000 respondents used in the survey.

The survey administered by FNACQ focused on reaching opinion leaders in four sectors: consumer; health; protection of rights and; professions and unions. Their survey was sent to 600 associations in Canada (300 in Quebec) and dealt with issues such as knowledge of biotechnologies, opinions on products and regulation. The second part of their study involved interviews with biotech firms. Questions were posed in areas such as regulation and their relationship with consumers and consumer associations, as well as products being marketed or developed (FNACQ,1994,4).

These opinions were echoed in the Optima study, where 62% of those citizens asked agreed with the statement that "the government should increase its regulation of biotechnology.[23]

Similarly, almost all respondents expressed a desire for labelling of biotech products to enable them to make choices.[24]

Perhaps most important was the insight FNACQ's study gave into the significant gap in opinion on the role of the public in dialogue and decision-making. According to the authors:

> Consumers and consumer associations would be prepared to play a part in the decision-making process at all stages of the marketing of biotechnological products.

> Furthermore they wish to engage in a dialogue with senior executives of companies so that they take into account the need to have their rights respected as part of their decisions and actions.
>
> For their part, companies believe that dialogue will be difficult, if not impossible, because of patents and industrial secrecy, but especially because they are convinced that consumers are incapable of understanding biotechnologies and correctly assessing the risks associated with the procedures and products.[25]

Clearly the biotechnology industry is concerned about who gets involved in dialogue and the process of decision-making. The majority of companies asked (90.8%) favoured either "No openness" or "Verbal openness only" to consumer associations, while 9.1% agreed with the "open involvement of consumer associations".[26]

3. Public Subsidies for Biotechnology Conflict of Interest - The Role of Government as Promoter and Regulator

The 1994 Optima Survey, Understanding the Consumer Interest in the New Biotechnology Industry, identified respondents concerns that the government should avoid financing biotech research other than for safety reasons, otherwise government would become involved in a conflict of interest. While they understood that government plays many roles, they considered that health and safety issues should not be overridden by other interests.[27]

The National Biotechnology Strategy and Federal Expenditures on Biotechnology

In 1983, the Canadian government established the National Biotechnology Strategy, or NBS. The main objectives of the strategy were outlined as:

- to identify areas where biotechnology could benefit Canadian businesses and the public;
- to ensure a number of people are trained as potential employees in the field;
- to support communication among researchers in various disciplines as well as the industry; and,
- to attract biotechnology companies to Canada.

To help meet these objectives, the government set up the National Biotechnology Strategy Fund. Money from this fund is distributed annually to various government departments and agencies for activities related to biotechnology. So far, government spending on biotechnology through this fund alone has been in the order of $110-$120 million. The NBS intends to spend a further $30 million over the two years 1995 and 1996.

The government has generously promoted biotechnology outside of the NBS Fund as well. Additional expenditures have risen steadily from around $10 million in 1982-1983 to over $200 million in 1991-1992. The total amount of taxpayer money spent so far, including NBS expenditures comes to about $1.8 billion (according to Industry, Science, Technology Canada, yearly biotech expenditures have remained flat since 1991-92 when they were calculated at over $200 million).

As the above figures illustrate, the government is already a significant contributor to biotech research and development. An examination of the nature of the governments role in biotechnology shows that the public subsidy to the biotechnology industry goes beyond the figures shown above.

Defined broadly, the public subsidy to biotechnology goes well beyond federal expenditures and the NBS. Major avenues of public support include the above category of direct federal expenditures as well as research and development networks, and corporate investment incentives.

Direct Federal Expenditures

This category includes financial expenditures (person-year expenditures are included in calculations in some cases) through individual government departments and agencies, including:

- Agriculture and Agri-Food Canada
- Industry, Science and Technology Canada
- Environment Canada
- the International Development Research Centre
- the Medical Research Council
- National Research Council
- Natural Sciences and Engineering Research Council
- Western Economic Diversification Fund.

It is worth noting that government figures in this category often do not tell the complete story. Expenditures not factored in include cases where: biotechnology was not isolated as a discrete expenditure; capital expenditures or salaries were not included; or information was not available.

The National Biotechnology Strategy accounts for only a portion of federal expenditures on biotechnology. Included in the governments spending are federal research institutes such as the Plant Biotechnology Institute and the Biotechnology Research Institute (funded by National Research Council) as well as grants given through the various research councils (e.g. Medical Research Council). Agencies such as the Natural Sciences and Engineering Council are also involved in grants to government and university research laboratories or individual researchers.

The nature of government expenditures is beginning, in part, to take on a slightly different appearance. The federal budget unveiled in February of 1995, proposed the elimination of direct subsidies to business and called for more co-operative funding partnerships between the public and private sectors. In remarks to the House of Commons Agriculture Committee, Brian Morrisey, assistant deputy minister for research in Agriculture Canada explained that cuts in government funds will require government and university researchers to work more closely with the private sector and cooperate in funding, meaning that research will be more practical (or commercially oriented) and this cooperation will "validate" what the government researchers do.[28]

Some examples of recent federal expenditures include:

- A joint project between federal and provincial governments and industry to build and operate a bio-fermentation plant, lab and office facility at Innovation Place, the biotech industry campus attached to the University of Saskatchewan. The Canada-Saskatchewan Infrastructure Works Program is contributing $3 million of the $12 million total cost, while the Saskatchewan Economic Development Corporation is contributing $9 million. Of the $3 million, $2.1 million is direct provincial money while the other $900,000 is federal. The role of private interests is to provide some of the equipment.[29]

- Agri-Food Canada's R&D Matching Investment Initiative, under which industry R&D contributions to collaborative research projects are matched one-for-one by the department. Government funding for this program is anticipated to reach $35.8 million by the year 2000. Agriculture Canada's spring 1995 bulletin of AGVANCE says that this will help stretch industry's research dollar and at the same time, help ensure that the department's research priorities accurately reflect the sector's real needs. Moreover, getting research investors directly involved will speed up the transfer of new technology to the private sector.[30]

- The federal government and the Royal Bank will establish a loan fund of up to $30 million to make loans available on commercial terms to biotechnology and agriculture biotechnology companies. The government part will be through Western Economic Diversification Canada which is investing $3.75 million as well as providing professional services for technology review of projects, support for business in developing their proposals, and project monitoring and management support.

- The International Development Research Centre will provide $1 million to encourage Canadian and Latin American cooperation in biotechnology.

Research and Development Networks

While the public subsidy to biotechnology companies includes the vast network of government, university and industry research funded directly through grants (as mentioned above) by various government agencies. It also includes the indirect public subsidy through various forms of partnership agreements or networks between industry and public funded institutions.

A vast network exists to facilitate communication and cooperation (i.e., transfer) between taxpayer-funded institutions (universities, government labs) and the users of research (i.e., industry). An example of this is provided by the Networks of Centres of Excellence, research centres which have been established at universities and teaching hospitals across the country. While research is partly funded through grants from government agencies and departments, this is only a portion of the costs. Capital costs, professors' salaries, etc., are costs borne by the university which is supported by public tax dollars. In most cases, only a small portion is covered by the companies involved.

In addition, there is the cost of educating the workforce needed by high-tech companies. According to Brewster Kneen, publisher of the magazine "The Ram's Horn":

> Finally, there is the issue of producing the scientists to do the science, whether public or private. Again using the words of an expert, Cargill points out that industry is simply not going to do the job of producing the scientists. It expects the public to pay for this expensive essential.[31]

Critics have raised several issues around public involvement in funding and supporting the biotechnology industry:

- Who pays and who benefits? The public makes a significant contribution to biotech companies. In addition, Canadians will bear the risks associated with the use of biotechnology. Furthermore, with certain technologies, (i.e., health related, reproductive technologies) there is the question of who will have access to them, given the projected high cost to the consumer/patient.

- Who decides the priorities for public sector research? A host of issues surround universities increased reliance on the private sector. Due both to cuts in government funding as well as the policies of granting bodies, funders are increasingly requiring applicants to find a corporate sponsor in order to receive government research funds.[32] Issues range from ownership of research to the privatization of the research agenda (e.g., what is being researched, and is it in the public interest?)

As an example, funding of biotechnology research for agricultural applications was over $26 million in 1991-1992. At the same time, total funding for the Pest Management Alternatives Office, the only clearly identifiable program sponsored by the federal government to support research on sustainable agricultural practices, has amounted to less than $2 million since the program began in November of 1992.

- Who decides? Opportunities for public participation have been widely criticized as being fragmentary and incomplete. The Federal government's position as promoter, funder and regulator of biotechnology, raises serious questions about conflict of interest and who speaks for the public interest. In 1991, for example, Agriculture Canada field-tested more genetically-engineered crops than private industry.[33]

4. Recombinant Bovine Growth Hormone(rBGH) - Corporate self interest versus public interest

On September 30, 1995, it was announced that despite approval for use in the United States, in Canada Monsanto was being asked to supply the government with further information about the animal health effects of their product. Company officials acknowledged that the approvals, if given, would be delayed until at least the end of 1996.

This latest development in the rBGH saga casts doubt on the thoroughness and impartiality of the US approval process and follows widespread producer and consumer opposition to the sale of this performance enhancing drug in Canada.

In the early 1980s, four chemical/pharmaceutical companies - Monsanto, Eli Lilly, Upjohn and American Cyanimid - with the help of university scientists, began researching a new technology they believed would revolutionize the dairy industry. Using genetic engineering techniques and a research and development investment of over $1 billion, they created recombinant bovine growth hormone (rBGH) to increase milk production in dairy cows by 10 to 25 percent.

In its natural form BGH is a hormone that controls milk production in mature cows. Commercial rBGH (also known as Bovine somatatropin or bst) is a growth hormone produced from bacteria which have been genetically modified. This drug is administered by injection twice a month as milk production begins to decline.

In November 1993, Monsanto received approval from the Food and Drug Administration (FDA) to sell rBGH in the United States and sales began in February 1994, amid widespread controversy over serious concerns about the effects of its use on human and livestock health and on the dairy industry itself.

Monsanto and Eli Lilly also applied to sell their performance enhancing drug in Canada. In the spring of 1994 the Parliamentary Committee on Agriculture unanimously recommended a legislated moratorium on the introduction of rBGH, in Canada similar to that imposed by the European Union, so its impact on animal and human health and on the dairy industry could be examined.

In response the Minister of Agriculture established a Taskforce to report on the issue but refused to legislate a moratorium. Instead he settled for a voluntary promise from Eli Lilly and Monsanto not to market the drug in Canada before July 1, 1995 even if they got approval.

The Taskforce delivered its report in May concluding that even a modest negative consumer reaction against the introduction of rBGH milk of a 3% reduction in milk consumption would wipe out any economic gains from the hormone's use. In mid-June both the House of Commons Standing Committees of Agriculture and Health recommended that the moratorium on rBGH sales be extended.

The voluntary moratorium on the sale of the drug expired on July 1st this year. The two companies declined the Minister of Agriculture's appeals to voluntarily extend it and instead threatened that failure to approve the drug for use in Canada might lead the companies to pull research and development spending out of Canada. Health Canada officials indicated to the media at that time that it would be several more months at least before a decision on the granting of a Notice of Compliance under the Food and Drug Act is issued and on September 30th they asked Monsanto for yet more information to substantiate its claims for the drug.

The level of opposition in Canada is significant and widespread. Hundreds of thousands of Canadians have told federal politicians they do not want rBGH to be approved. Almost 350 organizations representing consumers, farmers, dairy processors, health professionals, legal associations, humane societies, school districts, municipal councils and public health boards are opposed. And most members of parliament now oppose rBGH use given the extent of the popular opposition.

The level of public opposition, which has helped stall the approval process, is important because new scientific studies have been published recently suggesting that milk from rBGH-treated cows may not be as safe for humans as was previously believed. These unresolved scientific issues around the possible cancer causing effects of increased IGF-1 levels in rBGH milk led Codex Alimentarius, an international standards setting organization based in Rome, Italy, to reject a U.S. proposal to declare the use of rBGH safe, posing no significant health risk. The 14-nation European Union successfully opposed the U.S. initiative winning the final vote

34 to 31.

This growing body of scientific evidence continues to cast doubt on Monsanto's claim that rBGH milk is the same as natural milk and wholesome and safe beyond doubt. And it continues to keep the drug out of cows in Canada.

5. New Reproductive Technologies Voluntarism as Public Policy

"It took four years and $28.2 million of taxpayers' money.... made 293 recommendations on how to prevent that world from being controlled by the marketplace.... Yet when the Royal Commission on New Reproductive Technologies filed its massive, strongly worded report back in November, 1993, Ottawa's silence was deafening. Only late this July [1995] - 19 months later - did the Health Department finally move on any of the recommendations. But move perhaps overstates it. Health Minister Diane Marleau called for a voluntary moratorium on nine different areas...from the already existing surrogate pregnancy for profit, sex-selection clinics and the selling of sperm and eggs, all the way to still-in-the-future work on human embryo cloning and animal-human hybrids. To the amazement of many, Marleau said the issue needed to be studied more. But she was setting parameters on what was and wasn't acceptable: She was "drawing a line in the sand." Her line, in both senses, was greeted with near-universal scorn ...Dr. Patricia Baird, [is] the geneticist who headed the commission, ..."A voluntary ban, she says flatly, "is not going to work." More to the point "it's very apparent that Madam Marleau knows it is not going to work"[34].

The Biotechnological initiatives first practised on plants and animals increasingly have human applications. When techniques of plant and animal breeding are applied to humans they are called the New Reproductive and Genetic Technologies(NRGTs). In considering NRGTs, it is important to remember that since women are the ones who give birth and who are generally the ones most responsible for the care and rearing of children, the NRGTS, have particularly profound implications for women.

The term NRGT describes the various technologies such as sex selection, artificial insemination, in vitro fertilization (conception in a test tube), gestational "surrogacy", pre-natal testing, pre-symptomatic genetic diagnostics, etc. The new genetic technologies are part of the new "genetics revolution". Some of these procedures directly involve biotechnology. The new reproductive technologies on the other hand are "enabling technologies" for genetic and biotechnological research and development. Taken as a whole the NRGTs are intimately implicated in the biotechnological project which is intent on the control, ownership, patenting, marketing indeed the industrialization of life.

In Canada, the New Reproductive and Genetic Technologies have been an issue of some public concern for almost a decade. In the late eighties an intensive lobbying effort was initiated by a nation-wide coalition of women's groups, health groups and others concerned at their proliferation. They argued that the issue was important enough to warrant a federal response. In October 1989, after two years of lobbying, the Royal Commission on New Reproductive Technologies was established. Many feminists were later to regret their promotion of this federal fact-finding policy-making instrument. The opportunity to solicit and utilize the concerns of thousands of Canadians and develop a body of good Canada specific research was largely lost.

