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## **FINAL REPORT**

### **GENETIC PATENTS AND HEALTH CARE IN CANADA: AN INTERNATIONAL COMPARISON OF PATENT REGIMES OF CANADA AND ITS MAJOR TRADING PARTNERS**

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THE CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE  
BY THE CENTRE FOR INTELLECTUAL PROPERTY POLICY

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**GENETIC PATENTS AND HEALTHCARE IN CANADA: AN INTERNATIONAL COMPARISON  
OF PATENT REGIMES OF CANADA  
AND ITS MAJOR TRADING PARTNERS**

*This document was prepared by the Centre for Intellectual Property Policy (CIPP) at McGill's Faculty of Law thanks to the assistance of Richard Gold, Julia Carbone, Yann Joly, Lori Sheremeta, Martin Cloutier, Bartha Knoppers and Timothy Caulfield.*

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AN INTERNATIONAL COMPARISON OF PATENT REGIMES OF CANADA  
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**EXECUTIVE SUMMARY**

Canada has been slow, in comparison with its major trading partners, to develop any strategy with respect to gene patents despite substantial academic research and concerns raised by provincial health care authorities. This report, commissioned by the Canadian Biotechnology Advisory Committee, sets out the international context in which Canadian policy development occurs and draws on the lessons learned by Canada's major trading partners and emerging countries in respect to genetic patents and healthcare. The study was conducted by an Expert Group drawn from the membership of the Centre for Intellectual Property Policy at McGill University. These experts -- at McGill University, the University of Montreal, the University of Quebec in Montreal and the University of Alberta -- examined the patent laws of nine jurisdictions, including Canada, and related academic and public policy research.

The analysis undertaken involved four elements. First, it involved the selection of methodology with respect to the conduct of the analysis. Second, it involved a dissection of the patent regimes of Canada and its major trading partners in order to compare their various components. Third, it involved a review of existing empirical studies and research reports that identify and quantify the impact of particular country patent regimes on medical research and health services. Fourth, it required the identification of particular mechanisms that Canada could adopt to ensure that it derives maximum social benefit from genetics research. Each of these elements presents dangers of inappropriate analysis if care is not taken to identify and respect limitations imposed both by theory and by fact. These dangers include reliance on assumptions with little empirical basis, misuse of comparative analysis, the absence of substantial economic and non-opinion based evidence, and failure to recognise that the patent system is embedded in a larger innovation system that interacts with the health care system.

Taking these dangers into account and relying on the patent laws and literature collected, the Expert Group came to the following conclusions:

- 1. Canada ought to support efforts at obtaining more empirical research on the functioning of the patent system, the interaction between the patent system and innovation systems and the effect of particular components of the patent system on the provision of health care services.**
- 2. Canada ought not to change its rules regarding the patent-eligibility of human DNA sequences.**
- 3. Canada ought to create a clear statutory research or experimental use exception within the *Patent Act*.**

- 4. Canada ought to amend the *Patent Act* to include a compulsory licensing or government use provision aimed specifically at diagnostic tests.**
- 5. Canada ought to adopt a technology transfer strategy.**
- 6. Canada ought to adopt and adapt best-practice guidelines developed at the OECD and elsewhere.**
- 7. Canada ought to develop an opposition process within the Canadian Intellectual Property Office.**
- 8. The Canadian Intellectual Property Office ought to develop utility and description guidelines to aid patent applicants.**

## Introduction and Overview

Since the turn of the millennium, international organisations and Canada's major trading partners have investigated the policy effects of the patent system as it relates to human genetics on the development and delivery of health care services. The World Health Organization established the Commission on Intellectual Property Rights, Innovation and Public Health due to report in January 2006, the Organisation for Economic Co-operation and Development (OECD) is developing guidelines for the licensing of human genetic inventions, the Australian Law Reform Commission has recently completed a study entitled *Genes and Ingenuity: Gene Patenting and Human Health*, European countries are developing strategies to deal with some of the anticipated negative consequences of gene patenting (Gold, 2002), the National Institutes of Health (NIH) in the United States has issued draft guidelines on the licensing of genomic inventions (Spiegel, 2004), and the US National Research Council of the National Academies has recently issued a report entitled *A Patent System for the 21<sup>st</sup> Century*. This is in addition to developments in Canada that include two Supreme Court of Canada decisions, one late in 2002 and one early in 2004 and a 2002 report by the Canadian Biotechnology Advisory Committee (CBAC) entitled *Patenting of Higher Life Form.s*

The general approach taken by those governments and institutions that have issued interim or final work is to recognise that patent systems need to be adapted to the needs of the biotechnology sector, particularly in relation to health care. The recommendations and strategies revolve around four points. First, that a research or experimental use exception to patent infringement – whether formal or imposed through granting agency rules – is important to permit researchers to continue to develop genetic technologies into health care products and services. Second, that compulsory licence provisions exist in national law in order to discipline the market. Third, that industry and governments adopt licensing guidelines aimed at reducing unnecessary restrictions on the use of genetic inventions. Fourth, that patent systems provide for more straightforward and cost-effective means of challenging patents.

