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

# What We Heard . . .

## from Intellectual Property Experts and Economists

**Report of Roundtable 2**
**January 12, 2005**

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What We Heard . . .from Intellectual Property Experts and Economists, Report of Roundtable 2
January 12, 2005.



*Aussi disponible en français sous le titre, Ce que nous ont dit . . .les experts de la propriété intellectuelle et les économistes, Rapport de la deuxième table ronde, 12 janvier 2005.*

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## Summary of Advice

1. HGM technology is an emerging field and the genetics-related biotechnology industry is still young. This creates challenges in all three stages of the health-related IP environment, many of which have been highlighted by the Myriad case (e.g., high diagnostic test costs and a lack of alternative products (resulting from very aggressive protection of a very broad patent). The Myriad case is unlikely to be one-of-a-kind, as other diagnostic companies seem to have followed the same pattern. Nevertheless, these companies represent only a small part of the HGM-related biotechnology industry. In addition, the industry has yet to mature so it is impossible to predict whether, with maturity, Myriad type problems will lessen or increase.

2. The technical application of patent law to HGM is not substantively different than for other biotechnologies, medical technologies, or other patentable fields. However, the values of *health* and the importance of *individual privacy* and access to genetic information differentiate HGM-related biotechnology from other patentable fields resonate in the public consciousness. These values combine to create a context that places special expectations on the political environment and warrants a thoughtful, effective response and approach at all three stages of the health-related IP environment.

3. The rationale behind the patent regime is that it provides incentives for coordination and interaction among members of the research, development and commercialization, and health care system communities as well as economic incentives for research through the possibility of royalty-generating discoveries. While no rigorous empirical evidence exists to support this rationale, there is little evidence against it. In this situation, policy should generally be formulated with the presumption that patents, along with other formal and informal mechanisms (competition law, licensing practices, first to market, and so on) contribute to the development of the biotechnology industry.

4. Negative impacts on research and clinical practice include high license pricing, excessive restrictions on the use of patented HGM products, processes or services and a lack of a formal research exemption. These can all lead to high development costs and an abandonment of research. However, they could also lead to innovation as researchers look for a ‘work-around’ for a patented product, or a lower cost alternative to a highly priced product. The biggest hurdles to such innovation are the validity and scope of a patent, including the uncertainty in determining these.

5. The patent system may result in patents being issued with too large a scope and patents that simply should not be granted. In some cases, the licensing actions of patent holders may impede the ability of the health care system system’s ability to have control over its own key processes such as the provision of diagnostic services. This can also threaten the health care system by increasing costs and may threaten our long-term ability to attract and maintain the expert human resources that are required to conduct research and run a strong health system. To a large extent, this problem will be resolved over time.

6. Most participants indicated that IP protection is not the most important influence on the development of products, processes and services utilizing or based on HGM in the development and commercialization stage. Profitability is important. The marketplace shapes the demand for products and indirectly the type of patented innovations that reach the market and are ultimately put into use, but not necessarily towards the public good. Given Canada’s

public health care sector and the nature of healthcare itself, the market is only one force among many in shaping the products and services available to Canadians. Companies often receive a higher profit margin on products that may not necessarily meet health priorities of the system or patients so marketing is focused on products such as Viagra. As a result, companies may not focus on health system priorities and patients may not have access to the most effective treatments.

7. Some participants felt that, given the particular importance and nature of the health care sector, government should be more proactive in assuring access to health care products while maintaining competition in the marketplace. The United States has a dominant impact on patenting and development and commercialization in Canada. Our relationship with the U.S. with respect to patents and health-related IP protection is complex. Some participants noted a U.S. perception that Canada is unfriendly to biotechnology. This perception may limit American companies' willingness to invest in Canadian innovations and in Canada. No empirical evidence exists to support or refute this claim.

8. Any strategies to improve the patent regime as it relates to HGM technology and genetics-related biotechnology industry cannot be undertaken in isolation or without consideration of their wider and long-term impacts on health care, biotechnology research and patent environments more generally. Many of the issues recommended strategies would apply to all types of patents, not just those related to HGM.

9. Participants recommended several strategies for improving the administration and operation of the patent office, but no consensus existed to undertake revisions of the *Patent Act* at this time. They recommended more effective use of the provisions already contained within the *Patent Act* and better coordination with complementary legislation and systems (e.g., Competition Act). They also noted that these recommended intervention strategies would benefit the patent system overall, not just in the health-biotechnology field.

