Canadian Biotechnology Advisory Committee
Expert Working Party on
Human Genetic Materials, Intellectual Property, and the Health Sector

What We Heard . . .

at the Multi-Stakeholder Roundtable

Report of Roundtable 6
March 30, 2005

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What We Heard . . .at the Multi-Stakeholder Roundtable, Report of Roundtable 6,
March 30, 2005.

Aussi disponible en français sous le titre, Ce que nous ont dit . . lors de la table ronde multilatérale, Rapport de la sixième table ronde, le 30 mars 2005.

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1.0 Introduction

Health Canada and Industry Canada invited the Canadian Biotechnology Advisory Committee (CBAC) to address the subject of human genetic materials (HGM), intellectual property (IP) and the health sector. CBAC established an Expert Working Party (EWP) to undertake a program of research and consultation, and to prepare a report with recommendations on its findings.

In addition to commissioned research on these issues, the EWP held a series of five roundtable discussions with key stakeholders, including medical researchers and clinicians; intellectual property practitioners and economists; commercializers, regulators, and investors; health-system administrators; and representatives of federal, provincial and territorial governments. Representatives from all stakeholder groups were then invited to participate in the final multi-stakeholder roundtable session on March 30, 2005 in Toronto, Ontario. Forty individuals attended this session, including five EWP members and nine observers (see Appendix 1 for a list of participants).

The objectives of this roundtable were:

- to test and validate the summary of findings from the first five stakeholder roundtables as representing the state of the situation and of the debate on the IP protection of HGM;
- to consider and prioritize options for the way forward both within and outside the patent regime to address current and projected challenges; and
- to seek advice on the elements of an overall Canadian strategy to optimize the vitality and balance of mutual benefit and support for research, health care and innovation.

A background paper entitled, *Context, Issues and Options: A Background Paper prepared for March 30, 2005 Multi-Stakeholder Roundtable*[1] was developed to provide a basis for discussion at the multi-stakeholder roundtable. Participants also referred to two diagrams to help define the parameters of their discussion. The first illustrates the relationship between the research sector, development and commercialization sector and the health care system in the context of the IP system (see Appendix 2). It briefly describes the research and patent environment in Canada and provides a construct to foster understanding of the flow and linkages of different elements in the system, and to identify the needs and responsibilities of players at each stage. The second diagram provides an overview of the challenges and issues identified by participants in previous roundtables (see Appendix 3).

This report summarizes participants' discussions and recommendations at the multi-stakeholder roundtable. Section 2.0 of this report captures participants' comments and recommendations on the EWP's findings to date. Section 3.0 describes recommendations for potential elements of an overall Canadian strategy for IP protection of HGM and Section 4.0 outlines specific strategies that might be employed to address the impacts and implications of the presence or absence of IP protection of HGM on accessibility, availability and affordability of products, processes and services for the health system,

[1] See Appendix 4

research, and development and commercialization. Footnotes have been included only where additional background information is necessary for clarification or to provide context.

2.0 Comments and Recommendations on Findings to Date

Advice gathered from the first five roundtables as well as findings from the EWP's literature review and its study of international IP practices was summarized in a background paper prepared for the purposes of the roundtable and distributed to participants in advance of the event. Issues and options for government action outlined in the background paper[2] provided the basis for roundtable discussions.

While the Background Paper was prepared solely for this roundtable, many participants felt it was a good starting point for the EWP report. Suggestions reported in this summary pertaining to specific parts of the Background Paper will be treated as advice and recommendations to the EWP for the development of its report.

Participants' comments and recommendations arising from the background paper are listed below (in no particular order).

