A Reply to the Canadian Biotechnology Advisory Committee (CBAC) Consultation Document: Biotechnological Intellectual Property and the Patenting of Higher Life Forms

May 23, 2001

Introduction

We welcome the opportunity to participate in this consultation process. In our response, we will limit ourselves to comments on the ethical framework proposed by the CBAC, the first question posed on the patenting of higher life forms, and on governance models. We do have broader concerns about the issues raised in this consultation, but have not had the time to address them in this response.

The Proposed Ethical Framework

The CBAC's approach to an ethical framework includes a means to assess the material benefits of biotechnology's outcomes within the context of patent law, but does not facilitate an analysis of the broader philosophical and moral context of biotechnology practices. Thus, the proposed ethical framework is incomplete. We recommend that the CBAC establish a more complete ethical framework which considers the broader philosophical and moral context, including the principles that shape our public life together as Canadians, as well as the intent of biotechnology and its effects on our lives.

We appreciate that the CBAC analysis intends to make "all things considered" ethical judgments as it considers the issues of biotechnology and intellectual property rights. However we are concerned that there are two areas in the consultation document dealing with the proposed ethical framework that seem primarily outcome-oriented. The first is in the description of the public interest mentioned in the context of the CBAC's ethical task. The second is in the principles that provide the context for the framework.

The first area is found in the consultation document where the CBAC describes its ethical task. The CBAC intends to take into account economic, political, legal, environmental, and scientific factors, and develop recommendations on biotechnology that integrate these various factors and that best serve the greater good and overall public interest. The public interest is described as comprising a series of outcomes -- "the health of Canadian citizens, the quality of life of Canadians, the health of the environment, the prosperity of the Canadian economy, fair distribution of benefits and burdens, and a sustainable, peaceful global community" (p. 3). While it is necessary for ethical judgments to assess the outcomes of a course of action, ethical evaluation must include more than an assessment of outcomes if it is to seek the common good for all Canadians.
The second area is found in the seven principles that the CBAC identifies as providing the ethical context for the consultation. Of the seven, the first five listed are framed in terms of outcomes; the latter two concern an attitude towards scientific knowledge. For example, the principle of justice is defined in terms of the fair distribution of the benefits and burdens of biotechnology. The principle of respect for diversity is qualified in terms of “diverse ways and forms of life.” These principles are not framed in a way that probes the underlying moral and philosophical issues raised by the issue of patenting higher life forms, such as the nature of life, the ownership of life and the effects of these new technologies.

We recommend that the CBAC review its proposed criteria and principles and ensure that its ethical analysis includes principles and criteria that facilitate a consideration of deeper underlying questions. A more complete ethical analysis should consider the broader philosophical and moral context of biotechnology practices, including the principles that shape our public life together as Canadians, the intent of biotechnology practices and their effects on our lives.

A complete ethical analysis must also assess the implications of any course of action on those principles which undergird and shape our common life together. Using the Charter of Rights and Freedoms as an example, the preamble refers to two commitments, the Supremacy of God and the Rule of Law, which provide the interpretative context for the Charter. Section 1 of the Charter refers to “principles of fundamental justice,” principles that the interpretation of the subsequent clauses must not violate. For example, while human dignity is not mentioned in the Charter, it is a principle that underlies the spirit of the Charter, the Criminal Code and Canadian public policy.

A full ethical analysis would also assess the effects of the technology itself. Biotechnology is defined in the consultation document as "a body of technical knowledge about living organisms or their constituent parts"(p. 4). So stated, biotechnology is presented as a cluster of tools and techniques, and the ethical analysis considers the circumstances under which the use of these tools is appropriate. However, a few pages later the document states "this is because biotechnology does not limit itself simply to explaining how things work in nature; it seeks to harness the power of biological materials to do something new" (p. 6). Biotechnology combines technical knowledge with the intent to manipulate and change nature. Hence technology is more than the application of certain techniques, and an ethical analysis must include not only questions about the proper use of these tools or processes, but also the intent to which these tools are utilized and how the technologies shape and influence us. It is essential to ask whether something should be done, as well as how it should be done.

As well, we recommend that the principles that the CBAC considers as forming the foundation for ethical evaluation of these issues include respect for human dignity and our responsibility as stewards of all of life.

The question of whether or not higher life forms should be patentable creates unease for Canadians because it raises social, philosophical, moral and religious questions about the nature of life and the ownership of life. The CBAC’s ethical framework must take steps towards addressing these social, philosophical, moral and religious questions.

The Patenting of Higher Life Forms

As an association of evangelical Protestants we seek to understand issues such as those raised in this consultation document from out of our vision and understanding of what it means to be human and responsible to care for the creation. We derive this understanding from the Bible.

We evaluate the issues raised by this consultation document in light of several biblical principles. These principles include the sovereignty of God, the stewardship of creation, the sanctity of life, the dignity of the person and justice in community. In the following section, we will apply these principles to the issues of patenting human life and the ownership of life.

Patenting Human Life

As Christians, we believe that human beings are created in the image of God, and therefore have inherent dignity and worth. Human life is sacred and should be cherished. We therefore believe that human life must be valued, respected and protected through all its stages. Treating
human life as property violates human dignity. Granting a person or corporation ownership of human life through patenting would violate human dignity.

