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

An Integrated Summary of What We Heard…

from the Expert Roundtable Consultations held between December 2004 and March 2005

Prepared by the Canadian Biotechnology Secretariat
(based on the summary reports from Roundtables 1-6 prepared by InterQuest Consulting)

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What We Heard from the Expert Roundtable Consultations held between December 2004 and March 2005.

Aussi disponible en français sous le titre, *Sommaire intégré des commentaires recueillis dans le cadre des consultations de la table ronde d'experts tenues entre décembre 2004 et mars 2005*

Table of Contents

1.0 Introduction

In 2004, 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 (GIPH). CBAC established an Expert Working Party (EWP) to undertake research and consultation, and to prepare a report with recommendations on its findings.

The EWP program of work included analysis of existing reports and literature, commissioned research in specific areas (e.g., international comparisons of patent policy and experience with respect to HGM), and stakeholder consultations.

The EWP held a series of six roundtables with key stakeholders, as follows:

- medical researchers and clinicians (Roundtable 1, December 1, 2004);
- intellectual property practitioners/experts and economists (Roundtable 2, January 12, 2005);
- commercializers, developers and investors/financiers (Roundtable 3, February 1, 2005);
- health system administrators (Roundtable 4, February 16, 2005);
- federal, provincial and territorial government officials (Roundtable 5, February 23, 2005); and
- multi-stakeholder roundtable (Roundtable 6, March 30, 2005).

The roundtable consultations focused on the identification and analysis of systemic incentives and disincentives for relevant participants in conducting research; obtaining financing; establishing strategic alliances with private/public sector partners; developing and commercializing products and processes for use within the health sector; and providing access to health services involving genetic inventions.

This document summarizes the main findings from these consultations, noting major areas of consensus and divergence. Additional findings, and the list of participants, are presented in summary reports from each of the roundtables, available at http://cbac-cccb.ca, Publications, Consultations.

2.0 IP Protection of HGM

2.1 General Observations

Participants from all of the roundtables agreed that creating an environment in Canada that supports innovation means creating a strong biotechnology sector, a strong research sector, and a sustainable health care system. Participants recommended that a long-term, proactive and strategic national IP approach be developed that facilitates and builds on each of these sectors as well as encourages optimal interaction among them.

There was agreement that any changes to Canada's patent regime must be developed in an international context (e.g., be consistent with policies of our major trading partners) and must be in line with its international obligations (e.g., Trade Related Aspects of Intellectual Property Rights - TRIPs). Some participants, however, were of the view that this did not preclude Canada from taking its particular context (e.g., publicly funded health care system) into account in the design and application of its patent regime.

No consensus emerged as to whether the licensing strategies of some gene patent holders (e.g., Myriad Genetics[1] are likely to become a systemic problem. Some participants contended that this behaviour could become pervasive, while others cautioned that the HGM-related biotechnology industry has yet to mature so it is impossible to predict whether this will indeed happen. Some suggested that HGM patents, as has been seen with other new technologies, might receive broader protection when the technology is new but that the scope of patents tends to narrow as the technology matures (and as the amount of prior art increases). Other participants contended that there is little or no empirical evidence to support this assertion.

Multi-stakeholder roundtable participants were asked to recommend elements of an overall Canadian strategy addressing the impacts of IP protection of HGM on research and the health sector. Participants agreed that this strategy must:

- be flexible enough to accommodate change over time;
- encourage effective interaction between the research, development and commercialization, and health sectors to optimize mutual benefit and to contribute to strengthening the vitality and effectiveness of each sector;
- include a broad spectrum of solutions both within[2] and outside[3] of the patent regime;
- be in line with Canada's international commitments (as referenced above);
- support improved human resource capacity in the research, innovation and health sectors;
- support appropriate access to HGM inventions by all Canadians;

[1] Myriad Genetics patented the genetic tests for the BRCA1 and BRCA2 genes. Myriad charged high prices for the tests, employed highly restrictive licensing practices, and exercised control over where the tests were performed (in its own laboratories in the United States or those of its exclusive licensees in other countries), and over the information generated by the tests. Although Myriad has been the flash point, the issues associated with Myriad's exercise of its patent rights have also been raised with respect to patents held on the gene sequence for Apolipoprotein E (associated with Alzheimer disease), Canavan disease, haemochromatosis, and CCR5, which is the primary receptor through which the HIV virus establishes itself in the body.

[2] 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.