1. **Preferred Patent System** – Some participants questioned whether or not it is important for Canada to become a leader in patenting worldwide (e.g., as stated in paragraph 83 of the background paper: "It is important that the Canadian patent system become a preferred patent system..."). Furthermore, some participants suggested that the possibility of not patenting should be included as a viable option in the background paper. They felt the patent regime in Canada may be irrelevant since most patent holders file in the U.S. first and may never file for a Canadian patent. They also noted that investors are more interested in U.S. patents. However, other participants disagreed and noted that Canadian patents are valuable to Canadian inventors as a way of protecting their IP rights within Canada and to prevent "home-grown" competition. Some participants also observed that a strong patent system may support a strong healthcare system, although this view was not universally shared.
2. **EWP Consultations** – Participants recommended including a more detailed description of the EWP's roundtable consultation process in the background paper and/or in its final report to CBAC.
3. **Uniqueness of HGM** – Some participants questioned the view that the informational content of HGM suggests the need for a unique patenting approach. They noted that genes are not the only information molecule and that other examples exist (e.g., proteins). Other participants stressed the importance of creating a special approach for HGM within the overall context of innovation and the health system. At the same time, they felt that it is important that this special approach does not result in uneven access to services for Canadians.
4. **Request for Examination** – A participant referred to paragraph 82 of the background paper which states that examination starts immediately upon filing of the patent application in most countries but can be deferred in Canada. While it is

[2] See Appendix 4

true that examination can be deferred in Canada, the participant pointed out that Canada is not unique in this process; many countries have a delayed request for examination. Some participants felt that the requirement that an applicant must request the examination after filing is important as it provides a mechanism to manage CIPO's workload. It was also noted that patent applicants can time the request in one country to take advantage of examination results in another.

5. **Written Description Requirements** – Some participants felt that 'written description' requirements such as those used in the U.S. could be useful in the Canadian system and the issue should be addressed by the EWP.

6. **Voluntary Guidelines on Pharmacogenomics** – Some participants recommended additional consideration by the EWP of voluntary guidelines for pharmacogenomics. They felt that pharmacogenomic testing and diagnosis are likely to become increasingly important and that it is necessary to manage the potential impact. Guidelines could be used not only to ensure proper use but also to influence future decision-making in this field. One participant mentioned the U.S. Food and Drug Administration (FDA) draft guidelines "Guidance for Industry Pharmacogenomic Data Submissions" and cautioned against creating guidelines that are too prescriptive in nature. Participants noted that the FDA guidelines may spur further investment and commercialization of patented pharmacogenomic drugs/diagnostic kits internationally. This is likely to have a significant impact on cost and sustainability of uptake of patented HGM tests and therapies.

7. **Health Technology Assessment** - The background paper should include more extensive discussion of the benefits of strengthening health technology assessment (e.g., paragraph 87).

8. **Privacy** – Many participants indicated that privacy/information privacy issues are likely to become more important in the future. They felt the background paper should address these issues more thoroughly (e.g., how privacy and IP for HGM are related, legal protection for researchers and for the public, potential impacts of U.S. legislation on Canada). Other participants mentioned that privacy issues such as those raised when samples are sent out of the country for analysis and the genetic information generated is retained, may be less controversial in the future. As technologies mature, patents tend to become narrower in scope, allowing competitors to emerge. When alternatives are available, potential users of technology have more bargaining power and, for example, would be more likely to be able to obtain licenses to practice the patent in Canadian laboratories.

9. **Need for Public Education and Awareness** – Several participants felt that the issue of public education could be addressed at greater length in the background paper. For example, they noted how important it is for Canadians to understand whether they are at risk for a particular disease/condition so they can make informed decisions about their health care.

10. **Broad Patent Awards and Lack of Empirical Evidence** – Some participants noted that there is little or no empirical evidence to support the assertion in paragraph 33 that as knowledge and expertise increases, patent scope decreases.

Other participants cited evidence that scope has been narrowing for several years already in Canada and pointed to the U.S. and European experiences as examples of jurisdictions where significant progress been made to address scoping issues.

Paragraph 24 also raised questions from some participants about the appropriateness of drawing conclusions about whether or not patent scope is narrowing in Canada by studying the experience of other jurisdictions. They did not feel that empirical evidence exists to support this conclusion. However, other participants noted that while the details of another system may be different from the Canadian approach, when studied within a broad context, other countries can provide insights which are useful to Canada.