Twenty eight million dollars and four years later the Commission presented its wordy and substantially unworkable report. After yet another two years the federal government has made public its tepid response. The Minister of Health, Diane Marleau, announced a set of voluntary guidelines on July 27, 1995, which were without substance. Arguing that some of the new technologies threaten human dignity and do not reflect Canadian values Marleau called for a voluntary moratorium on nine technologies: sex selection for non-medical purposes; commercial pre-conception or "surrogacy" arrangements; buying and selling of eggs, sperm and embryos; egg donation in exchange for in vitro fertilization (IVF) services; germline genetic alteration, ectogenesis (creation of an artificial womb); the cloning of human embryos; formation of animal-human hybrids by combining animal and human gametes; and, the retrieval of eggs from cadavers and fetuses for donation, fertilization and research.

The response was rapid and definitive. Doctors in fertility clinics around the country stated categorically that they would not observe the moratorium. The Medical Research Council made clear that the only apparent muscle in the proposal - the threat of loss of federal research funding - was overstated. The Director of the MRC noted that he could think of no project they funded that might be affected. And the newspapers were filled with statements from members of the "scientific community" insisting that even such insubstantial restrictions were unwarranted: no limitation should ethically be imposed on the advancement of "science". Even Marleau's recommendation that germ-line gene therapy be avoided has been challenged.

It seems clear in hindsight that Marleau's office would have been aware of the likely response from the fertility doctors and other like-minded advocates. Though Madame Marleau has promised further "research" into the post-marketing surveillance of fertility drugs, and has stated that the voluntary moratorium is but an interim measure prior to the development of a "permanent management regime", the substance and reception of her first effort gives us no reason to anticipate meaningful action in the future.

International Influences

1. Approaches in other Jurisdictions

Various Experiences addressing Biotechnology Issues

The clash of perspectives that is generated by addressing such issues as the patenting of lifeforms, releasing genetically modified organisms into our environment and the implicit request being made for us to accept the socialization of the risks involved, is not unique to Canada and is playing out in jurisdictions in a number of other countries. The variety of responses and outcomes provide a useful, though not exhaustive, set of experiences to review as we attempt to develop our made-in-Canada responses to these major public policy decisions.

The diversity of the approaches taken in addressing the implications of this technological revolution is reflective of the very social nature of the process at the heart of responding to these complex issues. In the examples listed here a key component of the process has been active public engagement responding as a counterforce challenging the narrow interests of the biotechnology industry.

Canada: Two Models of Public Participation in Science, Technology and Medicine

The Royal Commission on Reproductive Technology recommended that biotechnology and medicine in the areas of genetics and reproduction be regulated by a National Commission composed of "persons knowledgeable about the interests and perspectives of those with disabilities, those who are infertile, and those who are members of racial minority, Aboriginal, and economically disadvantaged communities." In addition the report promised that women would "make up a substantial proportion" of the National Commission members.

Many critical groups, from the very constituencies that the report named in the above list objected strenuously to this model of public involvement. The National Action Committee on the Status of Women(NAC) was particularly critical: "NAC finds it completely unacceptable to support the concept of a national regulatory body that attempts to win credibility and legitimacy by loading the panel with women who do not represent and are not accountable to clearly defined women's advocacy groups. Similarly, NAC finds it completely inadequate to support the appointment of people, be they women or men, who are simply 'knowledgable about the interests and perspectives of those with disabilities, those who are infertile.."

NAC, like other organizations from a variety of perspectives strongly disagreed with a centralized national structure regulating these technologies. There was tremendous criticism of the extraordinary intrusion of federal powers over provincial jurisdiction. NAC maintained that "we are not prepared to see regulation determined by an exclusive, expert, industry-centred regulatory body that is designed to filter, mould and marginalize public process."

In all, this report was seen in many sectors as being seriously and perhaps irretrievably flawed in its recommendations about the regulation of biotechnology in human genetics and reproduction.

The major flaws in the report from the Royal Commission were particularly significant in the context of achievements of the women's health movement in Canada. The formal and informal, institutional and community structures of the womens health movement present a very positive model of public involvement in policy and regulation. Health policy includes by necessity the relationship between science, technology, industry and human values and needs. Much has been documented about the effectiveness of women's health research and practice. This model offers its constituents systems of information, communications, and risk-benefit assessment that are parallel to and independent of mainstream medicine, science, and biotechnology.

Central to these parallel systems of information, communication and assessment is the inclusion of empirical data which reflects experience, and knowledge of 'lay people' who use this network.

The consequences of exclusionary expertise is familiar to many women who have been active in the women's health networks. Advocates have worked to win recognition for the medical knowledge that has been gathered through individual and collective experiences with medicine, drugs and biotechnology. Much work has been done to ensure that the experience and research will be included in the development of scientific and medical theory and practice.

The European Union (EU): Attempts to harmonize diverse approaches and conflicting interests

The EU began developing its approach on patenting life forms in the early 1980s, tabling its first draft directive on the issue in the European parliament in 1988 (see section on Europe under patenting for more detailed discussion). Over the next four years the controversial directive, which was aimed at harmonizing approaches in member states, came up for a vote three times and was sent back each time for revisions. The November 1992 vote fell just 12 votes short, out of 627, of rejecting the directive completely. As it was 45 amendments were adopted. Under the Maastrict Treaty, the elected European parliament gained some new powers including the right of veto and the right to bargain with the European Commission on patent issues. The directive was in conciliation

process until late 1994. The outstanding issues were: whether farmers will have to pay royalties for re-sowing patented seeds; whether ethical criteria will operate to limit patents on animals and whether parts of the human body such as human genes can be patented.[35] The Parliament voted down the Directive on March 1, 1995.

Two other directives, one on the safe use of genetically engineered microorganisms in the laboratory and the other on the release of genetically engineered organisms (GEO) into the environment were adopted in 1990. Both of these directives have come under heavy industry criticism as being too stringent and requiring over-regulation of the environmental release of GEOs.

The latest draft EU regulation on novel foods requires labelling of all genetically engineered foods. The German government has pushed for this position but is being opposed by the British government.[36]

France: Turning the Bioethics debate into Law

France took a European lead in 1994, by passing three new laws on Bioethics. The laws are the result of a vigorous national debate and a two year parliamentary process. The laws represent a compromise between strongly opposed views. Law 1 covers general issues of "protection and respect for the human body". It bans eugenic practices, allows limited genetic testing, prohibits patents on parts of the human body, including genes, and bans interference with human eggs and sperm. Law 2 bans the sale of organs, limits the use of reproductive technologies to married couples or those living together for 10 years or more, only allows embryo research with consent of the couple and provided it does not harm the embryo and severely limits genetic screening of IVF embryos. Law 3 requires patient consent for the use of medical records for research.[37]

Norway: Europe's most restrictive legislation

Probably the most restrictive legislation with the greatest access and role for the public is Norway's 1993 Gene Technology Act. The purpose of the Act is "to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment".[38]

The deliberate release of GEOs can occur only after they have been "satisfactorily tested in natural environments that will be affected by the intended use ... when there is no detrimental effects on health and the environment ... and significant emphasis shall also be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development".[39] All applications for a deliberate release of a genetically modified organism "shall contain an impact assessment setting out the risk of detrimental effects and other consequences of the release".[40]

Under the Act the following information must always be made public: a) the description of the genetically modified organism, the users name and address, the purpose of the use and the location of use; b) methods and plans for monitoring emergency response; c) assessments of the foreseeable consequences.[41] A public consultation on each release may be held and conditions of approval including designating the best technical procedures and means of production and requiring insurance for liability purposes can be imposed. The law includes strong enforcement powers and establishes a public advisory board to "express its views" on the implementation of the Act and to address biotechnology issues.

Norway was the only European government to hold public consultations on the first request for the commercial release of a GEO in Europe.

Germany: Scaling back public access under industry pressure

Germany has seen some of the most confrontational responses to the introduction of GEOs anywhere in Europe. A number of test plots of GEOs have been occupied or destroyed, lawsuits to block biotech research are common and elected officials have put up local barriers to biotech companies. A significant amount of this awareness and activity can be traced to the first Genetic Engineering Act which built upon Germany's historic concerns about genetic engineering. This Act, to a significant degree the product of organizing and pressure from Germany's disability rights movement, includes significant requirements for the release of information, local notification of test releases and a system of local hearings and open comment periods to provide local input to decisions on releases. Industry complaints about the effectiveness of this opposition based on access to information resulted in revisions to the law passed in 1994 which greatly reduce the openness and public access to the decision making process.

It is important to note that industry representatives admit that public opposition is centred on food issues and environmental releases of organisms while genetically engineered medication is more acceptable to the public.[42]

Denmark and Britain: New forms of public input

(adapted from B. Ellahi, RUK National Consensus Conference on Plant Biotechnology. Trends in Food Science and Technology, February 1995, Vol 6.)

The so-called Consensus Conference model was developed in Denmark in the 1980s and is now well-established and influential there and in Holland. It puts together lay people and experts for informed, public debate on sensitive scientific

issues and offers the public the opportunity to have input on government policy. A panel of lay people is first given in-depth briefings and then selects a number of experts to question.

At a public meeting, the lay panel poses questions and then the panel and the audience cross-examine the experts. At the last day of the conference the panel presents a report of its conclusions for debate, presentation to the media and to government as input on government policy.

In Denmark the conferences are reported as making the public less hostile to subjects ranging from food irradiation to the burial of nuclear waste - without making them any less aware that things could go wrong.

The aims of the UK National Consensus Conference on Plant Biotechnology (held at Regent's College, London, UK, November 2 - 4, 1994) were to "present a report that might contribute to public policy-making by providing useful information about public perceptions of agriculture and food biotechnology in the UK, and to contribute to informed public debate in the UK.[43] As a pioneering conference, it was also used to evaluate the potential of CC's to contribute to public policy-making and debate.

The conference in the UK was organized and administered by the Science Museum of London, and funded by the Biotechnology and Biological Research Council. In Denmark, CC's have been organized by the Danish Board of Technology, an independent (arms length) body, with ties to the Danish Parliament.

Members of the lay panel were recruited through newspaper and radio advertisements and selected by a steering committee. This steering committee together with the lay panel was also partly responsible for selecting the expert panel. The lay panel of 16 members with gender balance was chosen from 370 applicants and members were selected to represent a typical cross section of the UK public. The panel also had a facilitator throughout the process.

In preparation for the conference, members of the lay panel were given information packs and participated in briefings and discussion sessions on plant biotechnology. The panel also discussed the selection of questions and together with the conference steering committee, decided on which experts to question at the conference.

The two days of the conference consisted of questions to panels of experts followed by opportunity for the lay panel to cross-examine, and to call upon members of the audience to comment and provide answers. The audience was also encouraged to ask questions of the experts. The lay panel then worked throughout the morning preparing their report. The final stage of the conference consisted of questions from the media and comments from the audience.

Reactions to the UK Consensus Conference process have been mixed in the UK.

The general sentiment of policy-makers is that CC's are a useful tool for discussion and debate. In conjunction with the recognition of the potential of consensus conferences, the need for meaningful consideration of the conferences at the parliamentary policy-forming level is noted.

However, an underlying sentiment which sees the conferences as a public relations tool does exist, as illustrated in the following comment by Basma Ellahi, writing a review of the UK conference in the journal, Trends in Food Science and Technology:

> "This unique exercise has shown that when the public is presented with the facts, it can have a positive response to the introduction of the technology as long as it is regulated and controlled.[44]

In Canada, little if any discussion on consensus conferences has taken place. However, a briefing on the conference was given to the federal governments Biotechnology Forum Steering Committee on the Societal Implications of Biotechnology. Comments from the meeting seemed to suggest that while it was too early to be definitive, such a forum should be seen as one source of advice for decision-makers. In addition, it was noted that while the Consensus committee has not really generated anything new, it does have the advantage of showing where the balance between opposing views lies.

United States: The consequences of deregulation as the norm

Under the climate of deregulation that has prevailed in the United States for more than a decade the regulatory oversight of biotechnology developments has one or two strong elements but is characterised overall as "a wobbly, ineffective structure"[45] by its critics. Since 1986 the U.S. has used existing agencies and laws to oversee biotech developments which has led to a fragmented approach with overlapping responsibilities and a strong pro-industry bias.

While Freedom of Information laws are strong in the U.S. timely access to useful information has often been frustrated and impeded the ability of the public to participate in the decisions being made. A number of developments are now occurring at the State level in response to deficiencies at the federal level.[46]

The Clinton Administration is now reviewing its Biotechnology framework and proposing an interagency process of cooperation in the commercialization process for agricultural biotechnology. It is unclear how much public involvement there will be in the review.[47]

Developments in the U.S. are critical internationally because conditions in the United States and the supposed advantages

the less stringent regulatory approach provides to U. S. based companies is a constant refrain as corporate interests pressure governments on their policy on biotech issues.

2. Biosafety Protocol Meeting Report

THE CONVENTION ON BIOLOGICAL DIVERSITY, BIOTECHNOLOGY AND BIOSAFETY
by Dr. Vandana Shiva

The Convention on Biological Diversity which was signed at the Earth Summit in Rio in 1992 has now been ratified by 120 countries. One of the most significant articles in the convention is article 19. 3 which states:

> The parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advanced informed agreement,in the safe transfer,handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

The Biodiversity Convention therefore does not merely set out the rules for ownership and sharing of biological resources, it also creates scope of setting out rules and regulations for the ownership and responsibility for any ecological effects that genetically engineered organisms might have when used on a large scale through commercial applications in agriculture, forestry, fisheries and environmental amelioration. The USA had resisted this clause during the negotiations of the convention in order to protect its biotechnology industry.

In fact, the term "genetically modified organism" (GMO) was substituted by the ambiguous term "living modified organism"(LMO) in the final draft of the convention on the insistence of the USA. This substitution was deliberately introduced to semantically wipe out the difference between the products of genetic engineering or modern biotechnology and the products of traditional breeding technologies. This equivalence is then used to argue that since GMOs are no different from traditionally bred crops or naturally occurring organisms, no new international regulation is needed to ensure safety in their application. The history of the Biodiversity Convention so far has been the history of the USA blocking the agreement on a biosafety protocol in accordance with article 19. 3 of the convention.

In 1992, the parties to the convention invited UNEP to establish four expert panels to assist in the follow up of the convention. One of these panels was Expert Panel IV on Biosafety with a mandate to follow up and provide background analysis for decisions on article 19. 3 on the need for and modalities of a protocol. I was one of the fifteen members of the panel which also had an expert from the USA, though USA was not a signatory of the convention. All members of the panel except the US representative were of the opinion that a protocol on biosafety was necessary. The US put in a dissenting opinion, and then tried to brush the Panel IV report aside on the grounds that it was not a "consensus document".

At its first meeting held in Nassau, The Bahamas, from 28 november to 9 December, 1994 the Conference of the parties(COP) expressed deep concern and interest about the need for the safe transfer, handling and use of all living modified organisms resulting from biotechnology to avoid adverse effect on the conservation and sustainable use of biological diversity. Accordingly, the COP decided to establish an open ended ad hoc group of experts to consider the need for and modalities of a protocol and to consider existing knowledge, experience and legislation in the field of biosafety. This meeting of experts on Biosafety took place in Madrid from 24 to 28 July 1995. In order to prepare for the work of the group of experts in Madrid, the COP requested the secretariat to establish a panel of fifteen members which met in Cairo from 1 to 5 May. Though the terms of reference of the Cairo panel were the same as Panel IV, the Cairo report made no reference to the earlier report, and in fact took the US position that GMOs were no different from products of traditional technologies. In the Madrid meeting, the head of the US delegation, Terry Medley, repeatedly referred to the Cairo report as "our" report. He had been on the Cairo panel and the US was quite understandably satisfied with this report. The head of the Indian delegation, Amarjeet Ahuja, however, disturbed the complacency of the US by asking for the Panel IV report to be tabled as a relevant background document.

