Report

Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians

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

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Report of the Expert Working Party on Human Genetic Materials, Intellectual Property and the Health Sector

PRESENTED TO:
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Human Genetic Materials: Making Canada's IP Regime Work for the Health of Canadians.

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- the expert facilitators at the roundtables; and
- the consultants who undertook background studies or synthesized documentation.

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In August 2004, the Canadian Biotechnology Advisory Committee (CBAC) established an Expert Working Party (EWP) to assist it in conducting a study of intellectual property (IP) protection involving human genetic materials (HGM) and its effects on the health sector. CBAC undertook the study at the joint request of the Government of Canada's ministries of health and industry (see Terms of Reference in Annex A). The request was made in the context of controversies surrounding "gene patents" in general and tests for genetic susceptibility to disease in particular.

The EWP's work was focused on two main areas:

- the identification and analysis of incentives and disincentives, related to the process of generating novel products and processes based on HGM for application in health care, that pertain to Canada's IP regime.
- a comparison of the current IP regimes of Canada and its major trading partners with respect to current patenting practices and the impacts of patents on HGM-based inventions on health research and the provision of health services; and, identification of appropriate responses to deal with these impacts.

Our report describes particular aspects of Canada's IP regime as they relate to HGM and discusses the issues and impacts of these aspects in three interconnected spheres of activity involved in making new HGM-based products and services available for use in health care: research; development and commercialization; and health services. The final sections of the report contain our conclusions and recommendations

Intellectual Property Protection of Human Genetic Material

Intellectual property law aims to promote innovation for the good of society and to make valuable knowledge from new inventions available to the public. IP can be protected in a variety of ways depending upon the nature of the invention, including through patents, trademarks, copyright or trade secrets. The patent is the most common form of IP protection for HGM. There are substantial similarities among the patent regimes of Canada and its major trading partners. These regimes have similar requirements for patentability (novelty, non-obviousness and utility) although there are nuances of definition and interpretation that differ amongst them. Databases of genetic information obtained from HGM may be protected by copyright or specific database protection rights.

HGM as they exist in nature cannot be patented, however, chemicals isolated from nature through human intervention are patentable and this precedent has been applied to the chemical sequences within HGM. Patents have thus been granted on processes for identifying and isolating (purifying) sequences of nucleotides in DNA that were not obvious before and on the isolated sequences of polynucleotides themselves. To obtain a patent, the inventor must be able to identify or modify the novel genetic sequence and specify the product of the sequence and how it functions in nature.

A fundamental issue in gene patenting is whether or not knowledge of the nucleotide sequence in a segment of DNA is qualitatively different from structural knowledge about any other molecule and, if so, whether that difference warrants differential treatment of HGM with respect to patentability of DNA sequences. Other issues have to do with the details of the criteria of patentability. There are questions about whether the claims contained in patents awarded on HGM have in some cases been unduly broad with respect to utility ("real world usefulness")

and about whether the criterion of non-obviousness ("inventiveness") is being applied too loosely now that high-throughput DNA sequencing has been so highly automated.

The recent surge in patenting of HGM has been accompanied by growing public debate and controversy about the effects of such patents and patent-related practices on the health sector. Some question the propriety of such patents on ethical grounds, while others are concerned about practices that act as barriers to industrial and economic development, to research, or to ready and affordable access to products and services.

The diffusion of patented IP in society is effected by patent holders who make, sell or distribute the patented product or process or by licensing others to do so. To ensure that their IP is widely used, some patent holders license it non-exclusively and readily. Others may choose not to license at all or to license in a highly restrictive manner thereby limiting research and impeding access to beneficial health innovations. Moreover, the profusion of patents can in itself impede diffusion of innovations by creating dense thickets of intersecting property rights that make licensing extremely complex.

There is also a considerable variability in the nature and extent to which patent holders enforce their patents or defend them against challenges. Both processes can be time consuming and expensive and therefore more likely to be pursued by patent holders who have substantial resources available to them.

Most if not all-patent regimes provide for government to use a patented invention or to issue a license to others where it believes that greater access to a patented product or process is required to serve the national interest. The conditions for invoking such provisions vary from country to country. In Canada, the provisions exist but have not been used.

Effects on Research

Two factors have contributed to the rapid increase in patenting of HGM in Canada in recent years: significantly increased investment in research involving HGM through the federal granting councils, provincial agencies, the voluntary sector, and special entities such as the Canadian Foundation for Innovation and Genome Canada and the private sector, and an increased emphasis on commercialization of IP. Growing links between the public and private sectors in research and development, the increasing activity of public sector institutions in facilitating and sometimes participating in commercialization of IP, and the various roles now played by researchers has added complexity to the debate about policies related to IP protection and to the efficacy of current provisions in IP regimes related to research.

Patents are intended to have a positive impact on research by virtue of the requirement that inventors disclose fully the nature of their invention and thus add to the store of public knowledge that researchers use to further their work. In some instances, patents have been reported to deter or impede research. Factors that create or contribute to such deterrents or impediments include: an unduly broad scope of protection, absence of an experimental use exemption against claims of patent infringements; refusal by patent holders to license patents; licensing fees that are too expensive; or transaction costs of negotiating licences within a "thicket" of overlapping patents that are too high.

BROAD PATENTS

The extent to which broad patents deter or impede research may depend on the type of research involved and the nature of the patented invention. With respect to HGM, broad patents are of two main types, those that cover a genetic sequence and all homologous sequences, and those that cover a generally applicable research technique or resource ("foundational" or "platform" technologies). Patents of the former type may be too broad if they can be used to claim rights over any use of, or product involving, the patented sequence not specifically identified in the patent application.

Broad patents typically appear as new technologies emerge; the scope of granted patents tends to narrow as knowledge grows and expertise in patent offices increases. Where the broad patent is on a DNA sequence, options such as "inventing around" the patent may not be possible, so that the impact of broad patents based on HGM may be greater than in other fields of technology.

RESEARCH TOOLS

Research tools used by scientists in the course of their genetic research include: laboratory techniques; consumables such as enzymes or reagents used in the laboratory; and DNA sequences used to identify targets for development of vaccines or therapeutic drugs.

A particular product or process may serve as a research tool when used in a research laboratory and as an end product when used in a diagnostic service laboratory. Access to patented research tools is determined predominantly by the availability and terms of licenses granted by the patent holders. Restrictive or costly licensing can increase the difficulty of obtaining access to research tools. Moreover, the time required to negotiate licences may be problematic if it erodes the time available for research, delays work and reduces productivity. In some cases, licensing may be provided with the purchase of products (e.g., the purchase price of a reagent includes limited, non-transferable rights to use the product for research purposes). In other cases, patent holders may distinguish between academic and commercial researchers in applying a licensing strategy so as to promote access for academic researchers.

There has been insufficient study to determine how widespread or quantitatively significant the effects of the foregoing disincentives are. Some suggest that, where patents are very broad and research tools are not readily licensable, most firms and universities have been able to develop "working solutions" to allow their research to proceed, such as "inventing around" patents, using patented IP without a licence (assuming experimental use will be exempted from claims of infringement), developing and using public tools, and/or challenging patents in court.

There is evidence that these ameliorating approaches may be less available for tools used in clinical genetic research. Providers of patented research tools do not accept their use as falling under a research exemption. As a result, researchers report that research has been hindered, certain areas of research have been avoided and sharing of data between researchers has been hampered.

Effects on Development and Commercialization

Although there may be those that question the strength of the link between patenting and the stimulation of innovation, it is clear that patenting is critical to attracting investment in development and commercialization in the pharmaceutical and biotechnology sector. In other industries, other strategies, such as first mover advantage, secrecy and the existence of complementary assets, are used to protect inventions without necessarily relying on patents. The degree of importance attached to patents is directly related to the scale of investment required to bring an invention to market and the time horizon for recouping development, marketing and regulatory costs and achieving an economic return.

Investment decisions may also be influenced by both reality and perceptions about the nature and operation of the IP regime. Recent court decisions in Canada have been portrayed in the U.S. as signifying that the strength of Canada's system is questionable. Moreover, the operation of Canada's IP regime has been criticized as not being as efficient and effective as that in some other countries.

IMPACT OF PATENTING AND LICENSING OF HGM
Many, if not all, of the deterrent and anticompetitive effects of excessively broad patents and restrictive licensing practices that act as disincentives for non-commercial research also apply to research, development and commercialization performed in industry. Moreover, increasing linkages between academia and industry have blurred the boundaries between commercial and non-commercial research. As gene patenting has expanded from a focus on genes as engines for production of therapeutic proteins to include genes as platforms for generating diagnostic products, the interaction of these actors has become more diverse and in some cases their interests have diverged or even come into conflict.

Effects on Health Services

To the extent that patents encourage investment in the development of new products and services of proven benefit and accessibility, the impact is clearly positive. However, the impact can be negative if patent holders exercise their rights in ways that place an undue cost burden on the health system, impede accessibility to products and services, make integrated and high quality patient care more difficult, interfere with appropriate access to information, or fail to protect against inappropriate use of information. As a result of a few high profile cases involving restrictive licensing practices, most of the recent debate about the impact of patenting and licensing of HGM on health services has been focused on diagnostic or prognostic genetic tests rather than therapeutic products.

COSTS
Concerns about the exercise of patent rights by patent holders have in part, been based on the assumption that they will use restrictive licensing practices (e.g., exclusive licenses) and that licensees will charge monopoly prices. The overall cost impact of genetic tests depends on, among other things, the characteristics of the test (e.g. its predictive power), the scope of its application (high-risk populations or general populations), and changes in health care utilization induced by the test result (e.g., surveillance, prevention, counselling and treatment). These considerations apply whether the tests are performed in public or private laboratories, are requisitioned by a health care professional or by patients themselves stimulated by direct to consumer advertising.

ACCESS
Access to patented genetic inventions can be limited if patent holders choosing to exploit their patent rights by employing restrictive licensing practices, exacting high royalty fees and charging high prices for in-house performance of services such as genetic testing. However, restrictive exercise of patent rights is only one of the factors that may affect access to services such as genetic testing. Other factors include funding priorities of health service providers, the technical capacity and accreditation status of laboratories, and the clinical and research interests of the laboratory. A significant proportion of clinical laboratory directors indicate they have abandoned efforts to introduce new genetic tests or have discontinued offering them because of patenting and licensing concerns.

QUALITY AND CONTINUITY OF CARE
A combination of broad patent scope and unduly restrictive licensing practices may block the improvement of existing genetic tests and the development, validation and implementation of new, possibly less expensive and/or technically superior, diagnostic tests. This clearly has consequences for the health system's ability to offer a range of alternatives to patients, for the opportunity to expand Canadian expertise and for the integration of clinical practice and research; should key expertise have been lost to non-Canadian laboratories and a particular genetic diagnostic capability lost through commercial instability, it will be an enormous task to rebuild these resources.

A number of privacy and access to information considerations are also raised by restrictive licensing practices, particularly where the facility performing the test operates outside of Canada and is not subject to Canadian privacy laws and regulations.

Conclusions and Recommendations

The request that CBAC undertake the present study stated:

> The objective of an effective and balanced intellectual property regime is to act as an important stimulus for innovation, by protecting and nourishing creativity and investment, to the mutual advantage of producers and users of such innovation, and in a manner conducive to economic and social benefits.

We concur with the view that, with respect to HGM-based innovations, Canada's IP regime, like those in other jurisdictions, can lead to circumstances in which fulfillment of the foregoing objective – particularly, the "mutual advantage to both producers and users" -- may be frustrated by the way in which monopoly rights are exercised or by the opportunity costs associated with uncertainty and inefficiency in the way the IP regime operates.

Although there is a paucity of empirical data on the quantitative, system-wide effects on the health sector of current deficiencies in the IP regime in respect of HGM, there is, in our opinion, enough qualitative evidence to warrant concerted action to prevent problems from escalating. We have therefore reached a number of conclusions.

1. It would be prudent to take steps now to improve the patent regime and its operation in order to broaden the opportunities for mutual advantage, to deal more effectively with undesirable consequences of the exercise of patent rights when they do arise, and, to improve the timeliness and transparency of patent processes. Moreover, we believe it is urgent that Canada proceeds forthwith to implement these improvements in view of the accelerating pace of scientific and technological innovation.

2. While much of the impetus for examining HGM-based patent came from concerns expressed by health care providers, we have concluded that strengthening the patent regime and its operation will redound to the benefit not only of the users of innovations, but also to inventors, investors and producers.

3. Although some contend that HGM should not be patentable because of what are presumed to be unique characteristics of DNA, the characteristics cited are not unique since the same characteristics are found in other patentable biological materials and therefore, HGM should not be excluded from patentability and we note that to do so, would set Canada apart from other countries, including its major trading partners.

4. Nonetheless, the scope and intensity of the concerns raised by "gene patents" is clearly greater than those related to other types of patented invention and should be addressed explicitly. Although some have urged including public order and morality considerations in the process of examining patent applications to deal with abuses of monopoly rights, we find that other more direct methods of social control would be more effective in prohibiting the manufacture, sale or use of socially undesirable or illicit products and services and would not impose a responsibility on patent examiners for which they are not equipped. Accordingly, matters of public order and morality should not be a consideration in the patent examination process.

5. Similarly, concerns about the issues associated with patenting of genetic tests can also be addressed through enhancement of current provisions of the Canada's IP regime or its operation rather than, as some have proposed, by excluding diagnostic methods from patentability or by providing an exemption for their clinical use - actions which could seriously slow innovation in this field.

6. Sections 19 and 65 of the *Patent Act* allow governments and other potential licensees respectively, to apply to the Commissioner of Patents to use patented inventions without the permission of the patent holder where they have been unable to secure licences on reasonable terms. Since neither governments nor other potential licensees have apparently availed themselves of these provisions, there is no evidence that they are inadequate. Accordingly, we see no need at present to reintroduce a general compulsory licensing provision in the *Patent Act*.

Recommendations

Our detailed recommendations are listed on pages x-xii.

We believe that the policy and practice initiatives we recommend will improve the IP regime and make it more conducive to the generation, acquisition and use within the health system of HGM based inventions that have been demonstrated to be safe and effective and constitute material advances in prevention, diagnosis or treatment of disease and disability. In our recommendations, we call for:

- ***the enhancement, clarification, and more rigorous application of patentability criteria;*** the development of interpretive guidelines; enhanced disclosure requirements on the part of applicants and application of sanctions for failure to meet them; (recommendations 1-3)
- ***significantly enhanced opportunities to challenge patents*:** before they are granted by a more open and responsive mechanism than exists now; and, after they are granted, by the introduction of an opposition procedure; (recommendations 4-5)
- ***increasing the scientific expertise of the Federal Court and consideration of establishing an Intellectual Property Division within the court*** in light of the speed of developments, not only with respect to HGM, but within technology as a whole; (recommendation 6)
- ***amendment of the Patent Act to establish an experimental use exemption from claims of infringement;*** (recommendation 7)
- ***enhanced voluntary mechanisms to limit unduly restrictive practices*** and remove barriers to diffusion of HGM-based innovations, for example through development, of licensing guidelines and encouragement of industry initiatives to create patent pools and other mechanisms to remove barriers to diffusion of HGM-based innovations. With respect to HGM-based inventions developed using public funds obtained through federal grants, the granting bodies should develop licensing guidelines adherence to which would be a condition of funding; (recommendations 8-10)
- ***strengthened legislative provisions*** *(e.g. those pertaining to competition and copyright)* to limit patent rights and copyright in cases of abuse or where the national interest is at stake, either by making current provisions more effective or by introducing new provisions to deal with these matters; (recommendations 11-12) and
- ***the Canadian Intellectual Property Office to review its operations*** with a view to making them consistent with international best practices and to improve its client services. (recommendations 13-14)

In our consultations and deliberations we also identified a variety of mechanisms or strategies that fall outside the IP regime per se, but which can facilitate the adoption of HGM-based innovations in ways that can ameliorate some of the impacts of the IP regime on health services by:

- ***strengthening the organization and performance of Health Technology Assessment*** (HTA): We concur with the view that a strengthened and effective HTA system could contribute significantly to the rational and efficient adoption by the health system of beneficial HGM-based inventions.

- ***employing ancillary mechanisms for facilitating access through control of prices or eligibility for public reimbursement***, including: bulk purchasing; establishing a price review board analogous to the patented medicine review boards, and the use of formularies and reference pricing mechanisms
- ***employing ancillary mechanisms for ensuring availability of innovations***, including: government buy-out of patents or copyright; guaranteed purchase; and, public-private partnerships. Most of the foregoing options are within the purview of the users/purchasers of HGM-based innovations. There is however considerable scope for cooperation and collaboration amongst governments and between the public sector and industry to ensure optimum access to health-enhancing innovations. (recommendation 15)

Concluding Observation

Canada's IP regime, like those of its major trading partners, is a legislated mechanism for reconciling the objectives of fostering innovation and ensuring access to its benefits. Our findings and recommendations are focused on identifying, and proposing modifications to Canada's IP regime to address issues brought to light by recent cases involving patented HGM in which the particular ways in which patent rights have been exercised have frustrated the achievement of such reconciliation.

The issues addressed in this report are part of the much larger challenge of how to create the capacity to adopt beneficial innovations in an already heavily burdened health care system. Meeting this challenge fully will require more than refinement of the IP regime. It will also require new institutional mechanisms and perhaps new organizations.

We believe collaborative efforts involving all levels of government, health care and research institutions, and industry must be intensified to ensure that a comprehensive array of policies, procedures and practices are pursued to realize fully the health and economic benefits of innovations based on HGM.

List of Recommendations

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Initiatives Within the IP Regime

PATENT QUALITY

Recommendation 1

CIPO should develop interpretive guidelines for the application of patentability criteria to genetic innovations, similar to those in the United States for applying the utility criterion to HGM, as well as for evaluating the adequacy of the written description of the IP in the patent application. As in the U.S. guidelines, CIPO should include not only the citation for judicial decisions, but explain what the decision means for patent examination and provide examples of how it would be applied.

Recommendation 2

CIPO should also improve quality control to ensure that the patentability criteria are applied rigorously and consistently to all applications.

Recommendation 3

Patent applicants should be required to disclose all prior art relevant to the claimed invention and sanctions for failure to do so should be established and applied.

OPPORTUNITIES TO CHALLENGE PATENTS

Recommendation 4

The processes whereby third parties may protest a patent application by filing prior art or requesting re-examination of a granted patent should be made more open and responsive.

Recommendation 5

The *Patent Act* should be amended to establish an opposition procedure within the Patent Office, with a time limit for filing oppositions of nine (9) months from the date the patent was granted. Processes should be established and resources allocated to ensure that proceedings could be concluded no more than 24 months from the date the patent was granted.

Recommendation 6

The Minister of Justice should, in appointing judges to the Federal Court, consider the need for increased scientific expertise. The Minister should also consider the desirability of creating an Intellectual Property Division within the Federal Court.

USE OF PATENTED INVENTIONS

Recommendation 7

The *Patent Act* should be amended to include an exemption from claims of infringement for research on a patented invention, as well as for certain research using a patented invention. We are of the view that the wording that follows is suitable; and recommend that the Minister of Industry provide such additional interpretative guidance for the courts as he deems desirable.

> *It is not an infringement of a patent to use a patented process or product:*
> *(a) privately and on a non-commercial scale or for a non-commercial purpose, provided that such purpose does not significantly prejudice the economic interests in the patent of its owner; and*
> *(b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or to create a new (i.e., not incorporating the patented invention) product or process.*

Recommendation 8

The federal government, in consultation with the provinces and territories, academia and the private sector, should facilitate the development of Canadian guidelines for the licensing of HGM-related inventions. We suggest as a starting point the final OECD Guidelines for Licensing Genetic Inventions, expected to be released by late 2005.

Recommendation 9

Ministers responsible for the national granting councils and other federal funding bodies should request them to establish guidelines to be followed by grant recipients with respect to licensing of patented HGM inventions based on research supported by the grant.

Recommendation 10

The federal government, in consultation with industry and academia, should encourage and facilitate the development of patent pools and other mechanisms to remove barriers to diffusion of HGM-based innovations.

LIMITATIONS ON INTELLECTUAL PROPERTY RIGHTS

Recommendation 11

The Competition Bureau should consider developing a policy statement or guidelines concerning the intellectual property law-competition law interface and, in particular, whether refusal to licence or refusal to licence on reasonable terms could be found to be anti-competitive.

