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Research + Communications

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Patenting of Higher Life Forms Research Findings

Report to Industry Canada

Prepared by

Earnscliffe Research and Communications

February 2003

Introduction

Earnscliffe Research and Communications is pleased to present the following report to Industry Canada. It provides findings of 4 focus groups with a total of 37 individuals, two groups in Toronto and two groups in Halifax, which took place in the first week of October, 2002. The groups were comprised of *Involved Canadians*, the 30% segment of the population that is made up of those who are most interested and active in public policy issues.

This research was prompted by a series of considerations:

- Intellectual property is one of the most pressing issues associated with biotechnology. It is likely to become one of the most important arbiters of success for nations that seek a leadership role in this growing field.
- As the only G7 country to not grant intellectual property protection for multicellular inventions (MCI's), the views of Canadians with respect to this issue was seen as useful. The issues raised by the intellectual property protection of MCIs are of increasing importance to the Government of Canada, especially in light of the upcoming Supreme Court of Canada decision in the Harvard Oncomouse case and the publication of the Canadian Biotechnology Advisory Committee's report entitled "The Patenting of Higher Life Forms".

The focus group discussions followed a moderator's guide that began with a thirty to forty-five minute discussion of biotechnology, its applications, regulatory processes and potential benefits and risks. The groups then proceeded to a detailed and structured discussion of patenting and specifically, the patenting of higher life forms. In each focus group, approximately 75 minutes was dedicated to discussion of patenting of higher life forms. The moderator's guide is appended to this report.

It should be noted that this was a qualitative exercise, so the results would not be deemed statistically significant. The results should be treated as general guidance about public opinion on these issues.

For more information on the research design and findings, please contact Earnscliffe Research and Communications, at 613 233 8080.

Awareness and General Attitudes: Biotechnology

The initial discussion revealed attitudes consistent with previous work among this segment of the population and consistent with the findings of a parallel set of groups being conducted during the same time period for the Biotechnology Assistant Deputy Minister Coordinating Committee (BACC). Those groups form part of a seventh wave of research conducted for BACC since the fall of 1999. For a detailed discussion of those findings, please refer to that report.

In short summary:

Involved Canadians show growing levels of awareness of biotechnology and the range of its applications. Biotechnology has become part of their landscape of important high technologies and they continue to invest much of their hope for the future success of the country and their children in these kinds of technologies.

They have inculcated the potential benefits of biotechnology to health and medical treatment and want access to them. They also understand the significant economic potential biotechnology represents and the degree to which it may be important to Canada's future economy.

Having said that, they still worry about the long-term risks of the technology and question whether enough is being done to understand and manage those risks. Those fears condition their views about the various applications of the technology.

Biotechnology food applications continue to be the least trusted and desirable – their benefits uncertain. There is significantly increased awareness of the high proportions of processed foods with GM ingredients and that has fuelled continuing demand for labeling of food products. Though most are sanguine about ingesting GM food and say they probably have few real options because of price and prevalence, they believe that consumers should have the information so they exercise informed choice.

Agricultural and environmental applications of biotechnology sometimes cause concerns to involved Canadians, particularly with regard to these products entering the food and water chains without appropriate testing or approval.

There continues to be a case by case analysis of applications with most people applying an implicit risk/benefit test that centers around the marginal personal benefit of any particular application. The larger the personal benefit, the more likely the risk is acceptable. Similarly, the more intrusive the process and the extensive the degree to which boundaries are crossed between plants, animals and humans, the more important the benefit has to be to trump emergent concerns. Cloning of entire humans continues to be widely feared, as it often connotes the idea of eugenics.

And though there is a desire to believe that governments have adequate regulatory safeguards in place, few continue to know much about those processes. A significant number of people continue to believe that genetically modified products can reach consumers without a formal approval process.

Most Involved Canadians are surprised to hear of the extent of Canadian success globally in biotechnology and want the country to maintain its position of leadership. They believe such leadership will gain them quicker access to beneficial products; will provide significant economic opportunity; and will ensure that the best and brightest remain in Canada.

There remains a small core of strong opposition to biotechnology driven by fear of long-term consequence and by concerns about interfering with natural selection. However, there appears to be a larger willingness to try to deal with biotechnology. Most people who are opposed to biotechnology now talk about ways to manage it – both in terms of mitigating risk and dealing with ethical concerns.

Attitudes Toward Patenting in General

Most people have a notional sense that patenting provides some form of rights but their understanding of the purpose and substantive policy behind patenting is extremely limited and widely misunderstood. However, since most are not aware that there are gaps in their knowledge and there seems to be nothing terribly complicated about the concept, they tend to have formed relatively strong opinions about patenting.

In the groups, there was a noticeable tendency to agree with the need for patenting though it was not an area that most who supported it had thought much about. Those who opposed it did so strongly and tended to have thought through their positions and reached philosophical or ideological conclusions – their opposition was driven by mistrust of large corporations and worry about restricted access to important products.

Supporters say patenting is necessary because it provides an incentive to develop ideas because people can then make money from those ideas. Opponents say it is unnecessary because it just adds to very high company profits (their reference point is drug patenting), and that it *holds back* innovation because no one else can develop a similar product. As well, they tended to believe and cited anecdotal evidence to establish that many patented drugs and seeds bore price tags too high for millions to afford. The cost of AIDS drugs in Africa and Monsanto's patenting of seeds to force annual repurchase were two spontaneously raised examples.

The gaps in knowledge are quite large and form a substantial obstacle to informed discussion. Because of those gaps, debate tends to proceed along a very narrow road without easy ways of bridging polarized opinion.

- Many people, including all of those who oppose patenting, do not understand that patents are only allowable for inventions, not discoveries or ideas.
- Many people, including most of those who oppose patenting, do not understand that there are time limits on patents.
- Not a single person in any of the groups realized that patenting makes the invention public and therefore promotes more research using that public information – many instinctively believe that patenting inhibits research, because a person or company has a monopoly on it.
- Though no one understood the concept of a trade secret – they tend to conflate its characteristics and those of patenting. Most thought holders of patents could withhold all information and refuse to proceed with the invention. A common anecdote involved car companies holding secret patents to cars that run forever on secret energy sources and refusing to manufacture them or to share the knowledge because that would bankrupt the industry.

Attitudes Toward Patenting in the Area of Biotechnology

Attitudes towards patenting in the area of biotechnology were initially not much different than attitudes toward patenting in general. Most people do not carry mental images of biotechnology "inventions" so the question was quite abstract initially and led to roughly similar discussion and support levels.

However, as discussion introduced the patenting of genes, body parts and whole organisms (some of these raised by more knowledgeable participants), most people became quite startled and began to revisit first principles, and in most cases resulted in diminished support for patenting of higher life forms (multicellular organisms). The discussion then tended to take on a much more serious tone and participants began to engage much more thoughtfully. Clearly, most people had never considered the juxtaposition of patenting and life forms and they were not quite sure how to evaluate it. Most carry mental images of things or products when they think about patenting. Initially, it was quite hard for them to use the word invention when talking about living things or their component parts.