The US and other countries like Australia, Canada, Germany and Japan continued to resist the biosafety protocol in Madrid. Their position quite clearly reflected the interests of their Biotechnology industry, and not the interest of their citizens. Citizen groups working on the ethical and ecological implications of genetic engineering were present in large numbers and the Northern Governments were facing a more difficult time from their own citizens than from the Southern Government delegates.

The biotechnology industry was also present in full force, as the International Bio-Industry Forum (IBF). The IBF was established in 1990. Its members are Senior Advisory Group Biotechnology (EUROPE), Japan Bioindustry Association, Biotechnology Industry Organisation (BIO) (USA) and Industrial Biotechnology Association of Canada. These industry lobby groups are quite clearly behind the decision of the powerful northern countries to try and block a Biosafety protocol. In a letter dated 9 March, 1994, to Senator Pell, Chairman of the Senate Committee on Foreign Relations, Carl Feldbaum, President of BIO, wrote:

> We urge the Senate to obtain an assurance that the United States will not seek, and will in fact oppose, the development of a biosafety protocol under the convention. We believe that the creation of any such entity would not result in scientific oversight to ensure human safety, but rather in promotion of a political agenda other than science.

In the case of biosafety, it is in fact the industry that is 'promoting a political agenda other than science'. This was made evident in an independent expert report on "Biosafety: Scientific Findings and the Need for a Protocol" prepared by Mae Wan Ho (UK), Tewolde Egziabher (Ethiopia), Brian Goodwin (UK), Elaine Ingham (USA), Beatrix Tappeser (Germany), Regine Kolleck (Germany), Nicanor Perlas (Philippines, Diana Pombo (Columbia), Gurdial Singh Nijar (Malaysia), Chee Yoke Ling (Malaysia), Dan Leskien (USA) and myself.

Recent trials with genetically engineered organisms confirm that they have significant and potentially devastating ecological effects, and that a legally binding regulatory framework is essential for protecting biodiversity and people's health.

Experiments done by Dr. Elaine Ingham of Oregon State University show that genetically engineered microorganisms (GEMs) can have ecologically devastating effects that are not always predictable. Klebsiella planticola is a typical bacteria that inhabits the root zone of plants. This organism has been genetically engineered to convert biomass into ethanol, an apparently environmental solution to the disposal of agricultural byproducts like straw, with the added advantage of producing renewable energy and fertilizer from the sludge left after the fermentation. However, if this GEM had been commercialized, it could have created an ecological disaster. The Oregon State University trials show that when soils were treated with the genetically engineered Klebsiella planticola, all the plants died. The soils treated with the un-engineered parent organism remained healthy. In additional, the GEM led to the reduction of the nitrogen fixing mycorrhizal fungi in the soil by more than half. The use of this organism by farmers to clear up their agricultural waste had the potential of turning their farmland into wasteland.

Ironically, the US environmental protection agency had cleared the engineered Klebsiella for commercialisation because US EPA tests are inadequate to assess the potential impact of GMOs. Dr. S. Shantharam who is Chief of Microorganisms Branch, US Department of Agriculture, had stated at a conference on Biodiversity organised in Delhi by INTACH in 1994

> At all international fora I have been asked'What is the scientific basis of your regulatory policy?'. Let me tell you we don't have a scientific basis for our regulatory policy. We have faced a great deal of criticism for this.

Recently, for the first time, the data from the US department of Agriculture was evaluated to see whether they support the safety claims. The Union of Concerned Scientists (UCS) which conducted the evaluation found the data collected by the USDA on small scale tests have little value for commercial risk assessment. Field trials done by the official agencies working on the assumption that GMOs are no different from there parent organisms are not scientifically based trials to assess full ecological impacts on ecosystems and on biodiversity. Existing field tests even in industrially advanced countries are not designed to collect environmental data, and test conditions do not approximate production conditions that include commercial scale releases. The argument put forward by the industry, the US administration and the Cairo report that the safety of field trials implies safety at the commercial scale is therefore untrue. It is often claimed that there have been 3000 releases of GMOs and "nothing has happened". However, the term "releases" in this context is totally misleading, because these are trials are carried out in small confined and ecologically irrelevant field plots. Dr. Phil Regal of the University of Minnesota has called this "non-data on non-releases".

The inadequacy of conventional small scale field trials carried out in ecologically isolated conditions has been exposed by another ecologically significant experiment carried out by Drs. R. Jorgensen and B. Anderson in Denmark, in which it was found that genes from plants engineered to be tolerant to herbicides could be rapidly transferred to their wild relatives. Oilseed rape plants genetically engineered to be herbicide resistant transmitted its transgene to a weedy natural relative, Brassica campestris. This transfer can take place in just two generations and can be as high as 90%. The spread of the transgene can be very wide because oilseed rape is insect pollinated, and can be carried to large distances by bees. The result can be the creation of superweeds in the form of wild relatives of crops which now have the transgene for herbicide tolerance. Instead of solving the problem of weeds, this strategy which dominates the research in agricultural biotechnology, could in fact make the problem of weeds unsolvable by creating superweeds. It could become a major threat to agriculture, especially in regions which are centres of diversity. Recognising this threat to agriculture, the governments of Denmark and Norway have stopped the commercial planting of genetically engineered oilseed rape.

Quite clearly, the potential threats to life support systems can be very high if genetically engineered organisms are released commercially without any regulation. Since such organisms can escape or be transferred deliberately across borders, national regulations are not enough and an international legally binding instrument is needed. This is the essence of the demand for a biosafety protocol by the Third World and by citizens world wide.

Obstructing the protocol are the corporations which control the investments in biotechnology research and production, and the governments of the countries which these corporations dominate politically. They are denying the rights of citizens to safety from ecological hazards by blocking an agreement to establish international law for governing the activities of these corporations in the area of biotechnology. Cynically, the resistance to the biosafety protocol is couched in the language of free choice. At the Madrid meeting, the paper distributed by the Biotechnology industry stated:

> The International Bio-industry Forum supports the free choice of every nation to adopt appropriate biosafety guidelines to help promote and make accessible on a world-wide basis the benefits of modern biotechnology.

The same corporations like Monsanto that come to the Biodiversity Convention and talk about the "free choice of nations" were in GATT, denying countries a free choice to have intellectual property rights regimes appropriate to their socio economic conditions. In the Biodiversity Convention, the biotechnology corporations treat genetically engineered organisms as the same as products of traditional technologies, requiring no new legal framework. In GATT, the same corporations treat the same organisms as "novel", requiring new laws of intellectual property rights to cover patents on lifeforms. The same subject matter, yet two sets of ontology, two systems of jurisprudence.

The powerful corporations and countries might succeed in blocking the biosafety protocol through coercion and undemocratic decision making when the Conference of Parties takes up the issue at its next meeting in Jakarta in November 1995. However, with all the internal, inconsistencies and incoherence in their perspective, they will never find support from the people for their agenda of a brave new world in which they have all the rights, and citizens have none.

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D. Appendices

1. CIELAP Citizen's Guide to Biotechnology
2. Table of Contents Critique of Biotechnology Council of Ontario Report to Ontario Government
3. Indigenous People's of the Americas Statement on Human Genome Diversity Project
4. Ted Schrecker - Ethics of Life Patenting
5. RAFI Statement on PNG Human patent
6. Letter to Lloyd Axworthy and reply on social implications of Biotechnology taskforce
7. Union of Concerned Scientists(UCS) on removing oversight for release of Genetically Modified Organisms(GMOs) in USA
8. Foundation on Economic Trends Neem patent Challenge in U.S.
9. Ethics and the Onco-Mouse - Debate
10. Internal Criticism of Environmental Protection Agency(EPA) evaluation of risk of release of GMOs
11. Organizations and information sources

Appendix 1

The Citizen's Guide to Biotechnology

☞ the most current source that details the environmental impacts of biotechnology today;
☞ a "plain language" guide to the extraordinary new science of genetic recombination and the questions it raises;
☞ includes graphs, tables, charts, glossary of terms and sources of additional information;
☞ 80 pages, perfect bound;

Synopsis:

"Biotechnology is here and it's affecting every area of our lives. In this century, we have seen three major revolutions that have touched nearly every aspect of our lives: the chemical industry, the nuclear industry, and an explosion in the field of information and computers. The new science of biotechnology and its offshoot, genetic engineering, promise an equally profound effect on our lives. If the trend in biotechnology continues, the foods we eat, the medicines and health care we receive and the way we view and use our natural resources will never be the same.

The Citizen's Guide is a thought-provoking exploration of the concerns about biotechnology. In illuminating fashion it untangles proteins, genes and chromosomes and explains why they are important and how industry is using biotechnology to create products. Emerging applications are explored, as well as the ethical, environmental and social concerns arising from this technology.

Scientists are speeding ahead with biotechnology, and our governments, both provincially and nationally, are spending enormous amounts of our tax dollars on this industry. But while they race forward, many fundamental issues have not been discussed or debated by Canadians, and remain unresolved. Find out how you can become involved in the debate about biotechnology with *The Citizen's Guide to Biotechnology.*"

The Citizen's Guide to Biotechnology

Table of Contents

Copies of the Guide are available for $19.99 from:

CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY

517 College St, Suite 400, Toronto, ON, M6G 4A2
tel (416) 923-3529 fax (416) 923-5949

The Citizen's Guide to Biotechnology

According to Michael Crichton, the author of Jurassic Park: "Biotechnology promises the greatest revolution in human history. By the end of the decade, it will have outdistanced atomic power and computers in its effect on our daily lives..."

It is precisely for this reason - the enormity of the potential consequences of biotechnology for the biosphere - that CIELAP created *The Citizen's Guide to Biotechnology.* After a very fruitful year of research and a great deal of effort from many researchers, contributors, and editors, the final product is now available. The *Citizen's Guide* is a thought-provoking exploration of the issues and concerns about biotechnology and provides a starting point for discussion and debate. The *Guide* notes that scientists are speeding ahead with biotechnology and our governments are spending enormous amounts of tax dollars on this industry. Yet, while they race forward, many fundamental issues have not been discussed or debated by Canadians and remain unresolved. Issues such as:

* Is it right to manipulate the blueprint of life of either humans or other species?
* In making genetic alterations in humans, how do we decide what is in need of improvement? Who decides what is normal?
* Who owns genetic information? For what purposes? Is ownership of genetic information - of reproduction and life itself - right? What are the implications of this kind of ownership?
* Is it right to use animals as bioreactors to produce drugs or chemicals? Or to alter the genetic makeup of animals to produce them certain qualities we desire?
* Do we want, or need, genetically engineered food?
* What will be the effect of an uncontrolled, or even a controlled release of genetically altered organisms into the environment?

How these issues arise, in various biotechnology applications, are detailed in the *Guide.* Some examples follow:

Fish Harvesting and Biotechnology

Did you know that genetic engineers have developed fish that grow faster? Coho Salmon have been genetically engineered to grow ten times faster than the normal rate in their first year. That is, the fish do not grow any bigger than they would otherwise, they simply reach their full size more quickly. The development of fish that mature more quickly is increasingly being viewed as a misplaced application of biotechnology. These fish will need to be isolated in fish farms, away from natural populations. Such herding of fish can be problematic in terms of disease propagation. It is unlikely that a natural habitat could support these fish (in the event of an uncontrolled release) because they consume biomass at an accelerated rate. The food supplies which the fish rely upon could simply become depleted from overconsumption causing catastrophic effects on an aquatic ecosystem.

Biotechnology and Milk Production

Bovine growth hormone (BGH) can be used to control several functions in cows, including milk production. Scientists can now produce BGH in large quantities through genetic engineering. The genetically engineered hormone, recombinant BGH, or rBGH, is injected into cows and increases their milk production by anywhere from 10 to 25%. Although the use of rBGH may at first appear to be beneficial, this application of genetic engineering could lead to many problems.

Monsanto's product label warns that use of rBGH will result in significant increases in mastitis, an inflammation of the cow's mammary glands, reduced immune defenses, and could lead to decreased fertility. In order to withstand the illnesses resulting from rBGH, the rBGH-treated cows must be treated with antibiotics which will then enter the cows' milk. Since, by Canadian law, milk carrying antibiotics may not enter the milk pool, farmers may have to throw away a lot of their cows' milk. If dairy farmers in Canada were to use rBGH, the country's milk production could increase by up to 20 percent. This would flood an already well-supplied market and almost certainly result in dairy farm closures.

Forests and Biotechnology

Scientists are developing fast-growing trees to be grown on clear-cut areas. These trees will regenerate the area quickly, presumably in preparation for the next clear-cut. The ability to regenerate deforested areas more quickly may initially seem like a good application of biotechnology. However, this concept of faster-growing trees pays little regard to the slow and intricate process of soil formation. Faster growing trees could very well extract nutrients from a soil at a far greater rate than they can be replenished. In short order the soil could be left depleted and sterile.

While this application may seem to solve some of the problems associated with logging, it fails to address the underlying cause of all these problems: unsustainable forest management practices. If forests were logged in a sustainable manner, instead of being clear-cut, problems with declining forest populations and related environmental degradation would be greatly reduced. By using faster-growing trees, some problems may be solved in the short-term but the destructive practice of clear-cutting, which the use of these trees encourage, will continue to create problems in the long-term.

Other topics Explored

To further the debate over biotechnology the *Citizen's Guide* attempts to explain some critical aspects of the technology and tackles some of the fundamental issues alive today.

Appendix 2

ENABLING BIOTECHNOLOGY?

An Analysis of the Report of the Biotechnology Council of Ontario

Preface

The Canadian Institute for Environmental Law and Policy (CIELAP) would like to thank the Ontario Ministry of Economic Development and Trade for its support to this project. This report has been prepared in conjunction with other non-governmental organizations, in response to the report of the Biotechnology Council of Ontario (BCO) *Enabling Biotechnology: A Strategic Plan for Ontario*.

In June 1994 several individuals representing diverse non-governmental organizations formed the Biotechnology Working Group and met to discuss issues of mutual concern around emerging applications of biotechnology in Ontario. This group has continued to meet, identifying overlapping issues of biotechnology in the areas of the environment, consumer interests, agriculture, new reproductive and genetic technologies, animal welfare, and intellectual property rights and patenting.

CIELAP would like to thank the members of the Biotechnology Working Group: Elisabeth Abergel, Brewster Kneen, Rod MacRae, Andrea Maenza, Fiona Miller, Laura Sky and Ken Traynor, as well as Casey Van Teeling, Penny Chan, David Oppenheim, Bob Gibson, Michael O'Sullivan and Ann Cavoukian for their valuable contributions to this report. Additional thanks go to Cyrus Mavalwala and Sally Leppard for their assistance and advise.