[3] Includes alternative and/or complementary mechanisms such as competition law, voluntary guidelines, publicly funded research policy, health technology assessment, government procurement, patent pooling, and third party advisory/facilitating mechanisms.

- provide guidance on IP management strategies (e.g., when and what to patent) to players in the IP system; and
- enlist all relevant stakeholders in actively contributing to short- and long-term strategies.

2.2 *Special Considerations of HGM*

Participants grappled with the issue of whether HGM is distinctive enough to warrant specialized treatment in the *Patent Act*. It was noted that the patent system is technology neutral and uses the same rules to grant patents over mousetraps as HGM.

Some roundtable participants were of the view that HGM *per se* is not inherently different from other forms of technology (differences lie in the *application* of the HGM product or process, not in the nature of the patent itself), so does not warrant special treatment in the *Patent Act*. Others, however, felt strongly that HGM is different due to the existence of personal and hereditary/familial information associated with HGM (and the related privacy and confidentiality concerns) and that a targeted approach in the *Act* is necessary. It was noted by some participants that TRIPs does not allow "discrimination among technologies" and that a special approach to HGM-related patents would contravene this agreement. Others noted that the TRIPs agreement provides enough flexibility to develop a Canadian approach to patenting as other European countries have done, for example.

On a related note, some roundtable participants discussed whether HGM should be considered a discovery or an invention. Some were of the view that new knowledge of DNA sequences is the result of a discovery (and is therefore not patentable) and that it is the application of the discovery that is the invention and, thus, patentable. Some participants recommended that this discussion of whether HGM are discoveries or inventions would benefit from a more in-depth policy discussion. Again, TRIPs obligations were cited as a reason to proceed with extreme caution in this regard.

3.0 Impacts and Implications of IP Protection

Participants were of the view that the impacts and implications of IP protection on research, development and commercialization, and on health system use need to be understood separately as well as within the context of the overall health-related IP system.4 Each stage has unique needs and characteristics, yet each one is linked to the other; overall success relies on success at each stage. Any changes implemented at one stage will have implications at other stages in the system.

[4] A continuum or spectrum of activity was used in the roundtables to describe the research and patent environment in Canada, and to understand the flow and linkages of different elements of the system.

Some participants made clear that many of the impacts and strategies outlined below reflect challenges and solutions that apply not only to health-related IP and HGM but also, more broadly, to the patent system and/or biotechnology field.

3.1 Impacts on Research

Participants agreed that patents provide both incentives and disincentives to research. Patents may encourage commercialization and may provide economic incentives for research (e.g., in some cases, royalties provide a source of funding which can be channeled into further research). On the other hand, most participants expressed significant concern about the potential negative impacts of patents on research. These impacts may occur due to the (broad) scope of patents and/or the ways in which patent holders exercise their patent rights, and are as follows:

- broad patents and/or restrictive licensing practices may preclude researchers from working in a specific research area (by limiting access to materials and tools for research) and may block further improvement of an invention or development of a new invention;
- patents may discourage the sharing of information (e.g., in a publicly accessible database), if researchers are/believe they are in violation of a patent;
- restrictive licensing practices may prohibit some research institutions from undertaking research;
- licensing fees and royalties (especially in the case of multiple licenses or royalties) could divert funding from research to the payment of these fees; and
- "reach through" licenses may deter downstream research.

It was noted that these impacts are exacerbated by the uncertainty about the nature and scope of the experimental use exemption.

Some of the roundtable participants expressed concern that patents may encourage researchers to forego "public good" research (e.g., population health research) and to focus on research with commercial potential. This is especially a concern given the blurring of lines between research and commercialization in universities (and other research institutions), where universities are encouraged to promote cost-recovery and profitability. Some participants felt strongly that there must be recognition that basic research is a key element of the economy and health system (whether or not all research is profitable) and that not all research will, or should, yield a profit.

Additionally, some participants expressed concern about the "fairness" of patent holders being able to capture a disproportionate return from publicly funded HGM research while public funders have little influence on the way in which patent holders exercise their patent rights vis-à-vis the health system.

3.2 Impacts on Development and Commercialization

It was noted that, while relevant, IP protection is not the most important influence on the development and commercialization of gene-based inventions. Commercial viability is a more important consideration.