It requires substantial discussion to get most people to understand the concept of patenting genetically modified higher life forms, largely because they are very hazy about the actual mechanics of genetic modification. Most people see genetic modification as incremental change to existing things or adding new ingredients. They tend not to see it as invention. It required some work by the moderator to inform respondents about the mechanics of genetic modification.

Once the concept of patenting multicellular organisms was understood, it substantially weakened support levels for patenting of these organisms, and was rejected out of hand by some participants. This included some who had been more positively inclined towards patenting. The issue raised moral and ethical concerns about patenting living things. Some would eventually agree to consider patenting new plants but they would stop at animals, largely because it seemed ethically inappropriate to them to patent beyond the plant family of organisms. Most don't conceive of plants and animals in the same way, and tend to see animal patenting as breaching an ethical code that plant patenting does not breach.

It was largely the issue of patenting whole animals (and substantial human body parts, such as organs) that animated substantial opposition. For instance, many more participants were willing to extend patent protection to golden rice. Opposition to this was rooted almost entirely in fair access issues – ethical and moral opposition virtually disappeared. Similar support (and objection) emerged for patenting human proteins that reduced the possibility of rejection of transplanted tissues and organs.

The use of the phrase "*higher life forms*" tempered the discussion in a significant way. To most people the phrase conjured up "aliens" and humans. It did not connote plants, or even animals, to most people. For some, the phrase crystallized their greatest fears about these technologies – that people will be cloned.

The instinctive reaction to the phrase was so strong that it raises the issue of whether alternative terminology to "*higher life forms*" can be employed in public discussion. Without explanation the terminology tended to catalyze opposition to the idea and dampen support for it among proponents.

Most people were willing to consider extending patent protection to the Harvard Oncomouse once they fully understood the fact base of the issue. The clear benefit to cancer research swayed many. Discussing the concrete example, learning how the Oncomouse had been developed and considering the way incentives might

work all helped participants to work through the issue. However, it should be emphasized that this required a bit of an educative process – it is clear that support would have been far lower at first reference.

In these groups, people were much more comfortable with the idea of patenting the process that developed the Oncomouse than patenting the mouse itself. To them, there was a fundamental difference between the two, because of their resistance to patenting living beings.

The Supreme Court decision would have had some, but not a great deal of influence on these participants. Most people understood that the Court would tend to address specific legal issues not the larger philosophical questions. They tended to assume that judges would not be expert on these issues. And though there was a high level of respect for the Court, many suggested that it had ruled on things they had disagreed with in the past and the ruling hadn't affected their views.

Most people were no more comfortable (and probably less comfortable) with Parliament ruling on this issue than they were with the courts ruling on it. Respondents were skeptical about the capacity of MPs to grasp the issues and make the appropriate decision – there was a sense that MPs were likely no more expert on these kinds of issues than they were.

In every group, people gravitated to the idea of an expert committee dealing with the issue, and making recommendations that should be followed. When asked what this committee should look like and who should be on it, people essentially described the (Canadian Biotechnology Advisory Committee (CBAC)). There was a widespread belief that the public voice should be heard but that the "expert" committee should decide – or recommend a decision that should be followed. Most felt that the Supreme Court decision should be one consideration that the experts should take into account before making a recommendation on the issue.

Argument Testing

In trying to simulate public debate over the issue of patenting higher life forms, the research tested arguments for and against the patenting of higher life forms.

A large majority said the arguments in favour of the patenting of higher life forms were stronger than the arguments against. However, it must be stated that the discussion constructed an opinion environment significantly different than that which prevails now – these results only emerged once respondents were "educated" on the issue, particularly on the policy foundations underpinning patenting.

In other words, absent detailed information and education about the issues involved, the default position – particularly when discussing "higher life forms" is likely to be much more negative, because of the basic moral resistance people have to the idea of commodifying living beings.

- Among the arguments in favour, one stood above all the rest:
 - That inventors make the information public that is contained in the patent application to create the product, which enables researchers to a) study the invention and test it and b) do further research and develop more improvements (and better products).
 - The parallel argument warning that without patents companies would revert to trade secrets and withhold information was powerful as well. These arguments reinforced support for the idea of

patenting among those supportive of the patenting of higher life forms, and they also reduced opposition among those opposed to patenting of higher life forms. The reason why this was the case is that it presented a public interest argument for allowing patenting where they as individuals could potentially benefit from the process.

- The other most powerful arguments in favour of patenting (in order of importance) were:
 - Other countries like the US, UK, and Australia already allow it, which means that research will be occurring in those countries, and that Canadians will likely move to those places to do their research
 - Canadians will gain access to the health and medical benefits of these technologies more quickly if patents are allowed than they would if patents were not allowed in this area
 - Because of the size of the investment required, this type of research will only be conducted in Canada if patent protection is available
 - The economic benefits of these technologies are more likely to be gained by Canada and Canadians
- One argument opposed to patenting was much stronger than the rest:
 - Allowing patenting for life forms other than humans is a slippery slope to allowing patenting of humans. This argument resonated among both supporters and opponents of the idea in principle.
- Two other opposing arguments resonated as well with certain individuals:
 - The idea of patenting a life form involves the commodification of life and hence is seen as morally wrong. This was particularly problematic in the case of the Oncomouse, where a sizeable number of people felt awkward about the idea of someone *owning* that mouse.
 - Limiting access because of high prices was a fairly powerful argument among a significant number. In general, these people oppose patenting in general on the same grounds – this is not an issue unique to patenting of higher life forms.

CBAC

As indicated earlier, many people were asking for a CBAC-type organization to weigh in on the patenting question before CBAC itself was raised in the groups.

CBAC's recommendations and exceptions on the patenting of higher life forms were widely accepted by respondents as credible and seemingly well thought through. However, not a single participant had heard of CBAC so support was tempered by the proviso that the public should be given more information about who exactly comprised CBAC, and reassured that CBAC was truly representative of a range of interests.

In the abstract, CBAC's involvement in this debate should carry public weight since people would likely be positive about its role if they were more aware of its existence. However, CBAC's current relative anonymity amongst the focus group participants makes it unlikely that it can bring much to the debate other than the implied credibility of an expert panel.

Some CBAC recommendations reduced opposition to patenting higher life forms.

- The experimental use provision was a compelling reason to allow people to come to accept patenting of higher life forms. It is consistent with the strongest argument in favour of patenting, the idea that the information would be made public and therefore more research would be done if patents were granted on higher life forms.
- Farmer's privilege and the innocent bystander exemptions did not convince people to support patenting but they strongly neutralized those who pointed to Monsanto and the Schmeisser case as a reason not to patent plants and seeds. Most participants had not heard of Schmeisser's conviction nor did they accept it as an appropriate outcome. Virtually all accepted that GM seeds had landed in his field.