11. **Impact on the Health System** – Many participants suggested strengthening the discussion of the impacts of IP protection of HGM on the health system. They noted that sustainability and quality are key issues for health system management.
12. **Licensing Practices** – Some participants noted that there is a distinction between obtaining a patent and how a patent is exercised (e.g., as illustrated by the licensing practices of Myriad) or enforced. They felt these issues should be discussed in more detail in the background paper.
13. **Patent Abuse** – The discussion of abuse of patents also could be expanded in the background paper.
14. **Research Exemption** – Some participants argued in favour of a codified research exemption in Canada that would remove uncertainty for both researchers using patented technologies and for patent holders. However, several participants noted potential difficulties in implementing a research exemption, since an increasing number of scientists at universities and hospitals and other non-profit research institutions are launching spin-off companies based on their research results and many universities are encouraging commercialization of researchers' work. If the research exemption is founded on the research being non-commercial in nature or carried out at a not-for-profit institution, confusion may arise as to which research is exempt from claims of patent infringement and/or conflicts of interest in allowing them. Individuals who are both researcher and commercializer should not automatically be entitled to a research exemption by virtue of their position at a university or hospital. The background paper could also include more options for addressing the research exemption issue.
15. **Challenge Procedures –** Participants noted that existing challenge procedures could be employed more effectively (e.g., re-examination) and that improvements in this area should be encouraged in the background paper. Some participants also recommended consideration of possible new challenge procedures (e.g., add an opposition period after patent grant as a mechanism for improving patent quality), although not all agreed that such approaches would be effective.
16. **IP Management Strategies -** Some participants encouraged universities, hospitals and other research institutions to develop more effective IP management strategies. These strategies should be directed to increasing the capacity of technology transfer (or similar) offices to determine what, when and how to protect intellectual property developed in the institution, appropriate licensing

strategies, advice on maintaining the ability to protect intellectual property while establishing joint ventures and partnerships, identifying training requirements for researchers and technology transfer officers, and increasing awareness throughout the institution of the relevant and importance of intellectual property protection through an educational/informational component.

3.0 Potential Elements of a Broad Strategy

Participants were asked to recommend elements of an overall Canadian strategy addressing the IP protection of HGM and its impact on research, development and commercialization, and health care. Consensus is indicated if it was reached for any of the elements below; otherwise the range of opinions expressed around a particular element is included.

1. **Create Recommendations that Promote Adaptability**- Participants agreed that any strategy or recommendations developed by the EWP must be sufficiently broad, flexible and adaptable to continually accommodate change in the evolving context of research and commercialization in the future. Recommendations should support Canada's ability to continually improve as lessons are learned, as genetic technology continues to develop and grow, and as new challenges arise in the future. They also agreed that attempts to apply a single model or approach for all players may not work. They suggested consideration of a minimum standard of criteria as a more useful construct for success. They also encouraged the EWP to consider ways in which relevant stakeholders could be actively enlisted to implement elements of a strategy for improving research, development and commercialization and health care in Canada.
2. **Create Targeted Recommendations** – A Canadian strategy should include recommendations with defined objectives that describe both the challenge(s) a particular recommendation is meant to address as well as the expected or desired outcome if action is taken.
3. **Acknowledge and Support Interdependency** – Creating an environment in Canada that supports innovation means creating a strong biotechnology sector as well as supporting a strong research sector and a sustainable health care system, all of which need to be supported by infrastructure such as knowledge dissemination systems. Some participants felt that investors (both private and government) should be able to expect a reasonable rate of return on their investments and noted that a positive relationship can and should exist between a vibrant biotechnology sector and a strong public health system. One participant suggested the possibility of implementing a 12-month patent completion process to better support and hasten innovation. However, most other participants disagreed with this approach, especially given the likely inability of the system to manage this timing with due diligence and quality.
4. **Encourage Effective Interaction Between Sectors** - Constructive interaction between sectors should be encouraged to optimize mutual benefit and support and to contribute to strengthening vitality and the effectiveness of each sector. IP should be considered within this context. Experiences in other countries (e.g.,

Ireland, Sweden, U.S., Singapore and others) seem to illustrate this relationship and can provide useful lessons for Canada. For example, several participants pointed out that the relationship between inventors and users is a symbiotic one and more consideration should be given to supporting it. Some participants also noted that the interplays among these systems are not linear. Each of these systems can positively affect the others; the strength of all three systems should be developed and encouraged both independently and together. Others urged the EWP to test common assumptions such as the idea that "what is good for business is not good for public health care." Some noted that a vital biotechnology sector can support a strong health care system, although others felt a strong relationship between the health of the biotechnology industry and a sustainable public health care sector cannot be assumed.

