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Report of Research Findings Patenting in the area of Health Genetics

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Introduction

Earnscliffe Research and Communications is pleased to present the following report to Health Canada. It provides findings of 10 focus groups, two groups in five cities nationwide (Halifax, Montreal, Toronto, Calgary and Vancouver) that took place in the first three weeks of October 2004.

The purpose of the research program was to broadly explore some of the issues associated with patenting in the arena of genes/gene sequences and genetic products, perceptions and associated attitudes regarding this arena.

Methodology:

- The focus groups took place in five cities nationwide, on the following dates:
 - September 29, 2004 – Toronto
 - October 5, 2004 – Halifax
 - October 6, 2004 – Montreal
 - October 18, 2004 – Vancouver
 - October 19, 2004 – Calgary
- Each focus group was 2 hours in length, with two groups in each city.
- Focus group participants were chosen to be representative of the population based on gender, education, and income.
- In each location, one group was comprised of the general public, and one group was comprised of *Involved Canadians*, the 30 percent segment of the population that is made up of those who are most interested and active in public policy issues.
- Preceding the focus group discussions, participants were provided with a brief discussion paper. The discussion paper was utilized as a tool to provide respondents with some basic information on patenting in general and specifically in the area of genetics. It was carefully written in as value neutral and objective a manner as possible.
- That discussion paper is appended to this report, as is the moderator's guide that was utilized in the groups.

- The research employed an iterative approach to the execution of the groups, utilizing the first night's groups to make adjustments to the methodology for the rest of the groups. Because this topic is a complex one that has not been explored before, it was determined by the client and the research team that such an approach would be appropriate. Three main elements were adjusted over the course of the groups:
- A re-ordering of questions, to better follow the logic that participants' deliberations tended to follow.
- Two case studies that had been initially integrated into the discussion guide were utilized as catalysts for discussion when necessary (ie. when the issues they raise were not spontaneously raised in the groups). In most cases the issues they raised were spontaneously raised, so they were not tabled in every group.
- One of the policy options that was widely seen by participants as central to a governance regime in this area was explored in more detail than the original moderator's guide had detailed. Specifically, two ways of operationalizing a "quasi-PMPRB" model were tested in groups, one that is similar in nature to the current model and another that is similar to the UK model where profits are regulated.

The focus group discussions followed a moderator's guide that began with a thirty-minute discussion of health genomics/biotechnology, its applications, and potential benefits and risks. The groups then proceeded to a discussion of patenting in general and the bulk of the time was focused specifically on the patenting of genes and genetic products.

While these group discussions were extensive and detailed, because they involve qualitative research only, they should be viewed as indicative of public opinion, but not representative of public opinion.

One key point worth noting in the introductory section of this report regards demographic and geographic differences of opinion. The focus groups revealed some clear differences of opinion based on such factors, particularly between men and women. However, while there were also differences in opinion across certain cities/regions, we suggest that most of those differences are an antecedent of the nature of the discussion in those respective groups, and secondarily an antecedent of regional differentiation. In some groups certain arguments were tabled that tended to sway opinion of other members of the group significantly, while in other

groups similar arguments were not always tabled and discussed to the same level of detail, resulting in a dynamic that was different.

Main Findings

Most focus group participants possess at least a general knowledge of human genomics research and discoveries, usually expressed in specific applications they have read or heard about. In particular, *Involved Canadians* exhibit high levels of awareness of this field and a high level of sophistication about some of the issues that surround it.

Canadians believe that there are and will be substantial benefits that flow from discoveries in human genomics. A significant number of participants believe that this field will form the core of the future of health treatment and health care in Canada.

While participants are for the most part hopeful about the benefits of these technologies, some also worry about their advance, from three main perspectives: risk, regulation and ethics. Each of these issues is distinctly expressed in discussions as areas of concern regarding this field and where it is going.

Many of the concerns regarding risk, regulation, and ethics connect and coalesce around a central theme: that there isn't a clear understanding of what parameters are in place to guide and regulate the development of these technologies.

In significant part, it is this lack of understanding about what parameters are in place to govern genetic research that drives concern. Once given a brief sketch of these parameters, concerns regarding unethical applications of genetic technology (e.g. cloning, eugenics) are not nearly as pronounced, and most participants are accepting of the technology (as long as vigilance on maintaining those parameters is maintained). This may be stressed too strongly in the report generally. While some of the more alarmist responses were tempered by the discussion of how these technologies are regulated, it would not be fair to attribute so much of participants concerns to an ignorance of parameters. Some very legitimate and informed concerns were raised that were not altered significantly by the discussion on regulation and research limits.

Before engaging in these focus groups, few focus group participants had given thought to the idea of patenting in this area, or issues that it might raise. It is not one of the issues, like genetically modified food or stem cell

research that is top of mind when they think about advances in the area of human genomics or biotechnology.

Most participants tended to believe that applications of genetic technology (like diagnostic tests or gene therapies) were currently patentable, but did not know that genes or gene sequences were currently patentable.

Many participants believe that there is something fundamentally different about patenting genes and gene sequences than other types of patenting, because the information associated with genetics is more fundamental, more personal, predictive and more powerful than information associated with other types of patents.

In terms of acceptability, participants made very clear distinctions between patenting of genes and genetic applications.

In the area of genetic applications, support for patenting is quite broad. While recognizing that there are access “benefits” (having more products available) and access “losses” (having to pay a monopoly price for products) that flow from having a patent system, at question is whether the benefit outweighs the loss. On balance, most participants believe that the access benefit outweighs that access loss, because they believe that the products would not be available at all if patenting were not available. The smaller group that was not supportive of patenting of applications felt this way in large part because of moral opposition to the development of the applications themselves, rather than patenting specifically.

In terms of patenting genes/gene sequences, opinion was much more divided. Although there were significant variations across the groups, overall there *was no consensus*, and roughly equal support for and opposition to patenting of genes/gene sequences. There were some notable demographic differences on this issue. Among involved Canadians overall, and women, there is a deep sense of concern about whether genes and gene sequences should be patentable. The reasons for opposition to patenting of genes and gene sequences rest on three primary grounds, each of which had about equal weight in expression, although the last of the three was the factor that tended to drive group opinion upon discussion.

- Moral/Ethical concerns. Genetic information is something that is intrinsically personal to humans and that it can not and should not be turned into “property”.

- Questions about whether a gene/gene sequence is truly an invention. This issue had two related dimensions, equally important to the discussion:
 - Many expressed a general belief that a gene is something that is naturally evident, and cannot be considered to be an invention, and therefore should not be patentable.
 - Of these participants, most rejected the argument that isolation of gene sequences in a lab provided an inventive step. On this question, some respondents indicated that isolating gene sequences in a lab was something that is relatively easy to do, which only underscored opposition to the premise that it represented “true” invention.
- Whether patenting a gene sequence might actually inhibit research. In some of the groups, participants questioned whether the idea of patenting a gene or gene sequence runs contrary to the principle inherent in the “bargain” or rationale behind of patenting, specifically the facilitation of further research and innovation. From this point of view, research appears to be *inhibited* by allowing genes and sequences to be patented, because the patent holder has the right to control access to that gene/sequence which means that others cannot carry out research to develop new products. In the groups where this argument was tabled and discussed in detail, it often swayed the majority of participants to decide that patenting of genes and gene sequences should not be allowed. In this context, the open-source model of patenting that the BC Cancer Agency is pursuing is a model that had a fairly broad appeal in groups.

The argument above, in combination with the rejection of the idea that isolating a gene in a lab represents an invention, were the most significant drivers of opinion against patenting of genes/gene sequences.

It was in this area of acceptability of genetic applications and genes/gene sequences where the most pronounced demographic differences lay.

- Women tended to express more trepidation about acceptability in both genetic applications and gene sequences than men. In general, women were more likely to express concerns about moral/ethical considerations associated with these technologies than men, and those views, combined with concerns (held by almost all participants) about access/cost issues, tended to lead more women than men to

oppose the idea of patenting in either applications or genes/gene sequences.

- Involved Canadians were as likely as others to raise concerns about moral issues and access issues, but in the case of genetic applications, they tended to believe that the benefits outweighed those considerations. However, involved Canadians tended to question the rationale behind allowing patents on gene sequences, and whether doing so truly facilitates innovation. In short, the more involved Canadians explored that rationale in detail, the more questions they tended to raise about the advisability of allowing patenting of genes/gene sequences.
- The Toronto and Calgary groups tended to express more support for patenting (of both applications and gene/gene sequences) than groups in the other cities. Vancouver and Montreal groups tended to be less supportive in both areas, while Halifax fell between the other centres. However, we submit that those geographic differences were in significant part a function of the discussions themselves rather than the region or city per se.

The final portion of the discussion focused on six current and potential safeguards that might be utilized within the patent regime.

Overall, there was widespread support for the use of most, if not all of the safeguard mechanisms tested in the groups. There was very strong interest in establishing some sort of price regulation for patented genetic health technology applications based on a model similar to the Patented Medicine Price Review Board (PMPRB). Many also expressed an interest in using compulsory licensing to open researchers' access to patented genes/gene sequences. A price regulatory regime was generally viewed as the most important safeguard that could be employed in the area of genetic applications, because it helped to ease concerns about the most significant problem participants come across regarding patents, the idea of price gouging and the limitation of access to products they need.

Given that the PMPRB is already in place, participants sensed that broadening it to include genetic applications and products might be a useful and relatively easy step to take.

Because a PMPRB-type body was so widely advocated, the groups further explored two ways of operationalizing a "quasi-PMPRB" model, one that is similar in nature to the current model (regulating price) and

another that is similar to the UK model where profits are regulated through a process of auditing input costs by the firms involved and then assigning a price according to an assessment of the market in light of those input costs.