Members of the Working Group prepared byackground papers on biotechnology and its effects in their areas of expertise for this report. These studies are included in full in Appendixes 1. These are, however, the views of the authors and do not imply endorsement by CIELAP.

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Canadian Institute for Environmental Law and Policy
January 1995

TABLE OF CONTENTS

Communications, Energy and Paperworkers Union of Canada/
Syndicat canadien des comminications, de l'énergie et du papier
The Humane Society of Canada/
Société de prévention canadienne pour la protection des animaux et de l'environment
Catholic Health Association of Canada/
Association Catholique Canadienne de la Santé
The Fédéderation Nationale des Associations de Consommateurs du Québec (FNACQ)
Environmental and Labour Member Groups of the Toxics Caucus of the Canadian Environment Network
Canadian Institute of Environmental Law and Policy

Additional Background Paper: Ethics for New Life Forms: Applying the Precautionary Principle to the Regulation of Biotechnology

EXECUTIVE SUMMARY

This study was commissioned by the Ontario Ministry of Economic Development and Trade as a result of public concerns expressed regarding the contents of the September 1994 report of the Biotechnology Council of Ontario Enabling Biotechnology: A Strategic Plan for Ontario. It seeks to outline the basis of the public concerns which exist with respect to biotechnology, and to propose directions forward for the government of Ontario in formulating its response to the Council's report.

The key failure of the BCO's effort was that it did not understand and respond to the range of ethical, social, environmental, and health concerns which exist among Ontarians regarding biotechnology. These concerns are reflected in the results of public opinion polls regarding biotechnology, the deep philosophical divisions which emerged within the federal Royal Commission on New Reproductive Technologies, and indeed, in the response prompted by the work of the BCO itself.

Given the existence of these concerns, and the lack of consensus regarding the appropriate role of the Ontario government in relation to the sector, no action should be taken on the BCO's recommendations regarding government support to the sector, **(Recommendations 1: Ontario Office of Biotechnology; 2: Capital Fund; 3: Purification Plant; and 5: Research and Development Tax Credit)** or with respect to the regulation of biotechnology **(Recommendation 12: Product Regulation)**.

The BCO's six recommendations dealing with the involvement of the industry and other non-governmental stakeholders in the development of public policy regarding biotechnology **(5: Biotechnology Network; 8: Human Resources Development; 11: Public Awareness Forums; 13: Government Program Review; and 14: Biotechnology Sector Council)** may provide a starting point for a public discussion of an Ontario policy framework for the support and regulation of the biotechnology industry. These recommendations should be considered together in terms of the potential means by which the Ontario government might address the public concerns which have been identified with respect to biotechnology in general and the contents of the BCO's report in particular.

It is recommended that the government of Ontario should consider the sponsorship of a Task Force on Biotechnology to assist it in the development of its policies for the support and regulation of biotechnology. This task force should include representatives with a wide range of perspectives. The specific functions of the task force should include:

* an examination of the appropriate role, if any, of the province in supporting the development of biotechnology industry and the forms which such support should take;

* the establishment of criteria, including ethical, social, health, environmental and economic considerations for the evaluation of requests for public support for the development of new applications of biotechnology;

* the establishment of a public process to apply these criteria and review them from time to time; and

* review federal and provincial roles in the regulation of biotechnology in the areas of health products, occupational health and safety, environmental protection and sustainable resources management, and outline a provincial regulatory framework for biotechnology.

The overall goal of the Task Force would be to develop a provincial policy and regulatory structure which protects the environment and human health, and promotes social justice, while permitting, and even supporting, applications of biotechnology which are beneficial from a public interest perspective.

The Task Force could utilize a variety of techniques to assist it in the development of its recommendations on these matters. These could include:

* providing information to the public regarding biotechnology and its implications;

* providing forums of public discussion of biotechnology;

* inviting and receiving submissions from interested groups; and

* commissioning independent research on the ethical, social, economic, environmental and health implications of biotechnology applications.

The establishment of a Task Force on Biotechnology as proposed here would offer a number of advantages to the Ontario government. It would provide a means of addressing the significant gap which exists in Ontario with respect to an overall policy framework for biotechnology in a manner which has the potential to educate the public and build consensus on a course of action by the province. In addition, a process of this nature would provide the province with a means of more effectively targeting public support for the development of biotechnology in areas where there are clearly established needs for new technology.

The development of the report of the Biotechnology Council of Ontario, and the response which it has prompted, has provided the province with an opportunity to take a major step forward in the development of public policy in Canada towards biotechnology. The province could take a leadership role in the establishment of a public space for discussion of the enormous implications of this technological revolution.

Appendix 3

Declaration of Indigenous Peoples of the Western Hemisphere Regarding the Human Genome Diversity Project

We are the original peoples of the Western hemisphere of the continents of North, Central and South America. Our principles are based upon our profound belief in the sacredness of all Creation, both animate and inanimate. We live in a reciprocal relationship with all life in this divine and natural order.

Our responsibility as Indigenous Peoples is to insure the continuity of the natural order of all life is maintained for generations to come.

We have a responsibility to speak for all life forms and to defend the integrity of the natural order.

In carrying out these responsibilities we insure that all life in its natural process and diversity continues in a reciprocal relationship with us.

We hold precious all life in its natural form. The harmonious progress of the natural order in the environment shapes and defines healthy genetic diversity.

The principle of harmony requires that we do not violate the principles of Creation by manipulating and changing the natural order.

Given that our natural relationship has been interfered with by foreign or non-indigenous external forces in a long history of destruction we have never abandoned those responsibilities.

In the long history of destruction which has accompanied western colonization we have come to realize that the agenda of the non-indigenous forces has been to appropriate and manipulate the natural order for the purposes of profit, power and control.

To negate the complexity of any life form by isolating and reducing it to its minute parts, western science and technologies diminishes its identity as a precious and unique life form, and alters its relationship to the natural order.

Genetic technologies which manipulate and change the fundamental core and identity of any life form is an absolute violation of these principles, and creates the potential for unpredictable and therefore dangerous consequences.

Therefore, we the Indigenous Peoples and Organizations participating in this meeting from North, Central and South America reject all programs involving genetic technology.

We particularly oppose the Human Genome Diversity Project which intends to collect, and make available our genetic materials which may be used for commercial, scientific and military purposes.

We oppose the patenting of all natural genetic materials. We hold that life cannot be bought, owned, sold, discovered or patented, even in its smallest form.

We denounce and identify the instruments of intellectual property rights, patent law, and apparatus of informed consent as tools of legalized western deception and theft.

We denounce all instruments of economic apparatus such as NAFTA, GATT and the World Trade Organization (WTO) which continue to exploit people and natural resources to profit powerful corporations, assisted by governments and military forces of developed countries.

We demand that scientific endeavors and resources be prioritized to support and improve social, economic and environmental conditions of indigenous peoples in their environments, thereby improving health conditions and raising the overall quality of life.

We reaffirm that indigenous peoples have the fundamental rights to deny access to, refuse to participate in, or to allow removal or appropriation by external scientific projects of any genetic materials.

We demand the Human Genome Diversity Project and any other such scientific project cease any attempts to seduce or coerce participation in their projects through promises of benefits and financial gain in order to obtain consent and participation of indigenous peoples.

We demand an immediate moratorium on collections and/or patenting of genetic materials from indigenous persons and communities by any scientific project, health organization, governments, independent agencies, or individual researchers.

We demand that nation-state governments and their departments do not participate, fund or provide any assistance to the Human Genome Diversity Project or any related programs, or seek to hold patents or otherwise benefit from the genetic materials taken from indigenous peoples.

We call on religious communities, human rights, social justice and environmental organizations, funding agencies, all individuals and institutions refuse to participate, fund, or provide other assistance to the Human Genome Diversity Project and any related programs.

We extend our support and solidarity to all those who are resisting these efforts, or are seeking the repatriation of genetic materials already taken or removed from their control.

We urge the international community and the United Nations to participate with Indigenous peoples in developing international policies and conventions which protect all life forms from genetic manipulation and destruction.

We call on our brothers and sisters of the indigenous nations around the world, and concerned peoples in the international community to stand up and unite in our efforts to protect the natural diversity and integrity of all life.

The support of all humans in this declaration would protect the sacredness of all life, the natural order, and would provide a healthy future for generations to come.

As declared by the undersigned participating organizations in Phoenix, Arizona on February 19 of 1995:

Amazanga Institute, Provincia de Pastaza, Ecuador
Asociacion Kunas Unidos Pro Napguana, Panama
Coordinadora de Mujeres Indigenas de Bolivia, La Paz, Bolivia
CONIC Consortium, Albuquerque, New Mexico
Council of Athabaskan Tribal Governments, Stevens Village, Alaska
En'owkin Center, Penticton, British Columbia, Canada
Independent Traditional Seminole Nation of Florida, Immokalee, Florida
Indigenous Environmental Network, National Office, Bemidji, Minnesota
Indigenous Environmental Network, Oklahoma Region, Tulsa, Oklahoma
Indigenous People's Alliance, Phoenix, Arizona
Indigenous Peoples Support Network, London, Ontario, Canada
Indigenous Women's Network, Boulder, Colorado
Inter-Ethnic Association of the Peruvian Rain Forest (AIDESEP), Peru
International Indian Treaty Council, San Francisco, California
South and Meso American Information Center (SAIIC), Oakland, California
Sovereignty People's Information Network, British Columbia, Canada
Tonantzin Land Institute, Albuquerque, New Mexico
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Appendix 4

Should Higher Life Forms be Patented?

by Ted Schrecker

Industry Canada has the federal responsibility for ensuring that the Patent Act is modernized to achieve Canada's socio-economic interests. In response to biotechnology advances and international developments, the Intellectual Property Policy Directorate of Industry Canada has undertaken a research program on issues related to the patenting of higher life forms. This article is based on one of the economic, legal and ethical research papers submitted to Industry Canada. That paper was written jointly by Ted Schrecker and Barry Hoffmaster of the Westminster Institute for Ethics and Human Values and Margaret Somerville, Carl Elliott and Ted Keyserlingk of the McGill Centre for Medicine, Ethics and Law. Cate McBurney of the Westminster Institute provided valuable comments on an earlier draft of this article.

Build a better mousetrap, so the saying goes, and the world will beat a path to your door. Many people were stunned in 1988 when the U.S. Patent and Trademark Office issued a patent not for a mousetrap, but for a mouse given the trade name Onco-Mouse. What makes this mouse special is that its genetic makeup, or genome, has been modified by inserting a human gene that makes it highly vulnerable to cancerous tumors. Onco-Mouse is an example of what scientists call a transgenic organism; it is both very useful in cancer research, and very profitable for the holders of the patent. Since 1988, eight more genetically engineered animals have been patented in the United States, and the Onco-Mouse was the focus of lengthy public protests after a patent was awarded in the countries that subscribe to the European Patent Convention (EPC).

The Onco-Mouse is just one illustration of how patents are being used to protect intellectual property (IP) rights in living matter. Broad "species" patents have been awarded covering *all* varieties of genetically engineered cotton (in the United States) and soybeans (in Europe). These are both the subject of ongoing legal challenges, arising from concern about the immense profits that might accrue to the firm which has sought the patents. Patents on human cell lines became a public issue in 1984 when a surgical patient named John Moore sued the University of California in an attempt to collect some of the profits from a patented cell line developed using cells from his diseased spleen. Moore lost, even though he had never agreed to the use of "his" cells for commercial purposes. More recent and even more controversial is the prospect of patents on human genes. For example, U.S. medical researchers have applied for a patent on the recently isolated BRCA1 gene, which confers hereditary susceptibility to breast cancer. If the patent is granted, researchers will be entitled to collect royalties for 17 years on all diagnostic tests and therapies developed from the gene.

Genetic engineering, like microelectronics, is a transformative set of technologies often hailed as promising immense benefits to society. Enthusiasts say that among its potential benefits are hardier and higher-yielding crops and livestock; new therapies for diseases with a genetic component, perhaps including major killers like coronary artery disease; and improved animal models for the study of such diseases as cystic fibrosis and even AIDS. Why are patents on cell lines, genes, and organisms so important? Both the basic research and the process of commercializing new discoveries are costly and time-consuming. According to scientists like Philip Leder, the co-inventor of the Onco-Mouse, "the patent system offers the only protection available for the intellectual product of this research." If patents on higher life forms were not available, according to their supporters, neither researchers nor investors would be assured of an adequate return on their investments of time and money. Critics of patenting respond that a great deal of beneficial scientific research has been done, and continues to be done, without patents and the associated prospect of financial returns.

The questions raised by animal patents illustrate the range and complexity of the ethical issues surrounding patents on living matter more generally. Does it ever make sense to treat living cells or organisms as "inventions," which are what patents are designed to protect? Will the availability of animals specially designed for particular research purposes increase the use of animals in laboratory research, with a (presumed) increase in animal suffering? How can we balance the possible increase in animal suffering

"Although most of us intuitively reject the idea that a living organism should be considered a machine or manufacture, patent law does not necessarily respect that distinction."

against the potential benefits for human beings in terms of medical breakthroughs? (The European Patent Office (EPO), which is responsible for granting patents in the EPC countries, explicitly engaged in such a balancing of benefits against harms before deciding to grant the Onco-Mouse patent; unlike the EPO, neither the Canadian nor the U.S. patent office has clear legal authority to take such public interest considerations into account.) Genetically engineered livestock might grow faster and leaner or yield more milk, yet be more vulnerable to disease; they might even feature designed-in infirmities. Perhaps most disturbingly, what does the ability not only to custom-design sentient beings but also to claim property rights over the results say about a society's attitude to life? How will attitudes and beliefs change in a future where, to quote a 1989 article in the journal *Agricultural Research*, "a computer 'cookbook' of recipes for custom designed creatures" is available?

Arguments about the ethics of genetic engineering generally take one of two forms, corresponding to the two main traditions in Western moral philosophy. The first form involves a claim that certain acts or practices are inherently right or wrong, for reasons that do not depend on their consequences. For example, creating intellectual property rights in a portion of the human genome for commercial purposes may be seen as contrary to a basic ethical requirement that we not treat other human beings as means to an end. Philosophers refer to such arguments as deontological. On the other hand, an activity can be judged right or wrong based on its beneficial or harmful consequences. Philosophers call such arguments consequentialist; when it granted the European patent on the Onco-Mouse, EPO was taking a consequentialist approach.

The consequences that are morally significant for purposes of such an argument need not be economic ones; they may be environmental, social or even spiritual. It is important to note that consequentialist arguments, like deontological ones, rely on pre-existing values or ethical commitments. Pointing to a particular set of consequences is not enough; we need an explanation of why those consequences are morally significant. For instance, in a health care system whose resources are already stretched thin, it might well be the case that new and very expensive treatments based on advances in genetic engineering could be made available only to the rich. Many people would argue that such a situation is morally significant and morally repellent, because access to health care should not be allocated in that way. Although it is not always strictly adhered to, this is the principle that underpins Canada's system of public health care.