## 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 is holding a series of roundtable discussions with key stakeholders including medical researchers and clinicians; intellectual property practitioners and economists; commercializers, regulators, and investors; and health-system administrators. Roundtable discussions will inform the EWP's interim report, which will then become the subject of a further roundtable session with representation from all stakeholder groups (multi-stakeholder roundtable).

IP experts and practitioners and economists were invited to the second roundtable session on January 12, 2005 in Toronto, Ontario. Twenty-four individuals attended this session, including three EWP members and three observers (see Appendix 1 for a list of participants). The goal of this roundtable was to engage IP practitioners and economists in a discussion of the intellectual property regime and the economic costs and benefits of the IP protection of HGM with respect to health-related research and development and the provision of health services. The EWP hoped to gain an understanding of:

- the role of IP protection in research and development involving HGM, the factors involved in choosing whether and how to protect IP in HGM (including factors related to the operation of the Canadian IP regime), how protected innovations are made available, and the impacts of those decisions,

- the broad economic impacts and implications of the presence or absence of IP protection of HGM on the research economy, the commercialization economy and the health services economy, and

- potential approaches/responses to these impacts and implications which could contribute to optimizing IP protection of HGM, research involving HGM, and accessibility and affordability of resulting new products and processes for Canadians.

Participants also were asked to provide their advice on the scope and focus of the planned multi-stakeholder roundtable.

This report contains a summary of the discussions and recommendations obtained from IP experts and economists at the second roundtable. Footnotes have been included only where additional background information is necessary for clarification or context.

## 2.0 Impacts and Implications of IP Protection on Research, Development and Commercialization, and the Health System

During the first roundtable, researchers and clinicians recommended a construct illustrating the flows and linkages between different elements of the health-related IP environment. A process diagram (see Appendix 2) subsequently developed identifies three stages of activity – research, development and commercialization, and health system use – as well as the flows and linkages between them.

Throughout their discussions, participants noted that HGM technology is an emerging field and that the genetics-related biotechnology industry is still young. This creates challenges in all three stages of the health-related IP environment, some of which are likely to lessen (but may be replaced by new challenges) as boundaries are created and tested, as the industry/environment matures and as more innovations become available in the marketplace.

The significant effects of the Myriad case were highlighted to illustrate some of the challenges that are currently being experienced in this developing field. For example, high diagnostic test costs and a lack of alternative products currently describe not only the Myriad case but also the approach of the diagnostic test industry generally. Whether these problems lessen or become worse as more products come to market in the future and other business models are applied is uncertain. Many participants were optimistic that the Myriad type of situation will resolve itself in time. Others felt that it is impossible to predict how these problems will be resolved. Taking a historical perspective, sometimes industry does solve its own problems but at other times government intervention is necessary (e.g., airplane industry, radio industry). Previously experienced difficulties in the agriculture field, with Monsanto, were cited as an analogy to this situation. In this case, researchers were forced to design around Monsanto patents, ultimately broadening the field of innovations available in the marketplace. This suggests that other competitors will enter the market with alternative products in the long-term. Nevertheless, given some of the unique characteristics of the health care sector, participants were uncertain whether the analogy with the agricultural sector would hold.

In their discussions at the second roundtable, IP experts and economists were asked to address specific questions responding to each of the three stages and to the health-related IP environment as a whole. The discussion questions are included in sections 2.1, 2.2 and 2.3 below along with a summary of participants' discussion and recommendations.

**Discussion Questions**

- *What impact has IP protection of human genetic materials had on basic and clinical research and on researchers?*
- *What are the short-term and long-term implications of those impacts for basic and clinical research?*

### *2.1 Stage 1: Impacts of IP Protection of HGM on Research and Clinical Practice*

While we do not know exactly how the patent regime functions, current theory suggests that patent rights may prompt and catalyze coordination and interaction between members of the research, development and commercialization, and health care system communities. For example, researchers and other parties coordinate with other patent holders to obtain and share licenses. Patents also provide opportunities to learn about

other work in a particular field. Interaction between parties can be a result of tension around a patent but is more likely to be collaborative. It is hoped overall to be a positive, systemic effect that will continue to shape and orient research in the future. While no empirical evidence exists to support this rationale, there is no evidence against it. In this situation, policy should generally be formulated with the presumption that patents, along with other formal and informal mechanisms (competition law, licensing practices, first to market, and so on) contribute to the development of the biotechnology industry.