5. **Consider International Context and Consistency**– Some participants stressed the importance of making recommendations related specifically to HGM in the context of the patent system more broadly and within an international context. They pointed out that the Agreement on Trade Related Aspects of Intellectual Property Rights[3] (TRIPs) does not allow "discrimination between technologies" (see paragraph 10, background paper) and were concerned that a special approach to HGM-related patents would contravene Canada's TRIPs obligations. Others noted that the TRIPs agreement provides enough flexibility to develop a Canadian approach to patenting, as have other European countries with public funded health systems, for example. They pointed out that it is also important to create policies that are consistent with those of our major trading partners to build positive international perceptions of the Canadian system and to encourage investment in Canada. Some participants noted that perception is very important internationally and that a strong patenting environment in Canada supports a vital Canadian biotechnology industry. Some others noted that there was no consensus on the effect a more harmonized patent system would have on total investment in Canadian biotechnology.

6. **Support Improved Human Resource Capacity** – The broad strategy for IP protection of HGM should include recommendations around training, hiring and retaining appropriate and adequate human resources to support research, innovation, the health care system and IP protection.

7. **Support Access to the Best Tools** - Some participants felt that a broad strategy should recognize that improved tools are needed to better treat patients and that genetic testing is likely to provide promising ways to improve treatment. However, they noted that cost-benefit analysis and targeted policy-making is required to determine which tests are best for certain needs and to ensure accessibility to better health care. They highlighted issues such as problems with direct-to-consumer marketing in the U.S. and potential funding difficulties.

8. **Develop IP Management Strategies** – Some participants encouraged development of effective IP management strategies to provide guidance on issues

[3] The Agreement on Trade related Aspects of Intellectual Property Rights (TRIPs) aims to harmonize the protection of intellectual property worldwide to facilitate trade among the members of the World Trade Organization.

such as when and what to patent and to include licensing strategies, training requirements, advice on joint ventures and partnerships as well as an educational component.

9. Other elements of an overall strategy which had been deduced from earlier roundtables were proposed in background materials and were generally found by participants to be useful. These included recommendations to:

   - improve the operation of the patent system without distorting the *Patent Act* or contravening international commitments;
   - include a broad spectrum of solutions both within and outside the patent system;
   - create a long-term vision and plan for improved support and management;
   - enlist all relevant stakeholders in actively contributing to short- and long-term strategies; and
   - develop and invest in enhanced capacity to anticipate, assess and address current and future challenges.

4.0 Proposed Strategies/Remedies for Addressing Impacts of IP Protection of HGM

Participants were provided with a list of issues gleaned from findings to date in the background paper and other background materials. Issues were organized according to whether they were primarily a *research, development and commercialization* or *health care system* issue. They provided a starting point from which participants were asked to identify improved or new strategies and remedies for addressing issues both within and outside the patent regime. Consequently, they were characterized as obstacles or problems (e.g., HGM-related patents may *deter* research...) even though, in some cases, issues could also positively affect the HGM-related patent regime (e.g., patents can be used to *encourage* research...).

For the purposes of the discussion at this roundtable, participants used the following definitions to describe the terms *within* and *outside* the patent regime:

- *Within the patent regime* – includes Canadian laws (e.g., *Patent Act*), regulations (e.g., *Patent Rules*) and administration (e.g., CIPO), and international agreements to which Canada is a party (e.g., TRIPs), as well as some aspects of licensing issues and government leadership resulting from the patenting approach inside the patent regime; and
- *Outside the patent regime* – includes alternative and/or complementary mechanisms such as competition law, voluntary guidelines, policies for publicly funded research, health technology assessment, government procurement, patent pooling, and third party advisory/facilitating mechanisms.