Recommendation 12

The federal government should ensure that users' rights are protected through amendments to the *Copyright Act*, such as those contained in Bill-C-60 introduced in Parliament in June 2005. Specifically, such amendments should:

- *permit the use of anti-circumvention devices* in a manner that enables fair dealing;
- *ensure that anti-circumvention provisions are specifically linked to traditional copyright infringement* by limiting a circumvention offence to those who intend to infringe;
- *consider granting users a positive right of circumvention;* and
- *ensure the Competition Bureau can address marketplace practices* that preclude fair dealing.

CIPO OPERATIONS AND SERVICES

Recommendation 13

CIPO should revise and clarify its procedures and services with a view to making them as consistent as possible with the best practices of Canada's major trading partners, bearing in mind that the largest market for Canadian products and the country to which the bulk of Canadian exports go is the United States.

With respect to handling of patent applications, CIPO should revisit its administrative procedures and consider or reconsider changes to:

- *Improve timeliness of examination of patent applications*: Begin examination promptly on request of the applicant.
- *Provide greater flexibility in initial filing requirements*: Canada should grant a filing date for initial filings in any language and/or where the application does not contain the filing fee. The applicant should be given a period, set by notice from CIPO, within which to cure defects in the application before it is considered abandoned.
- *Automatically issue a search report*: CIPO should consider automatically issuing a search report within a few months of examination being requested, and in advance of the first Official Action.
- *Provide relief for inadvertently missed deadlines*: Canada should provide for retroactive extensions to certain time limits to allow applicants an opportunity to revive filings which lapse due to unavoidable or unintentional omissions or delays.
- *Update further the rules for filing nucleotide sequences ("sequence listings") in patent applications*: Canada is out of step with other countries in that it requires that sequence listings be filed using an outdated filing standard and does not permit often enormously lengthy listings to be filed in electronic format only. Since applications may have become abandoned for failure to comply with the outdated sequence listing requirements, the update rules should be made retroactive.

- *Clarify the nature and extent of reliance on corresponding applications*: Patent applications in countries where examination begins immediately will be processed sooner than in Canada, even if filed at the same time. Both applicants and CIPO can take advantage of this to improve the quality of patent applications and patent examinations respectively. CIPO should specify how it currently makes use of corresponding applications and should consider how such use could be formalized.

With respect to service to clients and other interested parties CIPO should:

- *enhance the functionality of its key-word searchable patent database* (Tech Source)
- *make the database easily accessible to clients and the public* through its website rather than requiring those who wish to search the database to do so in person at CIPO offices.

Recommendation 14

CIPO will require increased resources in order to meet best practice performance standards especially in the face of an expanding workload related to growth in the number and complexity of HGM-based inventions. Accordingly it should:

- *Increase fees for patent applications and for maintenance of patents* so that they are comparable to those of Canada's major trading partners, and
- *Impose fees for the examination of large numbers of claims*: introduce supplementary fees for the examination of large numbers of independent claims and large numbers of sequence listings, as is the practice in other jurisdictions.

INITIATIVES OUTSIDE THE IP REGIME

Recommendation 15

We recommend that CBAC, in tendering its advice to the Government on HGM and the health sector, identify such further studies as may be desirable to assess the feasibility and desirability of initiatives outside the IP regime that would enhance access to beneficial HGM-based innovations.

Introduction

Introduction

In August 2004, the Canadian Biotechnology Advisory Committee (CBAC) established an Expert Working Party (EWP) to assist it in conducting a study of intellectual property (IP) protection involving human genetic materials (HGM) and its effects on the health sector.[1] CBAC undertook the study at the joint request of the Government of Canada's ministries of health and industry (see Terms of Reference in Annex A). The request was made in the context of controversies surrounding "gene patents" in general and tests for genetic susceptibility to disease in particular.

The EWP's work was focused on two main areas:

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- a comparison of the current IP regimes of Canada and its major trading partners with respect to current patenting practices and the impacts of patents on HGM-based inventions on health research and the provision of health services; and, identification of appropriate responses to deal with these impacts.

In preparing this report, the EWP reviewed research commissioned on its behalf by CBAC, several policy analyses developed in Canada and abroad, the scientific and policy literature and input from a series of expert roundtable consultations.[2] A summary of what we heard in the course of the latter consultations appears in Annex A. Our work included the development of a background paper that summarized the issues and options for government actions and provided the framework for discussion during the final roundtable consultation involving experts from several sectors. The background paper also received wider exposure and generated additional input to the EWP's deliberations.

Since CBAC has addressed the ethical dimensions of this topic in recent studies, our report does not deal with them except to touch on issues of an ethical nature involved in the reconciliation of conflicts between the legally protected rights of groups with different interests in regard to IP and HGM.[3]

[1] "Human genetic materials" or HGM in this document is defined as nucleotide sequences (including sequences of entire genes or parts thereof and non-coding sequences) that exist in humans, as well as the products (e.g., proteins) expressed by those sequences or parts thereof. Such materials can be used in prevention, diagnosis, and treatment of disease and disability in humans or in epidemiological and other kinds of research involving human subjects. "Genetic inventions" are inventions (defined in the *Patent Act, S.C., c. C-4, s. 2*, ("hereafter "the *Patent Act*," as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter") based on or derived from human genetic materials. "Health sector" in this document means all elements of society involved in the development, organization, management, delivery and application of health products and services.

[2] The EWP held five sectoral roundtables, with researchers and clinical specialists; patent lawyers, agents and economists; developers and commercializers of patented inventions; health system administrators; and representatives of federal, provincial and territorial governments. This series of consultations culminated in a multisectoral roundtable that brought together the full range of perspectives on the issues.

[3] Canadian Biotechnology Advisory Committee. 2002. *Patenting of Higher Life Forms*. Ottawa: CBAC. Also available at http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/E980_IC_IntelProp_e.pdf/$FILE/E980_IC_IntelProp_e.pdf, last accessed August 10, 2005; Canadian Biotechnology Advisory Committee. 2004. *Biotechnology and the Health of Canadians*. Ottawa: CBAC, also available at http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/BHI-Final_Dec-13-04-E.pdf/$FILE/BHI-Final_Dec-13-04-E.pdf (hereafter CBAC BHI), last accessed August 10, 2005.

Our report begins with a description of particular aspects of Canada's IP regime as they relate to HGM. It then goes on to discuss issues and impacts of these aspects in three interconnected spheres of activity involved in making new HGM-based products and services available for use in health care: research; development and commercialization; and health services. These spheres involve players with different interests:

- basic and applied researchers who are users and sometimes inventors of patented innovations;
- investors and companies involved in the commercialization and marketing of patented innovations;
- health care providers and administrators;
- consumers of health services; and
- Canadians generally.

Although some impacts of patenting and licensing pertain primarily to one sphere of activity, they often directly or indirectly influence the others.

The final section of the report contains our conclusions and recommendations.

Part I

Intellectual Property Protection of Human Genetic Materials

Introduction

The accelerating pace of advances in knowledge about the molecular basis of genetics has fuelled a rapid expansion in the development of products and processes for use in health care. As noted in CBAC's report, *Biotechnology and the Health of Canadians*,[4] modern biotechnology (in which genetic technologies play a prominent role) has the potential to contribute to improving health status by:

> *…addressing both genetic and environmental influences on health through advances in screening populations for susceptibility to disease; in reducing exposure to noxious agents in the environment and enhancing the body's ability to block or ameliorate the effect of such agents; in the application of genomics and proteomics to the development of vaccines and other preventive strategies against infectious agents long-associated with human disease and those emerging in recent years (e.g., HIV, the SARS virus and West Nile Virus); and in the application of pharmacogenomics to the development of antimicrobials for preventive use in special circumstances …. [Genetic technologies] broaden the array of sensitive and specific tests that speed diagnosis and permit greater individualization of treatment [and are anticipated to] play a significant and, in some cases, pre-eminent role [in] therapeutic drug development [and in] gene therapy to correct primary defects in the genetic makeup of individuals.*

Intellectual property law aims to promote innovation for the good of society and to make valuable knowledge from new inventions available to the public. IP can be protected in a variety of ways depending upon the nature of the invention, including through patents, trademarks, copyright or trade secrets. IP protection, in turn, operates within the larger context of a country's legal, governmental, economic and health care frameworks. Changes in any one form of IP protection may not have the intended consequences, as other forms may be used to produce countervailing effects. As well, the manner in which regulations are interpreted, enforced (or not enforced), controlled or challenged vary between countries as well as over time. Intellectual property law is an evolving field, with practices and legislation changing over time often in response to court decisions and international agreements.

The patent is the most common form of IP protection for HGM and is the main focus of this report. Recognition of the great commercial potential of genetic technologies has spurred a rapid increase in applications for patents on HGM. As of 2004, more than 3 million genome-related patent claims (many patent applications contain multiple claims) have been filed worldwide.[5] In order to put Canada's patent system in an international context the Centre for Intellectual Property Policy conducted a study on behalf of CBAC comparing Canada's system with those in other key jurisdictions.[6] Specific similarities and differences noted in that study are referred to at relevant points throughout this report. Some HGM-related inventions may be adequately protected by a combination of trade secret protection and first-mover advantage (i.e., getting market share ahead of competitors); however the use and impacts of these forms of IP protection are, by their very nature, difficult to assess. Databases of genetic information obtained from human genetic material may be protected by copyright[7] or specific database protection rights.[8]

[4] CBAC, BHI, note 3, pp. vi-vii.
[5] See Human Genome Project Information website www.ornl.gov/sci/techresources/human_genome/elsi/patents.shtml, last accessed May 2, 2005.
[6] Centre for Intellectual Property. 2005. Genetic Patents and Health Care in Canada: An International Comparison of the Patent Regimes of Canada and its Major Trading Partners. Prepared for Canadian Biotechnology Advisory Committee, available at http://cbac-cccb.ca, under Publications, Research.
[7] Copyright is a form of intellectual property that protects creative works. In Canada, where there is originality in the selection and arrangement of information in a database, the database is protected as a "compilation" *Copyright Act*, R.S.C. c. C-42. In some jurisdictions, compilations may also be protected on the basis of the effort ("sweat of the brow") that went into collecting and organizing the contents of the compilation.
[8] For example, Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, *Official Journal* L 077, 27/03/1996, pp. 0020-0028 (hereafter "European Database Directive"), available at http://europa.eu.int/eurlex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31996L0009:EN:HTML (last accessed August 12, 2005).

Patenting Human Genetic Materials

HGM as they exist in nature cannot be patented. A fundamental issue in gene patenting is whether or not knowledge of the nucleotide sequence in a segment of DNA is qualitatively different from structural knowledge about any other molecule and, if so, whether that difference warrants differential treatment of HGM with respect to patentability of nucleotide sequences. However, legal precedent has established that chemicals isolated from nature through human intervention are patentable. This precedent has been applied to specific chemical sequences within HGM.[9] Patents have thus been granted for many years on entire human genes, gene sequences, expressed sequence tags (ESTs), complementary DNA (cDNA), single nucleotide polymorphisms (SNPs), proteins, and methods of using RNA, if not elements of RNA itself, as well as on processes for identifying and isolating (purifying) sequences of nucleotides in DNA that were not obvious before, and on the isolated sequences of polynucleotides themselves.[10]

To obtain a patent, the inventor must show that the invention falls in the class of patentable subject-matter and is new, useful, and not obvious to someone skilled in the particular field. With respect to HGM, the inventor must be able to identify or modify the novel genetic sequence and specify the product of the sequence and how it functions in nature. It must also be shown to have utility. The utilities of nucleotide sequences patented to date include their role in gene regulation, encoding for therapeutic proteins, diagnostic probes, receptors used for identifying molecular targets for therapeutic drug development, immunogens, and gene replacement therapies.

The non-obviousness (inventive step) criterion of patentability is intended to enable innovations that justify the potential economic rewards of patenting to be distinguished from those that do not. There is a persisting concern, especially among scientists, that, in an era of high throughput DNA sequencing, some patents provide undue reward for minor advances that would in any case have been made by others working in the public domain and impose cost barriers on researchers working on fundamental problems in molecular genetics. With respect to the United States, this concern appears to be justified. The U.S. Report, *A Patent System for the 21st Century*[11] points out that, as a result of judicial decisions, a new genetic sequence claimed in the U.S. is automatically considered non-obvious, whereas the European Patent Office requires the applicant to "demonstrate either that obtaining the sequence was in fact a technical achievement or that they have discovered a new or unexpected property associated with the gene."[12] The extent to which the claims allowed are viewed as meeting the three criteria of novelty, non-obviousness, and utility is often referred to as "patent quality."[13]

[9] The term "gene patents" is a shorthand reference to a more complicated process. "Patenting a gene" refers to patenting a sequence of nucleotides derived by two general processes. The conventional process involves finding a protein involved with a specific biological function, purifying the protein, sequencing a few of its amino acids, making probes representing all the nucleotide combinations that might code for those amino acids, extracting the mRNA from cells producing the protein of interest, transforming it into cDNA (a product that does not occur naturally), using the probes to try to identify in the complex mixture of cDNA derived from the cellular mRNA the coding sequence ("exon") of the gene of interest. (Note that the coding sequence of a gene excludes large parts of the nucleotide sequences in the gene ("introns") that are non-coding. Thus "patenting of a gene sequence" obtained by this conventional method should be understood to mean patenting a nucleotide sequence in cDNA that is representative of an analogous sequence in the exons of a gene. Recently, the process by which most gene sequences are identified does not begin with determining a biological function and then searching for a sequence that encodes the protein involved. Rather high throughput sequencing is used to identify gene sequences and then to search for their functional role by "homology analysis" or by "microarray based expression analysis". Adapted from: Bendekgey, L., and D. Hamlet-Cox. 2002. Gene Patents and Innovation. *Academic Medicine* 77:1378-1380.

[10] For information on how Canada's patent system compares with those of other key jurisdictions, see Centre for Intellectual Property Policy, Genetic Patents and Health Care in Canada, note 6.

[11] Merrill, S.A., R.C. Levin and M. B. Myers, eds. 2004. *A Patent System for the 21st Century*. Washington, D.C.: The National Academies Press, also available at http://books.nap.edu/catalog/10976.html, last accessed September 8, 2005.

[12] Ibid., p. 93.

[13] Ibid. For a detailed discussion of patent quality in general, see pp. 46 –63; for non-obviousness in particular, see pp. 91-95. See also Paradise, J., L. Andrews and T. Holbrook. 2005. Patents on human genes: an analysis of scope and claims. *Science* 307:1566-7. While the methodology used in this study has been disputed (see Problems in Patenting Human Genes [letters from K. Murashige and J. J. Rolla], *Science*, 308:1868-9), this peer-reviewed article is one of the few available studies to date on patent quality.

Scope, Breadth and Reach of Patents on Human Genetic Materials

The scope of a patent is identified in the description (sometimes called specification) of the IP and the claims as set out in the patent application. Patent breadth is sometimes used to mean the extent to which the patent applies to unspecified future uses. The reach of a patent includes the extent to which the patent holder has rights over any future invention made by a licensee of the original invention. In common parlance, the terms scope, breadth and reach are often used synonymously. Accordingly, we use the term patent breadth to encompass the particular nuances conveyed by the terms scope and reach.

There is disagreement in the literature (reflected in the EWP roundtable consultations) about the consequences of granting patents that claim very broad rights or concern foundational techniques of wide applicability. Patents may be regarded as too broad if the utility criterion is applied so liberally that it is insufficiently specific, substantial and credible. This is illustrated, for example, in the case of certain current patents on DNA sequences that cover all possible tests that might be devised for determining the presence or absence of particular gene mutations. In other words, such a patent confers the right to prevent all others from copying, using or selling the patented sequence and, since copying of the sequence may be an essential element in tests to identify mutations, the patent holder can effectively prevent anyone from giving or taking an alternative test even if it is superior in sensitivity and specificity to the particular test described in the patent application. With no competition from other tests, the patent holder can set whatever fees and conditions it likes, 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. Furthermore, broad claims combined with diligent enforcement practices can create an environment that may inhibit research.

Broad patents are desirable from a business perspective because the broader the patent protection, the more likely the patent-holder will be able to bring the invention to market before any competition arises. By the same token, while broad patents make it more difficult for competitors to enter the market with similar innovations, they may encourage others to develop "leap-frogging" innovations. If patent protection becomes too narrow, the business case for pursuing development and commercialization can be undermined and useful inventions may never become available to the public.

One of the most contentious issues concerning patent breadth related to IP and HGM arises from the particular nature of nucleotide sequences. It has been argued that such sequences are of a "hybrid nature … they are both a chemical product and pure information" and the granting of patents on DNA can therefore be seen as "crossing an important barrier: the exclusion of information as such from patent coverage."[14] However all "chemical products" contain information, to the extent that their physical structure is known. The unique feature of nucleotide sequences therefore is not that they contain information, but rather its specificity. Not only can information be revealed about the genetic make-up and predisposition of the individual from which the sequence has been derived, but also information about their families and their progeny – matters that, in our society, are deemed to be private and are protected as such under law.

[14] Gold, E. R. 2000. Gene Patents and Medical Access. *Intellectual Property Forum*, 49:20.

As noted above, the conventional social justification for patents is that they provide incentives for investment in innovation by protecting inventors from competition, thus allowing them an opportunity to recoup their investment and realize the value of their inventions. This justification is also predicated on the assumption that, in the absence of patents, the inventor would not have made this contribution to innovation.[15] If patent holders abuse these monopoly rights, it is argued, potential customers can simply forego the use of the inventions in question, leaving them no worse off than they were without them. This is of little comfort when the invention may offer important health benefits.

The recent surge in patenting of HGM has been accompanied by growing public debate and controversy about the effects of such patents and patent-related practices on the health sector. Some question the propriety of such patents on ethical grounds, while others are concerned about practices that act as barriers to industrial and economic development, to research, or to ready and affordable access to products and services. For example, in its 2002 policy on the patenting of the human genome, the Canadian College of Medical Geneticists[16] stated:

We emphasize that the discoveries that result in patents on human genes are largely the product of massive public investment and decades of collaborative research involving innumerable participants around the world. We are concerned that human gene patents do not recognize the essential public investment in this process of collaboration and discovery. We are concerned that such patents can be used to unfairly restrict the potential benefits of discovery of the genome, and that unreasonable exploitation of the entitlements of a patent holder will be detrimental to the health and well being of Canadians.

The global importance of the issues raised by intellectual property protection of HGM is evident from the number of advisory bodies worldwide that have examined the subject[17] (see Annex C for a tabulation of the key recommendations from these reports) and from other international initiatives currently in progress.[18] As the preceding observations indicate, there are substantial similarities among the patent regimes of Canada and its major trading partners and therefore it is not surprising that these countries would face similar challenges in dealing with the particular characteristics of HGM-based inventions.

[15] Eisenberg, R. S. 2002. Why the gene patenting controversy persists. *Academic Medicine* 77:1381-1387.
[16] Canadian College of Medical Geneticists. 2002. *Patenting of the Human Genome*. Position statement approved by the CCMG Annual General Meeting, September 21, 2002, available at http://ccmg.medical.org/pdf/ccmg_genome.pdf (last accessed June 7, 2005).
[17] Ontario Ministry of Health and Long-Term Care. 2002. *Genetics, Testing and Gene Patenting: Charting New Territory in Health Care*. Toronto: MHLTC, endorsed by all provincial premiers of Canada, also available at www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf; Australian Law Reform Commission. 2004. *Genes and Ingenuity: Gene Patenting and Human Health*. Sydney: ALRC, also available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html; Nuffield Council on Bioethics. 2002. The Ethics of Patenting DNA: a discussion paper, also available at http://www.nuffieldbioethics.org/go/screen/ourwork/patentingdna/introduction; Danish Council of Ethics. 2004. *Patenting Human Genes and Stem Cells: A Report*. Copenhagen: Council, also available at http://www1.etiskraad.dk/graphics/03_udgivelser/engelske_publikationer/patenting_human_genes/patents04/index.htm; National Ethics Council. 2005. *The patenting of biotechnological inventions involving the use of biological material of human origin*. Opinion. Berlin: NEC, also available at http://www.ethikrat.org/_english/publications/Opinion_patenting-of-biotechnological-inventions.pdf. New Zealand Ministry of Health and Ministry of Economic Development. 2004. *Memorandum to Cabinet Policy Committee: Report Back with Recommendations and Options for addressing Genetic Material Patents*. Wellington: Ministry, also available at http://www.med.govt.nz/buslt/int_prop.html, under Patents (all last accessed September 8, 2005).
[18] See www.who.int/intellectualproperty/events/meetings3/en/index.html, last accessed May 2, 2005; OECD Guidelines for the Licensing of Genetic Inventions. Paris: OECD, also available at http://www.oecd.org/document/26/0,2340,en_2649_37437_34317658_1_1_1_37437,00.html, last accessed May 2, 2005; Federal Register. 2005. 70(68):18413-18415 (April 11). Available at http://frwebgate5.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=42019582005+7+0+0&WAISaction=retrieve, last accessed May 2, 2005.