However, coordination and interaction may also be stifled by a particular patent holder. If a patent holder excessively restricts the use of patented HGM products, processes or services by pricing licenses too high or placing severe restrictions on their use (e.g., restricting use of a genetic test to a single laboratory), a researcher's ability to both test the validity of a product and/or undertake related research is limited or eliminated. This impact is exacerbated by the lack of a formal research exemption in Canada (to date researchers have relied on an informal research exemption however this is actually infringement). It may also have human resource impacts (both now and in the future) by limiting the number of knowledgeable individuals who can undertake further research and/or assist physicians and others in diagnosis, management and care. Ultimately, these issues could limit patients' choices to receive the best medical care possible. This is a negative impact but may be only transitional; whether this impact lessens or increases as the field of genetic biotechnology matures is, at this point, uncertain.

Patents may also provide economic incentives for research through royalties. Again, this claim is not empirically supported but has similarly not been refuted. In some cases, royalties provide a source of funding which can be channeled back into further research. This is a positive, systemic effect of the IP system.

However, the effect of royalties can also have a negative impact on health care sustainability. High development input costs can be a limiting factor for research projects which may not offer economic outputs (e.g., public good research). Equally, high prices for new products or processes for use in the health care system may threaten economic sustainability of the system because the cost of providing those new products or processes is in the present, but the benefits from using them are some time in the future. The cost of licensing patents can be prohibitive for research institutions, especially where multiple licenses are required to conduct a certain type of research. In some cases, research has been abandoned due to these costs. This is a negative effect that is more likely to affect public good research where economic returns are not anticipated.

**Discussion Questions**

- *How important (and why) is IP protection in general and patents in particular to the development of products, processes and services utilizing or based on human genetic materials?*
- *How/in what ways is the current patent regime as it respects human genetic materials effective or ineffective and efficient or inefficient?*
- *What are the short-term and long-term implications of the current patent regime impacts on development and commercialization?*

Some participants also noted that high development costs could have a positive effect by stimulating innovation and research in other areas (e.g., as a 'work-around' for a patented product, or to find a lower cost alternative to a highly priced product). The

biggest hurdles to such innovation are the validity and scope of a patent and the uncertainty that surrounds these determinations. Overall, participants felt that this effect is systemic and expected to continue in the future.

### *2.2 Stage 2: Impacts on Development and Commercialization*

Participants indicated that IP protection is not the most important influence on the development of products, processes and services utilizing or based on HGM in the development and commercialization stage.

Profitability is important. Companies rely on the marketplace value of a product to determine whether or not to commercialize it. Companies go to market as soon as they can, sometimes without waiting for a patent. If a product can be sold to more people at a higher price than another product, it will be developed for commercialization. Patents have little effect on these decisions. Biotechnology start-ups (and research institutions, to a certain extent) may be an exception to this. They may rely on patent rights, and the related royalties, as a source of funding for further development and research. This is a systemic, long-term effect.

The United States has a dominant impact on patenting and development and commercialization in Canada. Canada is a small market on the world stage thus biotechnology businesses typically look to the U.S. and European markets for success because it is easier to make a profit in a larger market with stronger innovation supports. Investment in Canadian companies, research and product thus depends, to a very high degree, on access to U.S. and European markets.

Some participants also noted a perception that Canada is unfriendly to biotechnology. For example, some researchers and others, both within and outside Canada (e.g., U.S.), have the perception that the patent system is overly stringent in Canada (e.g., because it does not grant patents on plants and animals). They also believe that there is a long waiting period for issuance of patents. This perceived ineffectiveness in the patent system might discourage investment in Canadian innovations although no empirical evidence exists to support this claim. More likely, as long as Canadian companies and research have access to U.S. and European markets, Canadian patent law will play a very minor role in decision-making.

Related to this issue is the challenge that Canada faces in keeping its ownership of U.S. and European IP and product development in Canadian hands, and the associated positive impacts, within Canada. Internationally, Canada is not a major player in HGM-related IP so the state of IP systems in Canada needs to be addressed in an international context. Participants recommended an examination of the laws in other countries as some of these are seen to be more successful than Canada in maintaining IP expertise and products, and the associated benefits, under the control of their own nationals.[1]

[1] A comparison of Canada's patent system, both substance and administration, to that of other countries, is currently in progress.