There was no consensus on which of the two models was most preferred. Overall, those who expressed the most trepidation about patenting in this area tended to lean toward the “profit-regulation” model, because they felt that that this would significantly help to address their concerns about access and cost issues. Those who tended to believe that patenting should be allowed in this area tended to believe that a quasi-PMPRB model would be most appropriate, because it is a system that works now and because it would be relatively easy to operationalize. These people felt that the profit regulation model would necessitate significant cost and require extensive bureaucracy to administer.

In the area of genes/gene sequences, if a safeguard regime were the necessary approach (ie. if there was no way to reconsider the idea of patenting of genes/gene sequences), then a compulsory licensing model would be the preferred approach.

Finally, the groups were invited to discuss the extent to which the safeguards ought to be implemented, specifically whether implementing all or most of the safeguard measures would affect research or innovation (positively or negatively). Overall, there was not a consensus on this issue. Among most participants, there was a general sense that some of these safeguard mechanisms would be used fairly routinely, whereas others would only be used in certain clearly specified circumstances. Many felt that a regime that employed all of these measures would not necessarily have a significant negative effect on investment/innovation in this area.

This point of view was not universally shared, however. There were some who expressed strong concerns that a regime that included all of the safeguards would prove to be overly arduous and might dampen innovation as well as investment in Canada.

Finally, participants were also invited to weigh in on the extent to which moral considerations ought to be included in the patent regime.

Overall, most focus group participants preferred that moral considerations not be built into the patent approval process. By and large, they believed that the current arrangement, where parliament and the courts play the role of adjudicating on moral issues, is the best way to go about addressing these issues. Participants raised a few key concerns

regarding the advisability of allowing the patent office to play a role in this area. They questioned whether the patent office had the appropriate moral authority to play this kind of a role. Specifically, they were not sure that the individuals who worked there were appropriately suited to carry out that function. Moreover, it was felt that those who work at the patent office were not as accountable to citizens or to the Charter of Rights as legislators and the Supreme Court do.

Faits Saillants

La plupart des participants aux entretiens de groupe possèdent au moins une connaissance générale de la recherche et des découvertes sur les gènes humains. Ils l'expriment d'habitude sous forme d'applications spécifiques, aux sujets desquels ils ont lu ou dont ils ont entendu parler. Les Canadiens impliqués, en particulier, font preuve d'un niveau de notoriété élevé du sujet et d'un niveau de sophistication élevé concernant les débats qui l'entourent.

Les Canadiens croient qu'il y a et qu'il y aura des retombées positives importantes des découvertes sur les gènes humains. Un nombre important de participants croit que ce domaine constituera le noyau des traitements et des soins de santé futurs au Canada.

Si les participants sont, pour la plupart, optimistes quant aux retombées de ces technologies, certains demeurent préoccupés par leur progrès, selon trois perspectives principales : le risque, la réglementation et l'éthique. Chacune de ces trois questions ressort de façon nette comme une préoccupation dans la discussion sur ce domaine et son avenir.

Une grande partie des préoccupations concernant le risque, la réglementation et l'éthique est reliée à un thème central : il n'y a pas de compréhension claire des paramètres existants pour guider et réglementer le développement de ces technologies.

Pour une bonne part, c'est cette incompréhension des paramètres existants pour baliser la recherche génétique qui est source de préoccupation. Une fois qu'on a donné un bref aperçu de ces paramètres, les préoccupations concernant les applications moralement inacceptables de la technologie génétique (ex. : clonage, eugénisme) s'estompent de façon prononcée et la plupart des participants sont favorables à ces technologies (en autant qu'on préserve ces paramètres avec vigilance).

Avant de participer à ces entretiens de groupe, peu de participants avaient songé au concept de brevet dans ce domaine, non plus qu'aux questions que cela pourrait soulever. Contrairement à des sujets comme les aliments génétiquement modifiés ou à la recherche sur les cellules souches, ce sujet ne vient pas immédiatement à l'esprit lorsqu'on pense au développement dans le domaine de la recherche sur le gène humain ou la biotechnologie.

La plupart des participants avaient tendance à croire que les applications de la technologie génétique (comme les tests de diagnostiques ou les thérapies génétiques) peuvent être brevetées présentement, mais ne savaient pas que les gènes ou séquences géniques peuvent aussi faire l'objet d'un brevet.

Beaucoup de participants pensent qu'il y a une différence fondamentale entre les brevets dans le domaine des gènes et des applications génétique et d'autres types de brevets, parce que l'information associée à la génétique est plus fondamentale, plus personnelle, plus susceptible de prédire l'avenir et plus puissante que l'information associée aux autres types de brevets.

En termes d'acceptabilité, les participants font une distinction très nette entre le concept de breveter des gènes et celui de breveter des applications génétiques.

En ce qui a trait aux applications génétiques, l'appui aux brevets est plutôt général. Tout en reconnaissant que le fait d'avoir un système de brevets se traduit par des avantages (avoir un plus grande choix de produits), mais aussi par un élément négatif en termes d'accessibilité (avoir à payer le prix d'un monopole pour ces produits), la question est de savoir si l'avantage transcende l'élément négatif. De façon générale, la plupart des participants croient que l'avantage d'accessibilité est supérieur à l'élément négatif, parce qu'ils croient que les produits ne seraient pas offerts du tout s'il n'y avait pas de brevets. Le groupe minoritaire, qui n'appuie pas les brevets pour les applications, exprime ce point de vue en grande partie en raison d'une opposition morale au développement des applications elles-mêmes, plutôt qu'aux brevets comme tels.

Pour ce qui est de breveter les gènes/ séquences géniques, les points de vue sont beaucoup plus partagés. Bien qu'on ait noté des différences significatives entre les groupes, de façon générale, on n'a pas dégagé de consensus : l'appui et l'opposition au brevet pour les gènes/ séquences géniques sont à peu près équivalents. On a noté certaines

différences démographiques sur cette question. Parmi les Canadiens impliqués, en général, et les femmes, il y a une hésitation profonde à appuyer le concept de breveter des gènes et séquences géniques. Les raisons de l'opposition au brevet pour les gènes et séquences géniques reposent sur trois axes principaux qu'on a exprimé avec un poids égal, quoique le dernier des trois se soit avéré le facteur qui avait le plus d'influence sur l'opinion du groupe après discussion.

- **Des préoccupations d'ordre moral/éthique.** L'information génétique est quelque chose d'intrinsèquement personnel pour les êtres humains, et qui ne peut pas et ne doit pas devenir une « propriété ».
- **La question à savoir si un gène/ séquence génétique est vraiment une invention.** Cette question se pose sous deux angles connexes, qui sont d'importance égale dans la discussion.
 - Plusieurs croient fondamentalement qu'un gène est quelque chose de naturellement évident, qui ne saurait être considéré comme une invention et, par conséquent, ne devrait pas pouvoir faire l'objet d'un brevet.
 - Le rejet de l'argument que le fait d'isoler des séquences géniques dans un laboratoire constitue une étape d'invention. Sur cette question, plusieurs participants ont indiqué que le fait d'isoler des séquences géniques dans un laboratoire est quelque chose qui est relativement facile à faire, ce qui ne faisait que renforcer l'opposition à la prémisse selon laquelle cela représente une invention « véritable ».
- **La question à savoir si le fait de breveter une séquence génique, ne pourrait pas en fait inhiber la recherche, ce qui vient de l'encontre du principe même sur lequel le système de brevet est fondé.** Dans certains des groupes, les participants se sont interrogés à savoir si l'idée de breveter un gène ou une séquence génique ne serait pas contraire au principe inhérent dans le « compromis », la raison d'être du système du brevet, soit le fait de faciliter d'autres recherches et l'innovation. Selon ce point de vue, le fait de permettre aux gènes et séquences géniques d'être brevetés, paraît *inhiber* la recherche parce que le détenteur du brevet a le droit de contrôler l'accès à ce gène ou séquences géniques, ce qui signifie que d'autres ne peuvent pas mener la recherche pour développer d'autres nouveaux produits. **Dans les groupes dans lesquels cet argument a été mis de l'avant et discuté en détail, la majorité des**

participants ont souvent été influencés à conclure qu'on ne devrait pas permettre de breveter les gènes et séquences géniques. Dans ce contexte, le modèle de brevets ouverts préconisé par la BC Cancer Agency en est un qui a beaucoup d'attrait parmi les participants aux groupes.

Cet argument, en plus du rejet de l'idée que le fait d'isoler une gène dans un laboratoire constitue une invention, est le moteur principal de l'opinion contre le brevetage des gènes/ séquences géniques.

C'est sur cette question d'accessibilité des applications génétiques et des gènes/ séquences géniques qu'on a noté les différences démographiques les plus prononcées.

- Les femmes ont tendance à exprimer plus d'émotion quant à l'acceptabilité, à la fois des applications génétiques et des séquences géniques, que les hommes. De façon générale, les femmes étaient plus susceptibles d'être préoccupées des considérations d'ordre moral ou éthique associées à cette technologie que les hommes. Ce point de vue, combiné aux préoccupations (exprimées par presque tous les participants) concernant les questions d'accessibilité et de coût, ont conduit plus de femmes que d'hommes à s'opposer à l'idée du brevetage, tant pour les applications que pour les gènes/ séquences géniques.
- Les Canadiens impliqués avaient le même niveau de préoccupation que les autres concernant les questions morales et d'accessibilité. Cependant, dans le cas des applications génétiques, ils avaient tendance à croire que les avantages l'emportaient sur ces considérations. Pour ce qui est des gènes/ séquences géniques, les Canadiens impliqués avaient tendance à se laisser beaucoup influencer par les questions portant sur les raisons de permettre de tels brevets, spécifiquement si le fait de permettre ces brevets encourage vraiment l'innovation. Bref, plus les Canadiens impliqués exploraient en détail cette question, plus ils soulevaient des arguments qui avaient tendance à remettre en cause le bien-fondé de permettre le brevetage des gènes/ séquences géniques.
- Sur le plan géographique, les groupes de Toronto et Calgary avaient tendance à exprimer un appui plus considérable au brevetage, tant pour les applications que pour les gènes/ séquences géniques, que les groupes des autres villes. Les groupes de Vancouver et Montréal avaient tendance à être les moins positifs dans les deux cas, tandis que Halifax se situait à mi-chemin. Cependant, nous sommes d'avis

que ces différences géographiques furent en grande partie le résultat des discussions mêmes plutôt qu'une question de région ou de ville en soi.