Appendix: Moderator's Guide

Introduction and Warm-up (5 min)

- The moderator will take a few minutes to go around the table and ask respondents to introduce themselves, and outline a few ground rules: want to ensure that people share their views openly, let everyone participate, want people to talk about their views, not "other people's views", ensure that we don't want people to "debate" each other – everyone's views are valid, there are no right or wrong answers
- The moderator will also point out that there is a one-way mirror, observers in the back, and audio and video taping, but ensure that all discussion is confidential

General Impressions (15 min)

- I'm going to say a word to you, and after I say it, I want you to write down the first thoughts that come to mind right away, and whether the word/phrase has a negative connotation, a positive connotation or no connotation.
- Biotechnology ^a _{a'}
- Genomics ^b _{b'}

Definition: Biotechnology is an umbrella term covering a broad spectrum of scientific applications used in many sectors, such as health, natural resources, and agriculture. It involves the use of living organisms, or parts of living organisms, to provide new methods of production and make new products. Biotechnology is sometimes referred to as life sciences, genetic modification, or genomics. It includes numerous applications, everything from crossbreeding plants to genetic testing to screen for inherited diseases.

Applications (20 min)

- Biotechnology has applications in a number of fields. Can you recall any that you have heard of?
- How familiar are you with this subject? Is this the first time you have discussed it, or have you talked about it before?

We would like to hear your response to various applications of biotechnology. For each of the following, please tell me if you feel that this type of application is acceptable, or not acceptable to you. For Each:

- What are some of the risks associated with these products? Who takes those risks?
- What are some of the benefits? Who benefits?
- Do you think the risks of these technologies outweigh the benefits, or vice versa?
- Why do you say that?

(DISCUSS 2-3, ROTATED FOR EACH GROUP)

- Bioplastics, which involve the use of genetically modified bacteria or plants to produce plastic products that can be used as a substitute for plastics made from non-renewable resources like petroleum.
- The use of cloned animals as a source of food, such as using cloned cows as a source of beef.

- A genetically modified animal that produces a human protein to be used for medical purposes. For instance, tPA which assists in the dissolution of blood clots.
- Biofuels, such as ethanol, which are products that utilize genetically modified grains, forest products and other agricultural products to generate energy
- A "reverse engineering" technology that would remove all genetically modified elements from a plant after they had achieved their purpose – in the case of corn, for example, this would mean removal of the genetically modified trait that enabled it to resist a particular pest before the corn was harvested and distributed to consumers.
- The use of genetically modified bacteria in mouthwash, to eliminate the bacteria that cause tooth decay.
- The use of stem cells from bone marrow to develop cells that can treat certain forms of blindness

Brief discussion of stewardship and benefits:

11 What are some of the economic benefits that this research industry provides?

12a-12c Who regulates these products? Who approves them for safety? How confident are you in the safety and approval processes?

Patenting of Higher Life Forms (1 hour 20 minutes)

I'd like to speak with you for a few minutes about patenting in the area of biotechnology.

- There are arguments for and against the idea of patenting in the area of biotechnology, for products developed like new types of health products (pharmaceuticals) or agricultural products (like plants/foods)? REMINDER: *Patents are only allowable for inventions (involving some type of human intervention), not for discoveries (ie. things AS found in nature).*
- There are arguments for and against the idea of patenting in the area of biotechnology. What are some of those arguments?
- Which do you subscribe to? The arguments for, or against patenting?

In fact, there is currently a case before the Supreme Court of Canada on the issue. The Supreme Court was asked to provide guidance on whether the current *Patent Act* permitted the granting of patent on higher life forms (which includes plants and animals and certain human tissues and organs that have been genetically modified in some way). The Court's decision is anticipated by yearend. A lower court had ruled in favour of patenting higher life forms.

- If the Supreme Court of Canada were to rule in **favour** of allowing the patenting of higher life forms, would you be more likely to accept patenting of higher life forms? Would the Supreme Court decision likely be the most important factor that you would take into consideration on this question?
- If the Supreme Court of Canada were to rule **against** allowing the patenting of higher life forms, would that make you less likely to accept patenting of higher life forms? Would it be different than what you expressed earlier? Would the Supreme Court decision likely be the most important factor that you would take into consideration on this question?

- 16a → d
- What if the Supreme Court decision is made against allowing the patenting of higher life forms, **but only on the narrow "technical" issues involved?** (The Supreme Court would decide only on the question of whether the current patent act allows the patenting higher life forms not whether such patenting is a good idea). Would it be different than what you expressed earlier? If this is the decision, would the Supreme Court decision likely be the most important factor that you would take into consideration on this question?
- 16a
- 16b
- 16c
- 16d

17 Is this an issue that should be decided by Parliament, or by the Courts?

18 Is this issue one that is best decided by experts after the public and involved parties have been consulted, or one where public opinion should decide?

19 Do you think that the government of Canada should make its decisions on this issue with input from experts and the public irrespective of the court decision or should it wait until the decision is made by the Supreme Court?

Let me give you a more detailed overview of patenting, and the rationale behind it, and then let's discuss some of the arguments people make about this issue:

20 Many new inventions can be protected by what are called patents. Patents ensure that inventors, who have taken risks and incurred costs, are rewarded by making sure that their inventions cannot be copied by others for a limited period of time. However, in exchange for this right, the inventor must disclose to the public the manner in which the invention was developed and how it functions. Publishing the nature of the invention enables other researchers and scientists to do further research and develop further improvements. A patent provides the inventor with some ability to determine the availability and price of the invention. However, the *Patent Act* contains provisions that ensure the public can get access to a particular invention. Thus, the freedom of the inventor is circumscribed by the Act.

defn patenting

A major issue that Canada will have to address in the near future regards patenting of genetically modified higher life forms (which includes plants and animals and certain human tissues and organs that have been genetically modified in some way). The issue we are discussing here does not involve patenting an entire human being, because there are already restrictions about this in other laws. It also doesn't include micro-organisms, mostly like yeasts, moulds, and viruses – these are currently patentable. Some examples of the kinds of life forms we are talking about include:

- Golden rice: involves the introduction of beta-carotene producing DNA into rice so as to increase the production of Vitamin A in the human body. In developing countries, the consumption of this rice helps in reducing the rate of childhood blindness resulting from Vitamin A deficiencies.
- Harvard mouse: involves insertion of DNA into a mouse that makes it produce litters that are susceptible to developing Cancer. These mice can be used in cancer research, to understand the development of the disease and potential cures.
- Organ Transplantation/Skin graft protein: introducing a protein into organs, prior to their use for transplantations, which helps to ensure transplanted organs and skin grafts are not rejected by the receiver of the organ/skin.