Some participants felt that we must particularly reflect on our complex relationship with the U.S. with respect to patents and health-related IP protection. They noted that due to our universal health care system, we have different needs than the U.S.; these differences need to be recognized and addressed. They urged action to cultivate a uniquely Canadian IP presence designed to maintain our own culture and to encourage research and development and commercialization in Canada (by Canadians and others), especially by focusing on the diversity of Canada's population. These participants also noted that, especially in the health biotechnology sector, Canadian patent law plays almost no role in encouraging biotechnology research. This is because Canada represents, at best, 2% of the world market whereas, together, the U.S. and Europe represent more than 50% of the market. This means that Canadian companies will align their strategies with U.S. and European patent law, not with Canadian patent law. This is because patents apply only in the country in which they are issued. As Canadian patents have no effect on 98% of the market, Canadian policy should ensure that Canadians could easily access patents in other countries. On the other hand, other participants recognized that IP does not exist in isolation and that Canada should do its share in funding innovation, especially where this benefits developing countries. These sometimes competing objectives need to be successfully addressed and managed.

**Discussion Questions**

- *What impacts has IP protection of human genetic materials had on access to and delivery of health services?*
- *What are the short-term and long-term implications of those impacts?*

Whatever approach is chosen in the long-term, 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 and build a successful Canadian industry.

### *2.3 Stage 3: Impacts on the Health System*

Participants generally agreed that the technical application of patent law to HGM is not substantively different than for other biotechnologies, medical technologies, or other patentable fields. Issues around IP protection of HGM in Canada are raised in large part as a result of our universal health care system. This relationship between patent context and the health system must be managed carefully for success.

The HGM field presents two central values, namely the values of *health* and the importance of *individual privacy* around to genetic information, which differentiate HGM-related biotechnology from other patentable fields in the public consciousness. These values combine to create a context that places special expectations on the political environment and warrants a thoughtful, effective response and approach at all three stages of the health-related IP environment.

Patients' privacy and their right to have access to personal information must be taken into account and maintained. Provincial health system confidentiality was also raised as an issue. Some participants perceived an unwillingness by industry to talk on the record about what it is doing with information collected through the use of patented products.

The marketplace shapes the demand for products and indirectly the type of patented innovations that reach the market and are ultimately put into use, but not necessarily towards the public good. Given Canada's public health care sector and the nature of healthcare itself, the market is only one force among many in shaping the products and services available to Canadians. Companies often receive a higher profit margin on products that may not necessarily meet health priorities of the system or patients so marketing is focused on products such as Viagra. Companies may not focus on health system priorities and patients may not have access to the most effective treatments.

There was also some concern about companies putting products on the market too early, before they have been evaluated for their potential benefit (or detriment) to the health system. It is unclear how often and how effectively safety mechanisms around patents are used.[2] Participants felt that the government should take a lead in enforcing safety mechanisms.

The patent system may result in patents being issued with too large a scope and patents that simply should not be granted. To a large extent, this is because patent standards relating to HGM are evolving and the patent system attempts to be technology neutral and uses the same rules to grant patents over mousetraps as HGM. Too broad patents or patents of uncertain validity can limit the health care system's ability to have control over its own key processes and may prevent research from taking certain directions which may benefit the health care system and public good. This can also threaten the health care system by increasing costs. To a large extent, this problem will be resolved over time. Breakthrough technologies may receive broader protection as the technology is new but the scope of claims seems to narrow as the technology advances and the amount of known prior art increases. For example, it is possibly due to a lack of expertise around HGM and health biotechnology in the Canadian patent office.

A lack of an effective means to challenge patents was also identified as a negative impact. It is thought to be a symptom of a growing area of development and is not considered to be systemic.

Some participants felt that, given the particular importance and nature of the health care sector, government should be more proactive in assuring access to health care products while maintaining competition in the marketplace. These participants suggest that governments be provided with more tools to discipline the market when industry actors act against Canadian interests. Such measures include a more active enforcement of competition law, targeted compulsory licensing provisions aimed specifically at the diagnostic market and other measures. Like the patent system itself, there is little data available to analyze or determine this impact.[3]

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[2] Health Canada reviews therapeutic and diagnostic products for safety and efficacy; it is not the purpose of patents or the *Patent Act* to address these issues.

[3] Products come on the market either when they have been approved by some regulatory authority or when their manufacturer launches them (if they are not subject to regulatory approval). They may get into the health system "too early" if there is no effective health technology assessment (HTA) process which can compare similar products or new products and older ones to see which is most beneficial and most cost-effective, which helps keep system costs under control.