La dernière partie de la discussion portait sur six balises actuelles ou potentielles qui pourraient être utilisées dans les cadres du régime des brevets.

Au total, on a constaté un appui généralisé en faveur de l'utilisation de la plupart, sinon de tous les mécanismes de balise testés dans les groupes, sur la base de modèle du Conseil d'examen du prix des médicaments brevetés (CEPMB) pour ce qui est des applications génétiques et un modèle de licence obligatoire dans le cas des gènes/ séquences géniques. Le régime de réglementation des prix a été généralement perçu comme le mode de protection le plus important qu'on pourrait utiliser dans le domaine des applications génétiques, parce qu'il contribue à réduire les principales craintes au sujet des problèmes les plus importants que les participants associent au système de brevet : l'abus au niveau des prix et un accès limité aux produits dont ils ont besoin.

Comme le CEPMB existe déjà, les participants ont trouvé que d'élargir son mandat pour inclure les applications et produits génétiques serait plus une mesure utile et relativement facile à adopter.

Comme un organisme du type du CEPMB a été prôné de façon si généralisée, on a exploré plus à fond dans les groupes deux façon d'opérationnaliser un modèle « quasi CEPMB » : un dont la nature est similaire au modèle actuel (réglementation des prix) et un autre qui serait similaire au modèle du Royaume Uni en vertu duquel les profits sont réglementés via un processus de vérification des coûts intrants par les firmes impliquées et qui se voient subséquemment assigner un prix selon une évaluation du marché et compte tenu de ces coûts intrants.

On n'a pas dégagé de consensus à savoir lequel de ces deux modèles était préféré. De façon générale, ceux qui ont exprimé le plus de nervosité par rapport au brevetage dans ce domaine, ont eu tendance à pencher en faveur du modèle de réglementation des profits parce qu'ils croyaient que celui-ci répondait mieux à leurs préoccupations concernant les questions de coût et d'accès. Ceux qui avaient tendance à croire que le brevetage devrait être permis dans ce domaine avaient tendance à croire qu'un modèle quasi-CEPMB serait préférable, parce que c'est un système qui fonctionne maintenant et qu'il sera relativement facile de l'implanter. Ces personnes trouvaient que l'administration d'un système

de réglementation des profits impliquerait des coûts importants et exigerait une bureaucratie considérable.

Dans le domaine des gènes/ séquences géniques, si un régime de balises était l'approche indiquée (c-a-d, s'il n'était pas possible de remettre en question l'idée même de breveter des gènes/séquences géniques), alors un modèle de licence obligatoire serait l'approche privilégiée.

Finalement, on a invité les groupes à discuter du mode d'implantation des balises, spécifiquement à savoir si la mise en place de toutes ou de la plupart de ces mesures de protection pourrait avoir un impact sur la recherche et l'innovation (positif ou négatif). Au total, il n'y a pas eu de consensus sur cette question. Selon une majorité, on trouvait que la plupart de ces mécanismes de balises devraient être implantés sur une base constante, tandis que d'autres ne le seraient que dans des circonstances spécifiques claires. Dans ce sens, plusieurs trouvaient qu'un régime qui inclurait toutes ces mesures n'aurait pas nécessairement un impact négatif significatif sur l'investissement et l'innovation dans ce domaine.

Cependant, tous ne partageaient pas ce point de vue. Il y en a qui ont exprimé des préoccupations sérieuses à l'effet qu'un régime incluant toutes ces balises s'avérerait trop lourd et pourrait avoir un impact négatif sur l'innovation, de même que l'investissement, au Canada.

Finalement, on a invité les participants à s'exprimer à savoir jusqu'à quel point les considérations d'ordre moral devraient être parties intégrantes du régime de brevet.

Au total, la plupart des participants aux entretiens de groupe préféreraient que les considérations d'ordre moral ne fassent pas partie intégrante du processus d'approbation des brevets comme tel. La plupart trouvaient que la situation actuelle, en vertu de laquelle le parlement et les cours ont le rôle de décider des questions d'ordre moral, est la meilleure façon de procéder. Les participants ont soulevé trois préoccupations importantes concernant le bien-fondé de permettre au bureau des brevets de jouer un rôle dans ce domaine. Ils ont émis des doutes à savoir si le bureau des brevets avait l'autorité morale pour jouer ce rôle. Spécifiquement, ils n'étaient pas certains que les personnes qui y travaillent avaient la compétence voulue pour jouer ce rôle. De plus, on a trouvé que les gens qui travaillent au bureau des brevets n'ont pas d'imputabilité directe face aux citoyens ou à la charte des droits, contrairement aux législateurs et à la Cour suprême.

The Field and Applications

Most participants possess at least a general knowledge of human genomics research and discoveries, usually expressed in specific applications they have read or heard about. In particular, *Involved Canadians* exhibit high levels of awareness of this field and a high level of sophistication about some of the issues that surround it. Most participants can cite one or more examples of discoveries or applications, although most do not use the language that experts employ when they refer to categories of applications – such as genetic testing, gene therapies, pharmacogenetics, etc. Participants are more likely to refer to information about tests and therapies for diseases and conditions such as Diabetes, SARS, or Breast Cancer.

Participants expressed a general belief that there are and will be substantial benefits that flow from discoveries in human genomics. Many participants believe that this field will form the core of the future of health treatment and health care in Canada. In particular, virtually all participants who have a personal connection with a disease for which there is a potential genetic application are extremely positive and hopeful about these potential benefits. The recent discovery of a potential gene therapy treatment for type 1 diabetes was widely cited in groups as an example of this field and the promise it holds for health treatment.

“I read about this potential treatment for diabetes....I am a diabetic, and this would be a major breakthrough for people like me” – Calgary respondent

While participants are for the most part hopeful about the benefits, there is a fair degree of worry about the advance of these technologies, from three main perspectives: risk, regulation and ethics. Each of these issues is distinctly expressed in discussions as areas of concern regarding this field and where it is going. Overall, women tended to express higher levels of concern about all three of these areas than men. In addition, participants in the general public groups tended to express higher levels of concern about the risks involved than those in the *Involved Canadians* focus groups. In addition, groups in Montreal and in Vancouver tended to express greater than average concern about the risks involved.

“We all remember Thalidimide, which governments determined was safe, but then was found later to cause serious problems...I worry that one of these technologies might end up causing similar harm to people” – Halifax Respondent

Most participants did not show a great awareness of the parameters that are in place to guide the development of these technologies. This context seemed to underlay a number of concerns raised about biotechnology in general related to the management of risks, regulation, and ethical use of this technology. Participants who knew less about the way in which genetic health technologies are regulated voiced stronger and more alarmed concerns about potential risks. In the case of the general public groups, the higher level of perceived risk was clearly related to an absence of knowledge about what the current parameters are. The major concerns raised related to the following issues:

- Long-term risks associated with applications of the technology. The fact that these types of technologies may give rise to implications for health or the environment that are significant and serious, and that may not reveal themselves for years.
- The government safety and approval processes in place to regulate these technologies, specifically whether enough is being done to understand and manage the potential risks involved.
- Whether there are moral or ethical parameters in place to guide what is acceptable and not acceptable in terms of this kind of research.

In the absence of a discussion of the parameters in place to address these issues, concerns about the risks of genetic technology and potentially unethical or unsafe applications tended to dominate discussion. Often times, those discussions led to concerns about human cloning, and whether this kind of activity is occurring in research now.

When provided with a general sense of the existing parameters or safeguards that are in place now, it frames the discussion in an important way. In groups, three of the main parameters were outlined in general terms -- the ban on cloning in the *Assisted Human Reproduction Act*, the role of ethics boards that vet research at universities and research institutions, and the Supreme Court ruling on patenting of higher life forms. When participants are provided with a general description of the actual safeguards and parameters in place now in Canada, the concerns in all three areas abate to a significant degree, and participants tend to be more willing to engage in a discussion about how to manage these technologies in the most effective way possible. That said, participants are very strongly of the view that vigilance in all three areas should be of paramount concern in the governance of this area going forward.

As found in other areas of biotechnology public opinion research, most participants wish to assess these technologies on a case by case basis, and are unwilling to assess them as a whole other than to suggest that the field “shows promise”. For each case, most participants apply an implicit risk/benefit test that centers on the marginal personal benefit of any particular application. In some cases (such as genetic testing of pregnant women) a moral dimension is included in this assessment.

The larger the personal benefit (ie. over alternative products or treatments available), the more likely the risk and/or moral concerns are overcome. Similarly, the more intrusive the process and 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. Using a specific example to illustrate, the recent discovery of a potential diabetes gene therapy is almost universally supported, while the cloning of entire humans continues to be widely feared.

Categories of applications that are most widely known include:

- Stem Cell Research
- Genetic testing
- Identification of genetic causes of disease
- Gene sequencing
- Gene therapies
- Vaccines (although participants often do not realize vaccines are a genetic application)

Those that are less widely known are:

- Behavioural genetics
- Pharmacogenetics

Most participants are supportive of research in areas like stem cell research, gene therapies, and diagnostic testing. However there is a fairly significant level of discomfort with genetic testing of pregnant women, revolving around the area of unborn children, which makes some participants uncomfortable with these types of applications. In the area of behavioural applications, most participants are supportive, but a sizeable number wondered about potentially stigmatizing certain groups in society, which fuelled a fairly significant level of concern about some of these applications.

Attitudes Toward Patenting in General

Before exploring issues associated with patenting in the area of genetics, focus group participants were invited to discuss issues associated with patenting in general.