Advocates of allowing these higher life forms to be patented say that:

- This type of research and these types of organisms will only be developed in Canada if there are patents available, because it costs millions of dollars to conduct the research.
- Other countries, including US, Europe, and Australia already allow it, which means that research will be occurring in those countries, and that Canadian companies and researchers will be at a substantial disadvantage
- Canadians will gain access to the health and medical benefits more quickly.
- Because of the economic benefits of this research taking place in Canada it will improve the standard of living of Canadians.
- Without patents, the inventor would protect their invention through trade secrets, with the result that the scientific information would not be shared with the rest of the research community.
- The Canadian Biotechnology Advisory Committee, an independent body of experts asked by the government of Canada to produce recommendations on this issue, has tabled a report that says that higher life forms should be patentable, with some conditions and exceptions:
 - Reasons:
 - To ensure that Canada and Canadians receive the benefits that derive from this research and the applications that are developed; that researchers remain in Canada to do their work, rather than moving to other countries like the US;
 - Exceptions:
 - That an explicit statement be made that "no patent will be granted on human bodies at any stage in development";
 - Farmer's privilege, which allows farmers to continue farming activities that would normally infringe a patent (collect a seed from a planted crop, grow a new crop from those seeds and sell that crop);
 - The innocent bystander provision, which involves a situation where a person inadvertently ends up having in their possession an invention that is patented but without their having done anything to acquire the invention (i.e. farmers will not be subject to patent infringement if they inadvertently use a patented seed); and
 - The experimental use provision, which allows researchers to a) test the effectiveness of a patented product and b) to test potential improvements to a patented product.

21a & c Does this seem a reasonable position to you? 21a

- If you were inclined to oppose the patenting of higher life forms:
 - Do the exceptions make you more comfortable? 21b
- Does the fact that an expert advisory body suggests going ahead make you more comfortable? 21c

22a
22b
22c How strong are these arguments as a whole? Which is the strongest of these arguments in favour of patenting in this area?

Those opposed say that:

- They oppose the idea of patenting any products, including higher life forms
- Patenting of these higher life forms commodifies life, and is morally wrong
- They are concerned about the treatment of animals in medical research
- They believe that patents might limit access of some people to use the products.

23 Are these strong arguments?

24 Do they make you less inclined to allow patents on higher life forms?

25 Which of the arguments outlined for/against is strongest?

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However, as discussion introduced the patenting of genes, body parts and whole organisms (some of these raised by more knowledgeable participants), most people became quite startled and began to revisit first principles, and in most cases resulted in diminished support for patenting of higher life forms (multicellular organisms). The discussion then tended to take on a much more serious tone and participants began to engage much more thoughtfully. Clearly, most people had never considered the juxtaposition of patenting and life forms and they were not quite sure how to evaluate it. Most carry mental images of things or products when they think about patenting. Initially, it was quite hard for them to use the word invention when talking about living things or their component parts.

It requires substantial discussion to get most people to understand the concept of patenting genetically modified higher life forms, largely because they are very hazy about the actual mechanics of genetic modification. Most people see genetic modification as incremental change to existing things or adding new ingredients. They tend not to see it as invention. It required some work by the moderator to inform respondents about the mechanics of genetic modification.

Once the concept of patenting multicellular organisms was understood, it substantially weakened support levels for patenting of these organisms, and was rejected out of hand by some participants. This included some who had been more positively inclined towards patenting. The issue raised moral and ethical concerns about patenting living things. Some would eventually agree to consider patenting new plants but they would stop at animals, largely because it seemed ethically inappropriate to them to patent beyond the plant family of organisms. Most don't conceive of plants and animals in the same way, and tend to see animal patenting as breaching an ethical code that plant patenting does not breach.

It was largely the issue of patenting whole animals (and substantial human body parts, such as organs) that animated substantial opposition. For instance, many more participants were willing to extend patent protection to golden rice. Opposition to this was rooted almost entirely in fair access issues – ethical and moral opposition virtually disappeared. Similar support (and objection) emerged for patenting human proteins that reduced the possibility of rejection of transplanted tissues and organs.

The use of the phrase "*higher life forms*" tempered the discussion in a significant way. To most people the phrase conjured up "aliens" and humans. It did not connote plants, or even animals, to most people. For some, the phrase crystallized their greatest fears about these technologies – that people will be cloned.

The instinctive reaction to the phrase was so strong that it raises the issue of whether alternative terminology to "*higher life forms*" can be employed in public discussion. Without explanation the terminology tended to catalyze opposition to the idea and dampen support for it among proponents.

Most people were willing to consider extending patent protection to the Harvard Oncomouse once they fully understood the fact base of the issue. The clear benefit to cancer research swayed many. Discussing the concrete example, learning how the Oncomouse had been developed and considering the way incentives might

work all helped participants to work through the issue. However, it should be emphasized that this required a bit of an educative process – it is clear that support would have been far lower at first reference.

In these groups, people were much more comfortable with the idea of patenting the process that developed the Oncomouse than patenting the mouse itself. To them, there was a fundamental difference between the two, because of their resistance to patenting living beings.

The Supreme Court decision would have had some, but not a great deal of influence on these participants. Most people understood that the Court would tend to address specific legal issues not the larger philosophical questions. They tended to assume that judges would not be expert on these issues. And though there was a high level of respect for the Court, many suggested that it had ruled on things they had disagreed with in the past and the ruling hadn't affected their views.

Most people were no more comfortable (and probably less comfortable) with Parliament ruling on this issue than they were with the courts ruling on it. Respondents were skeptical about the capacity of MPs to grasp the issues and make the appropriate decision – there was a sense that MPs were likely no more expert on these kinds of issues than they were.

In every group, people gravitated to the idea of an expert committee dealing with the issue, and making recommendations that should be followed. When asked what this committee should look like and who should be on it, people essentially described the (Canadian Biotechnology Advisory Committee (CBAC) . There was a widespread belief that the public voice should be heard but that the “expert” committee should decide – or recommend a decision that should be followed. Most felt that the Supreme Court decision should be one consideration that the experts should take into account before making a recommendation on the issue.

Argument Testing

In trying to simulate public debate over the issue of patenting higher life forms, the research tested arguments for and against the patenting of higher life forms.

A large majority said the arguments in favour of the patenting of higher life forms were stronger than the arguments against. However, it must be stated that the discussion constructed an opinion environment significantly different than that which prevails now – these results only emerged once respondents were “educated” on the issue, particularly on the policy foundations underpinning patenting.

In other words, absent detailed information and education about the issues involved, the default position – particularly when discussing “higher life forms” is likely to be much more negative, because of the basic moral resistance people have to the idea of commodifying living beings.

- Among the arguments in favour, one stood above all the rest:
 - That inventors make the information public that is contained in the patent application to create the product, which enables researchers to a) study the invention and test it and b) do further research and develop more improvements (and better products).
 - The parallel argument warning that without patents companies would revert to trade secrets and withhold information was powerful as well. These arguments reinforced support for the idea of

patenting among those supportive of the patenting of higher life forms, and they also reduced opposition among those opposed to patenting of higher life forms. The reason why this was the case is that it presented a public interest argument for allowing patenting where they as individuals could potentially benefit from the process.