Overall, participants noted that IP protection of HGM could have negative impacts at all three stages of the health-related IP environment. Patents can be used to limit new research by restricting the use of a patented product, process or service. Breadth of patent scope and inappropriate granting of patents ("bad patents") mean resources that could have been put towards additional research go instead to obtaining licenses and perhaps paying royalties. The practices of exclusive licensing or high license fees and royalties may allow a company to restrict use of a patent in a manner that those wishing access consider inappropriate. The patent scope issue was seen by some participants to be the most problematic for all aspects considered affecting costs, ability to do research and ability to manage the public health system for sustainability.

## 3.0 Proposed Approaches/Strategies for Addressing Impacts of IP Protection of HGM

Participants recommended strategies for the identified effects/impacts by focusing on three broad areas:

a) impacts on health system and genetic testing, specifically addressing these questions:

- Is health genetics (biotechnology relating to human health) distinctive enough to warrant a specialized approach in the patent regime? If so, how and why?

- What is the impact of any strategy on the innovation/commercialization sector and how can we enable a strong, vibrant sector?

- Timing factor – to what extent is this transitional and how does this affect the timing of identified solutions? Which solutions should be immediate versus long term?

b) impacts of the U.S. system on IP protection of HGM (e.g., threats/concerns/opportunities, impacts of Canadian patents held by U.S. firms, impact on biotechnology strategies in Canada, etc.)

c) impacts on the administration/operation of the IP regime (e.g., length of time to patent, abuse of system, patent scope, resource efficiency, policy guidelines, etc.)

For each of these areas, participants addressed four questions:

- Can the patent regime address the challenges identified?

- Could other existing mechanisms address these challenges? Or be adjusted/expanded to do so?

- Are new mechanisms required and, if so, what would they look like?

- Are there other strategies that could help reach the goals of encouraging economic growth and maintaining an accessible, affordable and sustainable health care system?

### *3.1 Distinctiveness of Health Genetics*

Participants were divided on the issue of whether health genetics is distinctive enough to warrant changes to law or legislation with respect to the *Patent Act*. Patent innovation

does not distinguish between fields. Many felt that there is nothing inherently different about innovation in the health genetics field compared to other fields, so a specialized approach within the *Patent Act* is not recommended. Others felt that, because of the importance of genetics to health care solutions in the future and concerns over privacy, a targeted approach to HGM is appropriate.

However, participants agreed there are some considerations that must be addressed within the patent system and context as a whole and which may warrant separate strategies and/or specialized approaches, i.e.:

- privacy and access – as noted in Section 2.3, patients' privacy and their right to have access to personal information must be taken into account and maintained.

- relationship between innovation, commercialization and the health system – since our health system is government funded, there is a special relationship between health genetic-related biotechnology and the health system. This is a socio-political issue that could be addressed through non-legislative measures.

- government as purchaser - The health care system sets up a scenario where the government desires low cost products and tests, doctors want to provide the most effective tests, drugs, etc. for their patients and companies need to recoup their development costs and make a profit. While these needs overlap to some extent, it creates a situation where the end users (the patients) are not the first line consumers, which are rather health system players and government funders who become the purchasers.

- special relationship between the doctor and patient (e.g., with respect to privacy issues)

- some other countries view HGM as distinctive and are considering special approaches to address certain impacts on their health systems.

### *3.2 Strategies for Addressing the Impact on the Health System*

Participants discussed several aspects of the *Patent Act* that could improve elements of the health system and the IP protection of HGM. Some of the recommended intervention strategies would require legislative changes while others are administrative in nature.

#### *Legislative Approaches*

- Formalizing the experimental use exemption/research exemption - Participants noted that there could be a relatively important negative coordination effect if patents are used to limit research by others through a strong restriction of the use of the technology or product. This can have a negative effect at the research and development stages as well as on the health system. For example, this can have a detrimental effect on the sustainability of the health system if certain types of research cannot be undertaken even if they are beneficial to public health; it also contributes to the control issues. This can be a transitional problem that should settle over time as the genetic technology field matures. A clear research exemption scheme would prevent this negative effect on basic research.

However, participants were divided on whether the *Patent Act* should be amended to address this issue.

- Patent re-examination procedures are outlined in the *Patent Act*. They could be used more effectively and could be improved as the U.S. is currently doing.[4]

- Compulsory licensing and abuse of patent provisions could address some of the impacts identified by some participants. There was no consensus around this issue because of negative experience with the prior compulsory licensing system. However, some participants raised the possibility of a modified system of compulsory licensing, along with the development of guidelines around the use of an HGM patent by government, as a possible approach to address scope and granting of patents. These participants felt that this could be accomplished through more effective use of section 19 (use of patents by government) and section 65 (abuse of patent rights) but others felt that a specific compulsory licensing regime aimed at diagnostics was necessary. Other participants felt that instituting a compulsory licensing system would be undesirable.