The findings from these discussions were as follows:

Overall, there was a tendency among most participants to agree with the principle of patenting, that there were important benefits that flow from having a patenting system, particularly in terms of spurring innovation and the development of products. Virtually all participants expressed support for the principle of patenting.

“Patents have been with us for a long time, and we have to have them because otherwise someone could do research and someone else could just steal their ideas and profit from it” – Toronto participant

Supporters say patenting is necessary because it provides an incentive to develop ideas because participants can then make money from those ideas, and that there has to be protection “from those who will just steal ideas once they have been researched”. There were a small number of participants who opposed the principle of patenting, and did so on mostly philosophical or ideological grounds – their opposition was driven by mistrust of large corporations and worry about restricted access to important products.

There were modest demographic differences on this question, primarily between involved Canadians and the general public. Involved Canadians tended to be fairly universally supportive of patenting in general, whereas most of the opposition resided in the general public. In addition, there was slightly more resistance to the idea of patenting in the Montreal groups than in other parts of the country.

It should be noted that agreement with the notion of allowing patenting was offered somewhat grudgingly by many participants, because of concerns they had about access to products that are patented and are therefore expensive to buy. They realized that having a patent system was a necessary instrument to facilitate innovation, but that did not ease concerns about access to products and exorbitant profits that patent holders may reap.

There were several elements of the patenting regime that were not widely known to participants.

- Some focus group participants did not know that there is a 20- year limit on patents. These participants tended to believe that a patent lasts forever;
- Virtually none of the participants in the groups were aware that a patent begins before safety/regulatory approval research begins, and that this may limit the window of time during which the patent holder would have exclusive rights to market their product;
- Very few participants were aware of the idea that patenting makes an invention public and can therefore promote more research using that public information – many participants instinctively believe that patenting inhibits research, because a person or company has a monopoly on it;
- A number of participants did not previously understand the distinction made in patenting between inventions and discoveries or ideas;
- Few participants understood the concept of a trade secret – they had previously conflated its characteristics with those of patenting. None had previously drawn comparisons between having a patent system or a system of trade secrets, which in discussion was generally felt to be an extremely unpalatable alternative to patenting.

Participants were invited to indicate whether, based on the information they knew and had discussed, the patent system balances the interests of inventors/researchers and the public interest, or whether the system is skewed more toward one or the other of these.

Most focus group participants tended to believe that a relatively reasonable balance is being struck between the interests of facilitating innovation and the public interest now. A few tended to feel the patent system may be tilted slightly toward researchers and companies, particularly in the cases where those companies or researchers had not made huge initial investments in the application or products.

Demographically, men tended to feel that the balance was being relatively well struck now, whereas women tended to be more likely to feel that the system skewed toward benefits to researchers and companies. Again, those in Montreal also were more likely to believe the system was tilted toward patent holders and companies.

"I thought patents last forever....the fact that they only have 10 years to make their money back seems to be a fair approach" – Halifax respondent

Attitudes Toward Patenting in the Area of Genetics

Before engaging in these focus groups, few (if any) of the participants had given thought to the idea of patenting in this area, or issues that it might raise. It is not one of the issues, like GM food or stem cell research, which is top of mind to participants when they think about advances in the area of human genomics or biotechnology.

Although they had not given it much previous thought, most participants tended to show an understanding that applications of genetic technology (like diagnostic tests or gene therapies) were currently patentable. For the most part, participants saw these kinds of applications as analogous to pharmaceutical products. Concerns in the area of applications tended to revolve around access to these products at a reasonable cost, as well as the stringency of the safety/regulatory approval process.

Most participants did not know that genes or gene sequences were currently patentable. This was new information to most participants, and even with the explanation in the discussion paper, some had difficulty conceptualizing how this information could be patentable, or why someone would want to patent it.

There was a widely shared belief that there is something fundamentally different about patenting in the area of genes and genetic applications than other types of patenting. It is often difficult to articulate this difference, but many focus group participants made comments to the effect that there is something that is more personal, more fundamental to human nature, and more powerful about genetic information than information about other inanimate patentable products (like a mousetrap). That is not to say it is inherently unacceptable, just that it is perceived as being different, and therefore the stakes of allowing patenting in this area are greater.

Most focus group participants found patenting in the area of genetic research to be broadly acceptable, although upon discussion it was clear that people made significant distinctions between patenting of genes/gene sequences and patenting of applications. The opinion dynamic is analogous to that regarding the broad subject of human genetics and specific applications, in that participants tend not to want to make blanket assessments of acceptability about the field as a whole, they would rather make case-by-case assessments.

The distinctions that many participants made between patenting of genes and genetic applications were so significant that it is more appropriate to discuss them separately.

In the area of genetic applications, support for patenting is quite broad. While recognizing that there are access “benefits” (having more products available) and access “losses” (having to pay a monopoly price for products) that flow from having a patent system in this area, at question is whether the benefit outweighs the loss. On balance, most participants believe that the benefit outweighs the loss, because they believe that the products would not be available at all if patenting were not available. The smaller group which was not supportive of patenting of applications felt this way in large part because of moral opposition to the development of the applications themselves, rather than patenting specifically.

“It is a trade-off that we have to make, but if we don’t have a product available at all then no one has access to it” – Halifax participant

In terms of patenting genes/gene sequences, opinion was much more divided. Although there were significant variations across the groups, overall there was roughly equal support for and opposition to patenting of genes/gene sequences. Among involved Canadians overall, and women in particular, participants raised a deep sense of concern about whether genes and gene sequences should be patentable. The reasons for opposition to patenting of genes and gene sequences rest on three primary grounds, each of which had about equal weight in expression, although upon discussion, the last factor tended to drive group opinion.

- Moral/Ethical concerns. *“Genetic information is something that is personal to us, and it can not and should not be turned into “property” – Vancouver participant*
- Questions about whether a gene/gene sequence is truly an invention. This issue had two related dimensions, equally important to the discussion:
 - A fundamental belief that a gene is something that is naturally evident, and therefore does not meet the test of being an invention, and should not be patentable.
 - A rejection of the argument that isolation of gene sequences in a lab represents an inventive step that justifies patentability. On this question, some respondents indicated that isolating gene sequences in

a lab was something that is relatively easy to do, which only underscored opposition to the premise that it represented “true” invention.

*“A gene is like an element of the periodic table, it is not something that some one invented, it is something that was discovered in nature”-
Montreal participant*

- Patenting a gene sequence might actually inhibit research. In some of the groups, participants suggested that the idea of patenting a gene or gene sequence appears to run contrary to the principle inherent in the “bargain” or rationale behind patenting; specifically, the facilitation of further research and innovation. From this point of view, research appears to be *inhibited* by allowing genes and gene sequences to be patented, because the patent holder has the right to control access to that gene or gene sequence which means that others cannot carry out research to develop new products. In the groups where this final argument was tabled and discussed in detail, it was often the case that the majority of participants decided that patenting of genes and gene sequences should not be allowed. In this context, the open-source model of patenting that the BC Cancer Agency is pursuing is a model that had a fairly broad appeal in groups.

The argument above, in combination with the rejection of the idea that isolating a gene in a lab represents an invention, were the most significant drivers of opinion against patenting of genes/gene sequences. In other words, this argument was often the determining factor in individual decisions about whether patenting of genes/gene sequences should take place.

It was in this area of acceptability of genetic applications and genes/gene sequences where the most pronounced demographic differences lay.

- Women tended to express more trepidation about acceptability in both genetic applications and gene sequences than men. In general, women were more likely to harbour concerns about moral/ethical considerations associated with these technologies than men, and those views, combined with concerns (held by all) about access/cost issues, tended to lead more women than men to oppose the idea of patenting in either applications or genes/gene sequences.
- Involved Canadians were as likely as others to raise concerns about moral issues and access issues associated with patenting, but in the

case of genetic applications, they tended to believe that the benefits outweighed those considerations. However, in the area of genes/gene sequences, involved Canadians tended to be heavily influenced by questions surrounding the rationale behind the allowability of such patents. In short, the more involved Canadians explored that rationale in detail, the more questions they tended to raise about allowing patenting of genes/gene sequences.

- The Toronto and Calgary groups tended to express more support for patenting (of both applications and gene/gene sequences) than groups in the other cities. Vancouver and Montreal groups tended to be less supportive in both areas, while Halifax fell between the other centres. However, we submit that those geographic differences were in significant part a function of the discussions themselves than the region or city.

Policy Issues & Safeguards

The final portion of the discussion focused specifically on perceptions of the patenting regime, the main element being a specific discussion about six current and potential safeguards that might be utilized within the regime.

In the realm of genetic applications, most participants generally felt that the patent system, as it stands, was reasonable in balancing the interests involved. Although, like patenting in general, there were a sizeable number of participants who felt that the current balance tipped slightly in favour of researchers and companies because of the profits they would be able to gain as a result of the monopoly power that the patent provided to them.

In the realm of genes/gene sequences, participants were less certain as to whether the patent system was reasonable in balancing the interests involved. This was chiefly because they had come to the conclusion that having patenting in the area of genes and gene sequences at all should not be allowed, because it was morally wrong or because it was seen to inhibit research in some instances.

The discussion of the six safeguards was carried out with a view toward understanding the one or ones that would be most effective in creating a system that struck the appropriate balance between spurring innovation and protecting the public interest. Participants discussed each of the six specific safeguards, and then an open discussion took place to determine which of the safeguards were most important to participants.

All of these safeguards were seen as being important in one form or another. Some safeguards were seen as absolutely essential cornerstones of the system and others were seen as supplementary elements that should be in place but would not be utilized all that often. In order of importance, the six safeguards are:

- Mechanisms to regulate prices of patented genetic health technologies, like the PMPRB

This was generally viewed as the most important safeguard that could be employed in the area of genetic applications. Essentially, participants believed that taking a version of the Patented Medicines Price Review Board (PMPRB) and employing it in this area was an appropriate step, because it helped to ease concerns about the most significant problem participants come across regarding patents, the idea of price gouging and

the limitation of access to products they need. Given that the PMBRB is already in place, participants saw that as a useful and relatively easy mechanism to broaden to include genetic applications and products.