- The other most powerful arguments in favour of patenting (in order of importance) were:
 - Other countries like the US, UK, and Australia already allow it, which means that research will be occurring in those countries, and that Canadians will likely move to those places to do their research
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- One argument opposed to patenting was much stronger than the rest:
 - Allowing patenting for life forms other than humans is a slippery slope to allowing patenting of humans. This argument resonated among both supporters and opponents of the idea in principle.
- Two other opposing arguments resonated as well with certain individuals:
 - The idea of patenting a life form involves the commodification of life and hence is seen as morally wrong. This was particularly problematic in the case of the Oncomouse, where a sizeable number of people felt awkward about the idea of someone *owning* that mouse.
 - Limiting access because of high prices was a fairly powerful argument among a significant number. In general, these people oppose patenting in general on the same grounds – this is not an issue unique to patenting of higher life forms.

CBAC

As indicated earlier, many people were asking for a CBAC-type organization to weigh in on the patenting question before CBAC itself was raised in the groups.

CBAC's recommendations and exceptions on the patenting of higher life forms were widely accepted by respondents as credible and seemingly well thought through. However, not a single participant had heard of CBAC so support was tempered by the proviso that the public should be given more information about who exactly comprised CBAC, and reassured that CBAC was truly representative of a range of interests.

In the abstract, CBAC's involvement in this debate should carry public weight since people would likely be positive about its role if they were more aware of its existence. However, CBAC's current relative anonymity amongst the focus group participants makes it unlikely that it can bring much to the debate other than the implied credibility of an expert panel.

Some CBAC recommendations reduced opposition to patenting higher life forms.

- The experimental use provision was a compelling reason to allow people to come to accept patenting of higher life forms. It is consistent with the strongest argument in favour of patenting, the idea that the information would be made public and therefore more research would be done if patents were granted on higher life forms.
- Farmer's privilege and the innocent bystander exemptions did not convince people to support patenting but they strongly neutralized those who pointed to Monsanto and the Schmeisser case as a reason not to patent plants and seeds. Most participants had not heard of Schmeisser's conviction nor did they accept it as an appropriate outcome. Virtually all accepted that GM seeds had landed in his field.

Appendix: Moderator's Guide

Introduction and Warm-up (5 min)

- The moderator will take a few minutes to go around the table and ask respondents to introduce themselves, and outline a few ground rules: want to ensure that people share their views openly, let everyone participate, want people to talk about their views, not "other people's views", ensure that we don't want people to "debate" each other – everyone's views are valid, there are no right or wrong answers
- The moderator will also point out that there is a one-way mirror, observers in the back, and audio and video taping, but ensure that all discussion is confidential

General Impressions (15 min)

- I'm going to say a word to you, and after I say it, I want you to write down the first thoughts that come to mind right away, and whether the word/phrase has a negative connotation, a positive connotation or no connotation.
- Biotechnology
- Genomics

Definition: Biotechnology is an umbrella term covering a broad spectrum of scientific applications used in many sectors, such as health, natural resources, and agriculture. It involves the use of living organisms, or parts of living organisms, to provide new methods of production and make new products. Biotechnology is sometimes referred to as life sciences, genetic modification, or genomics. It includes numerous applications, everything from crossbreeding plants to genetic testing to screen for inherited diseases.

Applications (20 min)

- Biotechnology has applications in a number of fields. Can you recall any that you have heard of?
- How familiar are you with this subject? Is this the first time you have discussed it, or have you talked about it before?

We would like to hear your response to various applications of biotechnology. For each of the following, *please tell me if you feel that this type of application is acceptable, or not acceptable to you.* For Each:

- What are some of the risks associated with these products? Who takes those risks?
- What are some of the benefits? Who benefits?
- Do you think the risks of these technologies outweigh the benefits, or vice versa?
- Why do you say that?

(DISCUSS 2-3, ROTATED FOR EACH GROUP)

- Bioplastics, which involve the use of genetically modified bacteria or plants to produce plastic products that can be used as a substitute for plastics made from non-renewable resources like petroleum.
- The use of cloned animals as a source of food, such as using cloned cows as a source of beef.

- A genetically modified animal that produces a human protein to be used for medical purposes. For instance, tPA which assists in the dissolution of blood clots.
- Biofuels, such as ethanol, which are products that utilize genetically modified grains, forest products and other agricultural products to generate energy
- A “reverse engineering” technology that would remove all genetically modified elements from a plant after they had achieved their purpose – in the case of corn, for example, this would mean removal of the genetically modified trait that enabled it to resist a particular pest before the corn was harvested and distributed to consumers.
- The use of genetically modified bacteria in mouthwash, to eliminate the bacteria that cause tooth decay.
- The use of stem cells from bone marrow to develop cells that can treat certain forms of blindness

Brief discussion of stewardship and benefits:

What are some of the economic benefits that this research industry provides?

Who regulates these products? Who approves them for safety? How confident are you in the safety and approval processes?

Patenting of Higher Life Forms (1 hour 20 minutes)

I'd like to speak with you for a few minutes about patenting in the area of biotechnology.

- There are arguments for and against the idea of patenting in the area of biotechnology, for products developed like new types of health products (pharmaceuticals) or agricultural products (like plants/foods)?
REMINDER: *Patents are only allowable for inventions (involving some type of human intervention), not for discoveries (ie. things AS found in nature).*
- There are arguments for and against the idea of patenting in the area of biotechnology. What are some of those arguments?
- Which do you subscribe to? The arguments for, or against patenting?

In fact, there is currently a case before the Supreme Court of Canada on the issue. The Supreme Court was asked to provide guidance on whether the current *Patent Act* permitted the granting of patent on higher life forms (which includes plants and animals and certain human tissues and organs that have been genetically modified in some way). The Court's decision is anticipated by yearend. A lower court had ruled in favour of patenting higher life forms.

- If the Supreme Court of Canada were to rule in **favour** of allowing the patenting of higher life forms, would you be more likely to accept patenting of higher life forms? Would the Supreme Court decision likely be the most important factor that you would take into consideration on this question?
- If the Supreme Court of Canada were to rule **against** allowing the patenting of higher life forms, would that make you less likely to accept patenting of higher life forms? Would it be different than what you expressed earlier. Would the Supreme Court decision likely be the most important factor that you would take into consideration on this question?

- What if the Supreme Court decision is made against allowing the patenting of higher life forms, **but only on the narrow “technical” issues involved?** (The Supreme Court would decide only on the question of whether the current patent act allows the patenting higher life forms not whether such patenting is a good idea). Would it be different than what you expressed earlier? If this is the decision, would the Supreme Court decision likely be the most important factor that you would take into consideration on this question?

Is this an issue that should be decided by Parliament, or by the Courts?

Is this issue one that is best decided by experts after the public and involved parties have been consulted, or one where public opinion should decide?