Licensing Patents on Human Genetic Materials

The diffusion of patented IP in society is influenced by the ways in which patent holders seek to exploit their patent rights, including the approach they take to licensing; namely, whether they license at all or license exclusively or freely. Diffusion of patented IP can be affected by the transaction costs associated with negotiating licenses and/or the level of fees and royalties involved. Both of these elements can be particularly problematic where there are overlapping patents involving many patent holders, requiring the negotiation of multiple licenses ("patent thickets"). The time and effort involved in identifying relevant patents and patent holders, negotiating licenses, and the cost of royalty payments for those licenses may be impediments to research and development.

In many cases, patent holders wish to ensure that their intellectual property is widely used and adopt licensing practices that are conducive to achieving that goal. In fact, some researchers and organizations have obtained patents with the specific intention of licensing them liberally and at nominal cost. Moreover, many patent holders choose not to pursue claims of infringement where protected intellectual property is used for non-commercial purposes.

Some patent holders, however, seek to gain maximum economic benefit from their inventions by refusing to license them, license to only one or a very few licensees and/or charging high licensing fees. This behavior has been evident among some holders of genetic patents and has raised significant concern about the impact on research, development and on access to gene-based health products and services. For example, restrictive licensing of genetic tests may impede research to validate or improve upon these tests, may allow the patent holder or licensee to have control over where testing is performed (raising issues of cost, access and quality control) and over the information generated by tests, raising a number of social and ethical considerations related to privacy and autonomy.

To deal with such concerns, IP regimes include mechanisms to limit patent rights under certain circumstances. The Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) permits member countries to include a mechanism for issuing compulsory licenses under certain circumstances, providing that the mechanism does not discriminate among technologies.[19] Prior to revisions in 1987, the Canadian *Patent Act* permitted any company to produce patented drugs under a compulsory license on payment of a royalty of 4 per cent of sales. The Doha Declaration on the TRIPs Agreement and Public Health "reaffirms the right of WTO members to use, to the full, the provisions in the TRIPs agreement, which provide flexibility ... to protect public health, and, in particular to promote access to medicines for all."[20] Interestingly, in the context of its recent *Patients Right Act*, France has extended its *ex officio* licence beyond medicine to cover ex vivo diagnostics, including genetic testing. Although the patent laws of most countries contain provisions relating to compulsory licensing, they do not appear to be used often. The authors of the CIPP report observe that, "…while a government may never need to actually use this power, its existence not only disciplines the market, but provides encouragement to industry to create patent pools."[21]

[19] TRIPs Art. 31: Where the law of a member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: … (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time …

[20] Declaration on the TRIPs Agreement and Public Health, Ministerial Conference, Fourth Session, Doha [Qatar], 9-14 Nov. 2001, WT/MIN(01)/DEC/2, para. 4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose… .Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

[21] Centre for Intellectual Property Policy and Health Law Institute. 2004. *The Research or Experimental Use Exception: A Comparative Analysis*. Prepared for Health Canada, December.

Government use provisions are often referred to as a form of compulsory licence, although "involuntary licence" would be more apt, because government use of a patent is not automatic. It is an option available to governments as they aim to maintain an appropriate balance between the rights of patent holders and the public interest.[22] Section 19 of the Canadian *Patent Act* gives governments the right to request from the Commissioner of Patents a licence to use a patent. For a "public non-commercial use" of the patent, the application can be made without prior negotiation with the patent holder. It has been suggested that this section could be used in respect of any health care service provided (directly or indirectly) by government.[23] However, this provision has apparently never been used. In France, in the interest of public health, the State can at any time grant *ex officio* licences.

In the United States, the Bayh-Dole Act of 1980[24] includes a provision allowing a federal agency, in certain circumstances, to ensure that a federally funded invention is available for the public good. It allows the agency to license a funding recipient's invention to a third party who has tried and failed to obtain a licence from the patent holder on reasonable terms. The provision is not intended to allow third parties to compete against patent holders or other licencees of the patent-holder.

Abuse of Patent: Section 65 of the Canadian *Patent Act* allows any interested person to apply to the Commissioner of Patents for a license to a patented invention if the patent holder refuses to negotiate reasonable licensing terms or where a patent is not being practiced. However, this provision has rarely been used. There is very little guidance from the courts, legislature, or other sources of law on what factors are to be considered in assessing whether demand for a patented article is being met 'to an adequate extent and on reasonable terms', particularly where the 'patented article' is a diagnostic genetic test. Some wonder whether abuse of a patent under section 65 (2)(c) could include consideration of not only price terms but also of terms relevant to quality assurance, patient privacy, and access to health data generated through testing, since these are all terms with which a public health body would be concerned. Under this proposed interpretation, s. 65 remedies could be triggered by patent holder insistence on licence terms that severely limit the choice of test methods or laboratories, require samples to be exported outside the jurisdiction of Canadian privacy legislation without substituting equivalent safeguards, or do not account for the public health research value of health information generated through genetic testing. It has also been argued that a licence could be justified if the patent holder's refusal to negotiate reasonable terms meant preventing an individual from having access to their own genetic information, which could be seen as diminishing human health.[25]

[22] Adcock, M., et al. 2004. The Use of Patents by Governments. Prepared for Health Canada, December.
[23] Gold, E.R., and D. K. Lam. 2003. Balancing trade in patents – public non-commercial use and compulsory licensing. *The Journal of World Intellectual Property* 6:5-32.
[24] 35 USC §202(c)(4).
[25] Gold, E. R. and T. A. Caulfield: The moral tollbooth: a method that makes use of the patent system to address ethical concerns in biotechnology. *The Lancet* 359(9325):2268-2270 (June 29).

Part II

Effects on Research

Effects on Research

Introduction

A vibrant and productive research environment is an essential underpinning of Canada's economy and its health care system. Researchers create new knowledge and tools for improving the health of Canadians, provide the scientific and technical expertise necessary to understand and adapt discoveries made elsewhere, and train the scientists, technologists and professionals needed by our health care system and the private biotechnology and science sectors. As discussed at the 2001 forum *Advancing Health, Science and the Economy*: "The argument is as simple as it is compelling. Innovation drives competitiveness, and competitiveness drives prosperity. If you don't have competitiveness, you can forget about prosperity."[26]

A preliminary estimate of 2004 total gross domestic expenditures for research and development (R&D) in the health field was $5.7 billion (up from $5 billion in 2003), of which 61% (57%) was performed in the public sector (universities, teaching hospitals and affiliated organizations and not-for-profit research organizations) and 35% (38%) in the private sector (business enterprises), with the remaining 4% performed by government.[27] As well as being the major setting for research, the public sector is responsible for training the research personnel essential to both the public and private sectors.[28]

Over the past decade, there has been a significant increase in investment in research involving HGM through the federal granting councils, provincial agencies, the voluntary sector, special entities such as the Canadian Foundation for Innovation and Genome Canada and the private sector. This increased investment reflects recognition in all of the foregoing sectors of the importance of genetics research across the spectrum from basic to clinical.[29]

Timely and affordable access to HGM-based research tools (both products and processes) is an important requirement for leading edge research whether basic or applied. Many of these tools are patented and researchers may be users of tools patented by others or, increasingly, may be holders of patents on tools that they have invented.

Standardized IP policies do not exist in Canada's public institutions. A mixture of contract, common law rules, the Quebec Civil Code and other legislative mechanisms determines IP ownership by Canadian researchers. In many cases, ownership may be shared between a number of individuals, agencies and partners. Determining IP ownership may be particularly problematic when the research involves investigators at different organizations or is conducted by students or visiting researchers.

[26] Martin, R. (2001) Innovation and Canada's Prosperity. Innovation, Health Research and Canada's Prosperity. 20 recommendations from a national conference: Advancing Health, Science and the Economy. October 2001, Toronto.
[27] Estimates of total spending on research and development in the health field in Canada, 1988 to 2004 [Cat. No. 88-001-XIE2005005]. 2005. *Science Statistics*, 29(5). Ottawa: Statistics Canada, July.
[28] King, D. A. 2004. The scientific impact of nations. Nature 430: 311-316. See also *Converging Science and Leadership. The Key to the Future.* 2004. Ottawa: Canadian Biotechnology Human Resource Council. Also available at http://www.bhrc.ca/career/reports/downloadable/sectorStudy/surveyForm-SS.cfm, accessed August 30, 2005.
[29] A 2004 inventory of clinical genetics research in Canada identified almost 300 researchers in this area: Evans, J.A., T. Sjakowski and L. Erdile. 2004. Clinical genetics research in Canada: an inventory and annotated bibliography. A report and related databases prepared for the Canadian Institutes of Health Research Institute of Genetics, March 19. A summary of the report is available at http://www.cihr-irsc.gc.ca/e/24625.html, accessed August 30, 2005.

University-Industry Links/ Collaborative Research

Growing links between the public and private sectors in research and development, the increasing activity of public sector institutions in facilitating and sometimes participating in commercialization of IP and the various roles now played by researchers has added complexity to the debate about policies related to IP protection and to the efficacy of current provisions in IP regimes related to research.

The biotechnology industry, like other industries, depends heavily upon publicly supported basic research conducted in academic institutions.[30] Investments in basic research are not seen as economically feasible from a business standpoint because the returns are so widely diffused in society and often only emerge over a protracted period of time. The reliance of industry on basic research conducted in academia and an increasing involvement of academic researchers in applied research has resulted in growing interaction between university-based researchers and industry and an increasingly complex relationship between publicly funded research and the commercial sector.

Academic researchers are involved not only in generating intellectual property, but increasingly participate in later phases of development. In one U.S. study, it was reported that only about 12 per cent of the technology licensed by universities is ready for commercialization.[31] For 71 per cent of the inventions licensed, patents are secured before the commercial potential of the invention is clear. In such cases, ongoing faculty collaboration in further work is needed in order to develop the invention and prepare it for commercialization.

Because of its important role in innovation and commercialization, IP protection is becoming increasingly important in the publicly funded research sector – a trend that began in the 1980s in the US, with passage of the Bayh-Dole Act, and has been emulated in other countries including Canada.[33] Academic institutions are under growing pressure to facilitate commercialization of IP created by academic researchers and this is reflected in the rapid increase in invention disclosures reported by the Association of University Technology Managers.[33]

The commercialization thrust is not only built into the expectations of special purpose funding agencies (such as the Canada Foundation for Innovation and Genome Canada), it is also reflected in the program mix of research granting councils (e.g. the Canadian Institutes of Health (CIHR) Proof of Principle, Phase I and II grants). Rating criteria in some program themes now include an assessment in the grant application of the economic and/or social benefit to Canada, as well as the number of patents held by the principal investigator. The Association of Universities and Colleges of Canada has committed to a Framework Agreement[34] with the federal government, in which it is proposed that the amount of research performed by universities will double and commercialization will triple.

[30] McMillan, G. S., F. Narin and D.L. Deeds. 2000. An analysis of the critical role of public science in innovation: the case of biotechnology. *Research Policy* 29:1-8.
[31] Jensen, R. and M. Thursby. 1998. Proofs and Prototypes for sale: the tale of university licensing 5. National Bureau of Economic Research Working Paper No 6698. Washington: NBER. Also available at http://www.nber.org/papers/W6698, accessed August 30, 2005.
[32] Beachy, R. 2003. Intellectual property policies and serving the public [editorial]. *Science* 299(5606):473. See also Angell, M. 2004. *The Truth About the Drug Companies: how they deceive us and what to do about it*. New York: Random House.
[33] Association of University Technology Managers. 2003. 2003 Licensing Survey Summary. Available at www.autm.net/about/dsp.pubDetail.cfm?pid=5, last accessed August 30, 2005.
[34] Framework of Agreed Principles on Federally Funded University Research between the Government of Canada and the Association of Universities and Colleges of Canada. 2002, November 18. Available at http://www.aucc.ca/_pdf/english/reports/2002/frame_cadre_e.pdf, last accessed August 30, 2005.

While the foregoing developments have been too recent to properly assess their impact on the type, or amount, of research performed in Canada, some researchers feel that requirements for co-funding mean scientific excellence is no longer the primary consideration in awarding grants, thereby "[imperiling] scientific credibility and [failing] to engage the breadth and depth of national scientific expertise"[35] – a view strongly contested by Canada's National Science Adviser to the Prime Minister.[36]

Given that many Canadian innovations are patented in the U.S., American court decisions are of importance to Canadian researchers. A recent U.S. Federal Circuit Court decision suggests that inventions arising from research involving multi-centered teams (such as currently occurs in a number of urgent research areas such as SARS and HIV/AIDS) could be unpatentable. The Court held that, when researchers aren't under an obligation to assign their rights to the same entity, sharing of confidential information could be a reason to find an invention obvious.[37] In response, an amendment called the Cooperative Research and Technology Enhancement (CREATE) Act was proposed that would recognize the collaborative nature of research across multiple institutions by expanding the secret prior art exception. The Act came into effect December 10, 2004 and applies to patents granted after that date.[38] As a consequence, before key information is exchanged, researchers who wish to collaborate are advised to ensure agreements are in place setting out how IP rights will be handled.

Broad Patents

Surveys of researchers cited in a report by the Centre for Intellectual Property Policy[39] indicate that patents have, in particular cases, deterred or impeded research if the scope of protection is unduly broad, an experimental use exemption is unavailable and patent holders refuse to license the invention for research purposes, licensing fees are too expensive or because the transaction costs of negotiating licences within a "thicket"[40] of intersecting patents are too high.[41] In connection with the latter issue, Heller and Eisenberg[42] observe:

> By conferring monopolies in discoveries, patents necessarily increase prices and restrict use – a cost society pays to motivate invention and disclosure. The tragedy of the anti-commons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.

Patents covering a nucleotide sequence and all homologous sequences are the most upstream (furthest removed from identification of a commercializable product) category of gene patent and are often viewed as broad because they claim rights over any future use discovered for, or product involving, the patented sequence. Patents that cover a generally applicable research technique or resource

[35] Tyers, M., et al. 2005. Problems with Co-Funding in Canada. *Science*, 308:1867 (June 24).
[36] Carty, A.J. 2005. Co-Funding in Canada: Another View. *Science* 309:874 (August 5).
[37] Rimmer, M. 2004. The race to patent the SAR virus: The TRIPS Agreement and access to essential medicines. *Melbourne Journal of International Law* 5:335-74.
[38] Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Public Law 108-453, approved December 10, 2004. Available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ453.108, last accessed August 3, 2005.
[39] Centre for Intellectual Property Policy, Genetic Patents and Health Care in Canada, note 6, Appendix C.
[40] A patent thicket has been defined as a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology": Shapiro, C. 2001. Navigating the Patent Thicket: Cross Licences, Patent Pools and Standard-Setting. In A. Jaffe et al., eds. *Innovation Policy and the Economy, Vol. 1* (pp. 119-150). Cambridge: MIT Press, p. 120. Although a patent thicket can sometimes act as an incentive to research (by encouraging researchers to "invent around" existing patents), it can also increase the transaction cost of R&D and be a barrier to commercialization.
[41] As noted earlier, using someone's patented invention without permission is an infringement of their patent rights and makes the unauthorized user liable to pay damages to the patent holder if sued. Patent law in some countries exempts unauthorized use from liability if the use is "experimental," for "non-commercial purposes," or similar grounds. Canada's *Patent Act* does not include such a provision; however, one may exist through case law. Because it is not spelled out, its scope is not clear.
[42] Heller, M. A. and R. S. Eisenberg 1998. Can patents deter innovation? The anticommons in biomedical research. *Science* 280: 698-701.

("foundational" inventions) may also be described as "broad." A patent may be regarded as excessively broad if, for example, it includes a nucleotide sequence and all homologous sequences in the absence of any specific, substantial and credible utility being indicated. Unless widely licensed, broad patents have the potential to discourage research and innovation (and the development of products for the health system) because of concerns about infringement, licensing fees, or reach-through licenses.

Obtaining patents for strategic purposes – either to block the pursuit of research in a particular area or as leverage to obtain licences from other patent-holders -- is apparently a common practice. In some industries, such as telecommunications and software, the practice has been countered through a combination of transfer of rights and cross-licensing. In a study of the software industry,[43] for example, it was found that cross-licensing and imitation actually spurred innovation, and although competition could reduce profit from an initial invention, it had the benefit of expanding the market. This model may not, however, be applicable to the field of human genetics research, where the developmental and regulatory time frames are generally much longer and more rigorous.

The extent to which broad patents deter or impede research may depend on the type of research involved and the nature of the patented invention. Broad patents typically appear as new technologies emerge, but the scope of granted patents tends to narrow as knowledge of the new area expands and prior art is generated and expertise in patent offices increases. Where the broad patent is on a DNA sequence and homologous sequences, options such as "inventing around" the patent may not be possible. The impact of broad patents based on HGM, therefore, may be greater than would be the case in other fields of technology.

Some researchers use patented IP without permission. The latter practice may reflect an assumption by researchers that they do not require licences (see below re: experimental use exemption) or, as noted earlier, because in many instances patent holders tolerate this practice either to encourage research that is not harmful to their commercial interests or to avoid the expense of defending their patent rights (especially where there may be some doubt about the robustness of their patents). Researchers may also knowingly infringe, as the chances of being discovered are low and the costs to a patent-holder of suing for infringement are high.

The EWP roundtable discussions indicated that the deterrent effect of broad patents on innovation is a systemic problem, as there is no accepted norm or code of practice to help define and identify foundational inventions and how they should be treated. Some roundtable participants suggested that a code of ethics or of conduct addressing this practice be developed. Clarification and reconciliation of the roles and involvement of all key players in the patenting process was regarded as beneficial in addressing abuses of patent rights.

During EWP consultations it was suggested that care should be taken not to place too much emphasis on patenting and commercialization of HGM such that it could limit an academic investigator's ability to undertake "common good" research. In an editorial in *Nature* about the race by three publicly funded teams to patent the SARS gene, the point was made that:

> …when pre-emptive patenting is necessary to ensure that rapid solutions are found to an important health problem, something seems to be out of balance. Policy-makers should investigate what checks and balances are necessary to ensure that the patent system continues to do its job of stimulating innovation for the public good.[44]

[43] Bessen, J., and E. Marksin. 2002. Sequential Innovation, Imitation and Patents (Revd. version). MIT Working Paper. Boston: Massachusetts Institute of Technology.
[44] Gene patents and the public good [editorial]. 2003. *Nature* 423 (6937): 207.

The issue is complex, as there is no widely agreed upon definition of what constitutes "public good." Benefits can vary among different stakeholders and in different settings. There is no simple guideline or model for achieving public benefit from genetic research. As noted by the Australian Law Reform Commission:

> …In some instances, greater public benefit may result from making patented genetic materials or technologies freely accessible or widely licensed; in others, by allowing a patent to be exploited by a single company. The most appropriate approach to exploiting or using the results of genetic research can only be considered on a case-by-case basis.[45]

Research Tools

Research tools are products or processes used by scientists in the course of their research. In genetic research, research tools fall into three broad categories:

- research or laboratory techniques (e.g., polymerase chain reaction or PCR methodology for DNA amplification);
- consumables such as enzymes or reagents used in the laboratory (e.g., Taq polymerase used in PCR); and
- genetic materials that are used in research to identify therapeutic targets research (e.g., genes for receptor proteins used in designing new drugs or vaccines such as the HIV-receptor CCR5)

A particular product or process may serve as a research tool when used in a research laboratory and as an end product when used in a service laboratory.[46]

Access to patented research tools is determined predominantly by the availability and terms of licenses granted by the patent holders to researchers. Licenses may be exclusive or non-exclusive, expensive or inexpensive. Restrictive or costly licensing can increase the difficulty of obtaining access to research tools. Moreover, the time required to negotiate licenses may also be problematic if it erodes the time available for research, delays work and reduces productivity. In some cases, researchers try to circumvent these obstacles by developing new alternative tools – a process referred to "inventing around" patents.

[45] ALRC, *Genes and Ingenuity*, note 17.
[46] Ibid.