Canada has been slow, in comparison with its major trading partners, to develop any strategy with respect to gene patents despite substantial academic research and concerns raised by provincial health care authorities (Ontario, 2002). While the participation of the Canadian Biotechnology Advisory Committee in this debate may help to unlock policy development in Canada, the actual set of policies needed already exist in the policy work of Canada's trading partners and in Canadian academic publications.

Given this context, the present report sets out the international context in which Canadian policy development occurs and draws on the lessons learned by Canada's major trading partners and emerging countries. It is divided into three Parts. Part I sets out the empirical, policy and theoretical framework for international comparisons and policy development in the area of human genetics. Part II summarises the trends that exist in the various elements of the patent systems of Canada's trading partners and emerging economies. Part III sets out what is known

about patent systems and, importantly, the overwhelming lack of empirical data relating to those systems. Drawing on the evidence and the entire study, Part III also includes policy recommendations to bring the Canadian patent system both into line with international trends and, more importantly, to adapt that system to the needs of the Canadian health care system.

This report is the product of the Centre for Intellectual Property Policy (CIPP) at McGill University, which counts among its members the leading Canadian experts in intellectual property issues from a multitude of disciplines. The Centre's Director, Dr. Richard Gold, is Canada's leading legal expert on biotechnology intellectual property. The CIPP and its researchers have conducted or are conducting work for the World Health Organization, the Organisation for Economic Co-operation and Development, the World Intellectual Property Organization,, the Canadian federal Department of Justice, Health Canada, and the Ontario Ministry for Health and Long-Term Care on issues of intellectual property in the health care field. The CIPP has a wide international network of partner agencies and experts including BIOTECanada, the Hastings Center for Bioethics, the European University Institute, the OECD and the Center for Genome Ethics, Law and Policy at Duke University.

Through its Intellectual Property Modeling Group (IPMG),<sup>1</sup> the CIPP has developed an innovative research program on biotechnological intellectual property. This work, funded through competitive grants from the Social Sciences and Humanities Research Council and the Canadian Institutes for Health Research, has won significant support from experts from economics, social policy, management, science and law worldwide (Centre for Intellectual Property Policy, 2004). Its work has repeatedly been positively assessed through international peer review processes that, by design, occur at least every six months.

The CBAC commissioned the CIPP to undertake this study and to report its findings to CBAC. To carry out this study, the CIPP has brought the IPMG's work and methodology to bear on its analysis. In so doing, it has gathered the expertise of some of its leading members in biotechnology intellectual property including Dr. Richard Gold, the CIPP Director and Bell Chair in e-Governance, Dr. Bartha M. Knoppers holder of the Canada Research Chair in Law and Medicine at the University of Montreal, Timothy Caulfield, the Research Director of the Health Law Institute and holder of the Canada Research Chair in Health Law and Policy at the University of Alberta, and Dr. Martin Cloutier of the Department of Management and Technology at the University of Quebec at Montreal (see Appendix A for Biographies) into an Expert Group.

The Expert Group supervised the work of a strong team of researchers, including Yann Joly of the Centre de recherche en droit public, Lori Sheremeta of the Health Law

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<sup>1</sup> The members of the IPMG include the following: Dr. Richard Gold (McGill University), Prof. Wendy Adams (McGill University), Dr. David Castle (University of Guelph), Dr. Ghislaine Cleret de Langavant (AETMIS and University of Montreal), Dr. Martin Cloutier (UQAM), Dr. Abdallah Daar (University of Toronto), Dr. Amy Glass (Texas A&M University), Scott Kieff (Washington University), Lori Knowles and Dr. Pamela Smith (University of Minnesota).

Institute and Julia Carbone of the CIPP. Based on this research, the Expert Group has reached conclusions concerning Canadian policy in eight areas.

### **1. Support for Empirical Research**

Canada's ability to develop sound policy with respect to the impact of the patent system on the health care system is seriously compromised by the lack of empirical evidence with respect to whether and how the patent system encourages innovation, whether the system discourages or fails to encourage certain forms of innovation, and whether and how the patent system affects the delivery of health care services.

Empirical research needs to focus on the actual functioning of patent systems and not simply on investigating the effect of particular components of the patent system on the health care system. This is because no one component of the patent system operates on its own, but rather interacts with the patent and innovation systems, practices developed around those systems and the institutions that govern those systems.