In Section 4.1, participants identified several factors that could be used to measure successful implementation of recommended strategies/remedies within an overall Canadian strategy. Sections 4.2 – 4.4 list proposed strategies and remedies to address impacts on research, development and commercialization and the health care system. Where identified by participants, priority strategies are highlighted.

4.1 Success Criteria

Participants recommended the following criteria to measure successful implementation of recommended strategies/remedies. Consensus was not sought or achieved in producing this list and items appear in no particular order of priority. Participants recommended that the EWP consider remedies and solutions within and outside the patent regime that:

- support a level playing field for all partners;
- do not rely on one partner (e.g., government) to implement change; all partners must be actively involved for success to be achieved;
- encourage consistency and collaboration between government departments and between the public and private sectors to achieve goals;
- support the research community's ability to make themselves aware of existing patents/patent applications in their area of research (e.g., a 'freedom to operate' search), and to conduct public good research at a reasonable cost with reasonable freedom to utilize existing patented HGM and related-technologies;
- operate deliberately and effectively within an international context and in accordance with international commitments (e.g., both with respect to international patent regimes and the international business/trading context);
- recognize that, as knowledge increases in the field of HGM-related technology and biotechnology more generally, some issues surrounding HGM patenting might decrease with little intervention (e.g., the breadth of patents will narrow over time);
- strive for continuous improvement as lessons are learned domestically and internationally about IP protection of HGM and about patenting more generally;
- support strong human resource capacity in Canada (e.g., from researchers to consistently trained CIPO staff);
- support a health system that is based on a full analysis of relative needs as well as costs and benefits to the patient, the health care provider and the health system; and
- recognize the interdependencies and intrinsic linkages among the research system, development and commercialization, and the public health care system.

Other success criteria for solutions which had been deduced from earlier roundtables were proposed in the background materials and were generally found to be useful. These included choosing solutions and remedies both within and outside the patent regime that:

- have a maximum impact on identified problems with optimal benefits and minimal negative impacts or consequences to researchers, the biotechnology industry and the health care system;
- will not distort the intent of the *Patent Act* or create imbalance in the application of the *Patent Act* or regime across other patentable fields;

- can be fully implemented or achieve benefits within a reasonable time frame (e.g., 2-3 years); and
- support and advance Canadian values and beliefs.

4.2 Proposed Strategies/Remedies to Address Impacts on the Research System/Sector

It is thought that broadly patented HGM may impede or deter research.

- Broad patents may preclude other researchers from working in a specific research sector.
- Patents with an inappropriately broad scope may block further improvement of an invention or development of new inventions.
- Patent holder licensing practices may limit access to materials for research.
- "Reach-through" licenses may deter downstream research.
- Uncertainty about the nature and scope of an experimental use exemption may deter research and/or publication of research results.

Participants not only considered issues identified at previous roundtables (as above) but also suggested remedies and strategies to address additional challenges highlighted in their own discussions. Potential remedies and strategies to address these and other issues are identified in Table 1.

Table 1 - The extent to which patented HGM may impede and deter research and/or increase the costs of research

Potential Remedies and Strategies *Within* the Patent System	**Potential Remedies and Strategies *Outside* the Patent System**
Priority Remedies/Strategies - Legislate an experimental use exemption with restrictions on who can use it and how (e.g., for non-profit organizations unless researcher has a commercial endeavour). Some participants cautioned that this may have unintended negative consequences and should be considered carefully. - Reform novelty rules to avoid the situation where a conversation between researchers at different institutions simply to determine whether there is a potential for collaboration can destroy novelty. - Provide licensing practices guidelines	*Priority Remedies/Strategies* - Create better patent management techniques including education and guidelines where necessary. - Promote patent pools for experimental research for particular platform technologies to reduce costs to researchers. *Other Potential Remedies/Strategies* - Clarify issues around individual privacy and data confidentiality. - Encourage government purchasing of key IP (at market price) to ensure "public good" interest (e.g., for a remedy that serves the public interest such as a SARS