"We already have something in place that I think would be easily applied to this area, so we should use it" – Vancouver participant

When asked specifically whether it might be an unreasonable step to set price limits on these products given the investment that researchers had put into these products, there was a broad consensus that such limits are reasonable to introduce. Participants are not worried about inhibiting research by having these kinds of measures in place, largely because they see that in the area of pharmaceuticals that it has not inhibited innovation or access to products. It indicates again that while participants are willing to allow patenting because of the benefits it generates, that willingness has limits and is only really maintained as long as those benefits are in evidence.

Because a PMPRB-type body was so widely advocated, the groups further explored two ways of operationalizing such a model, one that is similar in nature to the current model and another that is similar to the UK model on patenting of genetic applications. In the UK model profits are regulated through a process of auditing input costs by the firms involved and then assigning a price according to an assessment of the market in light of those input costs.

There was no consensus on which of the two models was preferable. Overall, those who expressed the most trepidation about patenting in this area tended to lean toward the "profit-regulation" model, because they felt that that this would significantly help to address their concerns about access and cost issues.

"I think we ought to regulate their profits....that's the fairest way to do it because then they can make their money back and we pay a reasonable price for the products" – Vancouver participant

Those who tended to believe that patenting should be allowed in this area tended to believe that a quasi-PMPRB model would be most appropriate, because it is a system that works now and because it would be relatively easy to operationalize (these people felt that the profit regulation model would necessitate significant cost and require extensive bureaucracy to administer).

"The idea of sending auditors into companies to assess how much it cost them to develop products sounds like a lot of bureaucracy, I think that using the current approach for drugs will be less bureaucratic and still ensure that prices aren't as high as they are in places like the US" – Calgary participant

- Excluding certain products or processes from patentability

This measure was seen as very important to have in place by many participants, particularly members of the general public who had not known much about this field before participating in the focus group. Because so many participants possess a sense that there are no parameters to guide these technologies right now, the fact that some types of research and applications are excluded gives many participants a sense of comfort that someone in a position of authority is considering and addressing these issues. Most importantly, going forward, with a measure like this in place, participants have a sense that there is a tool available to set further limits as more of these controversial technologies are developed.

- Safeguards to allow the government to infringe on a patent

This measure was seen as important to have in place, although most focus group participants believed that it should only be used in extreme or emergency circumstances, such as an epidemic. When informed that this safeguard had not been used before, participants offered a clear view that governments should feel that it should use this measure where appropriate. A handful of participants wanted governments to utilize this mechanism more routinely when dealing with cases where patent rights are abused in a way that could jeopardize lives, rather than the more stringent test of only allowing it in an epidemic situation.

- Compulsory licensing

The idea of compulsory licenses was seen as an important mechanism to govern patenting of genes and gene sequences. While many focus group participants would prefer that genes/gene sequences not be patentable at all, if it was felt that such a significant change were impossible to make, this was seen as an important measure to have in place. This measure was seen to be essential to ensuring that the principle of spurring innovation that underlies patenting is maintained.

In the area of applications, a price setting system like the PMPRB was seen as the best way to govern the system, but it was also felt that a compulsory licensing system was necessary as a “stick in the closet” to ensure that products are made available to those who wish to use it at a reasonable price.

- Safeguards to ensure innovation and protect basic research

Most participants could not see that they would have a personal stake in this measure, so it did not always rank as highly as some other measures. However, a number of the involved Canadians expressed strong views that this measure ought to be codified. It was also viewed as crucial to have in place, to maintain the principle of innovation, and to ensure that university researchers and others in the public realm have the opportunity to conduct basic research – this belief flows directly from the principle that patenting is geared toward facilitating more research and more innovation. If it truly does that, participants can find it acceptable. Participants felt that if the government is serious about advancing science and preventing disease, it has to do this.

- Mechanisms to challenge a patent

There were mixed views expressed about this measure. Some participants felt that this would be a very compelling safeguard, particularly to address moral or ethical considerations associated with a patent that was granted. At the same time, there were some concerns raised that fringe groups could bring spurious challenges to patents, and this might inhibit progress in the development of and access to important and needed products.

Finally, the groups were invited to discuss the extent to which these six safeguards ought to be implemented, specifically whether implementing all or most of the safeguard measures would affect research or innovation. Overall, there was not a consensus on this issue. Among most focus group participants, there was a general sense that some of these safeguard mechanisms would be relatively active, whereas others would only be used in certain clearly specified circumstances. As such, many felt that a regime that employed all of these measures would not necessarily have a significant negative affect on investment/innovation in this area.

This point of view was not universally shared, however. There were some participants who expressed strong concerns that a regime that included

all of the safeguards would prove to be overly arduous and might dampen innovation as well as investment in Canada.

The Role of Moral Considerations

Focus group participants were invited to weigh in on the extent to which moral considerations ought to be included in the patent regime.

The overwhelming view was that indeed such considerations ought to be included, at question was how it should be included. Participants were informed that right now the patent system sees its functions as being mostly “value neutral”. This means that it follows the criteria set out in the *Patent Act* and if a product meets the tests of patenting, it is accepted. Apart from the notion of usefulness, there is no value judgment on whether it is good or bad for the health system or for society to patent a particular product.

Overall, most participants preferred that these considerations should not be built into the patent approval process per se. By and large, participants believed that the current arrangement, where parliament and the courts play the role of adjudicating on moral issues, is the best way to go about addressing these issues. Participants were not sure that the patent office had the appropriate moral authority vested in it to play this kind of a role, or that the individuals who worked in that role were not appropriate to carry out that function. Moreover, it was felt that the Patent Office had no direct accountability to citizens or to the Charter of Rights as legislators and the Supreme Court do.

“People in the patent office are lawyers and bureaucrats, they have no experience or expertise on moral issues, so they are not appropriate to play that kind of role” – Toronto participant

Appendix – Moderator's Guide

Introduction and Warm-up (5 min)

The moderator will take a few minutes to go around the table and ask 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

The field and applications of the technology (15 min)

I'm going to read a couple of words to you, and I want to know whether you have heard of it, and whether the word/phrase has a negative connotation, a positive connotation, no connotation to you:

1ab
2ab

Human Genomics
Biotechnology

3a { Definition: Biotechnology is a term that covers a range of scientific applications and tools that utilize genetics and genetic information. Human Genomics is a specific area within the broad field of biotechnology, and it involves work in the specific area of genetics, like the Human Genome Project. Some examples of genomics include genetic testing for inherited diseases, gene therapies, and genetic modification of cells). This discussion will focus on Human Genomics.

3a → c

Have you heard of the Human Genome project? What do you know about it? 3c

4

How important do you think research in this field will be to the future of health treatment/Health Care?

5

Can you think of any other applications in this field?

I'd like to start by discussing a few applications, first asking whether you have heard of it, then whether you have a favourable or unfavourable view about it, and why. Discuss risks and benefits, and moral/ethical issues associated with the applications.

(DISCUSS 2-3, ROTATED FOR EACH GROUP)

6a → d

New types of health treatments, such as gene therapies or new types of medicines that are developed using biotechnology.

7a → d

New types of health tests, such as genetic testing for certain inherited diseases (CF, Huntington) or common diseases (cancer, cardiovascular) and diagnostic tests for infectious diseases like SARS and West Nile virus
New types of health research, like the discovery of a gene in mice that triggers certain types of cancer, that is the same gene as found in humans

8a → d

New types of research into behavioural genetics, such as identifying genes that predispose people to experience alcoholism or mental health problems.

Patenting (15 minutes)

Now I would like to briefly discuss the subject of patenting with you. You all read the discussion paper that was circulated in advance of this discussion.

9a See paper in annex.

9abc

From what you read about patenting, were there any facts that were different than what you had previously understood? What was consistent with what you previously understood?

10ab

What are some of the benefits and drawbacks of patenting? (Do the benefits of patenting outweigh the drawbacks, or the reverse?)

Gene Patenting (45 mins)

I'd like to discuss patenting in the area of genes or DNA.

11a → f

What is gene patenting? From what you know, how does it differ from patenting in other areas (as described above)? Research in the area of human genomics has led to the patenting of genes and gene sequences, if they meet the three tests of being an invention. These three tests are the same as described above: Novelty, which means that the invention must be new, and cannot have been described previously in any source; non-obviousness, meaning that it can't be something that is obvious to anyone with scientific expertise in the area; utility or usefulness, which means that it must have commercial viability (it must work and have a purpose).

11d (DESCRIBE IF NECESSARY) Something is an invention if it would not exist in the form described in the patent claim without human intervention. For example, the discovery of a new chemical element as it occurs in nature can not be patented. In the context of human DNA, as long as the form in which DNA sequence is claimed would not exist in nature without human intervention, the sequence may be subject of a patent claim (e.g. DNA sequence in isolated form; DNA sequence together with another sequence, etc.). What is particular to patents in the area of genomics is that they are essentially based on purification & isolation of naturally occurring material (DNA, genes, and now proteins). The inventive component is the isolation of a pre-existing molecule.

11e Under the Canadian patent regime, patents may be granted over DNA sequences, on ways of making DNA sequences, or on ways of using DNA sequences. In other words, both the isolated genes or gene sequences that are proven to cause a certain outcome (such as a disease, like CF) are patentable, just as the applications that come from that gene or gene sequence once isolated are (such as a test that is developed to determine whether a person has the gene for CF). Like other patents, a patent on the DNA sequence itself provides a 20 year monopoly for the product, enabling them to have the exclusive right to license the technology or if they choose prevent others from making, using, selling or importing that DNA sequences for any purpose, short of pure non commercial research. Patents are not allowed for higher life forms that have been genetically modified in some way

11f Were you aware or unaware that certain genes and gene sequences are patentable, such as (use examples from beginning of the guide)?