The distinction between forms of ethical argument is important for purposes of public policy, because consequentialist objections to genetic engineering or to patenting have less force if there are ways of dealing effectively with the undesirable consequences. Another distinction is important as

Figure 1 — **Topic of Discussion**

Form of Argument	*Genetic Engineering*	*Patenting*
Deontological (arguments dealing with inherent or intrinsic rightness or wrongness)	**Pro:** Genetic engineering is part of humanity's obligation to expand the range of scientific knowledge and technological capability. **Con:** Genetic engineering, or certain kinds of human gene therapy, amount to "Playing God."	**Pro:** Patenting of higher life forms is justified on grounds of fairness to inventors and investors. **Con:** "Ownership of life," in the form of IP rights in portions of the human genome (or, in a different variant of the argument, of any organism's genome), violates basic ethical imperatives or requirements.
Consequentialist (arguments dealing with harmful or beneficial consequences)	**Pro:** Genetic engineering will make possible new kinds of therapies for debilitating diseases, and substantial increases in farmers' ability to produce more food at the same or lower cost. **Con:** The availability of such medical techniques as the genetic modification of embryos will lead inexorably to the revival of eugenics.	**Pro:** Patenting creates an incentive for investing in research and development that will lead to the benefits that can be realized from genetic engineering; without the incentive provided by patenting that investment will not be made, or will be made at lower levels. **Con:** Patenting will have destructive economic effects on family farms; will enable patent holders to reap monopoly profits even from lifesaving therapies and diagnostic techniques; will lead us to objectify life and living creatures, human and otherwise.

well: that between arguments about the ethics of genetic engineering itself and arguments about the ethics of patenting its products. It is perfectly reasonable to view genetic engineering as ethically acceptable, yet be strongly opposed to patenting because (for instance) of a conviction that ownership of any portion of the genetic blueprint of a particular life form is morally repugnant. Figure 1 shows how these distinctions interact in practice, and suggests how a variety of arguments for and against patenting can be categorized.

People who disagree strongly about the patenting of higher life forms may nevertheless agree that the ethical and political issues are profound and far-reaching; only a handful can be dealt with in this article. In terms of effects on agriculture, rural sociologists Frederick Buttel and Jill Belsky have noted that expanded IP protection for plant varieties has led chemical companies to buy up a number of major seed companies, apparently to ensure that crop research and development priorities emphasized the design of plant varieties with enhanced tolerance to the particular pesticides or herbicides marketed by the parent company. The effect is to make those products more marketable, but also to create yet another incentive for chemical-intensive agriculture. The National Farmers' Union in the United States claims that if patents on crop plants become widespread, the price of competitiveness in particular crop markets might become prohibitive for family-operated farms unable to foot the bill for higher-yield (and also higher-priced) varieties. A similar problem, it says, might arise with genetically engineered livestock. The ethical significance of all this depends, of course, on whether relatively small-scale farming is viewed as an important social institution or a quaint anachronism, and whether chemical-intensive agriculture is viewed as indefensible for environmental reasons or as indispensable to any economy where only a few percent of the population feeds an entire country.

Routine patenting of genetically modified higher life forms might also change the way we think about living beings. Canada and the United States allow patents on any new "machine, manufacture or composition of matter." Although most of us intuitively reject the idea that a living organism like a mouse should be considered a machine or manufacture, patent law does not necessarily respect that distinction. Concern that patents and the associated commercialization of higher life forms might erode that distinction in other contexts is fuelled by some of the language used to describe the genetic alteration of animals for commercial purposes: a 1992 article in the trade journal *Bio/Technology* referred to transgenic animals and plants as "production systems" for a variety of proteins, and wondered "which species is the most appropriate production vessel?" Critics of patenting argue that such language both reflects and reinforces a Cartesian view of all non-human organisms as automata devoid of consciousness or the ability to suffer.

Contemporary biological research, however, underscores the genetic similarity between human beings and non-human creatures. This understanding undermines the Cartesian dualism, and may serve to enhance respect for all living beings. As one biologist says: "We all knew that evolution was true, but now, every time I pick up a cell, I have the same amazement. These genes really are there, and they are the same genes across species. A little bit of tinkering here and there, that's all. We really are connected to all these organisms." On the other hand, some people are appalled by the implications of "tinkering" in the laboratory when, as in the case of the Onco-Mouse, it involves the transfer of genes between species. Even if one does not find this practice inherently wrong, it is important to ask what the implications might be of patenting and commercializing portions of the human genome (such as the BRCA1 gene), or of genetically modified human tissues and body parts. Quite apart from the potential economic impacts on the health care system, is there a risk that we might come to "objectify" our fellow human beings, to regard them as well as other living beings as collections of parts or of genetic information?

In contrast to the situation in the United States and the European Union, the ethical issues associated with patenting higher life forms have not had a high profile in Canada, despite the efforts of such organizations as the Ottawa-based Rural Advancement Foundation International (RAFI). RAFI has actively opposed attempts to patent human genes and gene sequences in the United States, arguing that "the commodification of human genetic material raises many profound questions," and was among many organizations protesting an application for a U.S. patent on a human T-lymphocyte line "collected" from a member of an indigenous population in Panama. (The application, filed by the U.S. Department of Commerce, generated such an outcry that it was eventually withdrawn.) RAFI has also cooperated with other groups in mounting legal challenges to the sweeping "species patents" on cotton and soybeans.

Many of the most contentious issues have not yet arisen directly in Canada. As of August 1995, Canadian authorities had not granted any patents on animals. Public attention to human gene patenting in the United States probably reflects the fact that much more advanced research on human genetics is taking place south of the border, both through government-supported initiatives like the Human Genome Project and with the support of private firms like Human Genome Sciences Inc. However, Canada's commitments under international agreements like NAFTA and the latest round of the General Agreement on Tariffs and Trade (GATT) will generate considerable pressure for "harmonization" of intellectual property protection across jurisdictions. The Clinton administration and its key private-sector advisors on trade policy also plan to seek further entrenchment of intellectual property protection through future bilateral trade and investment negotiations.

Canadians will therefore have to face these issues sooner or later, and probably sooner. The conflicts may be deep and divisive. Indeed, the more

important patenting turns out to be as an incentive for genetic engineering research and development, the more opposition will intensify on the part of people with basic ethical misgivings about genetic engineering and its applications. Will we be ready for these conflicts? At least in North America, the basic principles of patent law can be traced to an underlying assumption that the public interest is always best served by furthering commercial and industrial innovation. At least some of the arguments against patenting higher life forms are strong enough to call that claim into question, and with it the moral neutrality of the patent system. Patent offices, as presently constituted, have neither a legal or political mandate to deal with the ethical repercussions. One approach would be simply to ignore them; another would be to leave the ethics of patenting higher life forms for the courts to sort out. However, there is no assurance that either of these approaches will result in public policy decisions that reflect the complexity of the questions involved. Canada therefore needs to set up an institutional framework to deal specifically with the ethics of patenting higher life forms, and to find a way to stimulate informed and thoughtful public debate about the implications of genetic engineering. The most important end result might be a more creative and critical approach to the general question of how advances in science and technology will change Canadians' relationship to their society, and to each other.

• • • • • •

Ted Schrecker is Associate Director (Environmental Ethics), at the Westminster Institute for Ethics and Human Values, in London, Ontario.

Appendix 5

INDIGENOUS PERSON FROM PAPUA NEW GUINEA CLAIMED IN US GOVERNMENT PATENT

- 4 October 1995 -

"Another major step down the road to the commodification of life" says Rural Advancement Foundation International (RAFI) Director Pat Mooney.

RAFI moves to take the life patenting issue to the World Court.

Patenting Indigenous People

In an unprecedented move, the United States Government has issued itself a patent on a foreign citizen. On March 14, 1995, an indigenous man of the Hagahai people from Papua New Guinea's remote highlands ceased to own his genetic material. While the rest of the world is seeking to protect the knowledge and resources of indigenous people, the National Institutes of Health (NIH) is patenting them. "This patent is another major step down the road to the commodification of life. In the days of colonialism, researchers went after indigenous people's resources and studied their social organizations and customs. But now, in biocolonial times, they are going after the people themselves" says Pat Roy Mooney, RAFI's Executive Director, who is at The Hague investigating prospects for a World Court challenge to the patenting of human genetic material.

The Hagahai, who number a scant 260 persons and only came into consistent contact with the outside world in 1984, now find their genetic material - the very core of their physical identity - the property of the United States Government. The same patent application is pending in 19 other countries. Though one of the "inventors," resident in Papua New Guinea, apparently signed an agreement giving a percentage of any royalties to the Hagahai, the patent makes no concrete provision for the Hagahai to receive any compensation for becoming the property of the US Government.. Indeed, the Hagahai are likely to continue to suffer threats to their very survival from disease and other health problems brought by outsiders.

RAFI's Jean Christie has recently returned to Australia after consultations with the governments of Papua New Guinea and the Solomon Islands (one of whose citizens is also subject to claims in a related US Government patent application). On her return from Port Moresby and Honiara, Christie said "This outrageous patent has provoked anger in the Pacific and is a matter of deep concern worldwide." In response to 1993 investigations by the Government of the Solomon Islands and RAFI, NIH's Jonathan Friedlander (Physical Anthropology Program Director) wrote to the Solomon Islands Ambassador to the United Nations, allaying their concerns by saying that the patent applications "will likely be abandoned entirely or not allowed." Contrary to Friedlander's indication, in the course of routine research prior to Christie's trip to the Pacific RAFI discovered that the patent was issued 6 months ago.

Linked to the "Vampire Project"? The first-ever patent of an indigenous person comes as an international group of scientists are embarking on the Human Genome Diversity Project (HGDP), which aims to draw blood and tissue samples from as many indigenous groups in the world as possible. While the Hagahai are not specifically mentioned in the draft "hit list" of the HGDP -- dubbed the "vampire project" by its opponents worldwide -- it has targeted over 700 indigenous groups, including 41 from Papua New Guinea, for "sampling" by researchers. Friedlander, who wrote that the patent application would likely be withdrawn, participated in the development of the HGDP and was among those at its founding meeting. Within weeks of the patent's issue, Friedlander returned the Pacific on business related to the collection of blood samples.

At the same time, indigenous people and NGOs from across the Pacific are working on the implementation of a "Lifeforms Patent-Free Pacific Treaty." As recently as last week's UNESCO Bioethics Committee meeting, HGDP Director Dr. Luca Cavalli-Sforza claimed that the project did not support the patenting of indigenous peoples' DNA. In contrast, at the Beijing Women's Conference, Sami indigenous women from the Nordic countries added their voice to the dozens of indigenous peoples' organizations that have denounced the project as a violation of their rights. "The thin veneer of the HGDP as an academic, non-commercial exercise has been shattered by the US government patenting an indigenous person from Papua New Guinea," said Edward Hammond, Program Officer with RAFI-USA in North Carolina.

The Value of Human DNA: Mining Indigenous Communities for Raw Materials NIH's patent (US 5,397,696) claims a cell line containing the unmodified Hagahai DNA and several methods for its use in detecting HTLV-1-related retroviruses. The team that patented the cell line is headed by the 1976 Nobel Laureate in Medicine, Dr. D.Carleton Gajdusek. Recent cases have concretely demonstrated the economic value of human DNA from remote populations in the diagnosis and treatment of disease and development of vaccines. Blood samples drawn from the asthmatic inhabitants of the remote South Atlantic island of Tristan da Cunha were sold by researchers to a California-based company which in turn sold rights to its as yet unproved technologies for asthma treatment to German giant Boehringer Ingelheim for US $70 million.

NIH patent claims on indigenous people's genetic material are pursued abroad by the National Technical Information Service, a division of the US Department of Commerce. Ronald Brown, the US Secretary of Commerce has left no question as to his interpretation of the controversy, stating "Under our laws... subject matter relating to human cells is patentable and there is no provision for considerations relating to the source of the cells that may be the subject of a patent application." The Hagahai, and millions of other indigenous people, in other words, are raw material for US business.

RAFI believes that this is only the beginning of a dangerous trend toward the commodification of humanity and the knowledge of indigenous people. Whether human genetic material or medicinal plants are the target, there is scarcely a remote rural group in the world that is not being visited by predatory researchers. Indigenous people, whose unique identity is in part reflected in their genes, are prime targets of gene hunters. Says Leonora Zalabata of the Arhuaco people of Colombia: "This could be another form of exploitation, only this time they are using us as raw materials." **RAFI Challenges the Patenting of Human Beings** RAFI has been closely following the patenting of indigenous people since 1993, when pressure from RAFI and the Guaymi General Congress led to the withdrawal of a patent application by the US Secretary of Commerce on a cell line from a Guaymi indigenous woman from Panama. RAFI is currently investigating prospects to bring the issue of human patenting to the World Court at the Hague as well as the Biodiversity Convention and relevant multilateral bodies.

CONTACTS:

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Jean Christie, International Liaison Queensland, Australia (61) 79 394-792
Edward Hammond, Program Officer Pittsboro, NC (USA) (919) 542-1396

Appendix 6

COPY

June 30, 1995

The Hon. L. Axworthy
Minister of Western Economic Diversification
Room 418-N
Centre Block
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Mr. Axworthy,

We are writing to you in our capacities as members of the Steering Committee for the government's Societal Implications of Biotechnology Project. The Steering Committee is chaired by Mr. Don Stephenson, Director of Economic Development for the Department of Western Economic Diversification. The project was established by the government to create a process to deal with the long-term implications of biotechnology for Canadian society. It is co-sponsored by the Treasury Board Secretariat, Agriculture and Agri-Food Canada, Environment Canada, Health Canada, Industry Canada, and the Department of Western Economic Diversification.

We welcomed the government's decision to establish a process to deal with these dimensions of the biotechnology revolution. Discussions of the long-term social, ethical, environmental, economic and health implications of biotechnology have been conspicuously absent from the government's development of policies both to regulate and promote the biotechnology industry in Canada over the past decade. This has been despite evidence of growing concern among the public about biotechnology, particularly in the areas of agriculture and food, and health care (see for example, Optima Consultants Understanding the Consumer Interest in the New Biotechnology Industry (Ottawa: Industry Canada, November 1994)).

Unfortunately, we have serious concerns about the direction and content of the exercise currently being chaired by the Department of Western Economic Diversification. The process has appeared to lack any clear direction from the outset. It has not been at all clear what the government hopes to achieve through the process, or what impact it can be expected to have on public policy with respect to biotechnology. We have been prepared to participate to date, as it is the only consultation on the wider implications of biotechnology which has been sanctioned by the federal government.

However, our concerns have been reinforced by the unilateral decision of the chair of the steering committee, announced in a memo of June 8, 1995 to suspend indefinitely the meetings of the government/stakeholder steering committee for the project, and to draw the process of drafting an outline of social, economic, environmental, ethical and health issues related to biotechnology entirely within the Department of Western Economic Diversification. We note that the Department has no expertise in many of these fields, and little or no experience in the development of public consultation processes.

Under the circumstances, it is difficult to see how the results of this process can be expected to have any public credibility. Indeed, it raises serious questions as to whether we should continue to provide the process with legitimacy through our continued participation.