In most cases, it is to the benefit of patent holders to ensure that their products are widely used. In some cases, licensing may be provided with the purchase of products (e.g., the purchase price of a reagent includes limited, non-transferable rights to use the product for research purposes). In other cases, patent holders may distinguish between academic and commercial researchers in applying a licensing strategy so as to promote access for academic researchers. Walsh et al[47] found there was little evidence that patents on research tools systematically stopped or seriously impeded valuable university research in the U.S.; although they can delay or redirect investigations. Most firms and universities have been able to develop "working solutions" to allow their research to proceed. According to a study published in Science,[48] industry scientists admit to accepting a certain level of patent infringement by universities, especially of research tools, because litigation is costly, creates bad publicity, and there is the risk of their patent being found invalid by the courts. In addition, a low level of patent infringement is often tolerated because innovation could potentially contribute to the value of the invention.

A particular area in which access to patented research tools may be more problematic is in clinical research. There is some evidence that patent holders do not accept the use of genetic tests in clinical research as falling under the exemption.[49] Concerns about the effect of broad HGM patents on clinical research are focussed on a few cases involving restrictive licensing practices related to genetic testing. Surveys conducted in the US and by the OECD in 18 countries indicate that clinical researchers avoid some areas of research due to constraints imposed by the exercise or threatened exercise of IP rights.[50] In their 2001 study of US testing laboratories, Cho et al[51] found that half (53%) decided not to develop a new test because of patent concerns. The clinical geneticists surveyed indicated their research had been hindered and that patenting had a negative impact on the sharing of data among researchers. Researchers may not only avoid certain areas of investigation but they may also gravitate to areas that are free of patent related constraints.[52] Although no similar studies have yet been undertaken in Canada, we heard similar concerns expressed by a range of participants in EWP consultations.

[47] Walsh, J. P., A. Arora and W. M. Cohen. 2003. "Effects of research tool patents and licensing on biomedical innovation" In W. M. Cohen and S. A. Merrill, eds., *Patents in the Knowledge-Based Economy*. Washington: The National Academies Press.
[48] Walsh, J., A. Arora and W. M. Cohen. 2003. Working through the patent problem. *Science*, 299:1021 (Feb. 14).
[49] Health Law Institute and Centre for Intellectual Property Policy, *The Research or Experimental Use Exception*, note 21.
[50] US: Henry, M. R., M. K. Cho, M. A. Weaver and J. F. Merz. 2002. DNA Patenting and Licensing. *Science*, 297:1279 (Aug. 23); Merz, J. F., A. Kriss, D. Leonard and M. Cho. Diagnostic Testing Fails the Test, *Nature* 415:577-578. The Organisation for Economic Co-operation and Development surveyed molecular genetic testing laboratory practices in 18 OECD countries in 2003 to identify quality assurance practices in clinical labs and to compare practices throughout the OECD. The Biotechnology Working Party is now developing best practice guidelines.
[51] Cho, M. K., S. Illangasekare, M. A. Weaver, D. G. B. Leonard and J. F. Merz. 2003. Effects of patents and licenses on the provision of clinical genetic testing services. *Journal of Molecular Diagnostics* 5:3-8.
[52] Walsh et al., Working through the patent problem, note 47.

Part III

Effects on Development and Commercialization

Effects on Development and Commercialization

Introduction

Commercialization by the private sector is the predominant means through which new technology is made available to health care systems. According to the National Research Council of Canada (NRC),[53] the global market for health-related technologies exceeds one trillion dollars; 97 per cent of that market is accessible to Canadian firms. This market is expanding at an annual rate of eight per cent, more than double economic growth, and the market for biotechnology-derived products is growing at an even more substantial rate of 30 per cent.

A thriving health biotechnology industry is important for Canada. First, it contributes to the development of novel products and services to benefit the health of Canadians by enhancing the efficiency and effectiveness of health care interventions. Second, a strong human health biotechnology sector strengthens Canada's economy and enhances its competitiveness in a rapidly expanding global market.

In 2004, Canada had more than 470 biotechnology companies, with annual revenues of almost $2.7 billion (approximately 4% of global revenues). Sixty-six per cent of these companies were in the health sector (therapeutics 57%, diagnostics 6%, drug discovery 3%); in addition, many of the companies in advanced materials (3%) or genomics, proteomics and bioinformatics (9%) were likely also health-focussed. The Canadian biotechnology sector, however, continues to consist primarily of small firms facing a variety of sustainability challenges, including limited access to capital, and which are therefore at risk of failing or being acquired by companies outside of Canada.[54]

Given the size of its market, the United States is the preferred choice for filing patent applications in the first instance. Industry participants in the EWP's roundtable consultations indicated that perceptions of the efficiency and effectiveness of Canada's IP regime contribute to a sense of the general climate for investment. Monetary and opportunity costs involved in patent office processes that are inefficient and time-consuming may be particularly important to the small Canadian biotech firms operating under severe financial constraints. Since a majority of health care products and processes patented in Canada originate in other countries (notably the US), an efficient and effective IP regime is needed to ensure that Canadians have access to beneficial innovations without delay, whatever their source.[55]

While investments in health research have placed Canada among the world leaders in generating discoveries and innovations in this field, Canadian ideas and innovations are frequently developed and commercialized elsewhere. The EWP roundtable consultation with researchers underscored this weakness and its constraints on Canada's ability to reap the economic rewards from exploiting the commercial potential of IP.

[53] National Research Council of Canada, Office of Technology Foresight. 2004. *Towards a Sustainable Health Care System: Capturing the Commercial Potential of Bio-Health Innovations*. Ottawa: NRC, April.
[54] Ernst and Young. 2005. *Beyond Borders: Global Biotechnology Report 2005*. Ernst and Young Health Science Report, July, also available at www.ey.com/biotech.
[55] CBAC, BHI, note 3.

Importance of Intellectual Property Protection

Although some economists question the efficacy of patents in fostering innovation relative to what may be achieved through more open competition in the marketplace, pharmaceutical and biotechnology companies have long argued that because of high research costs and long development and approval processes, strong IP protection is critical to innovation in the health sector. As described in an OECD report, the perception within the pharmaceutical industry is that "a company's worth is tightly tied to its intellectual property."[56] Using data from 60 countries for the period 1960-1990, Park and Ginarte found the strength of IP protection (an index of pharmaceutical coverage, participation in international agreements, lack of compulsory licensing, strength of enforcement, and patent duration) was positively associated with R&D investment in the 30 countries with the highest median incomes.[57] Elsewhere, the relationship was positive but not significant. Although Cole's analysis of patents and copyrights found that, of the industry sectors he studied, the pharmaceutical sector was the only one in which patents are essential in the commercialization of innovations, there is evidence that patenting is as important in the biotechnology sector as it is in the pharmaceutical industry.[58] In other industries, other strategies, such as first mover advantage, secrecy and the existence of complementary assets, were used to protect inventions without necessarily relying on patents.[59]

While commercialization can occur without patents, most industry representatives state that public policies, particularly IP policies, are critical to the development of a strong biotechnology industry.[60] In a survey of the licensing practices of Canadian biotechnology companies, patented genetic inventions were more likely to be licensed than non-patented ones,[61] suggesting either that there may be a larger market for patented inventions or that patented inventions are more attractive to licensees.[62] Companies may be less likely to try to commercialize non-patented inventions due to disclosure concerns, which potentially could lead to a loss of competitive advantage and/or loss of opportunity for future patenting. In general, licence fees paid for patented genetic inventions were generally higher than those for non-patented ones.

[56] Organisation for Economic Co-operation and Development. 2002. *Genetic Inventions, Intellectual Property Rights and Licensing Practices. Evidence and Policies.* Paris: OECD. Also available at http://www.oecd.org/dataoecd/42/21/2491084.pdf, last accessed August 30, 2005.
[57] Parke, W. G. and J. C. Ginarte. 1997. Intellectual property rights and economic growth. *Contemporary Economic Policy* XV: 5 1-61.
[58] Cole, J. H. 2001 Patents and copyrights: do the benefits exceed the costs? *Journal of Libertarian Studies* 15(4):79-105; Enzing, C., A. van der Giessen and S. Kern. 2004. Commercialisation of biotechnology: do dedicated public policies matter? *Science and Public Policy* 31(5):371-83.
[59] Encaoua, D., D. Guellec and C. Martinez. 2003. The economics of patents: from natural rights to policy instruments. Available from ftp://mse.univ-paris1.fr/pub/mse/cahiers2003/V03124.pdf, last accessed August 30, 2005.
[60] Mooney, P.R. 2001. The impetus for and potential of alternative mechanisms for the protection of biotechnological innovations. Prepared for the Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms, March.
[61] Inventions protected by trade secrets or by the inventor's know-how. In the first situation, the inventor may need to licence the invention in order to have it manufactured; in the second, the licencee may need the inventor's expertise, especially with regard to a process.
[62] Cassels & Graydon LLP. 2004. Study of the Canadian Biotechnology Sector's Licensing Practices Regarding Patented Genetic Inventions. Prepared for Industry Canada, August.

The importance that the biotechnology industry attaches to patent rights is exemplified by the reaction to what some regard as signs of weakness in Canada's IP regime. In February 2005, the U.S.-based Biotechnology Industry Organization (BIO) put Canada on its "Watch List" because of concerns about the status of patent protection stemming primarily from the *Harvard Mouse* decision. In its brief to the Office of the United States Trade Representative, the BIO wrote:

> The developments on patent eligibility compound an ongoing problem of erosion in protection of intellectual property in pharmaceutical and medical technology in Canada. For example, the ability of companies to realize the full value of their intellectual property rights is limited by restrictive practices governing pricing of new, patented pharmaceuticals. In addition, health authorities in Canada interpreted regulations promulgated to implement the NAFTA provision on undisclosed test and other data in a manner that essentially removes any protection for these data associated with pharmaceutical products and that is inconsistent with that Agreement and the TRIPS [sic] Agreement.

The BIO also points out that, "For many of our companies, patent rights are the only significant assets they can use to attract capital to fund their product development activities" so that even the prospect of future restriction of these rights can affect "investment and business decision *now*."[63]

Effects of Patenting and Licensing Genetic Inventions

Excessively broad patents and restrictive licensing practices act as disincentives, not only for research, but also for development and commercialization. For example, participants in the EWP roundtable consultations noted that broad patents and/or restrictive licensing practices could create disincentives to develop or improve an invention, as the benefits mainly reside with the upstream patent holder(s). As noted earlier, in some cases, patent holders may actively use their patents to block others from developing new inventions.

The processes of development and commercialization of HGM-based products and services may include researchers in public institutions and in private industry, companies ranging from small spin-offs to multi-national enterprises, investors and regulators. As patenting of nucleotide sequences has expanded from a focus on genes as engines for production of therapeutic proteins to include nucleotide sequences as platforms for generating diagnostic products, the interaction of these actors has become more diverse and in some cases, their interests have diverged or even come into conflict.

The degree of importance attached to patents is directly related to the scale of investment required to bring an invention to market and the time horizon for recouping development, marketing and regulatory costs and achieving an economic return. Therefore, in analyzing the effects of gene patenting it is important to distinguish between therapeutic products (sometimes referred to as "biologics") and diagnostic products. In the case of biologics, constraints on competition include not only the level of patent protection but also the high costs of meeting regulatory requirements and of specialized facilities and expertise in manufacturing. By contrast, meeting regulatory requirements for diagnostic tests is much less costly and many laboratories in the health system have the expertise and facilities to perform diagnostic tests. Whereas the defence of patents on biologics may involve suing competing commercial manufacturers, the defence of patents on diagnostics may involve suing non-commercial end users and compromising relations with potential customers.[64]

[63] Biotechnology Industry Organization. 2005. Brief to Sybia Harrison, Special Assistant to the Section 301 Committee, Office of the United States Trade Representative. February 11.
[64] Eisenberg, Why the gene patenting controversy persists, note 15.

Part IV

Effects on Health Services

Effects on Health Services

Introduction

In Canada, insured health care (physician and hospital) services are provided within a national framework of principles (comprehensiveness, universality, accessibility, portability and public administration) embodied in the *Canada Heath Act*. The federal government is responsible for administering the *Canada Health Act* and contributing to the financing of provincial and territorial health care services. The provinces and territories are constitutionally responsible for the administration and delivery of insured health care services within their respective jurisdictions, while the federal government is responsible for direct delivery of insured health care services to specific groups (First Nations and Inuit peoples, members of the Canadian Forces and the RCMP, refugee claimants, and federal inmates).

Provincial and territorial governments also provide a broad range of non-insured health services to their residents, such as public health, pharmacare, residential care and home care services. Privately financed health care services (including those covered by, for example, "third party" payers other than governments through employee group insurance programs), while representing a minority of expenditures on health care, are nonetheless growing in prominence.

Health care expenditures in Canada, both private and public, have been growing steadily in recent decades (reaching $121.4 billion in 2003). In the provinces and territories, the rate of growth of public health care expenditures has exceeded the rate of revenue growth with the result that other publicly financed programs are being squeezed. Rising public expectations, the thrust of technological innovation and demographic changes are expected to exacerbate further the fiscal pressure on health care providers.

Introducing New Technology into Health Services

The challenges related to the introduction of biotechnological innovations in the health system are discussed in CBAC's report, *Biotechnology and the Health of Canadians*. That report notes:

> The adoption of biotechnology-based health innovations (BHIs) by the health system is a complex process, strongly influenced by the internal dynamics of health care systems on the one hand, and health practitioners and consumers on the other. Health care system managers face difficult choices in regard to the adoption and funding of BHIs because of their technical complexity and "disruptive" effects (on costs, organizational structure, professional roles) and, in some instances, because of their ethical and social implications.

Canada's health care systems do not have a systematic approach to dealing with these issues. Practices vary among provinces, regional health care systems, hospitals, and health care practitioners, in part because there has been relatively little systematic study on how health technology is introduced and on the identification of best practices.

Incorporating technological innovations into the health care system is a complex process. A new technology must be an essential component of a medically necessary insured service, its benefits must provably exceed its risks, and it must be more cost-effective than alternatives. Adopting a new technology may require new technical infrastructure and personnel and also, in the case of genetic tests for example, development of systems for managing and protecting the information generated by the tests and ensuring availability of health professionals involved in pre- and post-test counseling and follow-up. Follow-up will become particularly important as more and more predictive genetic tests are performed. Some fear that failure to effectively

manage the introduction of new technology into the health system will undermine its longer-term sustainability. It should also be noted that many of the issues involved in managing the introduction of HGM-based innovations in the health care system apply to managing technological change in general. There are, however, some characteristics of HGM-based innovations that require special consideration.

While the federal government is responsible for Canada's IP regime and its further development, the provinces and territories, as the principal purchasers of HGM-based products and processes, have a critical role to play, in concert with the federal government, in determining the "market" for such products and processes. In assessing market factors and their implications for the health system, it is important to distinguish between categories of patented HGM-based innovations services (e.g. diagnostics vs. therapeutics) since the market dynamics and the nature and extent of the regulatory processes involved are different.

The impact of patented HGM–based products and services on health care systems depends on how patent rights are exercised. To the extent that patents encourage investment in the development of new products and services that are of proven benefit and accessibility, the impact is clearly positive. However, the impact can be negative if patent holders exercise their rights in ways that place an undue cost burden on the health system, impede accessibility to products and services, make integrated and high quality patient care more difficult, interfere with appropriate access to information, or fail to protect against inappropriate use of information.

There is little empirical evidence on the system-wide impacts of gene patents on health services. This may reflect the fact that the use of HGM-based innovations in health services is still relatively new, even though patent applications may have been filed or even granted many years ago. It is difficult to disentangle the impacts of patenting per se from other effects of adopting new technology. There may also be considerable separation in time between the incurring of costs and other disruptions and the realization of benefits.

Much of the current interest in the impact of gene patents on health services has arisen primarily in relation to diagnostic genetic testing. It should be noted, however, that patented HGM might be important components of therapy (therapeutic proteins (biologics), stem cell transplantation, gene therapy, and tissue or organ transplantation). To date, there has been relatively little controversy related to the use of therapeutic proteins. This is likely due to the fact that they are developed and regulated as pharmaceuticals under market conditions and regulatory regimes (including price controls) that do not apply to genetic tests.[65]

[65] Health Canada approves for market both pharmaceuticals and medical devices. The Patented Medicines Prices Review Board regulates the price of pharmaceuticals approved for market by Health Canada. There is no equivalent price monitoring for medical devices. In any event, most genetic diagnostic tests are processes rather than products; they would not be classified as medical devices ("an article, instrument, apparatus or contrivance").

Costs of Using Patented Genetic Inventions

The increasing volume and complexity of genetic innovations is likely to contribute significantly to the strain on the resources of the health care system. Although innovations of proven benefit may result in reduced cost-per-case through better disease management and treatment and the use of more efficient and/or less costly diagnostic and therapeutic products, these cost reductions may not be reflected in aggregate costs if the volume of services increases. Part of the cost of new products and processes such as genetic tests may be incurred before their clinical utility ("real world effectiveness") has been fully demonstrated.[66] Public demand for genetic screening tests, for example, is based on the perception that early detection of a disease leads to improved health outcomes; in fact in many cases, earlier detection affects neither treatment nor health outcome.

Concerns about the exercise of patent rights by patent holders are in part based on the assumption that they will use restrictive licensing practices (e.g., exclusive licenses) and that licensees will charge monopoly prices. The extent to which this is happening or could happen is a matter of debate. Some contend that the undesirable behavior of some patent holders seen to date is and will remain uncommon, while others are of the view that this behavior could well become widespread. They assert that commercial pressures will continue to lead patent holders to seek to exploit maximum economic benefit from their patent rights.[67]

Miller et al. note that the cost impact of genetic tests depends on, among other things, the characteristics of the test (e.g. its predictive power[68]), the scope of its application (high-risk populations or general populations), and changes in health care utilization induced by the test result (e.g., surveillance, prevention, counselling and treatment).[69] The cost of performing the test may account for only a small part of the overall health care costs associated with its use. Hence, although the availability of genetic tests at reasonable prices is important, other cost factors associated with the introduction of genetic tests to the health care system deserve careful attention. These considerations apply whether the tests are performed in public or private laboratories, are requisitioned by a health care professional or by patients themselves stimulated by direct- to-consumer advertising (DTCA).

DTCA is a matter of considerable concern for reasons other than cost. The results of DTCA stimulated use of genetic tests may be misinterpreted, occasion delays in seeking proper medical attention, lead to unnecessary medical treatment, impose non-consensual testing of family members or others, and may be misused by employers, insurers and others. A number of reports have recommended strict controls on such testing.[70] Canadian provincial governments have recommended that federal standards for approval and review of "at home" tests (regulated under the *Food and Drugs Act*) should be carefully examined and monitored to ensure that they adequately protect the public.[71] The DTCA of prescription medications and professional services is currently prohibited in Canada by the *Food and Drugs Act*, though clearly

[66] Blancquaert, I. 2000. Availability of Genetic Services: Implementation and Policy Issues. *Community Genetics*, 3:179. Also available at http://content.karger.com/ProdukteDB/produkte.asp?Aktion=Ausgabe&ProduktNr=224224&Ausgabe=226864&searchWhat=books (registration required), accessed August 30, 2005).
[67] Walpole, I. R., et al. 2003. Human gene patents: the possible impacts on genetic services healthcare. *Medical Journal of Australia*, 179:203-205.
[68] Full penetrance tests, which have high predictive power, test for rare diseases and can be well-targeted, will likely have the smallest impact on health care costs. Predisposition tests, with lower predictive power, if well targeted, could also have a small impact on costs. Risk factor tests, used to predict common multifactorial conditions affecting large segments of the population, have much lower predictive power and are likely to have the largest impact on aggregate costs.
[69] Miller, F. et al. 2002. Predictive Genetic Tests and Healthcare Costs: A Policy Framework and Illustrative Estimates. Working Paper 02-03. Hamilton, Ont.: Centre for Health Economics and Policy Analysis. Also available at http://www.chepa.org/pdfs/02-03.pdf, last accessed August 30, 2005.
[70] Human Genetics Commission. 2003. Genes Direct: *Ensuring the effective oversight of genetic tests supplied directly to the public*. London: HGC. Available at www.hgc.gov.uk/UploadDocs/DocPub/Document/genesdirect_full.pdf; Australian Law Reform Commission (2003). *Essentially Yours: The Protection of Human Genetic Information in Australia*. Sydney: ALRC. Available at www.austlii.edu.au/au/other/alrc/publications/reports/96/; Task Force on Genetic Testing. 2003. *Promoting Safe and Effective Genetic Testing in the United States*. Bethesda, Md.: National Human Genome Research Institute. Also available at www.genome.gov/10001733, last accessed August 30, 2005; European Group on Ethics in Science and New Technologies. 2003. *Statement by the European Group on Ethics in Science and New Technologies on advertising genetic tests via the Internet* www.europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/273&format=HTML&aged=0&language=EN&guiLanguage=en. All websites last accessed on May 4, 2005, unless otherwise indicated.
[71] Ontario, *Genetics, Testing and Gene Patenting*, note 17.

advertising still penetrates the Canadian market via American broadcast media and the Internet.[72] Some contend that this ban should be extended to genetic tests, without which, it is argued, potential over-utilization (and the resultant costs associated with royalty payments and additional health costs induced by the test) is likely to be exacerbated.[73]

In the roundtable discussions it was suggested that a price control mechanism might be an appropriate mechanism for managing the costs of genetic inventions. Currently in Canada, only the prices of patented medicines[74] are subject to direct price control through the Patented Medicines Prices Review Board (PMPRB).[75] Created in 1987 under the *Patent Act* as an independent quasi-judicial tribunal, the PMPRB limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive. In addition to its regulatory role,[76] the PMPRB reports on pharmaceutical prices and trends, utilization, and on the research and development spending by pharmaceutical patentees. As a result of its activities, Canadian prices for patented drugs that were 23 percent above the median of foreign prices in 1987 now fall in a range from 5-10 percent below to slightly above the median of foreign prices.