Participants noted that excessively broad patents and restrictive licensing in the patent system might act as a disincentive to development and commercialization. Specifically:

- broad patents may confer monopolies on nucleotide sequences and on all other tests for the sequence (e.g., use in DNA micro arrays and in epidemiological research), and thus impede research and development;
- patents and/or exclusive licensing practices may create disincentives to develop or improve an invention due to increased development and commercialization costs and due to the fact that the benefits will largely reside with the patent holder(s);
- patents and/or licensing practices might be used to block other companies from developing new tests or cures; and
- pharmaceutical R&D companies depend mainly 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 (multiple royalties), may also be an impediment to commercial development.

Concern was also expressed about the deleterious marketplace impacts that the current functioning of the Canadian patent regime may have on development and commercialization, both nationally and internationally. Some stated that Canada's patent legislation, regulations and operating procedures generate uncertainty about the application of patentability criteria, and are perceived by some as comparatively less effective than in other jurisdictions and as having undue delays due to inefficiencies in the system.

3.3 Impacts on the Health System

All participants acknowledged the benefits of genetic inventions for the health of Canadians and to the Canadian economy. However, there was concern among most participants, to varying degrees, about the impact of patents on access to and on the delivery of genetic-based health care services. This is especially important in view of Canada's publicly funded, universally accessible health care system.

There was general agreement that there are a number of real or potential impacts associated with broad patents and restrictive licensing. These include:

Cost and Access

- strained health care budgets (to the extent that the health system depends on these inventions);
- increased burden on the limited resources currently devoted to assessing the costs, benefits and system impacts of HGM inventions before they are introduced;
- limited access to gene-based inventions (e.g., genetic testing) by controlling the number of sites where testing is available;
- fragmented patient care by, for example, separating genetic testing from counselling; and
- reduced ability by the health system to control its own key processes (e.g., provision of diagnostic tests).

Quality and Continuity of Care

- barriers to the improvement of existing tests or the development of new, possibly more effective and less expensive alternative tests. The patent holders' test may become the *de facto* standard, regardless of its quality, because there are no alternatives with which it can be compared;
- where only one or a few laboratories are licensed to conduct a test, researchers cannot develop the skills and expertise related to the test;
- reduced ability or inability to ensure quality control of HGM products (e.g., where few laboratories perform the test, there are fewer opportunities to share samples to assess the quality of testing); and
- threats to the privacy and confidentiality of Canadians' genetic information and their right to access this information (e.g., where samples are sent out of the country for testing).

In addition, some participants were concerned that companies focus on areas that are most profitable rather than on areas of priority for the health care system. There was also some concern expressed about companies putting products on the market too early, before they have been evaluated for their potential impact on the health system.

4.0 Proposed Approaches/Strategies for Addressing these Impacts

Participants discussed possible changes to the *Patent Act* but did not reach any consensus. While some were of the view that improvements were needed to the *Act* (e.g., better definition of patentability criteria), others felt that the focus should be on improved implementation of existing and new (where beneficial) incentive mechanisms. All participants agreed, however, that improvements were needed around the administration and operation of the Canadian Intellectual Property Office (CIPO). Such improvements would benefit the Canadian patent system overall (and not only the administration of HGM-patents).

There was agreement that many non-legislative approaches could also be taken to deal with many of the negative effects of patenting of HGM. For example, some participants were of the view that governments need a range of tools to "discipline" the market when industry acts against the public good (e.g., more active enforcement of competition law, targeted voluntary or compulsory licensing aimed specifically at the diagnostics market). However, others cautioned that decisions that are made to improve Canada's patent regime must be undertaken with thoughtful consideration of their implications on Canada's ability to attract investment both domestically and internationally and build a successful Canadian industry.

Main recommendations from roundtable participants are presented below. Both those recommendations that received general support as well as those without consensus are included. For a complete list of recommendations, please see the summary reports available at http://cbac-cccb.ca, under Publications, Consultations.

4.1 Main Recommendations with General Support of Participants

Within the Patent Regime

- ***Establish a clear research exemption.*** There was no agreement, however, on how this should be formalized (e.g., whether a legislative approach was the most appropriate and effective means to do so). Further, 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.

- ***Make better use of existing provisions in the Patent Act, including:***
  - anti-abuse provisions (Section 65)
  - government use provision (Section 19)
  - re-examination procedures in *Patent Act*.[5]

- ***Implement an opposition procedure*** as a mechanism to challenge issued patents.