We believe that if this project is to succeed, the following steps are required:

* the government must provide a clear statement of its goals and objectives for this exercise, and a clear statement of commitment to act on its results;

* the meetings of the project steering committee should be reinstated once such a statement is provided. The membership of the steering committee should be confirmed as 12 members, as previously agreed, and a decision-making process for the committee acceptable to all participants established;

* committee should work towards the selection of a consultant, acceptable to all stakeholders, to develop an overview of the long-term social, economic, environmental, health and ethical issues which arise out of the emerging applications of biotechnology. This could be used as a background document to some form of national consultation meeting or meetings. However, we continue to be strongly concerned that the $150,000 budget provided for this project is inadequate to produce a substantive and thorough background paper, and to support a meaningful national consultation process; and

* the government should provide a commitment to compensate the non-governmental organization (NGO) members of the steering committee for their time and expenses associated with participation in the process. This should include the costs and time associated with attending meetings, reviewing draft documents, and consulting with member organizations and individuals on specific issues. It is clear from the draft issues outline provided on June 8 by WED that the devotion of substantial time and effort on the part of the NGO participants will be required to ensure the development of a comprehensive, thorough and useful report. This matter was raised in correspondence with Mr. Stephenson on May 25 by Dr. Winfield. There has yet to be a response to his proposal.

We believe that this initiative is an important first step by the government to deal with the wider implications of biotechnology for Canadian society. The recent controversies over recombinant Bovine Growth Hormone (rBGH or rbST) and other biotechnology products,

and the recommendations of the House of Commons Standing Committees on Agriculture and Agri-Food, Health and Environment and Sustainable Development regarding biotechnology over the past year, have demonstrated the need for the government to address these issues in an effective and meaningful way. However, substantial changes need to be made in the government's present initiative, if it is to meet this challenge.

We look forward to your reply, and would be pleased to answer any questions which you or your staff might have regarding our views on this initiative.

Yours sincerely,

Mark Winfield
Chair, Biotechnology Caucus
Canadian Environment Network
Canadian Institute for Environmental Law and Policy
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cc: The Hon. S. Copps, Deputy Prime Minister and Minister of the Environment.
The Hon. A. Eggleton, Treasury Board President.
The Hon. R. Goodale, Minister of Agriculture and Agri-Food.
The Hon. J. Manley, Minister of Industry.
The Hon. D. Marleau, Minster of Health.
The Hon. C. Caccia, Chair, House of Commons Standing Committee on Environment and Sustainable Development.
R. Simmons, M.P., Chair, House of Commons Standing Committee on Health.
B. Speller, M.P., Chair, House of Commons Standing Committee on Agriculture and Agri-Food.
Don Stephenson, Director, Economic Development, Department of Western Economic Diversification.
Sr. Donna Geernaert, Canadian Conference of Catholic Bishops.

Minister of
Western Economic
Diversification

Ministre de la
Diversification de
l'économie de l'Ouest

Ottawa, Canada K1A 0A6

AUG 11 1995

Please Quote: 95-0780

Mark Winfield, Ph.D
Chair, Biotechnology Caucus
Canadian Environmental Network
Canadian Institute for Environmental
Law and Policy
517 College Street, Suite 400
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M6G 4A2

Dear Dr. Winfield:

Thank you for your letter of June 30, 1995, regarding consultations on public policy issues surrounding the products of biotechnology.

I would agree with you that issues related to all aspects of biotechnology are important and need to be examined carefully. Canadians want to be better informed about both the science and the implications of biotechnology. Public policy-makers need to understand the views of Canadians in order to frame regulations that address public concerns. It was in recognition of the importance of these questions that the national forum was proposed by the government, within the context of regulatory reform initiatives as outlined in the economic strategy paper entitled "Building a More Innovative Economy".

While the Department of Western Economic Diversification (WD) has no responsibility for the regulation of biotechnology, the department offered to take the lead in facilitating the biotechnology regulations project, which involves several government departments which share these responsibilities. These departments agreed that the regulatory reform and the public consultation process would be best advanced under the leadership of the Deputy Minister of WD, Dr. Janet Smith.

.../2

WD's approach was to invite these departments and a group of broadly representative public interest groups, to participate in a Steering Committee to guide the consultation process. Your organization, and those of the co-signatories to your letter, are members of that Committee.

I appreciate your desire to ensure the success of the consultation and to satisfy yourselves that its results will be taken into consideration by the government. I am also mindful of the financial constraints upon your organizations and the demands of such consultations.

I am concerned, however, that you take issue with several of the decisions made by the Steering Committee. I understand that the Committee discussed and endorsed many of the provisions of the consultation plan which is enclosed, as well as the statement of objectives for the consultation. Recognizing that the issues are numerous and complex, and that there is not likely a public consensus on many questions, the Committee agreed that the government would have difficulty in making specific commitments for implementing the recommendations from the consultation, if any. For that reason, the Committee proposed that Ministers be asked to respond in writing to the consultation report.

In view of the many consultations on related issues, and in order to ensure that the present consultations were not redundant, the Steering Committee agreed that the consultation plan should be approved in phases - the first phase being the preparation and distribution of an issues paper for public comment. The second phase - convening public consultation meetings - was to be approved by the Committee on the basis of the content of the public response to the issues paper.

The Committee discussed, and approved, a funding policy for participation in the consultation process, which provides for direct expenses to be paid only by request and on the basis of need. Committee members were canvassed to determine their views on the necessity of holding meetings in the absence of any substantive issues for discussion. A majority of the members agreed that given the expense and investment in time, meetings should only be held when major points needed discussion, and that the next meeting should be convened when the draft issues paper was available for discussion.

The need for an independent party to direct the consultation process and the ultimate cost and funding requirements were also set aside until decision on the second phase of the process was reached.

.../3

May I suggest, therefore, that you put your concerns before the Steering Committee and that the Committee can make recommendations to Ministers. To deal with these issues directly would be to call into question the Steering Committee process and the consensus approach. Should it prove impossible for the Committee to reach consensus on the matters you have raised, we would have to reexamine the feasibility of the national forum initiative and consider alternative approaches to invite public comment on the policy issues surrounding biotechnology products.

I understand that a draft issues paper which attempts to organize the themes for public consultation is being circulated amongst the Steering Committee members. The Steering Committee will meet at the earliest possible date to discuss the document and offer feedback. I have asked Don Stephenson, Director General, Economic Policy, to contact you directly to discuss how best to structure the agenda of the meeting.

I trust that the Steering Committee can resolve matters to your satisfaction and that we may count on your continuing contribution to this initiative.

Sincerely,

Lloyd Axworthy

Enclosure

c.c. The Honourable Sheila Copps, P.C., M.P.
The Honourable Art Eggleton, P.C., M.P.
The Honourable Ralph Goodale, P.C., M.P.
The Honourable John Manley, P.C., M.P.
The Honourable Diane Marleau, P.C., M.P.
The Honourable Charles Caccia, P.C., M.P.
The Honourable Roger Simmons, P.C., M.P.
Chair, Standing Committee on Health
Mr. B. Speller, M.P.
Chair, Standing Committee on Agriculture and Agri-Food
Sr. Donna Geernaert, Canadian Council of Churches

Appendix 7

P A N U P S - Pesticide Action Network North America Updates Service

USDA Proposes to Abandon Oversight of Field Testing of Genetically Engineered Organisms - October 4, 1995

On August 22, 1995, the U.S. Department of Agriculture (USDA) proposed a new rule to dramatically deregulate field testing and commercialization of genetically engineered crops (Federal Register 60:43567-73). According to the Union of Concerned Scientists (UCS), a non-governmental organization that closely follows this issue, the proposed rule will exempt almost all transgenic plants from the current field testing permitting process, leaving them subject only to notification requirements. With very few exceptions, USDA would no longer consider potential dangers of field tests as is required under the current permitting program. Field tests of genetically engineered plants, containing combinations of genes and traits not possible in nature, may involve hundreds and thousands of acres. UCS maintains that under such conditions in many cases the novel genes may be transferred via pollen from the crops to populations of wild relatives, potentially disrupting whole ecosystems.

Most viral genes, including those not yet discovered, also will be exempted from evaluation in the proposed rule, leaving them subject only to notification requirements. Genetic engineers take genes from viruses that cause plant disease and splice them into crop plants, which by some unknown mechanism makes the crops resistant to the disease. Scientists, however, know very little about the ecological implications of adding viral genes to plants.

In addition, the proposed rule would no longer require companies to submit reports on field trials to USDA. The rule would also expedite the commercialization of crop varieties that are "closely related" to varieties already approved for commercialization. However, the USDA does not define what the term "closely related" means.

The Union of Concerned Scientists urges readers to write letters telling the USDA that the proposal should be revised to protect the environment from the risks of genetically engineered crops. UCS suggests the following:
1. USDA should require thorough evaluation and permits for all plants which have wild relatives in the U.S. with which they can interbreed. Flow of new genes from transgenic crops to wild relatives may present serious ecological risks that should be evaluated before field testing is allowed. (Under the proposed rule, sunflowers engineered to produce insecticidal toxins could be tested on thousands of acres without any analysis of the possiblity of transgene flow, even though the sunflower is a native plant with many wild relatives in the U.S.)

2. USDA should require comprehensive evaluation and individual permits for all plants engineered to contain virus particles until more is known about the ecological impacts of viral genes in crops.

3. USDA should continue to require companies to submit reports on field tests that they conduct. This information is critical to the public's ability to assess the safety of field testing in the U.S.

4. USDA should not expedite the commercial approval of plant varieties that are "closely related" to varieties already commercialized. This provision potentially opens a huge loophole for companies to avoid evaluations of new crop varieties once they have obtained approval of one variety. For example, a company that has received approval for a variety determined to present little ecological risk may then reengineer that variety to contain genes that do present ecological concerns, but claim that the new variety is closely related to the approved one. To further guard against this happening, USDA should also carefully define "closely related" so that no variety with a potential for ecological impacts escapes a thorough evaluation.

5. USDA should provide data and scientific publications to justify any deregulatory proposal.

Source/contact: Dr. Jane Rissler, Union of Concerned Scientists, 1616 P St., NW, Washington, DC 20036; phone (202) 332-0900; fax (202) 332-0905; email jrissler@ucsusa.org.

Appendix 8

RECEIVED

The Foundation on Economic Trends

1660 L St., NW, Suite 216, Washington, DC 20036 Tel (202) 466-2823 Fax (202) 429-9602

October 11, 1995

KEN

RECEIVED OCT 16 1995

Ken Traynor
Canadian Environmental Law Assc
401-517 College Street
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Toronto, CANADA

Dear Ken,

I'd like to personally thank you and your organization for joining with us and more than 245 academic, farm, trade, science and environmental organizations from 42 nations in the filing of an unprecedented legal challenge against the W.R. Grace neem tree patent at the U.S. Patent and Trademark Office.

On September 14, The Foundation on Economic Trends launched a multi-year international campaign aimed at challenging current intellectual property law governing the commercial exploitation of the earth's genetic resources.

We view this legal challenge as a critical test of intellectual property laws under the new guidelines established by the World Trade Organization. The 245 organizations filing the complaint argue that hundreds of indigenous pharmaceuticals, agricultural chemicals, food and fiber products are being illegally usurped by global companies anxious to reap windfall profit off native inventions and discoveries.

The formal announcement of the coalition and the legal challenge to W.R. Grace's neem patent has received extensive worldwide media coverage, including in depth articles and reports in *The New York Times, Wall Street Journal,* the international editions of *Newsweek, Time Magazine*, and reports by the Associated Press and Reuters, as well as prime time network television and radio coverage in scores of countries.

We will be pursuing similar legal challenges against other global companies both in the United States and abroad in the coming months and hope to stay in close contact with you and your organization.

Our goal is to work with you to help develop a strong worldwide NGO response to the transnational companies efforts to extend intellectual property to native resources and knowledge.

I'll keep you posted on developments.

Regards,

Jeremy Rifkin

SCIENCE

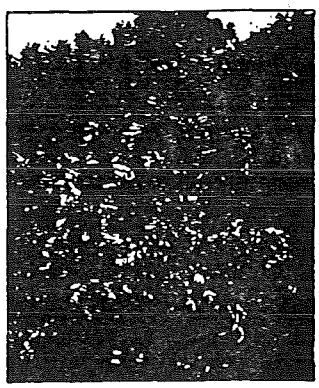
• 15 SEPTEMBER 1995

AGRIBUSINESS

Patents on Native Technology Challenged

The neem tree of India, known as the "blessed tree" and the "curer of all ailments," is at the center of a patent battle that pits advocates of indigenous agriculture against a major U.S. company. Valued in India for its use as a medicine, a spermicide, and as fuel and timber, the neem tree caught the attention of W. R. Grace & Co. of New York because its seeds contain a potent natural pesticide, azadirachtin. Grace patented a method of extracting azadirachtin and stabilizing it. But now the company faces a legal challenge from Jeremy Rifkin, a longtime foe of the patenting of genes and animals. Rifkin claims that Indian farmers have used neem tree seeds as a pesticide for centuries, making this application obvious and unpatentable.

Rifkin's nonprofit group, the Foundation on Economic Trends, has recruited 200 other organizations from 35 countries to join a campaign against the patent, issued in June 1992. Rifkin was scheduled to file a formal petition with the U.S. Patent and Trademark Office (PTO) on 14 September, calling for a revocation of the patent. Rifkin, a consummate coalition-builder (*Science*, 26 May, p. 1126), says the petition is the opening shot in what he hopes will be a widening battle over intellectual ownership of "native technologies." Rifkin argues that "the biological resources that have been discovered by natives ought to be maintained in the open."



AGRICULTURAL RESEARCH SERVICE/USDA

Pesticide factory. Seeds of India's neem tree yield patented product.

While Grace's patent may be under challenge, azadirachtin's effectiveness as a natural pesticide is not. In 1985, U.S. timber importer Robert Larson won approval from the Environmental Protection Agency (EPA) to use the chemical as a nonagricultural biopesticide, and in 1988 he sold the product rights to Grace, which has been marketing it since 1992 as Margosan-O (*Science*, 28 February 1992, p. 1070). In March 1994, the EPA registered Grace's NEEMIX as the first neem product cleared in the United States for use on food crops. Grace entered into a partnership with the Indian company PJ Margo Private Limited in 1993, becoming the minority owner of a factory in Karnataka, India, where seed extract is processed and stabilized for long-term storage. In the past, Indian villagers have not been concerned about storage because they soak the seeds overnight in water or alcohol and place the emulsions on crops the next day.

The Rifkin petition, brought by a coalition of scientific, business, trade, farm, environmental, and cultural organizations, is expected to trigger an automatic re-examination of the patent by the PTO. The agency must respond month after a petition is filed, and petitioners may appeal the decision in federal court.