  Those participants in favour of targeted compulsory licensing for the health system noted that such a system would not trigger TRIPs[5] and would provide some leverage in dealing with unreasonable patent holders. 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 "direct or indirect government use". It was for this reason that they suggested a more targeted approach to compulsory licensing.

  Section 65 of the *Patent Act* could be used to obtain a license from an unwilling patent holder. This section is rarely used and could provide an effective means of more directly addressing abuse of HGM-related patenting. However, participants cautioned that more use of Section 65, with no legislative change, might result in increased litigation, which is not desired or helpful.

  - The role of the PMPRB could be expanded to include HGM-based products, as well as pharmaceuticals. This would require a legislative change.

  - Some participants suggested an examination of the definition of "invention" to determine whether some subject matter (e.g., genes) should or should not be patentable.

  Participants did not reach consensus around any particular change to the *Patent Act* at this time. While there could be useful improvements made to the administration and operation of all of these provisions, participants concluded that administration and operation of the system as a whole should be improved as a priority over opening the *Patent Act* for

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[4] 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.

[5] These participants felt that this has been undertaken in Europe without significant negative impacts.

review. They also noted that such improvements would benefit patents overall, not just in the health-biotechnology field.

***Other Approaches***

There was some concern over whether the existence of a strong health-related biotechnology industry is in the public good as the interests of health care and industry may not converge well.

A few participants suggested that, in theory, a "patent-free" Canada could be a good strategy for encouraging international investment in Canadian biotechnology.[6] This may have adverse effects on the public health care system and would mean that Canada did not pay its fair share of research and development costs, an issue of particular moral importance when it comes to diseases that affect developing countries.

Others suggested that a patent system with very high interpretation of patentability requirements and very narrow scope would be interfere less with government's ability to provide health care at reasonable, sustainable costs.

Enhanced health technology assessment[7] capacity applied to HGM-related inventions would also assist in keeping costs manageable.

### *3.3 Strategies for Addressing the U.S. Impact on IP Protection of HGM*

Canada needs to encourage the development of small and medium-sized biotechnology companies. Some participants noted the success in the U.S. in supporting and creating a healthy biotechnology sector. A measurement of diversity, quantity and assets is necessary.

Participants discussed different ways of making the Canadian system more compatible with the U.S. system as a means of (a) lessening the impact of the U.S. on the Canadian research and development/commercialization environment, and (b) supporting greater Canadian competitiveness. Some participants are willing to consider dramatic approaches ranging from becoming a "patent-free" zone to merging U.S. and Canadian patent offices as a means of achieving a closer relationship with the U.S. system. This would need to be done in a manner that complies with TRIPs, meaning that Canada would simply adopt the most open patent regime available under that Agreement. Another solution might be to increase Canadian IP protection to reduce loss of research, products, or resources to the U.S., as when Canada increased copyright protection and reduced outflow of cultural resources to Hollywood. Some participants believed that a strong Canadian patent system would help keep a strong health-related biotechnology industry in Canada. Others felt that, given the relative insignificance of the Canadian market, Canadian patent law is largely irrelevant to investment decisions. Given this, Canadian policy-makers should be more concerned about U.S. and European patent law than that of Canada.

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[6] To the extent that this might be permitted under TRIPs.

[7] Technology assessment is a process of comparing various methods of achieving a goal and adopting the one (s) that provide the greatest benefit the most efficiently and/or at the lowest cost.

### *3.4 Strategies for Addressing the Administration/Operation of the IP Regime*

Improvements to the administration and operation of the IP regime broadly, and the *Patent Act* specifically, are needed. Many participants noted that the *Patent Act* is not used to its fullest extent and felt that it could be used more effectively to address some of the negative impacts identified in Section 2.0.

- The patent office must have the support, training (e.g., for examiners) and resources to make best use of the tools that exist, and to apply these tools consistently and effectively. For example, government use [s. 19] and abuse of patent [s. 65] provisions in the Act could be used more often and more effectively in situations of abuse of patent rights.[8]

- Development of a worldwide agreement on the acceptable scope of patents would help address negative impacts around the issue of "broad" patents.[9]

- Extension of patent terms may be a potential strategy for strengthening the system. 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. Given the relative lack of importance of the Canadian pharmaceutical market, there is significant doubt that such a measure would actually increase innovation. A possible negative aspect of this strategy is increased administration costs at the patent office to calculate the extension; these costs would be passed onto patent applicants.