Do you think that the government of Canada should make its decisions on this issue with input from experts and the public irrespective of the court decision or should it wait until the decision is made by the Supreme Court?

Let me give you a more detailed overview of patenting, and the rationale behind it, and then lets discuss some of the arguments people make about this issue:

Many new inventions can be protected by what are called patents. Patents ensure that inventors, who have taken risks and incurred costs, are rewarded by making sure that their inventions cannot be copied by others for a limited period of time. However, in exchange for this right, the inventor must disclose to the public the manner in which the invention was developed and how it functions. Publishing the nature of the invention enables other researchers and scientists to do further research and develop further improvements. A patent provides the inventor with some ability to determine the availability and price of the invention. However, the *Patent Act* contains provisions that ensure the public can get access to a particular invention. Thus, the freedom of the inventor is circumscribed by the Act.

A major issue that Canada will have to address in the near future regards patenting of genetically modified higher life forms (which includes plants and animals and certain human tissues and organs that have been genetically modified in some way). The issue we are discussing here does not involve patenting an entire human being, because there are already restrictions about this in other laws. It also doesn't include micro-organisms, mostly like yeasts, moulds, and viruses – these are currently patentable. Some examples of the kinds of life forms we are talking about include:

- Golden rice: involves the introduction of beta-carotene producing DNA into rice so as to increase the production of Vitamin A in the human body. In developing countries, the consumption of this rice helps in reducing the rate of childhood blindness resulting from Vitamin A deficiencies.
- Harvard mouse: involves insertion of DNA into a mouse that makes it produce litters that are susceptible to developing Cancer. These mice can be used in cancer research, to understand the development of the disease and potential cures.
- Organ Transplantation/Skin graft protein: introducing a protein into organs, prior to their use for transplantations, which helps to ensure transplanted organs and skin grafts are not rejected by the receiver of the organ/skin.

Advocates of allowing these higher life forms to be patented say that:

- This type of research and these types of organisms will only be developed in Canada if there are patents available, because it costs millions of dollars to conduct the research.
- Other countries, including US, Europe, and Australia already allow it, which means that research will be occurring in those countries, and that Canadian companies and researchers will be at a substantial disadvantage
- Canadians will gain access to the health and medical benefits more quickly.
- Because of the economic benefits of this research taking place in Canada it will improve the standard of living of Canadians.
- Without patents, the inventor would protect their invention through trade secrets, with the result that the scientific information would not be shared with the rest of the research community.
- The Canadian Biotechnology Advisory Committee, an independent body of experts asked by the government of Canada to produce recommendations on this issue, has tabled a report that says that higher life forms should be patentable, with some conditions and exceptions:
 - Reasons:
 - To ensure that Canada and Canadians receive the benefits that derive from this research and the applications that are developed; that researchers remain in Canada to do their work, rather than moving to other countries like the US;
 - Exceptions:
 - That an explicit statement be made that “no patent will be granted on human bodies at any stage in development”;
 - Farmer’s privilege, which allows farmers to continue farming activities that would normally infringe a patent (collect a seed from a planted crop, grow a new crop from those seeds and sell that crop);
 - The innocent bystander provision, which involves a situation where a person inadvertently ends up having in their possession an invention that is patented but without their having done anything to acquire the invention (i.e. farmers will not be subject to patent infringement if they inadvertently use a patented seed); and
 - The experimental use provision, which allows researchers to a) test the effectiveness of a patented product and b) to test potential improvements to a patented product.

Does this seem a reasonable position to you?

- If you were inclined to oppose the patenting of higher life forms:
 - Do the exceptions make you more comfortable?
- Does the fact that an expert advisory body suggests going ahead make you more comfortable?

How strong are these arguments as a whole? Which is the strongest of these arguments in favour of patenting in this area?

Those opposed say that:

- They oppose the idea of patenting any products, including higher life forms
- Patenting of these higher life forms commodifies life, and is morally wrong
- They are concerned about the treatment of animals in medical research
- They believe that patents might limit access of some people to use the products.

Are these strong arguments?

Do they make you less inclined to allow patents on higher life forms?

Which of the arguments outlined for/against is strongest?

EARNSCLIFFE

Patenting of Higher Life Forms Research Findings

Report to Industry Canada

Prepared by

Earnscliffe Research and Communications

February 2003

Introduction

Earnscliffe Research and Communications is pleased to present the following report to Industry Canada. It provides findings of 4 focus groups with a total of 37 individuals, two groups in Toronto and two groups in Halifax, which took place in the first week of October, 2002. The groups were comprised of *Involved Canadians*, the 30% segment of the population that is made up of those who are most interested and active in public policy issues.

This research was prompted by a series of considerations:

- Intellectual property is one of the most pressing issues associated with biotechnology. It is likely to become one of the most important arbiters of success for nations that seek a leadership role in this growing field.
- As the only G7 country to not grant intellectual property protection for multicellular inventions (MCI's), the views of Canadians with respect to this issue was seen as useful. The issues raised by the intellectual property protection of MCIs are of increasing importance to the Government of Canada, especially in light of the upcoming Supreme Court of Canada decision in the Harvard Oncomouse case and the publication of the Canadian Biotechnology Advisory Committee's report entitled "The Patenting of Higher Life Forms".

The focus group discussions followed a moderator's guide that began with a thirty to forty-five minute discussion of biotechnology, its applications, regulatory processes and potential benefits and risks. The groups then proceeded to a detailed and structured discussion of patenting and specifically, the patenting of higher life forms. In each focus group, approximately 75 minutes was dedicated to discussion of patenting of higher life forms. The moderator's guide is appended to this report.

It should be noted that this was a qualitative exercise, so the results would not be deemed statistically significant. The results should be treated as general guidance about public opinion on these issues.

For more information on the research design and findings, please contact Earnscliffe Research and Communications, at 613 233 8080.

Awareness and General Attitudes: Biotechnology

The initial discussion revealed attitudes consistent with previous work among this segment of the population and consistent with the findings of a parallel set of groups being conducted during the same time period for the Biotechnology Assistant Deputy Minister Coordinating Committee (BACC). Those groups form part of a seventh wave of research conducted for BACC since the fall of 1999. For a detailed discussion of those findings, please refer to that report.

In short summary:

Involved Canadians show growing levels of awareness of biotechnology and the range of its applications. Biotechnology has become part of their landscape of important high technologies and they continue to invest much of their hope for the future success of the country and their children in these kinds of technologies.

They have inculcated the potential benefits of biotechnology to health and medical treatment and want access to them. They also understand the significant economic potential biotechnology represents and the degree to which it may be important to Canada's future economy.

Having said that, they still worry about the long-term risks of the technology and question whether enough is being done to understand and manage those risks. Those fears condition their views about the various applications of the technology.

Biotechnology food applications continue to be the least trusted and desirable – their benefits uncertain. There is significantly increased awareness of the high proportions of processed foods with GM ingredients and that has fuelled continuing demand for labeling of food products. Though most are sanguine about ingesting GM food and say they probably have few real options because of price and prevalence, they believe that consumers should have the information so they exercise informed choice.