"We believe we have an airtight case," Rifkin says. The law says an invention may be patented only if it is different from the "prior art" or knowledge a person in the field would have. Grace argues that its patent claim is novel because it applies to "neither the extraction nor the processing of the extract, but to a unique formulation" of azadirachtin developed "to insure its shelf stability." However, according to Rifkin, the petitioners will present "several hundred" journal articles as evidence that Indian scientists had described the extraction method before the patent was issued. And Rifkin says Indian companies were already using the chemical in stable solutions. "The Patent Office was absolutely wrong in granting this patent," he says.

Rifkin also claims the patent will hurt Indian farmers because they may have to stop using their own technology or pay steep royalties. Grace disagrees: "No individual or company is prohibited from the historical or traditional uses of neem extracts," a company statement says. The statement maintains that Grace cannot gain exclusive use of the neem tree extract, because 22 different companies, including three Indian companies, own 40 different patents on neem-related procedures.

Some independent experts in patent law also question the soundness of Rifkin's legal arguments and the significance of the patent for the Indian farmer. John Barton, a Stanford law school professor, says, "It may actually help some Indians by creating an industry for neem seeds." He notes that because the patent covers only one particular method of extraction, it shouldn't directly affect the Indians already using neem seeds.

Rifkin remains confident of his case, however—and of its value as a rallying point for those who oppose patents based on the genetic resources of developing countries.

–Lori Wolfgang

The New York Times

THE NEW YORK TIMES, FRIDAY, SEPTEMBER 15, 1995

Tradition in India vs. a Patent in the U.S.

By JOHN F. BURNS

NEW DELHI, Sept. 14 — For more than 50 years, Dr. Vaidya Satya Pal has sat in his apothecary's shop in the teeming heart of this capital, dispensing the 2,000 ancient Indian remedies that cram the cupboards around him. Often, his treatment of choice is a derivative of the neem tree, a hardwood that is as common in India as a pine is in New England.

So when Dr. Pal heard that W. R. Grace & Company had an American patent granted in 1992 for a pesticide based on neem, and that the patent was under challenge from an international coalition that regarded it as a piracy of India's knowledge of the neem tree and its properties, he rose irritably from his table and pushed out among the throng gathered in the dimly lit pharmacy.

"It is ridiculous, just ridiculous," the 75-year-old physician said. "People in India have been using the neem tree since the beginning of time, since we learned to make fire. For anybody to say he has a patent on the neem tree, well, it only shows, anybody who has the muscle power and the money power, he will snatch whatever he can."

Similar opinions were common in India today as a legal petition challenging Grace's patent was presented to the United States Patent and Trademark Office in Washington. The Foundation on Economic Trends, the group that is heading the challenge, said the petition was backed by the signatures of more than 100,000 Indians, as well as by more than 225 agricultural, scientific and trade groups in 45 countries.

To its backers, the bid to strip Grace of the patent on Neemix, a nontoxic pesticide gaining popularity among American farmers for use on food crops, marks a watershed in the international battle over rights to intellectual property. With today's legal challenge, these groups say, developing nations have begun a counteroffensive against rich countries that have accused poorer nations of rampant intellectual piracy because of underground industries that make counterfeit copies of computer software and movie videos.

"What many Americans have not realized is that the anger, frustration and resentment in the developing countries against what they regard as piracy of their heritage is every bit as intense as the outrage that has been drummed up by the United States over the violation of our intellectual copyrights in the developing world," said Jeremy Rifkin, president of the Foundation on Economic Trends. "What we began today is the other side of the equation."

In documents supporting the petition, the foundation, which is based in Washington, and its allies portrayed the battle over the neem patent as a symbol of a looming confrontation over what they call "legalized bio-piracy," which they regard as a multibillion-dollar issue involving the world's forests, fields and oceans.

One organization backing the challenge, the Rural Advancement Foundation International, listed more than 40 companies and organizations, most of them American, that have extensive "bio-prospecting" programs in developing nations. Among them: Merck & Company, which is searching the tropical forests of Costa Rica for fungi and plants that could be used in developing anti-coagulants and other drugs, and the National Cancer Institute, a Government-financed body that has a program to collect organisms that could be helpful in developing cancer-fighting treatments.

Beyond the challenge to the neem patent, organizations like Mr. Rifkin's would like to see international legal standards adopted to guarantee poorer nations a greater share of profits earned from the exploitation of biological resources.

But the first step sought is a halt to

Dieter Ludwig for The New York Times

Indian men in the village of Mehrauli near New Delhi used twigs from the neem tree yesterday to clean their teeth. Indians, who have used neem in many ways for thousands of years, and some Western allies, are outraged that W. R. Grace & Company has patented a pesticide based on neem.

what these groups say is an attempt, through the patenting process in the United States and other rich countries, to get a legal hammerlock on resources that they view as belonging to mankind at large.

"The real battle is whether the genetic resources of the planet will be maintained as a shared commons or whether this common inheritance will be commercially enclosed and become the intellectual property of a few big corporations," Mr. Rifkin said. "We're talking here of something that is critical to future generations."

The battle over Grace's patent for Neemix is likely to hinge on judgments about the scientific work needed to bring it to market. In their legal challenge, Mr. Rifkin and his allies argue that the patent should be voided under a legal concept known as "prior art," meaning that a product cannot be patented if the technology is substantially the same as that in existing products. In the case of Neemix, the petitioners say, Grace is using a process little different from the one farmers in India have used for at least 2,500 years to protect their crops: grinding up the seeds of the neem tree, immersing them in water and spraying the resulting emulsion on their crops.

While the most widespread use of neem in India is as a crop spray, it has also been used for thousands of years to treat conditions as varied as ulcers, eczema, acne and prickly heat; twigs are even chewed by people too poor to buy toothpaste.

Chuck Suits, a spokesman for Grace, said by telephone from the company's headquarters in Boca Raton, Fla., that the company's research had resulted in a crucial breakthrough that extended the shelf life of the active neem ingredient, azadirachtin, from a few days to at least two years.

Mr. Suits said he had no figures on the amount spent developing the pesticide, which is made in the United States from a concentrate produced for Grace in the southern Indian city of Bangalore by the P. J. Margo Company, an Indian company in which Grace has a minority holding. While Neemix makes up only a small fraction of Grace's $5 billion in annual sales, critics of the company contend that its sales of Neemix could eventually be far greater than the company has stated.

THE WALL STREET JOURNAL

WEDNESDAY, SEPTEMBER 13, 1995

Grace's Patent On a Pesticide Enrages Indians

By RALPH T. KING JR.
Staff Reporter of THE WALL STREET JOURNAL

India's neem tree has provided peasant farmers with a potent, affordable and ecologically friendly pesticide for centuries. It is sacred to Hindus. It is also the source of an international trade dispute.

A coalition of 200 organizations from 35 countries led by biotechnology critic Jeremy Rifkin is seeking to invalidate a 1992 patent on a formulation of the neem pesticide held by W.R. Grace & Co., based in Boca Raton, Fla. The key assertion of the challenge, expected to be filed with the U.S. Patent and Trademark Office tomorrow, is that the formulation, from seeds of the neem tree, is insufficiently novel because Indians have been making versions of the neem-seed pesticide for generations.

"This is intellectual and biological piracy," says Vandana Shiva, one of the petitioners, who is president of Research Foundation for Science, Technology and Natural Resource Policy in New Delhi.

Not so, says Grace. Its patent is valid and defensible because its formulation process significantly improved the pesticide by giving it a shelf life of several years, instead of several weeks.

If the patent office rules against the challengers, the matter could go on to a federal appeals court.

Grace has a contract-manufacturing plant in Bangalore that employs the patented process to produce a natural pesticide. The plant's production has contributed to India's export production and a doubling in neem-seed prices. As a result, some smaller, poorer farmers who made the pesticide the old way, or need the pesticide, have been driven off the land, Dr. Shiva says. "To farmers in India, the neem-tree patent represents an attack on their way of life," she says.

The controversy is likely to reverberate far beyond the Indian countryside. It could intensify debate over who should control the planet's biological resources. As companies scour the earth for materials that can be modified and enhanced by new or complex technology, they face the same sort of resistance from "gene-rich" communities that foreign mining concerns did from mineral-rich nations decades ago.

Moreover, the dispute could cause some nations to reconsider their commitment to U.S.-style patent laws under the latest General Agreement on Tariffs and Trade, says Mark Ritchie of the Institute for Agriculture and Trade Policy in Minneapolis. Under existing law in India, for example, agricultural products are not patentable, in part to keep foreigners from usurping knowledge handed down by farmers through the ages.

That's just what Grace did, says Mr. Rifkin, who is president of the Foundation on Economic Trends in Washington. The traditional method of making neem pesticide is straightforward: The common tree's lime-green seeds are ground up and soaked overnight in water. Grace modified this process in minor technical ways that are not truly innovative and thus did not deserve a patent, Mr. Rifkin says. "Any chemist worth his salt could have come up with it," he says, citing 600 scientific-journal articles on neem's pesticidal properties dating back more than 60 years. "This amounts to genetic colonialism."

Martin Sherwin, a Grace vice president, acknowledges that "there's nothing Buck Rogers" about the company's pesticide, sold mostly in the U.S. and the Middle East under the trade name Neemix. But without Grace's critical chemistry steps, he says, the pesticide cannot be packaged and widely distributed.

In addition, the Grace product has limited profit potential because it is so costly to extract even on a large scale, Dr. Sherwin says. Grace, which had $5.1 billion in sales last year, doesn't expect Neemix sales in the U.S. to exceed $60 million over the long term, although it has taken the trouble to apply for patents in key markets around the world.

"We are guilty of encouraging a local entrepreneur to build a plant that employs 60 people and is responsible for millions of dollars of export value and making a profit," says Dr. Sherwin. "I think they should give us an award."

Stephen Bent, an intellectual-property attorney at the Washington firm Foley & Lardner, sees the challenge to the Grace patent as a "red herring." The patent, which covers only Grace's own formulation, "couldn't possibly jeopardize what the [Indian] farmers are already doing" to make the pesticide, he says.

India's poor patent protection has deprived it of the latest technology in other areas, such as computers. Many Indian entrepreneurs choose to leave the country to commercialize their inventions. But if India conforms to the GATT patent standard (which it has agreed to do but which is far from a certainty), Mr. Bent says, "it could be a real powerhouse in some areas of technology, particularly agricultural technology."

Patent challenges are rarely successful. However, Mr. Rifkin has proved adept at influencing public opinion in high-profile campaigns against biotechnological innovations. He helped to force many U.S. dairies to label milk containing artificial bovine growth hormone and halted attempts by Genentech Inc. to locate potential candidates for its human growth hormone through height screening of schoolchildren.

A few biotechnology companies have already recognized the need to compensate gene-rich countries where they are prospecting. Shaman Pharmaceuticals Inc. of South San Francisco, Calif., has struck a dozen agreements in South America and elsewhere that include upfront payments to improve local infrastructure and a contribution of future profits to a foundation dedicated to rain-forest preservation.

Aid groups back challenge to neem patents

London and New Delhi. An international coalition of more than 200 aid and environmentalist groups is backing a request to the US Patent and Trademarks Office (PTO) to withdraw a patent issued to the multinational company W. R. Grace on a method for extracting an active insecticide from the Indian neem tree.

The groups, which include several Indian organizations representing small farmers, are claiming that the patent is invalid because native knowledge of the tree, *Azirdirachta Indica*, whose extracts have been used for centuries not only to control insects but also for a range of medical purposes, should be regarded as 'prior art'.

Their request to the PTO follows a similar move in Europe at the beginning of June, organized by the Greens in the European Parliament. This challenges a patent issued earlier this year by the European Patent Office (EPO) jointly to Grace and the US Department of Agriculture (USDA) on a technique for using a chemical extract from the neem as a fungicide.

Both moves, which extend a campaign launched in India two years ago, are intended to focus attention on the way that the patent system permits multinational companies to lay claim to techniques based on the indigenous knowledge of Third World countries, if they are able to extend this knowledge using modern scientific methods.

Grace and other multinationals claim that their only responsibility is to demonstrate to patent authorities that the specific techniques for which they are applying for a patent meet conventional criteria for novelty and inventiveness (the PTO has already granted over 50 patents on neem-based products from toothpaste to contraceptives).

The US patent under challenge, for example, refers to a technique Grace claims to be unique for extracting the chemical azadirachtin from neem tree seeds in a way that allows the extract to be stored for far longer than when it is extracted by traditional techniques.

Neem: patent battle ranges from India to America.

Those seeking a re-examination of the US patent point out that long-term storage is in little demand in India, since the extract has traditionally been used soon after its preparation. But they claim to have evidence of several small Indian companies which have been engaged in developing storable neem extract, and the outcome of their challenge may depend on whether the practices of these companies will stand up in court as 'prior art'.

A spokesman for Grace, however, says that the patent concerned does not concern the processing of the extract, but only the unique formulation of its active ingredient, azadirachtin, without which the natural active ingredient degrades quickly. The company says that the claims against the patent, which have been filed in Washington by Jeremy Rifkin, director of the Foundation for Economic Trends, are "incorrect and without merit".

The neem issue is particularly sensitive because it has come to symbolize conflict between traditional and modern economic systems. Public protests against companies such as Grace delayed the passage through the Indian Parliament of new legislation on intellectual property designed to bring India's patent laws in line with those in the West as part of the outcome of the Uruguay round of the General Agreement on Tariffs and Trade.

Indian conservationists such as Vandana Shiva, director of the Research Foundation for Science, Technology and Natural Resources in Dehra Dun, one of the leading campaigners against the neem patent, hope that their campaign will draw world attention to the way that multinational corporations are patenting the biological resources of poorer nations.

"American people have only heard of software piracy," says Shiva. "What they don't know is that their companies are engaged in piracy of the worst kind in trying to profit from the traditional knowledge of India's farmers, who have been using neem as a pesticide for generations."

M. D. Nanjudaswami, head of the powerful Karnataka state farmers association, is confident that the patent will eventually be revoked. "If not, it would mean that indigenous populations around the world will not be able to freely use many of their local biological resources which they had developed and nurtured for centuries." Two years ago he led a widely publicized demonstration against a factory in Karnataka that supplies neem extracts to the US company.

One major concern to Indian farmers is the long term impact of the patent on the availability of neem seeds. With Grace already prepared to pay up to US$300 per tonne of neem seeds, what used to be a free resource has now become a highly priced one. Shiva claims that a shortage of seeds will eventually force India's farmers to rely on Grace's product.

David Dickson and K. S. Jayaraman

Neem unsheaths contraceptive potential

New Delhi. While the pesticidal quality of neem (*azadirachta indica*) is the main reason for the tree's attraction to multinational companies, scientists at the Defence Institute of Physiology and Allied Sciences (DIPAS) in New Delhi have filed a claim on a substance that they have isolated from neem oil which kills sperm on contact.

The substance DK-1, which the scientists hope to use as a vaginal contraceptive in the form of a cream or pessary, has been isolated from the volatile fraction code-named NIM-76 separated from neem oil. According to M. Selvamurti, DIPAS director, the substance is a potent germicide at a concentration of less than 0.2 per cent.

Pharmacological and acute toxicity trials on rats, rabbits and guinea pigs, carried out at the Central Drug Research Institute in Lucknow, have cleared DK-1 for phase-one human trials, due to begin in November. Selvamurti says these will be followed by a large-scale trial in 1996.