12a → c How do you react to this? 12a Do you think it is necessary and appropriate to have patents in this area, or not? Why? 12b 12c

13ab In your view, is there a difference between gene patenting and other types of patenting? If so, what is the difference? 13b

14a → c Do you have issues/concerns about this? 14a What are they? 14b Do they differ depending on the application you are discussing, or is it basically the same set of issues for all applications? 14c

15ab Do you think there is a correlation between access to health care/treatments and patenting? 15a Do you think there is less access because of patenting, or more access because of it? 15b

16ab

When we take into account how to deal with patenting, should we take into account the cost of the public health care system now? How should we do that? 16b 16a

17a → d

Is it reasonable to say that, given that Canada's health care system has high and growing costs associated with it, price limits be set for producers of these kinds of genomics products? Regardless of how much it cost to develop the products? Is there a downside to doing this? How serious is this downside? 17a 17b 17c

18ab

Do you think that the ability of researchers to patent their inventions helps promote health research and the development of new products? If so, to what extent? 18b 18a

19a → c

19a

Right now the patent system sees its functions as being "value neutral". This means that it follows the criteria set out in the *Patent Act* and if a product meets the tests of patenting, it is accepted. There is no value judgment on whether it is good or bad for the health system or for society to patent a particular product. Do you feel that patenting is "value neutral"? How should ethical and social issues be addressed in the patent system, if at all? 19b 19c

20a → c

In legislation and through court cases certain types of research have been outlawed, and some types of products that are banned from being patented, such as teaching methods. There have been suggestions that decisions have been affected by moral considerations. Do you feel that ethical and social issues associated with these issues should be taken into consideration in the assignment of gene patents? How so? 20a 20b
There are arguments for and against the idea of gene patenting. What are some of those arguments? 20c

Common info

Some of the arguments are in italic below:

Those opposed say that:

Patents might limit the ability of people and health care systems to use the products developed through these technologies

Patenting increases the cost of new research, because people who want to do research on certain genetic lines have to pay fees to access patented inventions

Patenting has the potential to inhibit research because companies may choose not to allow their patented sequences to be "licensed" for research, at any price

The gene patents have been granted that are considered to be too broad and have therefore ended up limiting research

Patenting genes commodifies life, and is morally wrong.

Common
info

Advocates say that:

This gene-based innovations 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 gene patenting, which means that research will be occurring in those countries, and that Canadian companies and researchers will be at a substantial disadvantage if it is prevented or made more difficult.

Allowing gene patents means Canadians will gain access to the health and medical benefits from these products more quickly.

Because of the economic benefits of this research taking place in Canada # gene patenting will improve the standard of living of Canadians.

Without patents, the inventor would protect their invention through trade secrets. (A trade secret is a formula or information about an invention that is protected by the holder from others, but with no period of monopoly. The formula for Coke is an example of a trade secret.). The result would be that the scientific information would not be shared with the rest of the research community.

21 What is the strongest argument in favour of allowing gene patenting?

22ab What is the strongest argument against it? Why do you say that? ^{22a} ^{22b}

23abc Overall, which do you subscribe to? The arguments for, or against patenting? ^{23a} ^{23b}

Test for strength/depth of support for the positions taken with each respondent ^{23c}

In fact, this area is one that is relatively new to the area of patenting, and some recent cases have brought to light some new and unique issues that may affect the way in which some people look at the patent system in this area. Discuss briefly:

Myriad

24a
Case.

In October 2001, Myriad Inc. was granted by the Canadian Intellectual Property Office a series of patents on two gene mutations for breast cancer: BRCA1 and BRCA2. The patents granted cover the DNA sequences, the role of the gene in breast cancer and the diagnostic tests derived. The result is two-fold. Myriad has insisted that it carry out all tests for the complete sequence for BRCA 1 or 2 at its Seattle facility, at a

cost of \$4000 US per case, or that tests for the partial sequence be carried out at a facility licensed by Myriad (also at a higher cost than what is charged by a non-licensed facility). Myriad argues that it has the right to prevent all others from making, using, selling or importing the DNA sequences or any diagnostic tests being developed using these DNA sequences.

The government of Ontario, as well as governments in other jurisdictions are challenging the fact that the patent holder of a patent on a gene or gene sequence (i.e. Myriad) can prevent anyone from even looking at the gene sequence and as such has control over all potential tests, treatments and drugs that involve that gene. Until the scope of Myriad's patent is challenged in front of a Canadian court, it is impossible to affirm whether Ontario will be in infringement of Myriad's patent while offering its new screening test.

24b.

BC Cancer Agency

The BC Cancer Agency (BCCA) is the agency along with several collaborators (NML, Winnipeg; Univ of Victoria, CDC Vancouver) that discovered the genetic composition of the SARS virus. BCCA have applied for patent protection for their invention, but in the meantime have advocated using a version of "open source" patent licensing. This idea of open sourcing is most known in the context of software, and it means providing access to the source code of a software program to allow easy access to the core code that can be improved upon with the only condition "that the improvement will also be revealed publicly and distributed freely in a process to encourage continual innovation". The open source model is not necessarily to give access for free to the source code but to give users certain freedom with the source code without having to pay royalty or for a very low royalty.

Various analogies have been utilized in the literature between programming a software and sequencing a genome. As such, the idea to import the open source model into the biotechnology sector might be an interesting approach, which could potentially resolve some concerns expressed with respect to access and cost.

In the context of genetic inventions, the open source model would consist of giving access to the sequence data of a genome (the sequence data being the source code) for free or a very low royalty. There is no direct commercial value associated with the sequence, which remains a free material to be used. However, the license granted allowed the author/inventor of the sequence to have a "droit de regard" on the use of

this sequence and to impose that the licensees respect certain conditions such as the free redistribution of the improved sequenced data. BCCA would also like to support the development of a Canadian SARS patent pool, where all SARS patents obtained by Canadian researchers/companies/institutes will be regrouped and managed by a unique entity (to be determined). Licence fees will be uniform and low in order to encourage broad use of the Canadians data and inventions and encourage collaborative research and treatment development.

It should also be noted that a goal of the non-exclusive licensing is to also provide commercial entities desirous of developing "products" (which would be their own separately patentable subject-matter) the freedom-to-operate where the commercialization of their product(s) is concerned. It is felt that this approach would serve to improve access to core "technology" and ultimately serve the public interest of the rapid developments of new and needed products as well as the private sectors needs as noted above.

24c When you hear about these cases, does this affect how you view the situation, and the benefits/drawbacks of patenting in this area?

Policy Options (40 mins)

25 First off, in your view does the system as it stands now seem to you to be reasonable (balancing the interests involved), or not?
There is a debate occurring worldwide, including in Canada, about these issues, specifically whether the current governance approach in this area is appropriate in this area or whether another model should be considered. Australia, the UK, the EU, and other developed countries are assessing the patent system as it applies to human genetics. The main focus of decision makers is whether the system as it currently operates does strike the right balance between facilitating innovation and serving the public interest.

26a
Comments Patent systems in Canada and elsewhere contain a range of different mechanisms that can be used to ensure that patents are appropriate, and balance the interests of patent holders and the general public. Not all countries use the same mechanisms, and some may be included in patent legislation, but rarely used. Possible mechanisms include:

Excluding certain products or processes from patentability
Safeguards to allow the government to infringe on a patent
Safeguards to ensure innovation and protect basic research
Compulsory licensing
Mechanisms to challenge a patent

Mechanisms to regulate prices of patented products ^{27b}

27a-c

27b-c

What kinds of safeguards or mechanisms do you think should be built into the patent system to balance all interests? To what extent would the exceptions/safeguards and limits on what is patentable resolve any concerns you may have over gene patenting? ^{27c}

Which of these mechanisms seem useful or appropriate to you, or not? ^{28a}

28a-c

Why is that? What are some of the benefits and drawbacks of these approaches? ^{28b}
^{28c}

Which do you think are the most appealing mechanisms or safeguards, or combination? ^{29a} Least appealing approach? ^{29b}

29ab

30

Overall, which of them do you think strikes the best balance between ensuring access to health care products and facilitating research and discoveries?

31

Overall, is it your view that 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?

Discussion Paper: Intellectual Property - Patents and Genes

Patents in Canada: A Primer

What is A Patent?

A patent is a grant of a term-limited monopoly for an invention, in exchange for disclosure of the "formula" or information that produced that invention.

There are two basic elements that form the basis of a patent system: to provide incentive for those to develop new products, and to ensure society can benefit from the development and contribution of knowledge that others can learn from. The patent system is supposed to establish an equilibrium between private monopoly and public domain.

Patents are granted for many different types of inventions, from types of tools or machines like a Hydrogen fuel cell engine, to computer software programs like Microsoft Windows, to health products like Tylenol.

In the Canadian Patent Act, an invention is defined 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".

In order to get a patent on a product, inventors must submit the product and the process from which it was created to the Canadian Intellectual Property Office, or CIPO, where the product is judged to warrant a patent or not.

In order to meet the "criteria" of being an **invention** under Canada's Patent Act, a product must meet three tests:

1. **Novelty**, which means that the invention must be new, and cannot have been described previously in any source. Something is an invention if it would not exist in the form described in the patent claim without human intervention.
2. **Non-obviousness**, meaning that it can't be something that is obvious to anyone with scientific expertise in the area;
3. **Utility**, which means that it must have commercial viability (it must work and have a purpose).

What does a patent provide to the patent holder?

In Canada, a patent provides its holder with the right to make, use, sell or import the invention for 20 years from the point of patent approval. In exchange for these rights, the information contained in the patent application is disclosed, within 18 months of the date of filing the application, to the general public so that further innovation is stimulated.

In the case of products that require regulatory/safety approval, like pharmaceutical products, the patent claim begins as soon as the patent is approved, before government regulatory and safety evaluation processes take place. Typically it takes about 7 years for regulatory approvals of these kinds of products to take place, so the monopoly rights

in the commercial sphere for products requiring regulatory approval is usually about 13 years.

In Canada, the patenting system is essentially the same as found in other countries like the US, UK, and Japan.