- Accelerating the examination process for the grant of patents may also improve the operation of the IP regime by extending the time in which a patent is effective after it has been granted. Patented products would then be in the market longer, allowing companies to recoup a greater percentage of their investment. This could help lower overall product costs for Canadians and the health system.[10]

- Strategies are needed to address patent infringement and to manage patents that should not have been granted. Participants were unsure that any existing administrative procedure is adequate to address these issues but noted that court litigation is too expensive a tool to do so effectively. Regardless, they recommended a

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[8] Although the provisions for government use of patents (s. 19) and remedies for abuse of patents (s. 65) are in the *Patent Act*, the use of these provisions is not initiated by the patent office. Rather, a government in the case of s. 19 and someone who wants to produce the patented invention in the case of s. 65 would have to apply to the Commissioner of Patents for a licence.

[9] The Standing Committee on Patents of the World Intellectual Property Organisation (WIPO) aims to bring a greater degree of harmonization to the substance of patent law, particularly with a view to improving the quality of granted patents, including breadth. Current priorities focus on patentability criteria of novelty and non-obviousness (called inventive step in some countries) and the written description requirement. The next meeting takes place in June 2005.

[10] While this may generally be true, where lengthy regulatory processes are involved, for example if the genetic invention is classified as a pharmaceutical, the key element may not be when the patent is granted, but when the approval to market the product is received from the regulator.

better, more open re-examination procedure, with additional available expertise to address issues and challenges.

- Better coordination between different elements of the whole system, and better use of complementary legislation and systems, was highly recommended. For example, coordination between the competition and patent offices, and more coordinated use of the Competition Act and the *Patent Act*, could help better address challenges such as those presented by the Myriad case.

- Examiner's guidelines to apply the criteria would help improve administration of the patent regime by encouraging a common approach among examiners and introducing additional consistency into the administration of the *Patent Act*. Patent examiners should be provided with guidelines on which criteria to apply and how with respect to HGM.[11] Guidelines would also be useful around the conditions that are set for federal funding. As with examiner's guidelines, this would help provide a common approach and consistency making the funding process more transparent for researchers and others seeking federal funding for projects.

- Participants noted a general lack of common understanding of (a) the use of patent terminology, and (b) the current operation of the patent system. They recommended undertaking education/awareness activities to help improve the administration and operation of the IP regime. For example, there is a need to be clear about whether or not a strategy should address gene patents or the health system more broadly. This also could help address the negative perceptions that exist around the Canadian patent system (e.g., long wait times for patent issuance).

- An education program might also help to raise the level of knowledge of this new field among examiners and others. The capacity and quality of expertise within the system (e.g., examiners) could be improved in this manner as well. This would provide better resources for researchers, companies and others, and would create more consistency in the system.

- Messages must be consistent and positive, addressing not only specific elements of the *Patent Act* but also operation of the system as a whole.[12]

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

[12] On February 2, 2005, the Canadian Intellectual Property Office (CIPO) launched a new website called IP Toolkit (http://strategis.gc.ca/sc_mrksv/cipo/toolkit/main-e.html) that would meet some of these requirements.

### *3.5 Overall Advice*

Participants considered, but did not reach consensus around, changes to the *Patent Act*. There was agreement that many non-legislative approaches could be taken to deal with many of the negative effects of patenting of HGMs.

Participants noted that impacts and implications of the IP regime at each stage (e.g., basic research, development and commercialization, the health care system use) need to be understood separately as well as within the context of the whole system. 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 that are implemented at one stage will have implications at other stages in the system. We must ensure that the overall impact is positive, not negative and that both short- and long-term goals are being met effectively and appropriately. They also stressed the importance of considering short-term solutions within the context of identified long-term solutions, e.g., short-term solutions undertaken to address impacts cannot undermine the success and long-term health of the health system and biotechnology industry.

They also noted that many of the issues and strategies they identified would apply to all types of patents, not just those related to HGM.

Lessons from other industries are useful to the biotechnology field and for biotechnology-related patents. For example, strategies to deal with Microsoft monopolies could be applied to the Myriad type of case. However, privacy and access issues that are unique to health-related biotechnology must always be considered and addressed.

Innovation and growth of the biotechnology sector is important to Canada's economy and to its health system. It is important to consider both domestic and international impacts of potential changes to the IP regime to the innovation agenda.