The institute has transferred the technology to two Indian drug companies who will scale-up production of the neem contraceptive to produce the supplies needed during the phase-two trial and subsequent marketing. DIPAS scientists say that neem's historical role as part of Indian folklore may make it more socially acceptable as a contraceptive than conventional birth control pills.

Tests have shown that DK-1 is stable at 45°C. and has a shelf-life of at least six months. The neem isolate, says Selvamurti, has been subjected to the rigorous tests needed for pharmaceutical regulation. The contraceptive formulation will be licensed — unlike other herbal preparations, whose biological effects tend to show considerable variation.

Two more substances isolated from neem bitters also showed promise as potential contraceptives. But DIPAS intends to conduct trials only after it brings the first neem contraceptive onto the market. One of the substances, coded DNM-5, prevents implantation when administered orally in the early stages of pregnancy. The other fraction DNM-7 acts as an abortifacient. DIPAS has filed patent applications for all the three. K. S. J.

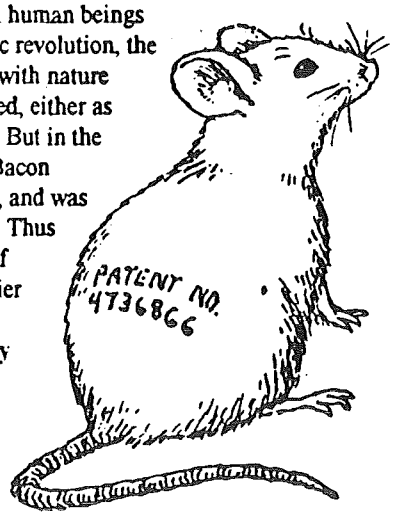
Appendix 9
Ethics and the Oncomouse

David King - Editor Genethics News

It is notoriously difficult to define 'ethics', and this is part of the reason that discussion of the ethics of genetic engineering often get nowhere. But however we define it, ethics is about *relationships*.

Humanity and nature

At the end of the twentieth century, the ethics of one particular relationship, between humanity and the rest of nature, has become increasingly central to the political agenda. Starting with the Scientific Revolution of the 17th century, a drastic change has come about in the relationship between human beings and the rest of nature. Prior to the scientific revolution, the majority of people existed in close contact with nature and often regarded it as in some sense sacred, either as God's creation or as inhabited with spirits. But in the 17th century, philosophers such as Roger Bacon began to say that nature was merely matter, and was a resource to be exploited for human aims. Thus people came to see themselves as outside of nature, and this was undoubtedly made easier by the move to cities. What people have begun to realise in the late twentieth century is that the result of the separation of humans from nature and its reduction to a passive object is the environmental crisis that we have today.



At the centre of many people's concern about patenting animals is the feeling that now our relationship with the rest of nature is changing again. By contrast, the standard argument of industry is that, since we already own animals and eat them, patenting makes no difference, but is merely a change in the commercial arrangements. There is no space here to properly discuss the extremely controversial question of the rights and status of animals. What is clear, however, is that animals are seen as entities which are not *dependent* upon us for their existence: a relationship exists between two independent entities which have different purposes and interests. The point of ethics is to try to work out how those independent and sometimes conflicting purposes and interests can be reconciled. Normally, at a very minimum in this society, human beings are regarded as having certain obligations and duties to any animals which are in their possession.

Machines

But what is the situation if I want to patent an animal? To understand this we first need to realise that the underlying philosophy and ethic of the patent system has inanimate objects, mainly machines, in mind. What the patent system does is to treat things as if they were inanimate machines. There is obviously no relationship between the inventor and his or her machine: whether relationship is taken in an ecological sense, or in the sense of having an interactive emotional relationship, **you cannot patent something with which you have a relationship.** In patenting an animal, it is therefore necessary to destroy any relationship which we may have with it, and to treat it as if it were no more than an inanimate machine, a commodity.

Another way of looking at this is to consider the claim that I have invented an animal. From the point of view of anyone who believes in God(s), this claim is simply claiming to be God. But to return to ethics: if I have invented an animal I am now in a different relationship to it altogether. I own the being of that animal in a far deeper sense than merely by virtue of having paid money for it. It is completely dependent upon me for its existence. It is no longer an independently existing part of nature: its purposes and interests are my purposes and interests, and I can therefore claim the right to mould and design its entire being to suit my interests. In terms of the ethical relationship between the self and the other, patenting an animal amounts to a simple annihilation of the other.

Is it merely a coincidence that the first animal to be patented, the Oncomouse, epitomises this destruction of the other? The Oncomouse is an animal designed to suffer for human purposes. Only if I lack any kind of ethical relationship to an animal could I design it to suffer. Can we view the oncomouse as an independently existing part of nature which has its own purposes and interests? No - it is a commodity, to be bought and sold. Its independence of being has been undermined from the start, by being stamped as an item of human intellectual property.

The patenting of animals is an ethical change, a qualitative change, of the highest order. In time it will no doubt have practical consequences. If the concept of patenting animals becomes established, the rights to humane treatment of such animals (even animals engineered for relatively harmless purposes), without interests and purposes of their own, will surely be eroded.

A new step

The reason that the patent on the oncomouse has become such a crucial test case is because, despite our ever-increasing alienation from the rest of nature, it is intuitively obvious to many people that here is a really new concept. At every point on the slippery slope there are always some who will argue that the latest developments or proposals are nothing more than a quantitative change. Part of the reason that this cuts no ice for many people in the case of the oncomouse is that they still do have real unalienated relationships with some animals: animals are not merely industrial commodities to them.

I have argued that the patenting of animals is a new step. In the context of historical changes of relationships between humanity and the rest of nature, it can be seen as the latest step in the gradual human enclosure of nature. Now, we are not merely dominating nature, but claiming intellectual origination. Historians and philosophers always debate whether changes in ideas come before or after political, economic and social changes. But for once we have a clearly identifiable decision to be made, which will have huge ethical and practical consequences. One of the bizarre aspects of the world we live in is that the decision makers will not be philosophers, nor even politicians, but obscure and unelected officials of a remote body, the European Patent Office.

The patenting of transgenic animals: an industry view

Meredith Lloyd-Evans

The industry view on the patenting of transgenic animals can be expressed simply: patent law as it stands, does not prevent in principle the patenting of an innovative and useful product of human discovery and ingenuity. From this point of view a transgenic animal, or at least the gene construct within it, is eligible for patenting. The basic principles of patenting law have not so far been challenged in court, although decisions by individual patent offices have been.

Moreover, industry in all successful systems is based on capitalist principles. Investors, whoever they may be, expect a return on investment and expect a company to prosper in the market by exploiting positions based on closely guarded intellectual property or creative marketing techniques, or both. From this viewpoint, industry is convinced that without the monopoly position implicit in the granting of a patent, the heavy investment required to discover, develop and make available a transgenic animal and its products cannot be justified.

Activist groups opposed to this have several realistic avenues to explore. One is to construct with industry a feasible alternative to the capitalist system, where success is not dependent on a monopolistic market position. Another is to contribute to an ethical position, which is expressed within national or supranational laws, that prevents transgenic animals from being developed, or, if patented, being marketed. A third way is to seek to change patent law, an avenue being pre-empted by recent ethics-oriented decisions by the European Patent Office (EPO).

A constructive dialogue is possible between industry and activist groups

My viewpoint is that a constructive dialogue is possible between industry and activist groups and that both parties should work harder to resolve the existing destructive conflict. Lines may need to be drawn somewhere, but not at extremes.

Transgenic opportunities

There are a number of opportunities that researchers see as justifying the effort and funding put into the development of transgenic animals.

Genetically manipulated animals (GMAs) could be used for human healthcare, as models for disease (eg. the Harvard 'oncomouse') or as producers of therapeutic substances (eg. pharmaceutical proteins from transgenic 'pharm animals'). In agriculture, GMAs could be developed: which resist disease better; which make better use of nutrients, reducing waste, helping return more foods to human use and reducing the environmental impact of farming; and which produce more food, milk, eggs, wool for human use. Companion animals could be developed which are disease resistant.

Overall, developers and exploiters of gene techniques believe these advances will reduce animal suffering, enhance human health and benefit the environment far more than existing and conventional technologies might.

There are other possibilities that are not, in my view, acceptable, and should be avoided by cooperation and agreement between researchers, industry and interest groups. These include: farm animals that have lost the anatomical characteristics of their species such as wings, or have gained new and abnormal features such as a second udder; and companion animals which have been engineered into new colours and forms (for example as suggested by some Southeast Asian sources in the context of decorative fish breeding).

Drawing a line

One issue for both industry and activist groups is where to draw the line. We should be identifying developments in GMAs, however few and limited, which the majority of interest groups believe are supportable, and others which all parties agree are not defensible and should not be explored. Industry is willing to work on ethics frameworks that foster beneficial developments and suppress those that damage animal or human welfare. It does not want to be judged on any past record, especially as the whole climate of social responsibility has changed. It is time for new approaches.

If we accept that technological advances might be able to make some useful contributions to improved animal, environmental and human well-being, we should ask what tools are best for ensuring an ethical approach to commercial and technical advances: fiscal inducements to acceptable action; codes of practices designed by committees on ethics; formal legal controls and penalties; or bans on patents?

My view is that a combination of the first three will be more effective for industry and more humanitarian in the short- and long-term than the last, which will irreparably affect intellectual freedom and technological development.

Unsubstantiated assertions

In my view there are a number of unsubstantiated assertions with regards to the patenting of animals, as follows: patents will make it illegal for farmers to breed from GMAs; patents will lead to a drastic decrease in farmers' independence; patents will decrease the numbers of small farmers; patents will inhibit access to diversity of germplasm; patents will lead to new foods being developed because of their patentability, not their quality; patents will undermine public research; patents will increase the power of the biotechnology companies; patents will produce a monopoly control of farming by a few large companies; patents on genes give multinationals control over the genetic resources of the Third World; patenting animals will lead to a destruction of the principles of animal welfare; patenting will result in the undermining of all respect for nature. The industries responsible for biotechnological advances and for agricultural inputs dispute these unsubstantiated assertions about the patenting of animals. If industry and interest groups start to co-operate, then we can avoid all these unsubstantiated assertions about the harm patenting might cause, which currently inflame the debate, distort decision-making and prevent constructive action.

Meredith Lloyd-Evans is the Director of the Biobridge consultancy, based in Cambridge. This article is excerpted from his chapter in Animal Genetic Engineering (see p 11 for review)

Appendix 10 US scientists attack Environmental Protection Agency

Scientists from the US Environmental Protection Agency (EPA), in a report entitled 'Genetic Genie', charged their own agency with 'failing to assess the risks associated with the massive release...of a new living organism that cannot be contained or eradicated'. The scientists, in the hope that the unusual action will prompt the EPA to reconsider its expected approval of a genetically engineered bacteria, acted through PEER, Public Employees for Environmental Responsibility. PEER executive director, Jeff deBonis, notes that the authors of the report 'are committed professionals who merely want to communicate that more research needs to be done before genetically engineered microorganisms are introduced on a commercial scale into the environment. They believe the EPA is currently unprepared to perform its statutorily mandated task of performing competent risk analysis prior to approving the release of new life forms'.

Debonis explains that, 'The authors remain anonymous in order to avoid the inevitable retaliation that would be taken against them by their supervisors in EPA. Amongst federal agencies, EPA is one of the least tolerant of internal dissent, even on purely scientific matters. EPA has repeatedly been found in violation of whistleblower protection statutes.'

The PEER report is very critical of an imminent EPA decision to release the genetically engineered *Rhizobium meliloti* RMBPC-2. The EPA scientist-whistleblowers point out that the engineered bacteria they are warning about contain genes drawn from several sources, including a gene from the pathogen *Shigella flexneri*, which causes dysentery in humans. The *Shigella* gene is an antibiotic resistance marker. According to the report, amongst the health risks their agency has not assessed are:

- the potential transfer of antibiotic resistance to other pathogens and the subsequent creation of drug resistant diseases in humans and livestock
- the potential toxicity to humans who are exposed to the micro-organism.

The scientists also note several significant environmental dangers for which the EPA has inadequate data including:

- the potential for a 'Frankenstein Effect', whereby wild plants colonized by the new bacteria could become serious problems that cannot be eradicated
- the risk of loss of endangered and other native plant species due to competition from newly created weedy species
- the risk of irreversible changes in soil ecology and fertility caused by RMBPC-2.

The *Rhizobium* in question was created as a soil inoculant, to increase yields in alfalfa and other legumes. However, the scientists' report indicates that the RMBPC-2's effectiveness 'is questionable'. The report says that the efficacy of the new bacteria was 'not even considered in the risk benefit analysis' conducted by EPA. According to the report, the EPA only looked at the potential market for the product; the report asks why any risk should be engendered for a product that may not work.

Overall, the report is scathing about the internal agency approval process, which was so shoddy, it says, that one prominent scientist resigned from the EPA's scientific advisory panel. It accuses the EPA of over-eagerness to promote biotechnology and of ignoring or suppressing its own staff's concerns. It recommend that the EPA declare a moratorium on the release of new organisms until appropriate risk assessment practices are in place.

'Genetic Genie' is available from PEER, 810 1st St NE, Suite 680, Washington DC 20002, USA

Report excerpted from an article by Beth Burrows, Director of the Edmonds Institute, Washington, USA, in *terrain*

USDA deregulates plant releases

US environmental organisations have issued an action alert as, two months before the Jakarta conference (see article on p11), the US Department of Agriculture (USDA) is proposing to virtually abandon regulation of releases of transgenic plants. The proposed rule would mean that for 99% of new plants, companies would only be required to notify USDA, rather than gain approval through submitting a risk assessment and environmental safety data. Companies would also no longer be required to submit reports to USDA of field trials. Commercialisation of crop varieties 'closely related' to varieties already approved would be expedited.

German activists disrupt field trials again

The German Gen-ethic Network informs us that 6 out of 23 field trials in Germany have been hit by direct action this year. In July, maize plants belonging to the University of Hohenheim were destroyed in Renningen, and this was followed by destruction of AgrEvo's sugar beet and maize plants at Gehrden. The occupation of maize fields owned by the Dutch company van der Have ended with a promise that the company would give up sowing the maize this year, because the sowing period had passed.

Genethics News Sept/Oct/95

Appendix 11

Contact Organizations and Information Sources

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Other Useful Contacts

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1212 rue Panet
Montreal, QC H2L 2Y7
514-521-6820

Council of Canadians
#1004 - 251 Lauriers West
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Council for Responsible Genetics
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Institute for Agriculture and Trade Policy (IATP)
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612-379-5980

Information Sources

There is all sorts of information of varying quality on the Internet although few sites feature significant Canadian content. Two useful sites to start from are:

Washington Biotechnology Action Council (WASHBAC) internet site address:
http://weber.u.washington.edu/~radin

Rural Advancement Foundation International (RAFI) internet site address:
http://www.charm.net/~rafi/rafihome.html

Two useful conferences on the Canadian web network are:
gen.biotech maintained by IATP and
biodiversity.