According to those who do research and develop products, without patent protection, there is no incentive to invest the significant resources required to develop products, because others could simply take the result of their work and use it to produce the invention themselves, without having done any of the original work to study and test it.

Others say there are negative impacts of patenting that make patenting an unappealing idea. The most widely held criticism is that patents serve to limit people's ability to use or have access to products, because the monopoly power that is assigned to patent holders results in products being expensive.

Patent Protection in Biotechnology/Genetics

Research in the area of biotechnology has led to the patenting of genes/DNA and gene/DNA sequences within the genetic structure of organisms, which are usually created in order to develop health products or applications (like vaccines, treatments for diseases, or genetic tests for diseases, for example). In Canada, genes/gene sequences can be patented if they meet the three tests of being an invention. The three patent "tests" are the same as for other products, as described above: Novelty; non-obviousness, and utility.

Like other types of products, in the area of DNA patenting something is an invention if it would not exist in the form described in the patent claim without human intervention. Typically the type of research that produces patents focuses on purification & isolation of naturally occurred material (usually molecules or proteins that exist in genes or gene sequences) that are then turned into applications. The inventive component is the isolation of a pre-existing molecule or set of molecules.

In the area of biotechnology, a patent may be issued 1) over DNA sequences, 2) on a way of making DNA sequence, or 3) on ways of using DNA sequences. In other words, both the genes or gene sequences that are proven to cause a certain outcome (such as a disease, like CF (Cystic Fibrosis)) are patentable, just as the applications that come from that gene or gene sequence are (such as a test that is developed to determine whether a person has the gene for CF).

Patents are **not** allowed for higher life forms, or entire "multicellular" organisms that have been genetically modified in some way. A supreme court ruling last year ("The Harvard Mouse" case) confirmed that this was **not** allowed under the provisions of the Canadian Patent Act. So whole organisms cannot be patented; only genes or gene sequences that have met the tests of being an invention can.

Like other patents, a patent on the DNA sequence itself provides a 20 year monopoly for the product, enabling the holder to have the right to use and license the technology or (if they choose) prevent others from making, using, selling or importing that DNA sequence for any purpose, with the exception of non-commercial research (basic research that has no potential means of economic gain for the researcher).

The way the system works now is that scientists/companies make investments in research and seek to commercialize applications of that research, the 20 year period helps them to recoup their investments and make a profit, which are in many cases 7-10 years in development and safety assessments once a patent is granted.

Patents are in place now for many products and processes used in health care such as pharmaceutical products, medical equipment, diagnostic kits, and other medical products. In the area of genes and gene sequences, patents are in place for many applications, some examples including the tests for genetic causes for breast Cancer, genetic tests for SARS, and gene therapies for diseases like MS.

Health care researchers and biotechnology companies (small and large) in Canada actively pursue patent protection for the gene or protein-based inventions they produce. That is because these industries are often characterised by high-risk research, significant costs of R&D and compliance with regulatory process involving significant disclosure. Moreover, many researchers fear that if they don't get a gene/gene sequence patented, they will not be able to work in that area if someone else patents it first.

In a study conducted by Ernst and Young in 1999, 90% of the Canadian biotechnology firms surveyed indicated they were protecting their most valuable technology with patents, regardless of whether they had produced a product from that patented material or not. The primary reasons why these firms apply for patents are the competitive advantage this form of protection gives and the fact that most investors seem to refuse to invest in a biotechnology project that is not protected by a strong patent portfolio.

Safeguards and Exemptions

There are safeguards in the patent system that limit patent holder rights in certain circumstances. Overall, it is important to note that safeguards tend to be used only in exceptional circumstances, and that the Canadian Intellectual Property office has generally not allowed or utilized these provisions in its decisions about what is patentable or not in the area of genetics.

Government use provision. The *government use* or *public interest provision* enables governments to suspend a patent if there is a legitimate public interest need to access and utilize the product. An example might be a situation where there is a serious disease outbreak and a patented treatment is the only product that can be used to treat it. In that case the patent would be suspended in order to ensure production of appropriate amounts of a product were produced. This public interest provision has

never been used in this area, and is generally treated similarly to the “notwithstanding clause” in Canada’s constitution – it would take a very serious event to warrant its use.

Research/Experimental use exemption: Research/experimental use exemptions apply to philosophic research i.e research with no aim to produce commercialized products. In other words, researchers are exempted from having to follow patent rules if their work is entirely non-commercial in nature.

Subject matter exclusions: Following case law, multicellular organisms, natural biological processes, substances as they naturally occur in nature and methods of treatment of human and animals such as surgical treatment are also considered as non patentable subject matter.

Compulsory licensing: A compulsory license allows the patent officer to seek a compulsory license that can be provided to another party in case of abuse by the patent holder. The purpose of compulsory licensing is threefold:

1. It is a way to prevent a patent holder from restricting access to basic research tools or essential diagnostic and therapeutic products.
2. It is a way to prevent prohibitive or anti-competitive licensing terms with respect to basic research tools or products.
3. It might be a way to avoid license arrangement where research tool patent holder will claim an ownership interest in anything developed using that tool

The rationale behind compulsory licensing is to ensure the use of a patented tool without permission by the patent holder for a reasonable fee. Usually before obtaining a compulsory license, a third party has to demonstrate attempt to negotiate directly a license with the patent holder without success.

Canada had compulsory licensing until the early of the '90 but since NAFTA conditions for compulsory licensing have been narrowed significantly, so there is some gray area in the law as it applies to compulsory licensing at this time. Legally, prior to granting a compulsory licensing, proof has to be made that reasonable efforts were made to reach an agreement from the right holder on reasonable commercial terms and conditions.

Document de Discussion:

Propriété Intellectuelle - Brevets et Gènes

Brevets au Canada: Une introduction

Qu'est-ce qu'un brevet?

Un brevet est une sorte de permis octroyé par le gouvernement, qui fait d'une invention la propriété exclusive de son inventeur. Pour une période de temps limitée, il confère à l'inventeur le droit d'empêcher quiconque de fabriquer, d'employer, de vendre ou d'importer l'invention sans son autorisation. Les brevets peuvent être achetés, vendus ou une tierce partie peut en obtenir une licence d'exploitation moyennant des frais.

Pourquoi émet-on des brevets?

Les systèmes de brevets ont été créés pour deux raisons principales: procurer un incitatif financier à ceux qui développent de nouveaux produits, s'assurer que tout le monde est au fait de l'existence de la nouvelle invention dans le but de faire progresser les connaissances du public, et que la société puisse bénéficier du développement de nouveaux produits. Le but d'un système de brevets est de créer un équilibre entre les intérêts de ceux qui sont intéressés au développement de nouvelles technologies et les intérêts de ceux qui souhaitent avoir accès cette technologie.

Des brevets sont accordés pour plusieurs types d'inventions, des outils ou machines comme le moteur à piles à combustible, aux logiciels informatiques comme Microsoft Windows, en passant par des produits pour la santé comme Tylenol. Au Canada, le système de brevets est à plusieurs égards semblable à ceux de ses principaux partenaires commerciaux, comme les États-Unis, le Royaume-Uni et le Japon, bien qu'il existe quelques différences.

Que peut-on faire breveter?

Au Canada, la *Loi sur les brevets* définit une invention comme "Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité".

Pour obtenir un brevet sur un produit, les inventeurs doivent soumettre une description du produit et du processus qui a mené à sa création à l'Office de la propriété intellectuelle du Canada, ou OPIC, où le produit et/ou le processus est évalué afin de déterminer si oui ou non il peut faire l'objet d'un brevet.

Pour être reconnu comme une **invention** en vertu de la *Loi sur les brevets* du Canada, un produit doit rencontrer 3 critères :

1.

Nouveauté, qui signifie que l'invention doit être nouvelle et n'a jamais été préalablement décrite dans une référence documentaire. Une chose est une invention si elle ne peut exister dans la forme décrite dans la demande de brevet sans intervention humaine.

2.

Apport inventif, qui signifie que l'apport ne peut être quelque chose d'évident pour des gens de compétence technique ou scientifique moyenne dans le domaine en cause ;

Utilité, qui signifie qu'il doit fonctionner, avoir une fonction utile, et être viable comme produit ou processus.

Que procure un brevet à son détenteur?

Au Canada, un brevet confère à son détenteur le droit exclusif de fabriquer, d'employer, de vendre ou d'importer l'invention. Si d'autres personnes souhaitent utiliser l'invention, elles doivent obtenir l'autorisation du détenteur, et doivent normalement payer des frais. 18 mois après la date de demande du brevet, les renseignements contenus dans cette demande sont rendus publics afin que les gens puissent prendre connaissance de l'invention. Ceci peut encourager la recherche et développement dans le même domaine, et permet aux consommateurs de savoir quand un nouveau produit a été développé.

Combien de temps dure la protection conférée par un brevet?

Normalement, les brevets durent 20 ans à partir de la date de dépôt d'une demande de brevet qui a éventuellement été accordée. Après cette période, quiconque peut fabriquer ou employer l'invention sans restrictions. Dans le cas de produits qui requièrent une approbation de sécurité ou réglementaire, comme un médicament ou un appareil médical, l'invention est protégée par le brevet dès qu'il est accordé, avant que les processus d'évaluation réglementaire et sécuritaire du gouvernement soient complétés. Généralement, 7 années peuvent être requises pour que les approbations réglementaires pour les nouveaux médicaments ou les appareils médicaux soient complétés. Ainsi, le droit exclusif de l'inventeur de fabriquer et de vendre le produit est habituellement inférieur à 20 ans.

Quels sont les avantages et les inconvénients des brevets en général?

Selon plusieurs personnes qui développent de nouveaux produits, la protection que confère un brevet constitue un incitatif majeur à l'investissement des ressources substantielles nécessaires au développement de produits. Sans les brevets, d'autres personnes pourraient tout simplement s'emparer du résultat de leur travail et l'utiliser pour produire l'invention eux-mêmes, sans avoir réalisé le travail initial qui consiste à l'étudier et à la tester.