[5] In Canada, any person may request a re-examination of a patent claim by filing "prior art" (patents, published patent applications or other publications) with the Commissioner, explaining how the prior art applies to the patent claim. If the re-examination board concludes that an issue has been raised, the patent holder is given an opportunity to explain why the prior art is not relevant or can amend the claims. The requester has no further involvement in the process, beyond being notified of the result of the re-examination. In other jurisdictions, the requester may respond to the submissions made by the patent holder.

- ***Improve administration and capacity of CIPO:***
  - better examination guidelines[6] for the application of patentability criteria (to encourage a more rigorous and common approach);
  - improved response times; and
  - increased number of and training for examiners.

- ***Formulate and promulgate licensing guidelines*** (e.g., consider implementing OECD draft guidelines).

<u>Outside the Patent Regime</u>

- ***Improve coordination*** between different elements of the whole system and better use of complementary legislation and systems (e.g., coordination between the competition and patent offices, and more coordinated use of the Competition Act and the Patent Act).

- ***Promote patent pooling*** for experimental research for particular platform technologies to reduce costs to researchers.

- ***Establish a third party body to educate, guide, mediate and inform the players in the IP process.*** Its mandate might include becoming a centralized information centre (e.g., to track gene patents, best practices, to raise awareness, and to provide support to researchers, clinicians and others); providing consistent rules, regulations and/or guidelines, promoting sharing of information across the health care system (across federal, provincial and territorial systems); advising on bulk purchasing decisions; acting as a mechanism for compulsory licensing; and studying ethical issues.

- ***Improve cost-benefit analysis.*** Strategies must be developed at the policy-making levels of provincial health care systems to deal with issues of clinical- and cost-effectiveness of HGM. National health technology assessment strategies should be utilized.

4.2 Other Major Recommendations Raised by Some Participants

- ***Introduce compulsory licensing.*** There was no consensus around this issue because of negative experiences associated with the prior compulsory licensing system. Some participants felt that a compulsory licensing regime[7] aimed at diagnostics was necessary to address the impacts of patents on access to gene-based products and services, while others contended that this would be undesirable and that the same objectives could be accomplished through more

[6] Such guidelines exist in the Manual of Patent Office Practice (MOPOP). The chapter on Biotechnology is currently being revised.

[7] Those participants in favor of targeted compulsory licensing for the health system noted that such a system would not trigger TRIPs (they noted that this had been undertaken in Europe without significant negative impacts) and would provide some leverage in dealing with unreasonable patent holders.

effective use of Section 19 (use of patents by government) and Section 65 (abuse of patent rights which could be used to obtain a license from an unwilling patent holder) of the *Patent Act*. However, some participants noted potential difficulties in utilizing Section 19 of the *Patent Act* because it is not clear what is encompassed in the phrase "public non-commercial use". It was for this reason that they suggested a more targeted approach to compulsory licensing. It was cautioned that more use of Section 65, with no legislative change, might result in increased litigation, which is neither desirable nor helpful.

- ***Create a regulatory body akin to Patented Medicine Prices Review Board (PMPRB).*** Some participants suggested that a PMPRB-type body could be established to address price of and access to HGM products, particularly where patents have significant impacts on access and the sustainability of the health care system.[8] Other participants cautioned that pursuit of this option should begin with careful consideration of PMPRB's current mandate and impacts with respect to the pharmaceutical industry. Still others disagreed with the establishment of such a body citing excessive government intervention in the marketplace.

- ***Provide for an exemption for methods of diagnosis.*** Some participants felt that methods of diagnosis should be treated in the same way as methods of surgery or therapy and excluded from patentability. Others thought they should be patentable, but that their use in clinical diagnostic labs should be exempt from claims of patent infringement. Still others pointed out that if patent rights and licenses were not respected and damages for infringement were not allowed, there would be no revenue for the patent holder and no incentive for anyone else to develop new tests.

- ***Give special consideration to HGM in the Patent Act***. Some were of the view that HGM may require special consideration in the *Patent Act* with respect to the definition of what is patentable and what is not (i.e., discovery or invention).

- ***Extend patent terms***. Before this strategy is implemented, data should be gathered to determine the actual effect of patent delays on bringing new products to market and whether a change would have a significant positive impact on development and commercialization.

- ***Provide for provisional patent approval***. This would require controlled application and clear evaluation of outcomes as a means of counteracting the unforeseen impacts on health care that may arise with broad patents.

[8] A few participants suggested that the mandate of the PMPRB could be extended to cover HGM products (as well as pharmaceuticals).