The Patent Act, as it stands, allows for patents on any composition of matter, with no distinction between simple and complex life forms or between human, animal and plant life. The breadth of the Patent Act and the prospect of patenting humans have been raised in the Harvard Mouse case. This case involves an application by Harvard University for a patent on a genetically modified mouse, known as the oncomouse. This patent, if granted, would be the first patent for a complex life form in Canada. This case has raised the question of what should and should not be patentable, causing some concern that patents on humans are possible. In the Federal Court of Appeal decision, the majority granted the patent for the oncomouse and argued that concerns about the patenting of genetically altered humans are unfounded because that would violate the guarantee of liberty in section 7 of the Charter. However, the Court did not explain how the guarantee of liberty would preclude a patent being granted on a human being.

As well, the Court's reasoning in granting patents for both the process that created the oncomouse and the mouse itself raises some questions. The Court said that it was not commenting on the patentability of human genes in the Harvard Mouse decision, merely on the patentability of humans. However, the Court did not distinguish between the process of altering a gene and the resulting genetically modified higher life form when it granted the patent for the oncomouse. The dilemma is that if parts or elements of humans are patentable, on what basis will the entire human being be deemed to be non-patentable? This reinforces our belief in the need for the patenting of human life to be specifically prohibited in patent legislation.

The CBAC consultation document raises the question about the definition of human being that should be used, if the patenting of humans is to be excluded in patent legislation. The document states “...it is generally understood that an entire human being could not or would not be patented. This is so because human beings are not thought to satisfy the tests for patentability and because of the concern that exercising patent rights over an entire human being would likely violate human rights (emphasis added)” (p. 8). In this context, the document asks “whether human embryos or animals containing a substantial number of human genes are considered 'human beings’ ” (p. 8, footnote 9). If human life in some of its stages is patentable, at what stage will the human life no longer be patentable and on what grounds will the distinction be made? In law the term 'human person' does not apply to an unborn child. This raises the possibility of commercial ownership until a child has fully proceeded from the womb in a living state.

As well, we wonder if life forms are reduced to their molecular or genetic composition, on what basis can a distinction be made between human life and non-human life?

We believe human life must be affirmed as having unique status and deserving special protection in law and public policy. The patenting of human life at any stage of its development would violate the sanctity and dignity of human life. We recommend that patent legislation not allow patents of humans at any stage of development.

The Ownership of Life

As Christians, we believe that God is sovereign; that the world and all that is in it belongs to Him, God, and God alone, is the creator. Human beings are God's appointed stewards, charged with the responsibility of using the gifts we have been given in ways that honour Him and acknowledge our accountability to Him. We are stewards of the earth, not owners, and our task is to care for that which has been entrusted to us. Our use and ownership of creation does have limits. For example, the Bible allows for various uses of animals but not for their torture. We may use the land and the fruits of the land in various ways, but not destroy it. Canadian law also recognizes that ownership of land, animals and human labour is not unqualified. Theology, philosophy and law remind us that human ownership is not limitless.

The Patent Act bestows upon a person or a corporation the legal ownership of an invention. The nature of the ownership afforded by obtaining a patent is different then the common understanding of owning an animal, such as a pet. With respect to higher life forms, the grounds for ownership under patent law would be that a person or corporation is deemed to have manufactured, and therefore invented, a complex life form when they have altered a genetic segment of the life form. Within the context of the Harvard Mouse case, the argument for patenting the oncomouse is that a genetic alteration of a complex life form means that the life form is a
composition of matter that is unique and useful, and is therefore patentable. According to the reasoning of the majority in the Federal Court of Appeal, if the unicellular organism leading to the oncomouse is patentable, then the oncomouse is also patentable. The entire animal is treated as an invention, not just the gene or the process by which the life form is genetically altered. As pointed out in the Attorney General of Canada’s Application for Leave to Appeal, this reasoning denies any distinction between the unicellular material and the complex and intelligent form of life represented by the ultimate animal (para. 52). In fact, Harvard’s contribution to the existence of the whole oncomouse is quite minor. The mouse develops naturally once the genetic alteration has been done.

This approach reduces life to its chemical components and treats higher life forms, including mammals, as a composition of matter, as a thing that has been made and is therefore the property of the maker. It affirms that persons or corporations can regard themselves as makers and owners of a life form, rather than its caretakers. This approach is contrary to the understanding that we are but stewards of life. We recommend that patent legislation not allow the patenting of a whole animal.

Governance

The consultation document raises substantive questions about various processes and exclusions that should be considered in a comprehensive review of the Patent Act and governance mechanisms. These raise significant moral and ethical issues which, given the time constraints, we are unable to fully address at this time.

The document asks whether a morality provision should be added to the Patent Act, and how this provision and/or other ethical issues raised by the application of the Patent Act be addressed. The various mechanisms identified in the consultation document have specific advantages and disadvantages. Our concern is that the process selected ensures deliberations are open, transparent and accessible to the public, and that in its deliberations it offers standing not only to those seeking patents, but also to other interested parties including faith communities.

Conclusion

In this reply, we have examined the issue of patenting higher life forms such as animals and humans, and conclude they should not be patentable. The most effective means of prohibiting the patenting of higher life forms is to specifically include the prohibition in patent legislation.