Access to Patented Genetic Inventions

Access to patented genetic inventions can be limited if patent holders choose to exploit their patent rights by employing restrictive licensing practices, exacting high royalty fees and charging high prices for in-house performance of services such as genetic testing. These factors raise serious concerns about the ability of health care providers to offer clinical genetic testing services and to conduct the research necessary to improve on existing tests or develop new tests or therapeutics. However, restrictive exercise of patent rights is only one of the factors that may affect access to services such as genetic testing. Other factors include funding priorities of health service providers, and the technical capacity, and accreditation status of laboratories.[77] The research interests of the laboratory or the clinical investigators in the institution may also influence whether a genetic test is available in a particular laboratory.

In Canada, most genetic testing occurs in provincially funded, hospital-based molecular genetic laboratories through referrals from clinical genetics hospital programs or from other physicians such as pediatricians and obstetricians. As of 2003, these laboratories offered approximately 160 different clinical genetic tests.[78] Under the Canadian health care system,[79] costs of royalties

[72] Some are of the view that this ban reduces the public's awareness of available medical treatments, contributing to unnecessary non- or under-treatment of conditions. Others argue that such advertising may harm public health (e.g., may result in incomplete information being provided to Canadians and potential switching to more expensive, and possibly only marginally better, new medications they may already be taking).
[73] Willison, D. J. and S. M. MacLeod. "Patenting of genetic material: Are the benefits to society being realized?" *CMAJ.* 2002 Aug. 6; 167(3):259-62. Also available at http://www.cmaj.ca/cgi/content/full/167/3/259, accessed August 30, 2005.
[74] Patented medicines are defined as drugs to which a Canadian patent pertains.
[75] The PMPRB was established in the context of significant evolution in pharmaceutical patent policy in Canada, characterized by introducing direct price controls for patented drugs and eliminating indirect controls through compulsory licensing. Canada had used compulsory licensing of pharmaceutical patents for many years to promote competition and facilitate access to affordable medicines. This system enabled the early entry of lower cost generic drugs and, according to the 1985 Eastman Commission of Inquiry, saved the health care system hundreds of millions of dollars per year. The elimination of compulsory licensing in 1987 extended patent protection in line with international standards, honoured Canada's trade obligations, and required a commitment by brand-name pharmaceutical companies to double investment in research and development in Canada from 5 per cent of sales to 10 per cent. In order to respond to consumer and provincial/territorial government concerns that this policy would result in major increases in drug prices, the PMPRB was established to protect consumers against abuses of increased patent protection by charging excessive prices to Canadians.
[76] Comparison countries are France, Germany, Italy, Sweden, Switzerland, the U.K., and the U.S. This principle reflects the apparent objective of the *Patent Act* that Canadians should not pay more than their fair share of the international costs related to the research and development of new medicines.
[77] Laboratories are provincially regulated to ensure appropriate training of personnel, quality of laboratory techniques, etc.
[78] Theoretically, any of the 818 genetic tests available worldwide for clinical use is accessible to Canadians. The issue is payment for tests done outside Canada. Most provinces and territories have provisions whereby Canadians can apply for payment of testing performed out of province. However, we have heard that success rates are variable and not necessarily based upon scientific logic.
[79] Genetic tests in kit form are regulated by Health Canada as Class 3 devices under the Medical Devices Regulations of the *Food and Drug Act*. Regulatory approval is required whenever these tests are intended to be used for clinical research trials/investigational testing involving Canadians, or for patient care purposes. Laboratory research conducted to gather pre-clinical data is not subject to these regulations. Note that the Medical Devices Regulations do not distinguish between genetic and other types of *in vitro* tests.

and licensing fees associated with patented tests cannot be "passed on" to the patient and, therefore, may place a cost burden on the hospital or regional health authority.[80] Anecdotal evidence suggests that some laboratories run deficits on an ongoing basis in order to be able to develop and offer genetic testing services.

Until recently, little empirical research has been conducted on the impact of patents on access to genetic testing. Analysis is based primarily on anecdotes, individual case studies or small surveys that suggest clinical laboratories avoid some areas of genetic testing due to constraints imposed by the exercise or threatened exercise of IP rights. For example, in a 1999 survey of American laboratories, Merz and colleagues[81] found that 30% of laboratories ceased to develop or provide a genetic test for hereditary haemochromatosis in light of the exclusive license granted on the patents covering clinical testing services. Cho et al.[82] reported similar findings in a 2001 survey of directors of American university-based and commercial clinical genetic testing laboratories. Twenty-five per cent of respondents reported that, upon being contacted by the patent- or licence-holder regarding potential patent infringement, they had ceased to perform a clinical genetic test.[83] Additionally, more than half (53%) of the laboratory directors reported that they had decided not to develop new clinical genetic tests because of a patent or licence.

The first comprehensive study was conducted by the Organization for Economic Co-operation and Development (OECD).[84] Its 2003 survey of laboratory practices in 18 OECD countries produced similar results. Of the 827 laboratory directors who responded to the survey, 65% indicated that they offer patented tests. Seventy per cent reported that the patent licenses "had an impact on the cost of the test "and 28% noted that patent licenses "had limited the number of tests being provided." Ten per cent of respondents indicated that they had stopped providing a test because of a patent issue. For those laboratories (35%) not providing patented tests, the most commonly cited reason was that the laboratory had not yet wanted to add a patented test to the test menu (79%). Other reasons reported included the inability to secure a patent license (3%), the high cost of associated fees (7%) and unacceptable licensing terms (7%). Based on these findings, the OECD concluded that there is no clear evidence that patents on genetic tests directly restrict access (to the tests), although it is noted that "there is evidence that some genetic testing service providers are withdrawing some patented tests from the menu they make available."[85]

Empirical evidence on the situation in Canadian genetic laboratories with respect to the impact of patents on the use of genetic tests is not available. What we heard from the EWP consultations is that laboratories are faced with the dilemma of either ignoring patents (which, we understand, some laboratories do on a regular basis) in order to undertake their day-to-day activities and to offer affordable products and services to patients, or sending patients elsewhere for services, either to another province (assuming the test is available there) or outside of the country. The latter practice raises the issue of equitability of access to these services by all Canadians.

[80] Gold, E. R., T. A. Caulfield and P. N. Ray. 2002. Gene patents and the standard of care. CMAJ 2002 167:256-257.
[81] Merz et al., Diagnostic testing, note 50.
[82] Cho, et al., Effects of patents, note 51.
[83] The tests which the laboratories ceased to perform include Apolipoprotein E (Apo E), hereditary breast/ovarian cancer (BRCA1/BRCA2), Duchennes/Becker muscular dystrophy, Hereditary haemochromatosis (HFE), myotonic dystrophy, Canavan disease, spinocerebellar ataxia (SCA1, SCA2, SCA3, SCA6), adenomatous polyposis of the colon, Charcot-Marie Tooth type 1A (CMT-1A, CMT-X), Fragile X syndrome, Huntington disease, and Factor V Leiden (activated protein C for thrombophilia).
[84] The survey was carried out between June and October 2003 in Austria, Belgium, Canada, the Czech Republic, Finland, France, Germany, Ireland, Italy, Japan, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The survey was designed to identify quality assurance practices in clinical labs and to compare practices throughout the OECD with a view to identifying areas for international co-operation in developing standards, proficiency testing and interpretative guidelines, developing international good practice guidelines based on general principles and fostering international collaboration among disease-specific consortia, particularly for testing of rare diseases.
[85] Organisation for Economic Co-operation and Development. 2005. *Quality Assurance and Proficiency Testing for Molecular Genetic Testing: Survey of 18 OECD Member Countries*. Paris: OECD.

The case study most often cited (both in the literature and by participants in the EWP consultations) as an example of the problems posed by the patenting of genetic tests is that of the test for the BRCA1 and BRCA2 genes, patented by Myriad Genetics. Myriad's exercise of its patent rights and related tests was widely regarded as objectionable because of the prices charged for the tests,[86] the highly restrictive licensing practices employed, and the control Myriad exercised 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, similar issues have been raised with respect to patents held on the gene sequence for Apolipoprotein E (associated with Alzheimer disease), Canavan disease, haemochromatosis, and CCR5 (the primary receptor through which the HIV virus establishes itself in the body). The problems experienced with the BRCA1/2 testing in North America and Europe did not become a matter of public concern in Australia due to a strategic cross-licensing agreement Myriad entered into with Genetic Technologies (GTG) in 2002.[87] In Europe, several of Myriad's patents were successfully opposed on technical grounds, reducing the impact of Myriad's licensing practices.[88]

Quality and Continuity of Care

There is concern that the actual or implied threats of patent infringement on patented materials may delay or block the improvement of existing genetic tests and the development, validation and implementation of new diagnostic tests. This clearly has consequences for the health system's ability to offer a range of alternative, possibly less expensive and/or technically superior or more appropriate tests to patients.[89] Equally important is the lost opportunity for Canadian health professionals to expand their skill sets. Clinical researchers contend that giving control over who may conduct diagnostic testing and where it is performed (e.g., through exclusive or limited licensing) interferes with both aspects of their dual function -- the practice of medicine and the conduct of research involving patients in order to study the efficacy and utility of innovations in these areas. In future, should key expertise have been lost to non-Canadian laboratories and a particular genetic diagnostic capability lost through commercial instability, it will be an enormous task to rebuild these resources.

Some are of the view that these problems may become more prominent in the future if patent holders increasingly come to "dictate which genetic tests are performed and how and where they are performed, without any consideration of societal

[86] Myriad charges $3500 U.S. for its test. It has been estimated that a Canadian public sector laboratory could conduct this test for half the cost.
[87] Myriad and GTG agreed to cross-license certain technologies related to the identification of non-coding DNA alterations and the assessment of inherited human diseases (e.g., breast and ovarian cancer, colon cancer, melanoma and hypertension). Myriad received a broad, non-exclusive license to GTG's non-coding DNA analysis and mapping patents for all applications in human therapeutics and diagnostics. For its part, GTG was tapped as Myriad's exclusive marketing and testing agent in Australia and New Zealand for its BRCA1/2 test. GTG is also Myriad's marketing agent for other predictive tests for colon cancer, melanoma and hypertension. These tests are performed by Myriad in its laboratory in the United States. Myriad has granted GTG an option to perform the other tests in Melbourne upon future payment of agreed fees and royalties. GTG has decided not to enforce the breast cancer patents against other health service providers in Australia. It is, however, enforcing its patents on non-coding DNA, which is essential to many diagnostic tests. GTG website http://www.gtg.com.au, last accessed August 30, 2005.
[88] In May 2004, the Opposition Division of the EPO revoked the Myriad patent on the BRCA1 gene and its application on the basis of a lack of inventiveness. The patent is now held by Cancer Research UK, which is licensing it broadly. In January 2005, the Opposition Division also rejected the main points of both this patent and a second Myriad patent concerning BRCA1 gene mutations associated with breast and/or ovarian cancer on grounds of failure to comply with European Patent Convention provisions relating to errors in the sequence description and relevance of priority claims.
[89] For example, the manner in which Myriad exercised its patent rights blocked research that could have improved the technology. A French study comparing Myriad's patented, direct-sequencing (DS) method of detecting BRCA1 mutations to 19 alternative strategies found that the Myriad technique was the most expensive, with other strategies obtaining four- to seven-fold reductions in the average cost per mutation detected. The authors concluded that gene patents with very broad scopes that cover all potential medical applications could prevent health care systems from identifying and adopting the most efficient genetic testing strategies): Sevilla, C., et al. 2000. Impact of gene patents on the cost-effective delivery of care: the case of BRCA1 genetic testing. *Int J Technol Assess Health Care*, 19(2):287-300.

needs or input from professional and government stakeholders."[90] Further, in some cases, the method mandated by the patent holder for conducting the genetic test, or the test itself, may not be the most appropriate for a particular patient.[91]

Where, due to restrictive licensing, only one or a few laboratories perform genetic testing, issues of quality are problematic for a number of reasons. First, patent holders may, in fact, set a standard for a particular genetic test that may not be in line with the best scientific evidence. Second, efforts at quality control may be impeded since comparison of test results between laboratories is a key component of quality assurance programs. This inability to validate tests and ensure their quality in terms of specificity, sensitivity and replicability could result in a high number of false results (either positives or negatives) and their associated impacts on individuals and on the health care system. Additionally, as noted by the Ontario Ministry of Health and Long-Term Care, restrictive licensing practices could disrupt publicly funded clinical genetic services, which closely link medical advice, genetic testing and counseling, by requiring that the test itself be provided elsewhere, or by controlling the number of sites where testing can be performed.[92]

A number of privacy and regulatory considerations are also raised by the collection of genetic test results. Questions as to whether genetic information is properly and securely stored and retrievable should anything happen to the laboratory (e.g., bankruptcy), whether the laboratory is using the information only for the purposes for which consent was given when the information was originally gathered, and whether and how the laboratory restricts access to this information (e.g., patients may not want it known that they are in a genetic disease database), clearly require policy attention. While these issues are not unique to patented genetic materials, the highly personal, private and hereditary/familial information associated with genetic information and genetic tests make these issues of particular concern. Information generated from samples processed by businesses outside Canada will not be subject to Canadian privacy laws and regulations.[93]

[90] ALRC, *Genes and Ingenuity*, Chapter 19, p. 7, note 17.
[91] Gold, Caulfield and Ray, Gene Patents and the Standard of Care, note 80.
[92] Ontario. *Genetics, Testing and Gene Patenting*, note 17.
[93] While it would be possible to extend these provisions through appropriate contractual terms, the purchaser of the diagnostic services may not have much bargaining power, particularly if there are no alternative service providers.

Part V

Conclusions and Recommendations

The request that CBAC undertake the present study stated:

> The objective of an effective and balanced intellectual property regime is to act as an important stimulus for innovation, by protecting and nourishing creativity and investment, to the mutual advantage of producers and users of such innovation, and in a manner conducive to economic and social benefits.

We concur with the view that, with respect to HGM-based innovations, Canada's intellectual property regime, like those in other jurisdictions, can lead to circumstances in which fulfillment of the foregoing objective – particularly, the "mutual advantage to both producers and users" – may be frustrated by the way in which monopoly rights are exercised or by the opportunity costs associated with uncertainty and inefficiency in the way the IP regime operates.

Conclusions

Although there is a paucity of empirical data on the quantitative, system-wide effects on the health sector of perceived negative impacts of the IP regime in respect of HGM, there is, in our opinion, enough qualitative evidence to warrant concerted action to prevent problems from escalating. We have therefore reached a number of conclusions.

1. It would be prudent to take additional steps now to improve the patent regime and its operation in order to broaden the opportunities for mutual advantage, to deal more effectively with undesirable consequences of the exercise of patent rights when they do arise, and to improve the timeliness and transparency of patent processes. Moreover, we believe it is urgent that Canada proceeds forthwith to implement these improvements in view of the accelerating pace of scientific and technological innovation.

2. While much of the impetus for examining HGM-based patents came from concerns expressed by health care providers, we have concluded that improving the patent regime and its operation will benefit not only the users of innovations, but also inventors, investors and producers. The enhancements to the IP regime that we believe are desirable to address concerns related to HGM will benefit other areas of biotechnology and, arguably, technology in general.

3. Although some contend that HGM should not be patentable because of what are presumed to be unique characteristics of DNA, the characteristics cited are not in fact unique, since the same characteristics are found in other patentable biological materials (e.g., proteins). Consequently, HGM should not be excluded from patentability. We also note that doing so would set Canada apart from other countries, including its major trading partners.

4. Nonetheless, the scope and intensity of the concerns raised by "genetic patents" is clearly greater than those related to other types of patented invention and should be addressed explicitly. Although some have urged including public order and morality considerations in the process of examining patent applications, we find that other more direct methods of social control would be more effective in prohibiting the manufacture, sale or use of socially undesirable or illicit products and services; we would not, therefore, impose a responsibility on patent examiners for which they are not equipped. Accordingly, matters of public order and morality should not be a consideration in the patent examination or review process.

5. Similarly, concerns about the issues associated with patenting and licensing of genetic tests can also be addressed through current provisions of the Canada's IP regime or its operation rather than by, as some have proposed, amending the *Patent Act* to exclude diagnostic methods from patentability or by providing an exemption for their clinical use -- actions which could seriously slow innovation in this field.

6. Sections 19 and 65 of the *Patent Act* allow governments and other potential licensees respectively, to apply to the Commissioner of Patents to use patented inventions without the permission of the patent holder where they have been unable to secure licences on reasonable terms. Since neither governments nor other potential licensees have apparently availed themselves of these provisions, there is no evidence that they are inadequate. Accordingly, we see no need at present to reintroduce a general compulsory licensing provision in the *Patent Act*.

Recommendations

We believe that the policy and practice initiatives we recommend will improve the IP regime and make it more conducive to the generation, acquisition and use within the health system of HGM based inventions that have been demonstrated to be safe and effective and constitute material advances in prevention, diagnosis or treatment of disease and disability. In our recommendations, we call for:

- ***the enhancement, clarification, and more rigorous application of patentability criteria;*** the development of interpretive guidelines; enhanced disclosure requirements on the part of applicants and application of sanctions for failure to meet them;
- ***significantly enhanced opportunities to challenge patents:*** before they are granted by a more open and responsive mechanism than exists now; and, after they are granted, by the introduction of an opposition procedure;
- ***increasing the scientific expertise of the Federal Court and consideration of establishing an Intellectual Property Division within the court*** in light of the speed of developments, not only with respect to HGM, but within technology as a whole;
- ***amendment of the Patent Act to establish an experimental use exemption from claims of infringement;***
- ***enhanced voluntary mechanisms to limit unduly restrictive practices*** and remove barriers to diffusion of HGM-based innovations, for example through development, of licensing guidelines and encouragement of industry initiatives to create patent pools and other mechanisms to remove barriers to diffusion of HGM-based innovations. With respect to HGM-based inventions developed using public funds obtained through federal grants, the granting bodies should develop licensing guidelines adherence to which would be a condition of funding;
- ***strengthened legislative provisions (e.g. those pertaining to competition and copyright) to limit patent rights and copyright*** in cases of abuse or where the national interest is at stake, either by making current provisions more effective or by introducing new provisions to deal with these matters; and
- ***the Canadian Intellectual Property Office to review its operations*** with a view to making them consistent with international best practices and to improve its client services.

Initiatives Within the IP Regime

THE PROCESS OF PATENTING

To address some of the issues associated with the scope and breadth of patents, policy makers could strengthen and clarify the criteria for patentability (novelty, non-obviousness, utility) or improve the mechanisms to challenge a patent that might be considered too broad or invalid.

CRITERIA FOR PATENTABILITY OF HGM

Methods of medical treatment: Methods of diagnosis or treatment involving surgery or therapy on the human body are not patentable in Canada, but methods not applied directly to the body are patentable.[94] Products or processes used in medical diagnosis or treatment have been treated like any other products or processes. We have therefore concluded that diagnostic products and techniques of other kinds should not be excluded from patentability.