Agricultural and environmental applications of biotechnology sometimes cause concerns to involved Canadians, particularly with regard to these products entering the food and water chains without appropriate testing or approval.

There continues to be a case by case analysis of applications with most people applying an implicit risk/benefit test that centers around the marginal personal benefit of any particular application. The larger the personal benefit, the more likely the risk is acceptable. Similarly, the more intrusive the process and the extensive the degree to which boundaries are crossed between plants, animals and humans, the more important the benefit has to be to trump emergent concerns. Cloning of entire humans continues to be widely feared, as it often connotes the idea of eugenics.

And though there is a desire to believe that governments have adequate regulatory safeguards in place, few continue to know much about those processes. A significant number of people continue to believe that genetically modified products can reach consumers without a formal approval process.

Most Involved Canadians are surprised to hear of the extent of Canadian success globally in biotechnology and want the country to maintain its position of leadership. They believe such leadership will gain them quicker access to beneficial products; will provide significant economic opportunity; and will ensure that the best and brightest remain in Canada.

There remains a small core of strong opposition to biotechnology driven by fear of long-term consequence and by concerns about interfering with natural selection. However, there appears to be a larger willingness to try to deal with biotechnology. Most people who are opposed to biotechnology now talk about ways to manage it – both in terms of mitigating risk and dealing with ethical concerns.

Attitudes Toward Patenting in General

Most people have a notional sense that patenting provides some form of rights but their understanding of the purpose and substantive policy behind patenting is extremely limited and widely misunderstood. However, since most are not aware that there are gaps in their knowledge and there seems to be nothing terribly complicated about the concept, they tend to have formed relatively strong opinions about patenting.

In the groups, there was a noticeable tendency to agree with the need for patenting though it was not an area that most who supported it had thought much about. Those who opposed it did so strongly and tended to have thought through their positions and reached philosophical or ideological conclusions – their opposition was driven by mistrust of large corporations and worry about restricted access to important products.

Supporters say patenting is necessary because it provides an incentive to develop ideas because people can then make money from those ideas. Opponents say it is unnecessary because it just adds to very high company profits (their reference point is drug patenting), and that it *holds back* innovation because no one else can develop a similar product. As well, they tended to believe and cited anecdotal evidence to establish that many patented drugs and seeds bore price tags too high for millions to afford. The cost of AIDS drugs in Africa and Monsanto's patenting of seeds to force annual repurchase were two spontaneously raised examples.

The gaps in knowledge are quite large and form a substantial obstacle to informed discussion. Because of those gaps, debate tends to proceed along a very narrow road without easy ways of bridging polarized opinion.

- Many people, including all of those who oppose patenting, do not understand that patents are only allowable for inventions, not discoveries or ideas.
- Many people, including most of those who oppose patenting, do not understand that there are time limits on patents.
- Not a single person in any of the groups realized that patenting makes the invention public and therefore promotes more research using that public information – many instinctively believe that patenting inhibits research, because a person or company has a monopoly on it.
- Though no one understood the concept of a trade secret – they tend to conflate its characteristics and those of patenting. Most thought holders of patents could withhold all information and refuse to proceed with the invention. A common anecdote involved car companies holding secret patents to cars that run forever on secret energy sources and refusing to manufacture them or to share the knowledge because that would bankrupt the industry.

Attitudes Toward Patenting in the Area of Biotechnology

Attitudes towards patenting in the area of biotechnology were initially not much different than attitudes toward patenting in general. Most people do not carry mental images of biotechnology "inventions" so the question was quite abstract initially and led to roughly similar discussion and support levels.

However, as discussion introduced the patenting of genes, body parts and whole organisms (some of these raised by more knowledgeable participants), most people became quite startled and began to revisit first principles, and in most cases resulted in diminished support for patenting of higher life forms (multicellular organisms). The discussion then tended to take on a much more serious tone and participants began to engage much more thoughtfully. Clearly, most people had never considered the juxtaposition of patenting and life forms and they were not quite sure how to evaluate it. Most carry mental images of things or products when they think about patenting. Initially, it was quite hard for them to use the word invention when talking about living things or their component parts.

It requires substantial discussion to get most people to understand the concept of patenting genetically modified higher life forms, largely because they are very hazy about the actual mechanics of genetic modification. Most people see genetic modification as incremental change to existing things or adding new ingredients. They tend not to see it as invention. It required some work by the moderator to inform respondents about the mechanics of genetic modification.

Once the concept of patenting multicellular organisms was understood, it substantially weakened support levels for patenting of these organisms, and was rejected out of hand by some participants. This included some who had been more positively inclined towards patenting. The issue raised moral and ethical concerns about patenting living things. Some would eventually agree to consider patenting new plants but they would stop at animals, largely because it seemed ethically inappropriate to them to patent beyond the plant family of organisms. Most don't conceive of plants and animals in the same way, and tend to see animal patenting as breaching an ethical code that plant patenting does not breach.

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Appendix: Moderator's Guide

Introduction and Warm-up (5 min)

- The moderator will take a few minutes to go around the table and ask respondents to introduce themselves, and outline a few ground rules: want to ensure that people share their views openly, let everyone participate, want people to talk about their views, not "other people's views", ensure that we don't want people to "debate" each other – everyone's views are valid, there are no right or wrong answers
- The moderator will also point out that there is a one-way mirror, observers in the back, and audio and video taping, but ensure that all discussion is confidential

General Impressions (15 min)

- I'm going to say a word to you, and after I say it, I want you to write down the first thoughts that come to mind right away, and whether the word/phrase has a negative connotation, a positive connotation or no connotation.
- Biotechnology
- Genomics

Definition: Biotechnology is an umbrella term covering a broad spectrum of scientific applications used in many sectors, such as health, natural resources, and agriculture. It involves the use of living organisms, or parts of living organisms, to provide new methods of production and make new products. Biotechnology is sometimes referred to as life sciences, genetic modification, or genomics. It includes numerous applications, everything from crossbreeding plants to genetic testing to screen for inherited diseases.

Applications (20 min)

- Biotechnology has applications in a number of fields. Can you recall any that you have heard of?
- How familiar are you with this subject? Is this the first time you have discussed it, or have you talked about it before?

We would like to hear your response to various applications of biotechnology. For each of the following, *please tell me if you feel that this type of application is acceptable, or not acceptable to you.* For Each:

- What are some of the risks associated with these products? Who takes those risks?
- What are some of the benefits? Who benefits?
- Do you think the risks of these technologies outweigh the benefits, or vice versa?
- Why do you say that?

(DISCUSS 2-3, ROTATED FOR EACH GROUP)

- Bioplastics, which involve the use of genetically modified bacteria or plants to produce plastic products that can be used as a substitute for plastics made from non-renewable resources like petroleum.
- The use of cloned animals as a source of food, such as using cloned cows as a source of beef.