Potential Remedies and Strategies ***Within*** the Patent System	Potential Remedies and Strategies ***Outside*** the Patent System
Other Potential Remedies/Strategies - Encourage research institutions, rather than individual researchers, to seek patents. Some participants suggested this approach could simplify identification of patent holders by centralizing patents within institutions making it faster, more exact and possibly less expensive to undertake due diligence research. - Guidelines and/or education programs may help ensure that "public good" research more directly benefits Canadians. Some participants noted that Canadians 'pay for' research through their taxes, it is unfair that the benefits of such research could be lost to Canadians when, for example, U.S. companies, rather than Canadian ones, develop products from Canadian research. - Add an opposition period after patent grant as a mechanism for improving patent quality. - Clarify "reach-through" licensing (e.g., clarify validity of a claim of ownership of for an invention based on the reach-through license clause). Some participants pointed out that "reach-through" licensing itself can be a beneficial business arrangement and that clarifications should be considered on a case-by-case basis. - Continue to revise the Manual of Patent Office Practice to include both disclosure and written description.	vaccine). One technique that could be used to enable this would be to use research grant criteria and rules to support public good research (e.g. include provisions to provide research results at no/low cost in situations where public good interests are affected). Some participants were concerned that this approach could have unintended consequences, such as a reduction in the amount of private funding that is available for research. - Public funding bodies could encourage or require researchers to seek Canadian development and commercialization partners or licensees.

4.3 Proposed Strategies/Remedies to Address Impacts on Development and Commercialization

Excessively broad patents and/or restrictive licensing may act as disincentives for development and commercialization.

- Broad patents with broad use claims could not only confer monopoly on nucleotide sequences, but also on all other tests for the sequence, use in DNA micro arrays and in epidemiological research.

- Patents and/or licensing practices may create disincentives to develop or improve an invention, as the benefits will mainly reside with the patent holder(s).
- Patents and/or licensing practices might be used to block other companies from developing a new test or cure.
- Pharmaceutical R&D companies depend to a significant extent on discoveries/inventions made by academic researchers to drive their own development programs. Any impediment to investigator-initiated research, such as patent thickets and royalty stacking, may also be an impediment to commercial development.
- The cost of development and commercialization increases, especially in the context of exclusive licensing. However, some participants felt that patent holders generally are licensing research tools non-exclusively, although there are some exceptions. Holders of non-research tool patents are more likely to offer an exclusive license in order to have the invention brought to market, particularly if the development and commercialization costs will be high.

As well, the current patent regime may have deleterious market place impacts for patented HGM because Canada's patent legislation, regulations and operating procedures generate uncertainty about the application of patentability criteria, are perceived by some as comparatively less effective than in other jurisdictions, and are perceived as involving undue delays due to inefficiencies.

- Examination of patent applications appears to take longer in Canada than in other countries.
- Application of the novelty, non-obviousness, and utility criteria in Canada may not be sufficiently rigorous.
- Differences in what can be patented in Canada compared with other countries may disadvantage the Canadian industry.
- Some elements of filing requirements and maintenance of patent applications and patents are arbitrary and unduly harsh.

Participants not only considered issues identified at previous roundtables (as above) but also suggested remedies and strategies to address the additional challenges highlighted in their own discussions. Potential remedies and strategies to address these and other issues are identified in Table 2.

Table 2 – The extent to which excessively broad patents and restrictive licensing may act as a disincentive for development and commercialization and/or may have deleterious marketplace impacts for patented HGM