Patent Criteria: Patent laws are to be applied without discrimination on the basis of technology.[95] Consequently, the criteria of novelty, non-obviousness and utility apply to all patent applications. Patents involving DNA sequences have resulted in patent offices specifying how DNA sequences are to be described and, in some cases, explaining how the three criteria should be applied. The U.S. revised its guidelines with respect to the utility criterion in January 2001. With respect to utility, the patent application (either in the claims or in the description) must not only identify uses, but they must also be "specific, substantial, and credible," an interpretation later recommended by the Australian Law Reform Commission. The European Patent Convention rules require the industrial application of a sequence to be disclosed.[96] In Canada, the description must disclose an invention that will produce an essentially economic result in relation to trade, commerce, or industry. For a product, the applicant must have established utility, at the claim date, either by demonstration (i.e., testing the invention and conclusively proving utility) or by sound prediction.

It has been suggested that it is open to patent offices to be more particular with respect to the use of DNA sequences. Although claims that attempt to cover all diagnostic tests involving a DNA sequence should be refused unless there is sufficient support for all uses, inconsistent application of the criterion could result in such broad patents being granted.

In 2002, CBAC recommended that CIPO develop policy guidelines for patents on biological material that address the criteria of novelty, non-obviousness (inventiveness), and utility, as well as the breadth of patent claims. CBAC suggested that CIPO follow the practice of the U.S. Patent and Trademark Office (USPTO) of issuing guidelines on how it applies patent criteria to different types of inventions. The USPTO guidelines on utility were last updated in January 2001 and include a section specifically on the patenting of living matter. CIPO has begun the process of updating the Manual of Patent Office Practice (MOPOP) and expects to have it completed by 2006. The revised chapter on Utility and Patentable Subject Matter was released in early 2005 and, certainly in terms of accessibility to the non-specialist; the new format is a significant improvement over the previous version. In the previous version of the chapter, relevant court cases were simply listed in the last section under relevant keywords. In the current version, court cases are footnoted to the text, many with explanatory notes. More extensive elaboration by CIPO of examination standards as they apply to HGM, using examples as in the US Manual, would assist the development of strategies for industry in filing patent applications, as well as helping those considering whether to challenge the validity of a patent.[97]

[94] Canadian Intellectual Property Office. 2005. *Manual of Patent Office Practice*, Ch. 12, Sections 12.04.02 (last updated February). Available at http://strategis.gc.ca/sc_mrksv/cipo/patents/mopop/mopop_dnld-e.html, last accessed August 30, 2005. See also European Patent Convention, note 9, article 52(4).
[95] Non-discrimination is an international norm under Article 27(1) of TRIPs. Nevertheless, Articles 27(2) and (3) allow members to invoke "ordre public" against some types of inventions and specifically to exclude from patentability diagnostic, therapeutic and surgical methods and plants and animals other than micro-organisms. The European Patent Convention, in Article 53(a), excepts from patentability inventions which would be contrary to ordre public and Rule 23d identifies cloning processes, germ-line modification processes, industrial or commercial uses of embryos and processes for genetically modifying animals where their suffering would not result in substantial medical benefit to humans or animals. While Canada also does not allow plants and animals to be patented, the basis for the exclusion is that plants and animals do not fall within the definition of invention in the Patent Act, which requires inventions to be either manufactures or compositions of matter: *Harvard College v. Canada (Commissioner of Patents)*, [2002] SCC 76; 219 D.L.R. (4th) 577.
[96] Rule 23(3), Implementing Regulations to the Convention on the Grant of European Patents of 5 October 1973 as last amended by Decision of the Administrative Council of the European Patent Organisation of 13 December 2001. Available at http://www.european-patent-office.org/legal/epc/e/r23e.html#R23e, last accessed Aug. 15, 2005.
[97] For example, if only breakthrough drugs are approved for market, funds currently being spent on developing "me-too" products and on "evergreening" existing patents would be shifted toward other products, perhaps health-improving or disease-curing research.

Recommendation 1

CIPO should develop interpretive guidelines for the application of patentability criteria to genetic innovations, similar to those in the United States for applying the utility criterion to HGM, as well as for evaluating the adequacy of the written description of the IP in the patent application. As in the U.S. guidelines, CIPO should include not only the citation for judicial decisions, explain what the decision means for patent examination and provide examples of how it would be applied.

Recommendation 2

CIPO should also improve quality control to ensure that the patentability criteria are applied rigorously and consistently to all applications.

Disclosure of Prior Art: Applicants in the US have statutory obligations to disclose all relevant prior art of which they are aware, with significant sanctions available for those who fail to comply. Japan requires that the application contain reference to relevant documentation of prior art known to the applicant. In Australia the applicant is required to inform the Commissioner of the results of any searches carried out by or on behalf of foreign patent offices regarding corresponding applications and failure to provide such information limits the possibility for amendments after grant. In Canada, the requirement to disclose prior art in response to a request from the examiner is found in the *Patent Rules*. While there are no specific sanctions, a failure to respond to the request can be treated as having abandoned the application.

Recommendation 3

Patent applicants should be required to disclose all prior art relevant to the claimed invention and sanctions for failure to do so should be established and applied.

OPPORTUNITIES TO CHALLENGE PATENTS

Opportunities should be expanded for challenging patents before and after they are granted in order to improve their quality and reduce the number of patents that are invalid or overly broad in scope.

PRE-AND POST-GRANT CHALLENGES

The quality of patents could also be improved if there were more efficient methods for third parties to bring to the attention of the examiner information that might not otherwise be taken into consideration.

In Canada, the processes of protesting the granting of a patent, filing of prior art, and requesting re-examination of an application are all carried out in a "closed" process. Once material supporting an objection to the grant of a patent has been submitted, the patent office considers the material, may request the applicant or patent-holder to respond to it, and makes a decision. The only way the person "objecting" can participate further is to monitor the progress of the file and submit additional material. This process is not very efficient and may not enable all relevant issues to be addressed. In addition, court rules prevent any issue that has been raised this way from being raised again in a lawsuit to impeach the patent. Consequently these processes are rarely used in Canada. While similar processes in other countries are also closed, the United States has recently allowed third parties to participate directly in the review.[98]

Recommendation 4

The processes whereby third parties may protest a patent application by filing prior art or requesting re-examination of a granted patent should be made more open and responsive.

[98] An optional *inter partes* procedure for re-examination became available in February 2001 and is described in Chapter 2600: United States Patent and Trademark Office. 2004. *Manual of Patent Examination Practice*. Washington: USPTO. Also available at http://www.uspto.gov/web/offices/pac/mpep/mpep.htm, last accessed August 30, 2005.

A Limited-Time Opposition Procedure: In 2002, CBAC recommended adoption of an administrative process for challenging an issued patent through the Patent Office, as had CBAC's predecessor (the National Advisory Committee on Biotechnology) in 1988. Opposition procedures currently exist in Australia, the EPC, France, Germany, India and Japan. CIPO has begun exploring this possibility and has commissioned studies examining the systems of other patent regimes.[99] These processes provide a forum for raising challenges, typically in terms of novelty and inventiveness. In its recent report, the Australian Law Reform Commission recommended that a "lack of usefulness" might also be a ground on which to oppose a patent. Several countries allow oppositions to be filed on "ordre public" grounds; as noted with respect to the patent examination process, we have concluded that socially undesirable uses of genetic inventions are better dealt with through funding criteria, research guidelines, and market approval mechanisms. Where opposition procedures already exist, the time limit for filing is nine months after the patent has been granted, a limit also proposed in legislation currently before Congress in the United States.[100]

Recommendation 5

The *Patent Act* should be amended to establish an opposition procedure within the Patent Office, with a time limit for filing oppositions of nine (9) months from the date the patent was granted. Procedures should be established and resources provided to ensure that proceedings can be concluded no more than 24 months from the date the patent was granted.

Expanding Judicial Expertise: Each new development in genomic science leads to new understandings and then to new ideas for applying that knowledge which, in turn, lead to patent applications. Courts are likely to be faced with increasing numbers of patent disputes involving genetic inventions in the coming years. The more prepared the courts are, the more likely a consistent, coherent jurisprudence will develop in Canada.

Recommendation 6

The Minister of Justice should, in appointing judges to the Federal Court and the provincial/territorial superior courts, consider the need for increased scientific expertise on those courts. The Minister should also consider the desirability of creating an Intellectual Property Division within the Federal Court.

USE OF PATENTED INVENTIONS

AN EXPERIMENTAL USE (RESEARCH) EXEMPTION

A patent grants the patent-holder the exclusive right to decide how it is to be used and by whom, if the patent-holder does not itself wish to exploit the patent. Any use of a patented invention without the patent holder's consent is therefore an infringement of the patent holder's rights. One of the grounds on which an alleged infringer may defend against a claim from the patent-holder is that the use complained of was experimental, non-commercial, and (implicitly) not therefore, undermining the patent-holder's economic interests in the patent.

Patent laws in many countries include provisions specifically protecting certain types of research or experimental uses of patented inventions from claims of infringement. Canadian patent legislation does not have a general research exemption, nor does that of the United States.[101] Nevertheless, the NAS report and other studies reveal that many academic researchers, as well as many patent-holders, believe there is and that, at minimum, it covers "basic" researchers in academic and not-for-profit settings.[102]

[99] Information provided by Industry Canada, July 25, 2005
[100] H.R. 2795, The Patent Reform Act of 2005. Available at http://thomas.loc.gov/cgi-bin/query/z?c109:H.R.2795, last accessed August 4, 2005.
[101] Both have "early working" exemptions (see below).
[102] Merrill et al, A Patent System, note 12; Hagelin, Ted, "The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold" (August 5, 2005), available at http://ssrn.com/abstract=776865 (accessed Aug. 15, 2005); ALRC, *Genes and Ingenuity*, note 17.

The scope of the research exemption in a particular country, whether statutory or the result of rulings in infringement cases, is likely to be determined through the courts. Two recent decisions in the United States have addressed the scope of the research exemption in that country. In *Madey v Duke University,*[103] the appeals court concluded that the experimental use exemption applied only to a narrow set of activities, such as research to satisfy "idle curiosity" or "philosophical inquiry." The court held that Duke University did not qualify because its use of the patented invention (a free electron laser) fell within normal "business" activities of the university, such as fulfilling government grants. Following the *Madey v Duke University* decision, a number of American universities have received letters claiming infringement on patents.[104] Because the methods for conducting biotechnology research are often patented, research in this area may be particularly vulnerable. Although this case was decided in the United States, the increasing emphasis on the commercialization of university research in Canada means Canadian courts might take a similar view.

While *Madey* severely restricted the scope of the general research exception, the scope of the "early working" exemption related to fulfilling regulatory requirements for market approval of generic drugs has been radically broadened. The U.S. Supreme Court, in *Integra v. Merck*,[105] appears to exempt any and all research whose ultimate end may be a regulatory application and not just the research required to generate the specific information necessary for filing an application for market approval.

Canada has a provision similar to the one in question in *Integra v. Merck*, exempting research required to generate information for regulatory applications.[106] It is quite likely that, at least until the Canadian courts have a chance to rule, some researchers in Canada will work on the assumption that Canadian courts will rule the same way as American ones. And since the Supreme Court questioned whether a general research exemption continues to exist in Canada[107] (despite section 55.2(6) of the *Patent Act*, intended to preserve the common law research exemption[108]), it could be argued that the research exemption in Canada is, at best, the very limited one left after Madey and, at worst, does not exist at all.

In 2002, CBAC recommended adding to the *Patent Act* a general experimental use exemption provision to supplement the exemption for research conducted for regulatory purposes under section 55.2. In light of developments since that time, we have reconsidered how such an exemption should be framed. In a recent article, Hagelin points out that, while the scope of the exemption varies, the minimum protection permits use of the patented invention to determine whether the invention is " feasible, useful or technically operable."[109] Most European countries have modeled their statutory provisions on Article 27 of the Community Patent Convention,[110] even though it is not yet in force, the relevant portion of which reads: The rights conferred by a Community patent shall not extend to

(a) acts done privately and for non-commercial purposes;

(b) acts done for experimental purposes relating to the subject-matter of the patented invention; …

[103] *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), cert. denied, 123 S. Ct. 2369 (2003).
[104] Wysocki, B. 2004. A laser case sears universities' right to ignore patents. *Wall Street Journal*, Oct. 11, p. A1. See also Blumenstyk, G. 2005. Science Association Assesses Impact of Quickening Drive for Patents. *Chronicle of Higher Education*, March 4, p. A31.
[105] *Merck KgaA v. Integra Lifesciences I*, 545 U.S. xxx (2005). It can be anticipated that a similar dispute over the interpretation of the early working provision will soon emerge in Canada and the court process will begin.
[106] The *Patent Act*, s. 55.2(1), excludes from infringement the making, construction, use or sale of a patented invention in order to conduct research aimed at satisfying federal or provincial regulatory requirements with respect to the sale of a product. This provision is primarily aimed at the generic pharmaceutical industry.
[107] *Harvard* mouse case, note 95.
[108] Section 55.2(6): … in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.
[109] Hagelin, The Experimental Use Exemption, note 102, p. 35.
[110] 89/695/EEC: Agreement relating to Community patents - Done at Luxembourg on 15 December 1989 *Official Journal L 401, 30/12/1989 P. 0001 – 0027*. See also Hagelin, The Experimental Use Exemption, ibid., pp. 34-35 and Merrill et al., A *Patent System*, note 12, pp. 111-112. Some countries have qualified the activities permitted in (b) by adding "solely" or "exclusively" to the phrase "for experimental purposes"; others have used the more general phrasing.

A parallel provision has been proposed for the WIPO harmonized substantive patent law treaty.[111] The proposed language of Article 19 (3) (a), Alternative B, adds to the CPC version, in the first sub-paragraph by recognizing that the experimental use must be balanced with the economic interests of the patentholder and, in the second, by strictly limiting the ambit of experimentation permitted.

(a) Any Contracting Party may provide that the owner of a patent has no right to prevent third parties from performing acts: …
(ii) where the act is done privately and on a noncommercial scale or for a noncommercial purpose, provided that it does not significantly prejudice the economic interests of the owner of the patent;
(iii) where the act consists of making or using exclusively for the purpose of experiments that relate to the subject matter of the patented invention; …

As noted above, there is a consensus in favor of an exemption for "research on" a patented invention to understand it. An exemption for "research using" a patented invention, especially if the invention is a research tool, is highly controversial. In his review of proposals for reform of experimental use provisions, Hagelin pointed out that the concern over research tools is focused solely on the biotechnology industry and, even though a large proportion of research tools are patented, there is little evidence to suggest researcher access to them is a major problem.[112] He would exempt "education, scientific research, evaluating patent specifications, disclosures and claims, improving on the patent subject matter, engineering around …, and developing competing, non-infringing patent subject matter."[113] He also proposes the rather common sense test that, if a patented invention is being used as it is intended to be used (e.g., using as a probe a patented nucleotide sequence intended for use as a probe), that use is not exempt.

Recommendation 7

The *Patent Act* should be amended to include an exemption from claims of infringement for research on a patented invention, as well as for certain research using a patented invention. We are of the view that the wording that follows is suitable; and recommend that the Minister of Industry provide such additional interpretative guidance for the courts as he deems desirable.

It is not an infringement of a patent to use a patented process or product:
(a) privately and on a non-commercial scale or for a non-commercial purpose, provided that such purpose does not significantly prejudice the economic interests in the patent of its owner; and
(b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or to create a new (i.e., not incorporating the patented invention) product or process.

LIMITING PATENT RIGHTS

VOLUNTARY MECHANISMS TO LIMIT RESTRICTIVE PRACTICES

As discussed earlier, the diffusion of patented IP in society is influenced by the ways in which patent holders seek to exploit their patent rights. Indeed, licensing practices are recognized as an important part of the patent regime.

[111] Draft Substantive Patent Law Treaty. 2003. WIPO/SCP10/2 (Sept. 30). Available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=18412, accessed August 30, 2005.
[112] Hagelin, The Experimental Use Exemption, note 102, p. 57.
[113] Ibid., p. 63.

Diffusion of patented IP can be affected by the transaction costs associated with negotiating licenses and/or the level of fees and royalties involved. Both of these elements can be particularly problematic where there are overlapping patents ("patent thickets") involving many patent holders, requiring the negotiation of multiple licenses. The time and effort involved in identifying relevant patents and patent holders, negotiating licenses, and the cost of royalty payments for those licenses may be impediments to research and development.

In many cases, patent holders wish to ensure that their intellectual property is widely used and adopt licensing practices that are conducive to achieving that goal. In fact, some researchers and organizations have obtained patents with the specific intention of licensing them liberally and at nominal cost. Moreover, many patent holders choose not to pursue claims of infringement where protected intellectual property is used for non-commercial purposes.

As access to patented HGM inventions is primarily by licence rather than sale, it would be desirable to encourage the development of licensing guidelines that would reflect a balanced approach to their development and use. As elaborated earlier, unduly restrictive licensing practices or excessively high royalty rates can have significant negative effects on research, development and commercialization and the provision of health services.

Licensing Guidelines: The National Institutes of Health[114] has developed and the OECD[115] is in the process of developing guidelines on licensing of human genetic inventions. These guidelines aim at providing a legally non-binding, but morally persuasive, set of principles and best practices to assist industry and universities in negotiating license arrangements that serve both the interests of industry and the public at large, including the health care sector. Likewise, the World Intellectual Property Organization (WIPO) and the International Trade Centre (ITC) have a new, practical guide on negotiating technology-licensing agreements.[116] The use of similar guidelines in Canada could be highly beneficial.

Recommendation 8

The federal government, in consultation with the provinces and territories, academia and the private sector, should facilitate the development of Canadian guidelines for the licensing of HGM-related inventions. We suggest as a starting point, the final OECD Guidelines for Licensing Genetic Inventions, expected to be released by late 2005.

A Licensing Policy for Publicly Funded Research and Commercialization: It would be possible to require that applicants for public funding of research or of support for commercialization be required to undertake to license non-exclusively any patented IP the generation or commercialization of which is based in whole or in part on said funding unless there is a compelling reason acceptable to the funding agency to license on another basis,. This would be analogous to the requirement that to be eligible for granting council funding, grantees must comply with the guidelines contained in the Tri-Council Statement on the Ethical Conduct for Research Involving Humans.

[114] National Institutes of Health. 2005. Best Practices for the Licensing of Genomic Inventions: Final Notice. *Federal Register* 70(68):18413-18415.
[115] OECD. Draft Guidelines for the Licensing of Genetic Invention. February 1, 2005. www.oecd.org/document/26/0,2340,en_2649_37437_34317658_1_1_1_37437,00.html.
[116] WIPO: Exchanging Value – Negotiating Technology Licensing Agreements. WIP/UPD/2005/237.

Recommendation 9

Ministers responsible for the national granting councils and other federal funding bodies should request them to establish guidelines to be followed by grant recipients with respect to licensing of patented HGM inventions developed with federal funds.

Patent pools or private collective rights organizations: In the manufacturing sector, cross-licensing or the creation of "patent pools" (in which patent holders agree to license their inventions to one another) have frequently been used to reduce patent barriers and to reduce the time and effort needed to negotiate with multiple partners. Some authors have suggested that they may be an option in HGM biotechnology[117]; an "open source" patent pool has already been established in plant biotechnology.[118] Mgbeoji and Allen[119] argue that, if used appropriately, patent pools specific to HGM could alleviate the problem of overlapping patents and royalty stacking. Through integration of complementary technologies, the reduction on transactional costs, the clearance of blocking patent positions and the avoidance of costly infringement litigation, patent pools could "maximize the social and economic benefits to innovators and the state, the parties subject to the contract of a patent." The U.S. Federal Trade Commission considered whether biotechnology patent pools could avoid running afoul of anti-trust law.[120] Initiatives are underway to establish patents pools related to HIV/AIDS and SARS.[121] Assistance may also be found in a forthcoming OECD study on genetic technologies and patent pools.

Recommendation 10

The federal government, in consultation with industry, should encourage and facilitate the development of patent pools and other mechanisms to remove barriers to diffusion of HGM-based innovations.

LEGISLATIVE PROVISIONS TO LIMIT PATENT RIGHTS

Under certain circumstances, particularly if a major public interest is at stake, legislative mechanisms can be used, either as they currently exist or in revised or expanded form, to enhance the diffusion and use of patented inventions in the health sector. The provisions of particular interest are those pertaining to compulsory licensing and competition law. As noted in the conclusions section, we are of the view that, since sections 19 and 65, which allow licences to be granted without the permission of the patent holder, have not been demonstrated to be inadequate, we will not address compulsory licensing.