D'autres affirment que les brevets peuvent avoir des impacts négatifs, selon la manière dont les droits sur les brevets sont utilisés, ce qui peut affecter la recherche scientifique

et le public. La critique la plus répandue consiste à dire que les brevets servent à limiter la capacité des gens à utiliser ou à avoir accès aux produits, puisque les détenteurs de brevets peuvent faire payer plus cher pour leurs produits brevetés en sachant que personne d'autre ne peut produire le même produit à moindre coût sans enfreindre le brevet. Certains chercheurs affirment que leur travail est limité par certains brevets, notamment par les brevets protégeant des outils de recherche comme les tests médicaux ou les nouveaux types d'équipement de laboratoire.

Est-ce que les gènes et les séquences d'ADN sont protégés par les brevets?

Les brevets existent actuellement pour plusieurs produits et procédés utilisés dans les soins de santé, notamment pour les produits pharmaceutiques, de l'équipement médical, des trousse de diagnostics, et autres produits médicaux. Dans le domaine des gènes et des séquences géniques, les brevets existent au niveau de plusieurs applications, incluant les tests pour déterminer les causes génétiques du cancer du sein, les tests génétiques pour dépister les maladies infectieuses, et la thérapie génique pour des maladies comme la sclérose en plaques.

Au Canada, les chercheurs en soins de santé et les compagnies de biotechnologies (petites et grandes) recherchent activement la protection que peut leur procurer un brevet sur les inventions liées aux gènes ou aux protéines qu'ils produisent. Ces industries entreprennent souvent des recherches à haut-risque impliquant des coûts considérables en recherche et développement, ainsi que des années de travail pour se conformer aux processus d'examen réglementaires. De plus, plusieurs chercheurs craignent que s'ils ne font pas breveter un gène ou une séquence génique, ils ne seront pas en mesure de travailler dans ce domaine si quelqu'un d'autre le brevète avant eux.

Les gènes humains tels qu'ils existent dans notre corps ne peuvent être brevetés, puisqu'ils ne constituent pas des inventions. Toutefois, des copies de gènes isolés ou manipulés en laboratoire peuvent être brevetées. Les tests génétiques pour diagnostiquer la probabilité d'existence d'une maladie peuvent être brevetés, tout comme les gènes qui ont été modifiés pour être utilisés dans les thérapies géniques, ou les gènes produisant des protéines à caractère thérapeutique. Au Canada, les gènes/séquences géniques peuvent être brevetés si elles passent les trois tests requis pour obtenir le statut d'invention. Les trois "tests" de brevet sont les mêmes que pour les autres produits, tels que décrits plus haut : nouveauté, apport inventif et utilité.

En quoi les brevets sur les gènes ressemblent aux autres types de brevets?

Comme pour les autres types de produits, dans le domaine des brevets liés à l'ADN, une chose est une invention si elle ne peut exister dans la forme décrite dans la demande de brevet sans intervention humaine. Généralement, le type de recherche aboutissant à des brevets se concentre sur la purification et l'isolement de matière se produisant naturellement (habituellement des molécules ou des protéines existant dans les gènes ou dans les séquences géniques), qui est ensuite transformée en applications, tels les tests et thérapies. La composante innovatrice est l'isolement d'une molécule ou d'un groupe de molécules déjà existants.

Un brevet peut être accordé 1) sur des séquences d'ADN, 2) sur une manière de fabriquer une séquence d'ADN, ou 3) sur les manières d'utiliser des séquences d'ADN. Autrement dit, à la fois les gènes isolés ou les séquences géniques trouvés responsables de produire un certain résultat (par exemple une maladie, comme la fibrose kystique) sont brevetables, de la même manière que les applications provenant de ce gène ou de cette séquence génique le sont (par exemple, un test mis au point pour déterminer si une personne possède ou non le gène de la fibrose kystique).

Comme les autres brevets, un brevet sur une séquence d'ADN confère un monopole de 20 ans sur le produit qui en résulte, permettant à son détenteur d'avoir le droit d'utiliser et d'autoriser la technologie ou (s'il le choisit) d'empêcher que d'autres fabriquent, emploient, vendent ou importent cette séquence d'ADN pour quelque raison que ce soit, à l'exception de la recherche non-commerciale (recherche fondamentale qui ne peut présenter de gains économiques potentiels au chercheur).

À quel point les brevets sont-ils importants pour la recherche biotechnologique?

Dans une étude menée par Ernst & Young en 1999, 90% des entreprises canadiennes de biotechnologie sondées ont affirmé protéger leur technologie ayant le plus de valeur par des brevets, même dans les cas où elles n'avaient pas encore élaboré de produits au moyen de la technologie brevetée. Ces entreprises déposent des demandes de brevets pour deux raisons principales: plusieurs investisseurs refusent d'investir dans un projet biotechnologique qui n'est pas protégé par un brevet, et la protection que confère un brevet leur procure un avantage sur les concurrents qui pourraient développer des produits similaires.

Système de biens et de contrepoids: Sauvegardes, Exemptions et Exclusions

Il existe une série d'outils et de politiques que les gouvernements utilisent dans le système de brevets qui limitent les droits du détenteur d'un brevet dans des circonstances spécifiques, afin d'établir un équilibre entre le détenteur de brevets et l'intérêt public. Le système canadien de brevets, comme celui d'autres pays, contient des clauses qui peuvent être utilisées pour empêcher certains produits d'être brevetés ou limiter la portée des brevets, pour suspendre temporairement les droits des détenteurs de brevets ou pour s'assurer que les produits brevetés sont accessibles aux chercheurs et au public. Des sauvegardes et des clauses comme celles décrites ci-dessous sont utilisées selon certaines combinaisons d'un pays à l'autre. Établir ou renforcer tels mécanismes au Canada pourrait permettre de résoudre certains des impacts non intentionnels ou indésirables du système de brevets.

Exclusions en fonction du sujet: Il existe des inventions qui ne sont pas brevetables à cause du sujet qu'elles touchent, comme par exemple une méthode d'enseignement, un principe scientifique, une théorie scientifique abstraite ou une méthode de traitement médical. Les éléments chimiques nouvellement découverts ne peuvent non plus être brevetés (incluant les éléments semblables à ceux que l'on retrouve dans le tableau périodique des éléments, comme le fer, le carbone, l'hydrogène, etc.)

Sauvegardes pour permettre au gouvernement d'enfreindre un brevet: Les gouvernements peuvent, dans des circonstances très particulières, suspendre un brevet s'il est dans l'intérêt public légitime d'avoir accès et d'utiliser le produit. Par exemple, il pourrait survenir une situation où le seul traitement possible à une grave épidémie serait un traitement breveté. Dans un tel cas, le brevet serait suspendu pour s'assurer qu'une quantité adéquate d'un produit puisse être fabriquée. Jusqu'à aujourd'hui, la clause de l'intérêt public n'a jamais été utilisée dans le secteur de la santé au Canada.

Sauvegardes pour assurer l'innovation et pour protéger la recherche fondamentale: Les chercheurs n'ont généralement pas à suivre les règles liées aux brevets si leur travail est de nature strictement non commerciale. Les systèmes de brevets se servent des exemptions pour la recherche et l'expérimentation pour s'assurer que la recherche philosophique sans objectif de produire des produits commercialisables puisse être menée par des personnes, des universités ou des instituts publics de recherche.

Licence obligatoire: Une licence obligatoire peut être délivrée par le gouvernement pour permettre à une tierce partie l'utilisation d'une innovation brevetée à frais fixes, dans le cas d'abus de la part du détenteur du brevet.

La logique derrière la licence obligatoire est d'assurer l'utilisation d'un outil breveté sans la permission du détenteur du brevet à un coût raisonnable. Habituellement, avant d'obtenir une licence obligatoire, une tierce partie doit démontrer qu'elle a tenté de négocier directement avec le détenteur du brevet, et que cette tentative s'est soldée par un échec.

Le Canada appliquait la licence obligatoire pour les produits pharmaceutiques jusqu'en 1993, date à laquelle des changements ont été apportés à la *Loi sur les brevets*, principalement pour harmoniser ses politiques avec celles de ses partenaires commerciaux à l'étranger et pour se conformer aux obligations commerciales internationales. En retour d'une protection accrue des brevets par l'élimination de ce système de licence obligatoire, l'industrie pharmaceutique s'est engagée publiquement à augmenter de manière significative les montants qu'elle investit annuellement en recherche et développement. Pour s'assurer que les détenteurs de brevets dans le domaine pharmaceutique n'exigent pas de prix excessifs, le gouvernement a mis sur pied le Conseil d'examen du prix des médicaments brevetés (CEPMB).

Enfin, dans des cas très spécifiques d'abus commerciaux ou non concurrentiels liés aux brevets, le gouvernement peut toujours obtenir une licence obligatoire pour une tierce partie, afin de limiter les entraves aux échanges ou au commerce dans ce domaine spécifique.

Mécanismes pour contester un brevet: Des procédures d'opposition peuvent être utilisées dans certains systèmes de brevets pour permettre que ces derniers puissent être contestés par un jugement (semblable à un processus d'appel dans le système judiciaire, mais mené par le Bureau des brevets ou toute autre entité administrative). Citons comme exemple la procédure d'opposition de l'Office européen des brevets. Dans les 9 mois suivant l'obtention d'un brevet européen, quiconque peut loger une contestation contre ce brevet dans le but d'obtenir sa révocation ou d'en limiter sa portée.

Mécanismes de régulation des prix des produits brevetés: Des systèmes administratifs peuvent également être mis en place pour limiter les prix des produits brevetés en vue de protéger l'intérêt public. Le Conseil d'examen du prix des médicaments brevetés (CEPMB) en est un bon exemple. En effet, il exerce un contrôle sur le prix des médicaments brevetés – les autres technologies médicales brevetées ne font pas partie de leur examen.