- A genetically modified animal that produces a human protein to be used for medical purposes. For instance, tPA which assists in the dissolution of blood clots.
- Biofuels, such as ethanol, which are products that utilize genetically modified grains, forest products and other agricultural products to generate energy
- A “reverse engineering” technology that would remove all genetically modified elements from a plant after they had achieved their purpose – in the case of corn, for example, this would mean removal of the genetically modified trait that enabled it to resist a particular pest before the corn was harvested and distributed to consumers.
- The use of genetically modified bacteria in mouthwash, to eliminate the bacteria that cause tooth decay.
- The use of stem cells from bone marrow to develop cells that can treat certain forms of blindness

Brief discussion of stewardship and benefits:

What are some of the economic benefits that this research industry provides?

Who regulates these products? Who approves them for safety? How confident are you in the safety and approval processes?

Patenting of Higher Life Forms (1 hour 20 minutes)

I'd like to speak with you for a few minutes about patenting in the area of biotechnology.

- There are arguments for and against the idea of patenting in the area of biotechnology, for products developed like new types of health products (pharmaceuticals) or agricultural products (like plants/foods)?
REMINDER: *Patents are only allowable for inventions (involving some type of human intervention), not for discoveries (ie. things AS found in nature).*
- There are arguments for and against the idea of patenting in the area of biotechnology. What are some of those arguments?
- Which do you subscribe to? The arguments for, or against patenting?

In fact, there is currently a case before the Supreme Court of Canada on the issue. The Supreme Court was asked to provide guidance on whether the current *Patent Act* permitted the granting of patent on higher life forms (which includes plants and animals and certain human tissues and organs that have been genetically modified in some way). The Court's decision is anticipated by yearend. A lower court had ruled in favour of patenting higher life forms.

- If the Supreme Court of Canada were to rule in **favour** of allowing the patenting of higher life forms, would you be more likely to accept patenting of higher life forms? Would the Supreme Court decision likely be the most important factor that you would take into consideration on this question?
- If the Supreme Court of Canada were to rule **against** allowing the patenting of higher life forms, would that make you less likely to accept patenting of higher life forms? Would it be different than what you expressed earlier. Would the Supreme Court decision likely be the most important factor that you would take into consideration on this question?

- What if the Supreme Court decision is made against allowing the patenting of higher life forms, **but only on the narrow “technical” issues involved?** (The Supreme Court would decide only on the question of whether the current patent act allows the patenting higher life forms not whether such patenting is a good idea). Would it be different than what you expressed earlier? If this is the decision, would the Supreme Court decision likely be the most important factor that you would take into consideration on this question?

Is this an issue that should be decided by Parliament, or by the Courts?

Is this issue one that is best decided by experts after the public and involved parties have been consulted, or one where public opinion should decide?

Do you think that the government of Canada should make its decisions on this issue with input from experts and the public irrespective of the court decision or should it wait until the decision is made by the Supreme Court?

Let me give you a more detailed overview of patenting, and the rationale behind it, and then lets discuss some of the arguments people make about this issue:

Many new inventions can be protected by what are called patents. Patents ensure that inventors, who have taken risks and incurred costs, are rewarded by making sure that their inventions cannot be copied by others for a limited period of time. However, in exchange for this right, the inventor must disclose to the public the manner in which the invention was developed and how it functions. Publishing the nature of the invention enables other researchers and scientists to do further research and develop further improvements. A patent provides the inventor with some ability to determine the availability and price of the invention. However, the *Patent Act* contains provisions that ensure the public can get access to a particular invention. Thus, the freedom of the inventor is circumscribed by the Act.

A major issue that Canada will have to address in the near future regards patenting of genetically modified higher life forms (which includes plants and animals and certain human tissues and organs that have been genetically modified in some way). The issue we are discussing here does not involve patenting an entire human being, because there are already restrictions about this in other laws. It also doesn't include micro-organisms, mostly like yeasts, moulds, and viruses – these are currently patentable. Some examples of the kinds of life forms we are talking about include:

- Golden rice: involves the introduction of beta-carotene producing DNA into rice so as to increase the production of Vitamin A in the human body. In developing countries, the consumption of this rice helps in reducing the rate of childhood blindness resulting from Vitamin A deficiencies.
- Harvard mouse: involves insertion of DNA into a mouse that makes it produce litters that are susceptible to developing Cancer. These mice can be used in cancer research, to understand the development of the disease and potential cures.
- Organ Transplantation/Skin graft protein: introducing a protein into organs, prior to their use for transplantations, which helps to ensure transplanted organs and skin grafts are not rejected by the receiver of the organ/skin.

Advocates of allowing these higher life forms to be patented say that:

- This type of research and these types of organisms will only be developed in Canada if there are patents available, because it costs millions of dollars to conduct the research.
- Other countries, including US, Europe, and Australia already allow it, which means that research will be occurring in those countries, and that Canadian companies and researchers will be at a substantial disadvantage
- Canadians will gain access to the health and medical benefits more quickly.
- Because of the economic benefits of this research taking place in Canada it will improve the standard of living of Canadians.
- Without patents, the inventor would protect their invention through trade secrets, with the result that the scientific information would not be shared with the rest of the research community.
- The Canadian Biotechnology Advisory Committee, an independent body of experts asked by the government of Canada to produce recommendations on this issue, has tabled a report that says that higher life forms should be patentable, with some conditions and exceptions:
 - Reasons:
 - To ensure that Canada and Canadians receive the benefits that derive from this research and the applications that are developed; that researchers remain in Canada to do their work, rather than moving to other countries like the US;
 - Exceptions:
 - That an explicit statement be made that “no patent will be granted on human bodies at any stage in development”;
 - Farmer’s privilege, which allows farmers to continue farming activities that would normally infringe a patent (collect a seed from a planted crop, grow a new crop from those seeds and sell that crop);
 - The innocent bystander provision, which involves a situation where a person inadvertently ends up having in their possession an invention that is patented but without their having done anything to acquire the invention (i.e. farmers will not be subject to patent infringement if they inadvertently use a patented seed); and
 - The experimental use provision, which allows researchers to a) test the effectiveness of a patented product and b) to test potential improvements to a patented product.

Does this seem a reasonable position to you?

- If you were inclined to oppose the patenting of higher life forms:
 - Do the exceptions make you more comfortable?
- Does the fact that an expert advisory body suggests going ahead make you more comfortable?

How strong are these arguments as a whole? Which is the strongest of these arguments in favour of patenting in this area?

Those opposed say that:

- They oppose the idea of patenting any products, including higher life forms
- Patenting of these higher life forms commodifies life, and is morally wrong
- They are concerned about the treatment of animals in medical research
- They believe that patents might limit access of some people to use the products.

Are these strong arguments?

Do they make you less inclined to allow patents on higher life forms?

Which of the arguments outlined for/against is strongest?