Potential Remedies and Strategies *Within* the Patent System	**Potential Remedies and Strategies *Outside* the Patent System**
Priority Remedies/Strategies - Encourage stricter examination of patent applications to ensure the scope of patents granted is fully justified by the patent application. - Some participants suggested encouraging non-exclusive licensing to support research. They supported using this approach up to the development phase but not in the commercialization phase because they believed that it is essential to compensate a patent holder if commercialization of a new product is likely. Not all participants agreed with this approach. - Implement an opposition procedure and encourage better use of existing mechanisms (e.g., re-examination). - Provide education and better guidance on patenting and licensing (e.g., when and what to patent, best practices in licensing, etc.). - Provide licensing guidelines. *Other Potential Remedies/Strategies* - Link litigation to opposition (i.e., a party who did not challenge a patent during the opposition period could not later challenge it in court).[4] Not all participants agreed with this approach, noting that this could prevent a challenge by a newly affected party or a party that did not exist when the patent was granted. - Extend the length of the grace period. Some participants noted that this remedy goes against international trends, but others felt that it may address the issue of	*Priority Remedies/Strategies* - Use the *Competition Act* more effectively to protect patents and the public good *Other Potential Remedies/Strategies* - Increase education and awareness around the concept of 'freedom to operate'. Some participants suggested that researchers could improve their ability to conduct patent searches to determine if they are accidentally infringing on a patent(s). Others pointed out that commercializers might be more willing to provide researchers with the opportunity to operate outside patents if the benefits of doing so were clearly articulated to them. - Promote patent pools for experimental research for particular platform technologies.

Potential Remedies and Strategies ***Within*** the Patent System	Potential Remedies and Strategies ***Outside*** the Patent System
universities or their researchers filing for patents too early. - Create a body like the Patented Medicine Prices Review Board (PMPRB) to address licensing issues. - Governments could seek licenses for technologies or products broadly in the public interest or critical to public health practices (provincial or country-wide) from companies to reduce costs. Some participants noted that if this approach were implemented, government should be required to pay market rate for licenses in order to continue to support innovation. - Create a clearinghouse for patents to make it simpler and more efficient for developers and commercializers to identify researchers and existing patents, potential royalty costs, licenses needed, etc.	

[4] This would be the reverse of the situation concerning re-examinations, where a party whose basis for requesting a re-examination of a patent is rejected may not raise the same objection in litigation.

4.4 Proposed Strategies/Remedies to Address Impacts on the Health System

4.4.1 The extent to which patented HGM may limit access to diagnostic or genetic services

Patented HGM may limit access to diagnostic or genetic services in a number of ways.

- The existence of broad patents and licensing fees may impede the improvement or development of, or access to, new tests.
- Licensing practices may fragment patient care by, for example, separating genetic testing from counselling.
- Licensing practices may limit access by controlling the number of sites where testing is available.
- Patients may refuse to undertake testing involving patented HGM where a database monopoly exists.

Participants not only considered issues identified at previous roundtables (as above) but also suggested remedies and strategies to address the additional challenges highlighted in their own discussions. Potential remedies and strategies to address these and other issues are identified in Table 3.

Table 3 - The extent to which patented HGM may limit access to diagnostic or genetic services

Potential Remedies and Strategies *Within* the Patent System	**Potential Remedies and Strategies *Outside* the Patent System**

- Create an exemption from patentability for diagnostic tests. This would require clarity around commercial and non-commercial use. Other participants disagreed with this approach. They noted that such an approach is different from most other countries and would negatively affect diagnostics companies in Canada**.**
- Create a PMPRB-like body with functions such as:
  - price control and access;
  - setting fees for broad access (e.g., similar to the music industry);
  - quality control; and
  - education of patentees. Some participants noted that CIPO has an education component to its mandate as well.
Some participants disagreed with this approach as it requires too much government intervention.
- Encourage researchers and developers to request licenses under s. 65 of the *Patent Act* where patent holders are not licensing patents on reasonable terms and conditions.
	- Clarify issues around individual privacy and data confidentiality
	- Strengthen Health Technology Assessment (HTA) by employing countrywide health technology assessment strategies and promoting consideration of HTA more broadly.
	- Promote patent pooling.
	- Use the collective power of governments working together (either as a single purchasing agency or through a PMPRB-like body) to ensure equitable access.

4.4.2 The extent to which patented HGM may affect the quality of diagnostic tests and technical capacity of researchers and practitioners

Patented HGM may affect the quality of diagnostic tests and the technical capacity of Canadian clinical researchers and practitioners.