## 4.0 Advice and Recommendations for the Multi-Stakeholder Session

Participants at the multi-stakeholder roundtable should consider the impacts and implications of recommended strategies. The implications of a strategy must be considered for other sectors in addition to the biotechnology and health sectors, as well as across all stages of the system, by asking questions such as:

- What specific actions would be needed to accomplish a particular strategy?
- Is a particular strategy achievable and/or practical?
- How long would it take to achieve it?
- Who is needed to implement the strategy?
- Who will be affected by it and how?

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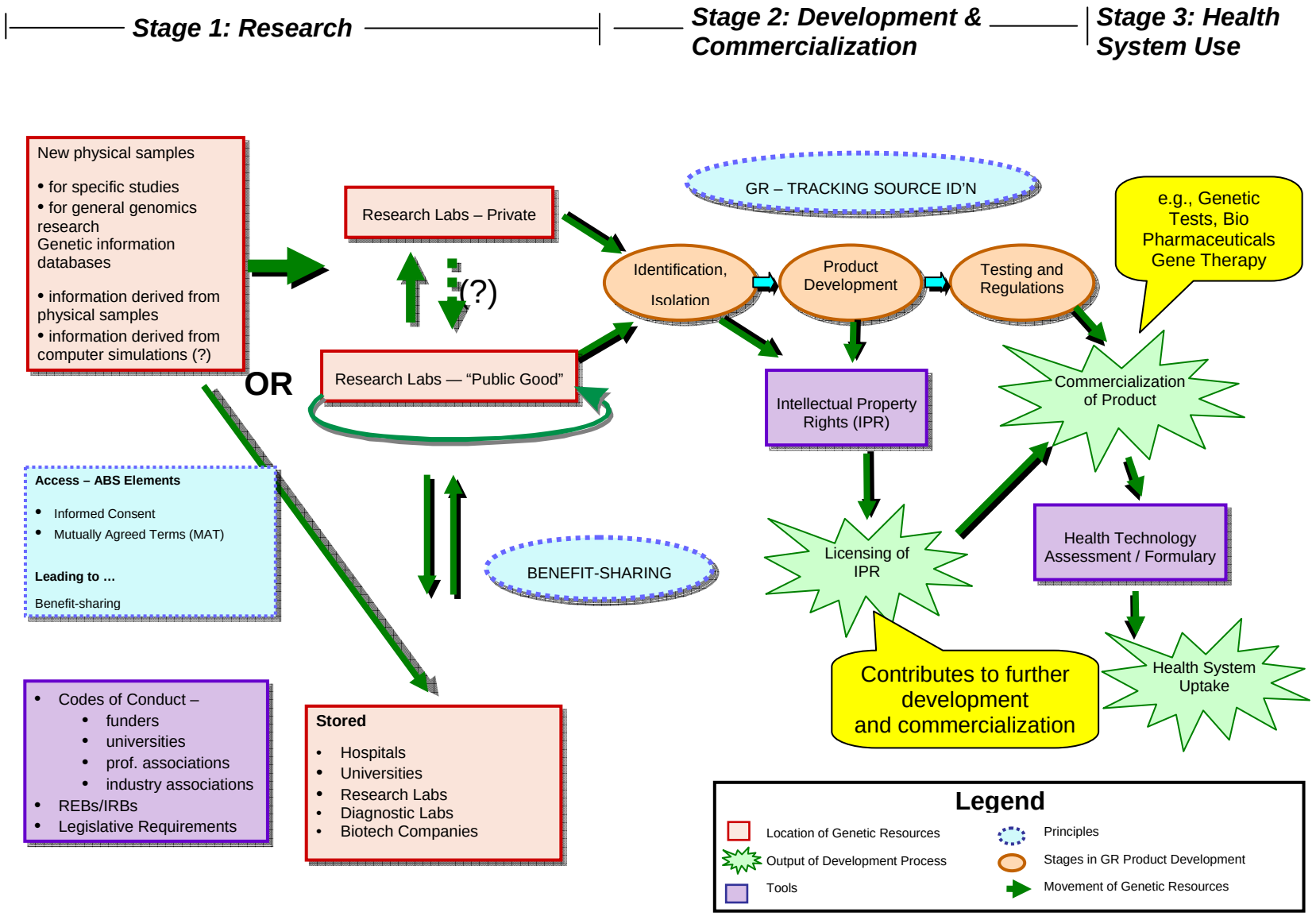
## Appendix 2 – Health-Related IP Environment Process Diagram




Adapted with permission from a diagram prepared by Dr. Stuart Lee, Environment Canada, for a workshop on the ABS S&T Agenda, Ottawa, December 1, 2004.