Competition Law: Competition legislation in many countries contains provisions to limit the anti-competitive impact of market dominance or monopoly. The mere exercise of patent rights is not anti-competitive; the Competition Act specifically states that the exercise of an intellectual property right does not constitute abuse of dominant position.[122] It has nevertheless been suggested that there may be exceptional circumstances that should not be beyond the reach of anti-trust authorities. In guidelines issued in 2000, the U.S. government noted that even a refusal to licence the intellectual property is not anti-competitive on its own; other anti-

[117] Resnick, D. B., 2003. A Biotechnology Patent Pool: An Idea Whose Time Has Come? Journal of Philosophy, Science and Law, www.psljournal.com, Volume 3, January. Available at www.psljournal.com/archives/papers/biotechPatent.cfm, last accessed August 30, 2005.
[118] See, e.g., Rimmer, M. 2004. The race to patent the SAR virus, note 37. See also The triumph of the commons: Can open source revolutionise biotech? 2005. *The Economist*, Feb. 10, pp. 61-2.
[119] Mgbeoji I, A. B. 2003. Patent first, litigate later! The scramble for speculative and overly broad genetic patents: implications for access to health care and biomedical research. *Canadian Journal of Law and Technology* 2: 83-98.
[120] Clark, J. , et al. 2000. Patent Pools: A Solution to the Problem of Access in Biotechnology Patents? Washington: United States Patent and Trademark Office, December 5.
[121] Experts Discuss Essential Drugs Patent Pool Proposal. 2005. IP Watch (May 19). Available at http://www.ip-watch.org/weblog/index.php?p=55&res=800&print=0, last accessed August 30, 2005. See also Simon, J. 2005. Dealing with patent fragmentation: the SARS-patent pool as a model. Presentation prepared for *Gene Patents and Public Health* conference, Leuven, Belgium, May 27. Available at http://www.law.kuleuven.ac.be/cir/27-05-05%20studiedag%20presentaties/SARS%20patent%20pool-JSimon.pdf, accessed August 30, 2005.
[122] R.S.C., c. C-34, section 40.

competitive on its own; other anti-competitive behaviour, such as tied selling, must also be involved.[123]Abuse of dominant position could also be found if the patent holders' actions make sense only by injuring competitors.[124]

In 2004, the European Court of Justice[125] ruled that refusal to license a database would be an abuse of copyright if the requester intends to offer a product not offered by the other and for which there is potential consumer demand; there is no objectively justifiable reason to refuse a licence, and the refusal would reserve the relevant market to the IP owner by eliminating all competition in that market. This reasoning appears to be equally relevant in the patent context.[126]

Adcock et al.[127] have suggested that refusal to license could be found anti-competitive where a major purpose of the refusal to license a patented genetic invention was not simply to gain the monopoly profits, but rather to gain privileged access to genetic material as a research tool for other genetic discoveries.

Recommendation 11

The Competition Bureau should consider developing a policy statement or guidelines concerning the intellectual property law-competition law interface and, in particular, whether refusal to licence or refusal to licence on reasonable terms could be found anti-competitive.

COPYRIGHT AND RESEARCH USING GENETIC DATABASES

Compilations of genetic information, whether obtained specifically for research or as a by-product of genetic testing, can be useful in epidemiological investigations of, for example, the prevalence of susceptibility to disease or responsiveness to medications. Compilations of data can be protected by copyright if there is originality in the selection and arrangement of the data. Increasingly, databases of genetic information are maintained on websites. Some databases of genetic information, like that of the Human Genome Project, are in the public domain and accessible to any interested person. Other databases are proprietary. In either case, however, the information in the database is not protected by copyright. It should be noted, however, that the European Union database directive does provide some protection on the information stored in the database.[128]

Copyright law provides that it is not infringement to engage in "fair dealing"[129] with the copyrighted material. In Canada, it is not an infringement to copy copyrighted work for (among other things) the purpose of research. Many rights-holders have begun using a variety of technological protection measures (TPMs), to protect against digital piracy. However, these measures not only prevent deliberate large-scale infringement (piracy), they also prevent users from exercising their non-infringing rights. As more and more copyright material, including pure information (which is not copyrightable), is stored in digital formats, the risk increases that researchers will not be able to use information compiled in databases to generate new knowledge, even though they have a legal entitlement to do so.

[123] Antitrust Guidelines for Licensing of Intellectual Property, Issued by the Federal Trade Commission and the United States Department of Justice. 2000. Available at http://www.usdoj.gove/atr/public/guidelines/0558.wpd last accessed August 24, 2005.
[124] Carrier, M. A. 2002. Unraveling the Patent-Anti-trust Paradox. *University of Pennsylvania Law Review*. 150(3):761-864.
[125] *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG*, cited by Adcock, note 22, p. 68.
[126] For example, in the case of alternative diagnostic methods to those patented by Myriad Genetics.
[127] Adcock et al., The Use of Patents by Governments, note 22, p. 68.
[128] EU Database Directive, note 9. The Directive provides a sui generis protection for databases, which runs 15 years and can be extended a further 15 years if significant revisions are made.
[129] "Fair use" in the United States. The concepts are similar, but not identical.

Recommendation 12

The federal government should ensure that users' rights are protected through amendments to the *Copyright Act*, such as those contained in Bill-C-60 introduced in Parliament in June 2005. Specifically, such amendments should:

- permit the use of anti-circumvention devices in a manner that enables fair dealing;
- ensure that anti-circumvention provisions are specifically linked to traditional copyright infringement by limiting a circumvention offence to those who intend to infringe;
- consider granting users a positive right of circumvention; and
- ensure the Competition Bureau can address marketplace practices that preclude fair dealing.

OPERATIONS

Currently, inventors – including Canadian inventors – tend to patent their inventions in the U.S., Europe and Japan, and only later in Canada. In part, this pattern reflects market forces (size of potential markets) but it is also influenced by the perception that the Canadian patent system tends to be slow in rendering decisions and "unfriendly" to biotechnology. This perception may affect the ability of Canadian biotechnology firms and start-ups to attract investment capital from the U.S. and elsewhere.

The CIPO has recently significantly expanded its staff in the biotechnology sector, although the benefit of additional staff will not be seen in reductions in turnaround time for a while yet, especially as CIPO has now become an International Search Authority under the Patent Cooperation Treaty, which has increased the workload. CIPO is also in the process of updating its Manual of Patent Office Practice used by patent examiners and available to the public, and has made efforts to improve consistency and rigor in the review of claims against patentability criteria. As noted earlier, the quality of the patent review process would be improved further if there were (a) more fully elaborated guidelines for applying patent criteria, (b) specific guidelines on how patent criteria apply to genetic inventions, and (c) more rigorous and consistent application of patent criteria.

Patents can serve an important signaling function, identifying to potential partners and investors a new entrant in the field. To facilitate this function and support innovation, the Canadian patent system should ensure that the operations of the Patent Office are as conducive to timely and efficient handling of patent applications as possible. Patent applications should neither be hampered nor defeated by requirements that are not among internationally recognized best practices. At the same time, it must be recognized that patent applicants in Canada have five years to request examination, while examination commences automatically on filing in the United States. Controlling for the time examination commences, the time taken for patent examination does not differ significantly between Canada and the United States. CIPO's outreach material should clearly identify this difference, given the large number of patents that are filed first in the United States.[130]

Recommendation 13

CIPO should revise and clarify its procedures and services with a view to making them as consistent as possible with the best practices of Canada's major trading partners, bearing in mind that the largest market for Canadian products and the country to which the bulk of Canadian exports go is the United States.

With respect to handling of patent applications, CIPO should revisit its administrative procedures and consider or reconsider changes to:

- ***Improve timeliness of examination of patent applications*:** Begin examination promptly on request of the applicant.

[130] Another area where Canada is perceived as not as friendly to biotechnology as other countries is the fact that patents on higher life forms are not granted here. While this statement is true, it is misleading if not accompanied by the explanation that the genes, modified genes, and cells containing them are patentable subject-matter and, since *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, properly worded claims on cells or genes will provide essentially the same level of patent protection as if a patent on the entire organism had been obtained.

- ***Provide greater flexibility in initial filing requirements*:** Canada should grant a filing date for initial filings in any language and/or where the application does not contain the filing fee. The applicant should be given a period, set by notice from CIPO,
- ***Automatically issue a search report*:** CIPO should consider automatically issuing a search report within a few months of examination being requested, and in advance of the first Official Action.
- ***Provide relief for inadvertently missed deadlines*:** Canada should provide for retroactive extensions to certain time limits to allow applicants an opportunity to revive filings which lapse due to unavoidable or unintentional omissions or delays.
- ***Update further, the rules for filing nucleotide sequences ("sequence listings") in patent applications*:** Canada is out of step with other countries in that it requires that sequence listings be filed using an outdated filing standard and does not permit often enormously lengthy listings to be filed in electronic format only. Since applications may have become abandoned for failure to comply with the outdated sequence listing requirements, the update rules should be made retroactive.
- ***Clarify the nature and extent of reliance on corresponding applications*:** Patent applications in countries where examination begins immediately will be processed sooner than in Canada, even if filed at the same time. Both applicants and CIPO can take advantage of this to improve the quality of patent applications and patent examinations respectively. CIPO should specify how it currently makes use of corresponding applications and should consider how such use could be formalized.

With respect to service to clients and other interested parties CIPO should:

- Enhance the functionality of its key-word searchable patent database (Tech Source)
- Make the database easily accessible to clients and the public through its website rather than requiring those who wish to search the database to do so in person at CIPO offices.

Recommendation 14

CIPO will require increased resources in order to meet best practice performance standards especially in the face of an expanding workload related to growth in the number and complexity of HGM-based inventions. Accordingly it should:

- ***Increase fees for patent applications and for maintenance of patents so that they are comparable to those of Canada's major trading partners, and***
- ***Impose fees for the examination of large numbers of claims*:** introduce supplementary fees for the examination of large numbers of independent claims and large numbers of sequence listings, as is the practice in other jurisdictions.

Initiatives Outside The IP Regime

In our consultations and deliberations, we also identified a variety of mechanisms or strategies that fall outside the IP regime per se, but which can facilitate the adoption of HGM-based innovations in ways that can ameliorate some of the impacts of the IP regime on health services. Most of the relevant options are within the purview of the users/purchasers of HGM-based innovations. They include:

HEALTH TECHNOLOGY ASSESSMENT

- *strengthening the organization and performance of Health Technology Assessment (HTA)*: We concur with the view that a strengthened and effective HTA system could contribute significantly to the rational and efficient adoption by the health system of beneficial HGM-based inventions.

AFFORDABLE ACCESS

- *employing ancillary mechanisms for facilitating affordable access to genetic innovations* through control of costs or eligibility for public reimbursement. A number of price control mechanisms could be used to help ensure equitable, timely and affordable access including some that are already in use with respect to pharmaceuticals:

  Bulk Purchasing: Discounts are usually available for purchases of large quantities of any commodity.

  A Price Review Board: A price control mechanism analogous to the Patented Medicines Prices Review Board could be developed for non-pharmaceutical patented health innovations.

  Formularies: Governments and private insurance companies use formularies in order to control global costs of prescription medications and/or other medical services.

  Reference Pricing: A process by which diagnostic or therapeutic products with similar clinical effect are reimbursed at the same rate, typically based on the lowest-cost products and services in the group.

AVAILABILITY OF INNOVATIONS

- *employing ancillary mechanisms for ensuring availability of innovations*

  Government Buy-Out: If it were seen to be in the public interest, the government could buy the patent from the patent holder and then either produce the goods itself or license others to do so.

  Guaranteed Purchase: A Guaranteed Purchase is an incentive provided by the purchaser to encourage private sector development of a desired commodity. It is used to ensure there is adequate production of essential products, such as flu vaccines.

  Technology Transfer Body: A body could be created that has the mandate of negotiating licensing agreements needed to promote the commercialization and production of products or processes.

  Public/Private Partnerships: PPPs are created to address issues that neither sector was capable or willing to tackle on its own. Many of these partnerships have occurred in the arena of international health, such as the coalition to develop a malaria vaccine involving the public health systems in Africa and private (foundation and industry) players.[131]

RECOMMENDATION 15

We recommend that CBAC, in tendering its advice to the Government on HGM and the health sector, identify such further studies as may be desirable to assess the feasibility and desirability of initiatives outside the IP regime that would enhance access to beneficial HGM-based innovations.

[131] GSK, WHO-TDR and the Medicines for Malaria Venture collaborate to fight malaria. 2004. Medical News Today News Article (April 23). Available at www.medicalnewstoday.com/printerfriendlynews.php?newsid=7590, last accessed February 24, 2005.

Concluding Observation

Concluding Observation

CBAC has noted that health-related biotechnology can play an important role in Canada's innovation strategy – a strategy that seeks to realize the full social and economic benefits of technological advances by striking a sustainable reconciliation between different objectives and social values. Canada's IP regime, like those of its major trading partners, is a legislated mechanism for reconciling the objectives of fostering innovation and ensuring access to its benefits. Our findings and recommendations are focused on identifying and proposing modifications to Canada's IP regime to address issues brought to light by recent cases involving patented HGM in which the particular ways in which patent rights have been exercised have frustrated the achievement of such reconciliation.

The issues addressed in this report are part of the much larger challenge of how to create the capacity to adopt beneficial innovations in an already heavily burdened health care system. Meeting this challenge fully will require more than refinement of the IP regime. It will also require new institutional mechanisms and perhaps new organizations. Such institutional innovations are particularly important in rapidly advancing fields of scientific and technical knowledge with major implications for social and economic development and regulatory stewardship. Although we have touched on some possibilities and others have been proposed and implemented in other jurisdictions (e.g. the national human genetics commissions in Britain and Australia), a substantive consideration of these matters was beyond our mandate. However, we suggest that CBAC may wish to explore them in greater depth with a view to providing specific advice to Government.

Collaborative efforts involving all levels of government, health care and research institutions, and industry must be intensified to ensure that a comprehensive array of policies, procedures and practices are pursued to realize fully the health and economic benefits of innovations based on human genetic materials.

Annexes

Annex A: Referral to CBAC: Terms of Reference

PROJECT:
Human Genetic Materials, Intellectual Property Regime and the Health Sector

DEPARTMENTS:
Industry Canada, Health Canada

CONTENT FOR THIS STUDY

- The Government of Canada is committed to the promotion of innovation in biotechnology as a means of strengthening the country's economy and its international competitiveness, as well as improving Canadians' quality of life.
- Recognizing the importance of intellectual property for obtaining financing, establishing strategic alliances, and stimulating research and development in the biotechnology sector, the Government of Canada is also committed to ensuring that our *Patent Act* remains modern and progressive in order to stimulate innovation and to enable Canada to be a world leader.
- The Government of Canada, together with its provincial and territorial partners, is also committed to the sustainability of Canada's publicly funded health care system, which constitutes a public good, an economic strength and a central facet of the Canadian identity.
- Advances in human genetic technologies have the potential to benefit Canadians in many ways, yet they also raise a number of ethical, economic, legal and social issues-and concerns.
- Similarly, intellectual property protection for inventions involving human genetic materials also seems to raise issues.
- The objective of an effective and balanced intellectual property regime is to act as an important stimulus for innovation by protecting and nourishing creativity and investment, to the mutual advantage of producers and users of such innovation, and in a manner conducive to economic and social benefits.
- Canada's intellectual property regime exists within a framework of international agreements, obligations and practices, most notably those pursuant to TRIPS and NAFTA.
- The provincial and territorial governments as well as several foreign governments and international organizations are studying, from a variety of perspectives, a range of issues concerning human genetic materials, intellectual property and the health sector.
- As CBAC's report on the Patenting Higher Life Forms suggests, studying the interaction between human genetic materials, the intellectual property regime, and the health sector is a worthy endeavour.

DESCRIPTION OF ISSUES TO BE CONSIDERED

1. With respect to human genetic materials, identify and analyze possible systemic incentives and disincentives for relevant participants of the current intellectual property regime on:
   a. obtaining financing and investment;
   b. establishing strategic alliances with private/public sector partners, including international ones;
   c. conducting research in the health sector, whether it be basic research or applied research (i.e.: access to and exchange of research materials and tools, diversity of research sectors, types of research undertaken or improvements of products and processes);
   d. developing products and processes for diagnostic, preventive, therapeutic and/or epidemiological use within the health care sector;
   e. the ability to commercialize or distribute products and processes; and
   f. access to, and provision of, health care services (i.e.: production, assessment, distribution and use of genetics innovations, including their interpretation where appropriate, in our health system, etc.)

2. With respect to the field of human genetics and related technologies, compare the current patent regimes of Canada and its major trading partners (EU, Japan, US, Australia) with respect to:
   a. current patenting practices, including:
      i. patentability criteria and their application;
      ii. the nature and scope of exclusions/ exemptions;
      iii. mechanisms for challenging granted patent (e.g., re-examination, opposition procedure, appeal to court etc.); and
      iv. features, which encourage diffusion and exchange of information (e.g., absolute novelty, grace period, laying open of patent applications, etc.);
   b. the impact of patents for inventions involving human genetic materials on health research and the provision of health care services, particularly as a result of licensing and/or pricing practices of patent-holders; and,
   c. practices for overseeing and/or regulating these impacts (e.g., provisions for compulsory licensing, price regulation, abuse of rights provisions, etc.).

METHODOLOGY

These comparative analyses should take into consideration the specific nature and features of the Canadian intellectual property regime, health care system, genomic industry and its industrial/business practices as well as the judicial system.

In performing this work, CBAC is requested to:

- take into account the current and future potential applications and advancements of this technology for the development of diagnostic, preventive, and therapeutic products/processes for the health sector.
- obtain and take into account the views of key stakeholders, including the health and biotechnology sector, provincial/territorial governments, the research community, and patent lawyers/agents.

TYPE OF INPUT REQUESTED FROM CBAC

Research report with recommendations.

Annex B: What We Heard: Summary of Main Findings from Stakeholder Consultations

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,
- 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 appendix 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.

Intellectual property protection of Human Genetic Materials

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[132] are likely to become a systemic problem. Some participants contended that this behaviour

[132] 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 licencees 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.

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[133] and outside[134] 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;
- 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.

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.

[133] 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.
[134] 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.

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.[135] 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.

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.

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 licences 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 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.

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;

[135] 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.

- 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.

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.

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.

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.[136]
- ***Implement an opposition procedure*** as a mechanism to challenge issued patents.
- ***Improve administration and capacity of CIPO:***
  - better examination guidelines[137] 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).

OUTSIDE THE PATENT REGIME

- ***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,

[136] 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.
[137] Such guidelines exist in the Manual of Patent Office Practice (MOPOP). The chapter on Biotechnology is currently being revised.

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.

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[138] 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 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.[139] 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.

[138] 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.
[139] A few participants suggested that the mandate of the PMPRB could be extended to cover HGM products (as well as pharmaceuticals).

The following summarizes the main areas of convergence and divergence in the recommendations of a number of international gene patenting reports (detailed information on these recommendations is found in the chart at the end of this summary).[140]

Recommended Changes to Patent Regime

PATENTABILITY CRITERIA AND THEIR APPLICATION

- All reports recommend greater clarity in the definition of and more stringent application of patentability criteria, particularly the non-obviousness, inventiveness, and utility criteria, through, for example, clear examination guidelines.
- There is also a suggestion by the Nuffield Council that there be greater collaboration between the major patent systems (European, U.S. and Japanese), a sentiment echoed in the NAS report ("reduce redundancies and inconsistencies among national patent systems"). Furthermore, the Nuffield Council argues that once a gene associated with a disease is identified, the use of the relevant DNA sequence in gene replacement therapy is obvious, particularly when such use is claimed on a purely speculative basis. Therefore, product patents should seldom be permissible. Patents over DNA sequences used to make new medicines that are therapeutic proteins are generally patentable, but should be narrowly defined and extended only to the protein described.

METHODS OF MEDICAL TREATMENT

- The ALRC, Ontario and New Zealand reports consider a legislated exemption for methods of medical treatment. The Australian report does not support such an exemption, while the Ontario report is in favor of this. New Zealand supports such an exemption in theory but prefers instead to see the focus on more stringent application of patentability criteria.

EXPERIMENTAL USE EXEMPTION

- All of the reports (with the exception of the German National Ethics Council[141]) discuss the need for an experimental use exemption. The ALRC, Nuffield, Ontario and CBAC reports call for the creation or clarification (where the exemption already exists) of a legislated experimental use exemption. The NAS report recommends that some research uses of patented inventions should be protected from infringement liability and suggests that Congress consider appropriate targeted legislation. In the meantime, federal government agencies sponsoring research should consider extending "authorization and consent" to those conducting federally supported research. The New Zealand report recommends that such an exemption should be considered but that further study is required prior to proceeding in this regard.