- If licensing fees are so expensive (compared to the potential volume of the test) that a laboratory's ability to offer a test is compromised, few laboratories will be able to offer the tests, there will be fewer opportunities to share samples between laboratories to assess the quality of testing, there will be less opportunity to improve the test, and/or there will be a risk that the patent holder's test, regardless of its quality, becomes the *de facto* "gold standard" because there are no alternatives with which it can be compared.

- Canadian laboratory scientists may be prevented from developing their own tests without risking infringing an existing patent.
- Restrictive licensing practices may limit the number of licensed laboratories and, therefore, may impede the skills development of Canadian clinical researchers.

Participants not only considered issues identified at previous roundtables (as above) but also suggested remedies and strategies to address the additional challenges highlighted in their own discussions. Potential remedies and strategies to address these and other issues are identified in Table 4.

Table 4 - The extent to which patented HGM may affect the quality of diagnostic tests and technical capacity of researchers and practitioners

Potential Remedies and Strategies *Within* the Patent System	**Potential Remedies and Strategies *Outside* the Patent System**

- Create a PMPRB-like body with functions such as:
  - price control;
  - access;
  - setting fees for broad access (e.g., similar to the music industry);
  - quality control; and
  - education of patentees.
Some participants disagreed with this approach as it requires too much government intervention.
	- Employ a quality assurance/control mechanism for standard of care
	- Create metrics to measure profit and "public good" benefits that could be used to assess value at all stages – research, development and commercialization, and health care – of the HGM-related IP environment.
	- Address and balance expectations and values around the dual responsibilities of universities to conduct research and to commercialize.

4.4.3 The extent to which patented HGM may affect the cost and introduction of diagnosis and treatment

Patented HGM may affect the cost and introduction of diagnosis and treatment.

- Holders of broad patents can set virtually any conditions they like, including setting a high price for the test, specifying by whom, how and where tests will be performed and how information gathered from performing tests will be handled and stored and by whom it may be accessed.[4]
- Some patented tests are more expensive than equivalent tests that could be developed "in house."

[4] Although this is true, section 65 of the *Patent Act* provides a remedy. If the patent-holder refuses to license on reasonable terms and conditions, an application can be made to the Commissioner of Patents for a license on terms to be set by the Commissioner.

- Patent rights on HGM may make health care more expensive to the extent that it depends on these inventions.
- The increased volume and complexity of patented HGM inventions are likely to place an increasing burden and strain on the currently limited resources devoted to assessing the costs, benefits and system impacts of HGM inventions before they are introduced.

Participants not only considered issues identified at previous roundtables (as above) but also suggested remedies and strategies to address the additional challenges highlighted in their own discussions. Potential remedies and strategies to address these and other issues are identified in Table 5.

Table 5 - The extent to which patented HGM may affect the cost and introduction of diagnosis and treatment

Potential Remedies and Strategies *Within* the Patent System	**Potential Remedies and Strategies *Outside* the Patent System**
- Create a PMPRB-like body to address licensing issues. Some participants disagreed with this approach as it requires too much government intervention. - Create mechanisms for negotiated settlements - Some participants suggested employing a compulsory licensing system for diagnostic tests but others did not agree with this approach. Such an approach would have to be undertaken cautiously with considerable thought given to its potential benefits and potential challenges (e.g., raising negative perceptions of the Canadian patent system, etc.).[5]	- Use professional organizations to determine standard of care in order to target tests to need - Employ countrywide HTA strategies and promoting consideration of HTA more broadly. - Improve communication between implicated government departments. - Create an agency to track legal considerations, royalties, etc. for hospitals. - Create an approach and a shift in thinking that focuses on the positive linkages and interdependencies between the health care system and innovation rather than on the negative tensions. - Use confidentiality agreements to address privacy issues if testing is done outside Canada, or samples moving out of Canada. There was some concern that confidentiality agreements would not adequately address this issue as they might not "trump" the laws and responsibilities of individuals/organizations in another country.

[5] It should be noted that, under s. 65, an application can be made to the Commissioner for a license if agreement on reasonable terms and conditions cannot be reached.