MECHANISMS FOR CHALLENGING PATENTS

- The CBAC, ALRC, Ontario and NAS reports discuss the need for reinvigorating existing mechanisms by which patents may be challenged or for developing new mechanisms. Challenges are discussed during the application process (ALRC, NAS) or post-grant (CBAC, Ontario, NAS), as well as by governments (ALRC, NAS) or individuals/private interests (ALRC, Ontario, NAS).

[140] Canadian Biotechnology Advisory Committee (CBAC), *Patenting of Higher Life Forms Report*, 2002. Australian Law Reform Commission (ALRC), *Genes and Ingenuity*, 2004. Ontario Ministry of Health and Long-term Care, *Charting New Territory in Healthcare*, 2002. New Zealand Ministry of Health and Commerce, *Memorandum to Cabinet Policy Committee, Report Back with Recommendations and Options for Addressing Genetic Material Patents*, 2004. German National Ethics Council, *The Patenting of Biotechnological Inventions Involving the Use of Biological Material of Human Origin*, 2004.
Nuffield Council, *The Bioethics of Patenting DNA*, 2002.
National Academy of Sciences (NAS), *A Patent System for the 21st Century*, 2004.

[141] Because an experimental use exemption already exists in Germany, it is not mentioned in the German National Ethics Council's report.

ORDRE PUBLIC

- The ALRC, Ontario, New Zealand, German and Nuffield reports discuss the need for a statutory ordre public provision. The ALRC is of the view that social and ethical concerns should not be addressed through patent legislation, while Ontario and New Zealand recommend that consideration be given to a legislated ordre public provision. The German and UK reports call for better disclosure and clarification of the criteria under which the German and European ordre public provisions can be invoked.

GOVERNMENT USE

- The ALRC, Ontario and New Zealand reports discuss the need for clearer policy around when it is appropriate to invoke existing government use provisions in the *Patents Act* (e.g., to ensure health care system access to genomic products and services). The ALRC and Ontario reports additionally recommend that their respective patent legislation be amended to provide that remuneration that is to be paid must be just, reasonable and promptly paid.

COMPULSORY LICENSING

- Compulsory licensing is discussed in the ALRC, Ontario, New Zealand, German and Nuffield reports as a means of ensuring reasonable access to patented products or processes. The Ontario, New Zealand, German and Nuffield reports suggest that reasonable compulsory licensing, particularly for diagnostic products, should be permissible to ensure that these products are available for use by the health care system.

PATENT OFFICE PRACTICES

- The CBAC, ALRC, Ontario, German and NAS reports discuss the need for improved efficiency and effectiveness of their countries' respective patent offices. Recommended remedial measures include increased training for examiners, harmonization of major patent systems (CBAC and NAS), and the development of detailed examination guidelines (CBAC, ALRC and NAS).
- The ALRC report also addressed the issue of patent fees and recommends that an assessment be undertaken of the impact of patent fees on the actual term or Australian patents. Periodic review of patents fees is recommended to ensure that fees are set at level capable of discouraging patent holders from maintaining patents that lack real commercial value.

Recommended Changes outside of the Patent Regime

COMPETITION LAW

- The ALRC and NAS reports discuss the use of mechanisms to handle cases in which patents are used in an anti-competitive manner. The ALRC report recommend that, as the need arises, the conduct of firms dealing with patented human genetic materials and technologies should be reviewed to determine whether conduct is anti-competitive within the meaning of the *Trade Practices Act*. The NAS recommends that under its proposed open, post-grant review, the Department of Justice or the Federal Trade Commission could request that the patent office initiate a review where a valid patent is being used to adversely affect competition.

GOVERNMENT PURCHASING/PRICE OVERSIGHT

- The ALRC report recommends that government examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of health care. The ALRC report also discusses mechanisms for controlling the price of genomic products or services, contending that if there is evidence of prices have adversely affected access to healthcare, the matter should be referred to the Productivity Commission for study or inquiry, or to the Australian Competition and Consumer Commission or other body.

HEALTH/GENETIC TECHNOLOGY ASSESSMENT

- The ALRC and Ontario reports discuss the need for expertise in health and/or human genetic health technology assessment in order to evaluate and guide the utilization of emerging technologies.

SUMMARY OF MAIN RECOMMENDATIONS FROM INTERNATIONAL GENE PATENTING REPORTS [142]

A Recommended Changes Within the Patent Regime

Mechanism	Charting New Territory in Healthcare, Ontario Ministry of Health and Long-term Care, 2002 (Jan.)	Patenting of Higher Life Forms, Canadian Biotechnology Advisory Committee, 2002 (June)	Bioethics of Patenting DNA, Nuffield (UK), 2002 (July)	Memo. to Cabinet Policy Committee, Report … Addressing Genetic Material Patents, New Zealand, 2004 [143] (June)	Genes and Ingenuity, Australian Law Reform Commission, 2004 (Aug.)	Patenting of Biological Material of Human Origins, German National Ethics Council, 2004 (Oct.)	Patent System for the 21st Century, NAS, US, 2004
Patentability Criteria and their Application	Develop clear examination guidelines (especially regarding novelty, non-obviousness and utility). Particular attention must be paid to SNP and EST patenting and include a determination as to whether and under what conditions these sub gene patents might be granted. Exclude broad-based gene patents covering multiple potential uses and limit patents to clear and well-defined specific uses.	Develop and publish interpretative guidelines on patentability criteria and the process to be followed by applicants and the benchmark time frames for each step.	Stringently apply criteria for the granting of patents, particularly inventiveness and utility. This should substantially reduce the number of patents granted involving DNA sequences.	Undertake more stringent application of patentability criteria. Identify mechanisms to narrow the application of patents on genes (e.g., develop interpretive examination guidelines).	Assess HGM patent applications according to same legislative criteria for other technologies. Review 'manner of manufacture' test as the threshold requirement for patentable subject matter. Include "usefulness" as an examination requirement (specific, substantial, credible use). Include 'lack of usefulness' as basis to oppose a patent.	Limit scope of patent to technical application of a function specifically set forth in the patent claim. Develop statutory obligation to furnish evidence of origin of biological substances of human and non-human origin. Use restrictive interpretation of "invention" (until adoption of more precise definition).	Preserve an open-ended, unitary, flexible patent system but reinvigorate the non-obviousness standard. Development of examination guidelines for new or newly patented technologies.

[142] Some of these reports also address policy issues and approaches related to IP protection of HGM (e.g., ethical questions around gene patenting, need for a national coordinating body on genetics, IP protection of publicly funded research, and privacy, discrimination and disability/protection of indigenous rights. Readers are invited to consult these documents for additional information. Bibliographic information appears at the end of each section of this table.

[143] Note that New Zealand has been reviewing its patent legislation over the past few years (with amended legislation due in 2006). The issue of gene patents had not been specifically addressed in this review. However, due to the national and international debate over the patenting of genetic material, government requested that this present memorandum be prepared for its consideration.

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Mechanism	Charting New Territory in Healthcare, Ontario Ministry of Health and Long-term Care, 2002 (Jan.)	Patenting of Higher Life Forms, Canadian Biotechnology Advisory Committee, 2002 (June)	Bioethics of Patenting DNA, Nuffield (UK), 2002 (July)	Memo. to Cabinet Policy Committee, Report . . . Addressing Genetic Material Patents, New Zealand, 2004[143] (June)	Genes and Ingenuity, Australian Law Reform Commission, 2004 (Aug.)	Patenting of Biological Material of Human Origins, German National Ethics Council, 2004 (Oct.)	Patent System for the 21st Century, NAS, US, 2004
Methods of Medical Treatment	Expand "methods of medical treatment" exclusion in the *Patent Act*. Ensure appropriate protections from infringement for health care professionals and institutions when using patented genetic materials in research or the provision of care.			Consideration could be given to expanding the methods of medical treatment exclusion in the Patents Act to exclude from patentability methods of diagnostic testing that are carried out outside the body. However, preferred approach is to focus on more stringent application of patentability criteria.	The *Patents Act* should not be amended to enact either: (a) a medical treatment defence of general application; or (b) a defence applying specifically to the use of patented genetic materials and technologies in medical treatment.		
Experimental Use Exemption	Clarify "experimental use" and "clinical non-commercial use" exceptions in the *Patent Act* to indicate that non-commercial clinical use of patented HGM and general research use of patented material are excluded[144]. Ensure appropriate protections from infringement for health care professionals and institutions when using patented genetic materials in research or the provision of care.	Legislate experimental use exemption for use of patented process or product for private and non-commercial purposes, or for further study to improve upon the product or process, or to create a new one.	The research exemption should be given a statutory basis in the U.S. and clarified in Europe (there is a statutory research exemption in Europe, however, the scope of the exemption is not clear). The granting of patents that assert rights over DNA sequences as research tools should be discouraged by stringent application of the criteria for patenting, particularly utility.	A legislative exemption should be considered which would apply to all patented inventions, but requires further study. (Note that the Ministry of Economic Development, in consultation with the Ministry of Research, Science and Technology and the Ministry of Health is to report to the Cabinet Policy Committee by 31 July 2005 on the desirability of adding a research exemption in New Zealand's patent ligislation.)	Legislate an exemption for the study or experimentation on the subject matter of a patented invention. Provided that experimentation is on the subject matter of the patented invention, the existence of a commercial objective should not preclude the exemption, since the patent system is intended to facilitate research and promote innovation/ commercialization.	Experimental use exemption already exists in Germany.	Shield some research uses of patented inventions from infringement liability through appropriately narrow legislation. In the meantime, government research funders should consider extending "authorization and consent" to those conducting federally supported research.

[143] Note that New Zealand has been reviewing its patent legislation over the past few years (with amended legislation due in 2006). The issue of gene patents had not been specifically addressed in this review. However, due to the national and international debate over the patenting of genetic material, government requested that this present memorandum be prepared for its consideration.

[144] Section 55.2 of the *Patent Act* states that it is not an infringement to make, construct, use, or sell a patented invention in order to conduct research aimed at satisfying federal or provincial regulatory requirements with respect to the sale of a product. Another exception has been judicially created which permits research with a non-commercial end on the subject matter of the patent. As the law currently stands, however, it is unclear whether a researcher conducting research using a patented invention could successfully be sued where that research has the potential in the longer term to result in a commercial product.

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Mechanisms for Challenging Patents	Introduce an opposition period of nine months upon issuance of a new gene patent to allow interested and affected parties to bring forward reasons for which the content, scope or validity of the patent should be reviewed.	Introduce a timely opposition procedure (i.e., time limit for filing oppositions be six months from the date the patent was granted and the proceedings be concluded 18 months from the date that the patent was granted).			No changes are currently required to the mechanisms for challenging gene patent applications or granted gene patents. However, "lack of usefulness" should be included as a basis upon which an accepted application may be opposed (in addition to its current role as a ground for revocation). Information about patent litigation should be readily accessible to the public. Governments should have the option of challenging patent applications or grants if the patent is considered to have an adverse impact on medical research or the cost-effective provision of healthcare.		There is a point beyond which it is not practical or economical to invest all of the resources that would be needed to ensure uniformly rigorous and timely examination. Nor can the courts be expected to review patents' validity in a timely, efficient manner. Thus, a post-grant, open review process is recommended to enable third parties to challenge the validity of issued patents on any grounds in an administrative proceeding within the patent office. Federal District Courts would confine themselves to resolving issues of infringement.

[143] Note that New Zealand has been reviewing its patent legislation over the past few years (with amended legislation due in 2006). The issue of gene patents had not been specifically addressed in this review. However, due to the national and international debate over the patenting of genetic material, government requested that this present memorandum be prepared for its consideration.

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Ordre Public	Consider adopting an ordre public or morality clause within the *Patent Act*.		In cases of patents that assert property rights over DNA, consideration should be given to whether the balance between public and private interests have been fairly struck. The European Patent Office should consider producing further guidance that clarifies the principles of ordre public.	Inventions whose commercial exploitation would be contrary to morality or ordre public should be excluded from patent protection. Guidelines would be needed to determine whether a commercial exploitation of a particular invention would be contrary to morality or *ordre public*.	Social and ethical concerns should not be addressed through the *Patents Act* but primarily through direct regulation of the use or exploitation of a patented invention.	Ordre public already exists. However, better disclosure and clarification of the criteria under which it can be invoked is needed.	
Government Use	Amend Patent Act to provide that, when a patent is exploited under the Crown use provisions, the remuneration that is to be paid must be just and reasonable and paid promptly.			The use of patented inventions for services of the Crown is allowed for in the Patents Act. The provision allows any Government Department (or a person authorized by a Government Department) to make, use, exercise and/or vend a patented invention for the services of the Crown. Guidelines could be developed to describe how and when the Crown Use provision can be applied.	Develop government policy on when it is appropriate to exploit a patented invention under the Crown use provisions of the *Patents Act*. Clarify in the *Patents Act* that an invention is exploited 'for the services of the Commonwealth or of a State' where such exploitation is for the provision of health care products or services. Amend *Patents Act* to provide that remuneration to be paid under Crown use will be reasonable and prompt.		

[143] Note that New Zealand has been reviewing its patent legislation over the past few years (with amended legislation due in 2006). The issue of gene patents had not been specifically addressed in this review. However, due to the national and international debate over the patenting of genetic material, government requested that this present memorandum be prepared for its consideration.

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Compulsory Licensing	Revise compulsory licensing provisions in the *Patent Act* to cover genetic diagnostic and screening tests in the public health care system, thereby allowing the Commissioner the power to grant a compulsory license and to set an appropriate royalty rate after engaging appropriate industry and health sector expertise, if required, but without prior negotiation with the patentee.		In the case of patents granted for diagnostic tests based on genes, compulsory licensing may be required to ensure reasonable licensing terms are available to enable alternatives tests to be developed.	Patents Act provides for the granting of a compulsory licence. The grounds for the granting of a compulsory licence are that a market for the invention is not being supplied or is not being supplied on reasonable terms in New Zealand. Guidelines could be developed to describe how and when compulsory licensing provision can be applied.	Amend the provisions of the *Patents Act* relating to compulsory licences by: -- inserting the competition-based test recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence; -- clarifying the scope of the 'reasonable requirements of the public test'.	Compulsory licenses, especially in the case of diagnostic or therapeutic methods, should be granted in a deliberately targeted manner.	
Patent Office Practices	Adapt the delivery of intellectual property services provided by the patent office to provide a sound, predictable IP environment. Involve industry in discussions to ensure that the patent office provides globally competitive services for biotechnology patenting.	Regularly update service standards for processing of patent applications. Develop and publish interpretative guidelines on patentability criteria and the process to be followed by applicants and the benchmark time frames for each step. Pursue international harmonization of policies and procedures.			Enhance education and training of examiners in technology areas. Develop examination guidelines. Amend *Patents Act* to require examiners to be satisfied on the balance of probabilities when assessing all statutory requirements for patentability that are relevant at the stage of examination. Assess the impact of patent fees on the actual term of Australian patents.	Careful monitoring of practice of patents offices and courts, especially regarding the ordre public-based prohibition, and compulsory licensing to ensure there is disclosure and clarification of decisions.	Increase examiners and provide training. Provide early warning of new technologies being proposed for patenting Conduct reliable, consistent, reputable quality reviews that address patent office-wide as well as subunit and examiner performance. Harmonize U.S., European and Japanese patent examination s ystems (e.g., accept first-inventor-to-file system).

[143] Note that New Zealand has been reviewing its patent legislation over the past few years (with amended legislation due in 2006). The issue of gene patents had not been specifically addressed in this review. However, due to the national and international debate over the patenting of genetic material, government requested that this present memorandum be prepared for its consideration.

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Mechanism	Charting New Territory in Healthcare, Ontario Ministry of Health and Long-term Care, 2002 (Jan.)	Patenting of Higher Life Forms, Canadian Biotechnology Advisory Committee, 2002 (June)	Bioethics of Patenting DNA, Nuffield (UK), 2002 (July)	Memo. to Cabinet Policy Committee, Report … Addressing Genetic Material Patents, New Zealand, 2004[143] (June)	Genes and Ingenuity, Australian Law Reform Commission, 2004 (Aug.)	Patenting of Biological Material of Human Origins, German National Ethics Council, 2004 (Oct.)	Patent System for the 21st Century, NAS, US, 2004
					Periodically review structure and quantum of patent fees to ensure that they are appropriate to discourage patent holders maintaining patents that lack real commercial value.		

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Ontario Ministry of Health and Long-Term Care. 2002. *Genetics, Testing and Gene Patenting: Charting New Territory in Health Care*. Toronto: MHLTC, endorsed by all provincial premiers of Canada, also available at www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf, last accessed May

Canadian Biotechnology Advisory Committee. 2002. *Patenting of Higher Life Forms*. Ottawa: CBAC. Also available at http://cbac-cccb.ca/epic/internet/incbaccccb.nsf/vwapj/E980_IC_IntelProp_e.pdf/$FILE/E980_IC_IntelProp_e.pdf, last accessed August 10, 2005.

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National Ethics Council. 2005. *The patenting of biotechnological inventions involving the use of biological material of human origin*. Opinion. Berlin: NEC, also available at http://www.ethikrat.org/_english/publications/Opinion_patenting-of-biotechnological-inventions.pdf.

Merrill, S.A., R.C. Levin and M. B. Myers, eds. 2004. *A Patent System for the 21st Century*. Washington, D.C.: The National Academies Press, also available http://books.nap.edu/catalog/10976.html.

All last accessed September 8, 2005.

B Recommended Changes Outside of the Patent Regime

Mechanism	Charting New Territory in Healthcare, Ontario Ministry of Health and Long-term Care, 2002 (Jan.)	Patenting of Higher Life Forms, Canadian Biotechnology Advisory Committee, 2002 (June)	Bioethics of Patenting DNA, Nuffield (UK), 2002 (July)	Memo. to Cabinet Policy Committee, Report … Addressing Genetic Material Patents, New Zealand, 2004[143] (June)	Genes and Ingenuity, Australian Law Reform Commission, 2004 (Aug.)	Patenting of Biological Material of Human Origins, German National Ethics Council, 2004 (Oct.)	Patent System for the 21st Century, NAS, US, 2004
Competition Law					Patents and patent applications can be challenged by making a complaint to the Australian Competition and Consumer Commission where there is evidence of a potential breach of the *Trade Practices Act 1974*. As the need arises, the conduct of firms dealing with patented HGM materials and technologies should be reviewed to determine whether conduct is anti-competitive within the meaning of the *Trade Practices Act*.	Under the open post-grant review recommended by the NAS (see "Mechanisms for Challenging Patents" section of this chart), the Department of Justice or the Federal Trade Commission could request that the patent office initiate a review where a valid patent is being used to adversely affect competition.	
Judicial Reform	Examine the creation of a specialized court to handle appeals of the Commissioner's decision and to adjudicate in matters of patent validity and infringement.				Courts exercising jurisdiction under the Patents Act should continue to develop their practices and procedures for dealing with patent matters. They should also continue to develop procedures and arrangements to allow judges to benefit from the advise of assessors or scientific advisors.	The Federal Circuit should encourage submission of briefs that draw on insights from other judicial decisions, legal scholarship on the patent system, and the growing body of patent-related economics literature. There should be more interaction between federal and regional judges to give a better sense of how patent law fits with other laws influencing innovation and how economics fits into decision making.	

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Government Purchasing/ Price Oversight	Consider adopting an ordre public or morality clause within the *Patent Act*.				Government should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare. If there is evidence the prices of patent genetic materials/ technologies have adversely affected access to healthcare, the responsible Minister can refer the matter to the Productivity Commission for study or inquiry, or to the Australian Competition and Consumer Commission or other body.		
Health/ Genetic Technology Assessment	Establish a work plan, objectives and time frame for developing optimum current and future collaborative capacity in genetic technology and testing assessment and evaluation. Examine the feasibility of " conditional approvals" for certain testing where sufficient evidence is not yet in place to allow a complete determination of direct and indirect implications of test coverage.				Establish national process for the economic evaluation of medical genetic testing and other new genetic technologies and the financial impact of gene patents on the delivery of healthcare services.		

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Australian Law Reform Commission. 2004. *Genes and Ingenuity: Gene Patenting and Human Health*. Sydney: ALRC, also available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html;

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