### **2. No change to rules of patent-eligibility**

Canada ought to maintain its current rules concerning the patent-eligibility of DNA sequences. The absence of any clear empirical evidence supporting or arguing against the patent system makes any change to patent-eligibility rules unwise. In particular, the empirical evidence highlighting negative effects of human DNA sequence patents is not sufficiently strong to hold these sequences to be non-patentable subject matter. Although there is disagreement on this point (for example, by Brazil), it is arguable that Canada's international law commitments under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) may require that governments make DNA sequences patent-eligible.

In addition, any move to hold human DNA sequences unpatentable may lead to the belief that Canada is unfriendly toward biotechnology research. Despite strong government support of the biotechnology industry in Canada, such a negative belief may undermine foreign investment in Canada. Given the lack of strong empirical evidence against the patent-eligibility of DNA sequences, Canadian policy ought to take into account the beliefs – even if wrong – of the international community.

### **3. Research/experimental use exception**

Canada ought to develop a mechanism to ensure that both academic and commercial researchers can conduct research on the subject-matter of inventions in order to investigate their properties, improve upon them or to create a new product or process. This recommendation is in line with CBAC's Recommendation 5 in its report on the *Patenting of Higher Life Forms*, is consistent with the law in European countries, agrees with the policy recommendations of the Australian Law Reform Commission

and the National Research Council in the United States and reflects the thinking behind the National Institutes of Health policy on the licensing of genetic inventions.

The Canadian government can implement a research or experimental use exception either through legislative change, as CBAC has recommended, or through the development of intellectual property rules by the granting agencies which underwrite virtually all academic research in Canada. While the latter approach is easier to implement, it may not provide Canadian researchers with access to foreign-controlled intellectual property. As Canadian granting agencies do not provide funding for foreign research, they have no ability to require foreign patent-holders to follow Canadian agency rules. Thus, an amendment to the *Patent Act* may be required.

#### **4. Targeted Compulsory Licensing**

Canada ought to develop compulsory licensing provisions that are more targeted than the current s. 19 of the *Patent Act*. The goal of a compulsory licence provision is to discipline the market should market actors unreasonably interfere in the attainment of important health care goals. Section 19 is a general compulsory licensing provision that permits governments to seek the right to practice an invention without the consent of the patent-holder. To be valuable, the government threat of exercising these rights must be credible. The current s. 19 fails this test as its exercise would create too much uncertainty in the pharmaceutical and biotechnology sectors. A more focused compulsory licensing provision aimed specifically at the provision of products and services relating to health care would provide this credibility. The scope of the compulsory licensing provision would need to be worked out, but must provide a credible threat to discipline the market. This recommendation would bring Canada in line with most European countries as well as with the recent recommendations of the Australian Law Reform Commission. It would also be compliant with Canada's international trade obligations.

#### **5. Technology Transfer Strategy**

Canada needs to develop a clear strategy on the role of university to industry technology transfer (CIPP, 2004a). Currently, governments demand both that universities maximise their returns from the licensing of university-based innovation and that universities help Canada attain such socio-economic goals as assisting the health care system, job creation and community building. While either of these goals can potentially be justified, universities cannot meet both simultaneously. Maximising revenue will often mean licensing technology on an exclusive basis -- perhaps to foreign companies -- while attaining Canada's socio-economic goals may require the issuance of several non-exclusive licences primarily to Canadian-based companies, with a concomitant decrease of revenue to the universities.

Industry Canada and the federal granting agencies should work together with the universities to develop a consistent and rational technology transfer strategy (CIPP, 2004a). They should also investigate links between this strategy and the research/experimental use exception, and also consider whether one component of

this strategy is the development of granting agency guidelines to ensure research access to inventions as suggested above.

## **6. Development and Implementation of Licensing Guidelines**

Canada ought to adopt and adapt licensing guidelines similar to those being developed by the OECD and the NIH. These guidelines would provide tips to new entrants in the licensing marketplace and normative standards for existing participants on how to develop licensing strategies and to actually license health care technologies.

Industry groups within Canada, such as BIOTECCanada, ought to participate in the development and promulgation of these guidelines and provide internal sanctions for non-compliance (e.g., through loss of membership or public criticism). The guidelines must be flexible and take into account the variety of ways in which health-related technologies could be licensed. The guidelines must also be periodically reviewed and revised to take into account both scientific and business practice developments.

## **7. Development of an Opposition Process**

Canada lags significantly behind its trading partners in providing an inexpensive, efficient and transparent mechanism through which to challenge issued patents. Europeans have a well-established opposition process that, apart from causing easily-remediable delays, provides a mechanism through which third parties can challenge the validity of patents issued by the European Patent Office. Similarly, the United States recently adopted a transparent re-examination process through which third parties can actively challenge issued patents. Even that system has been the subject of criticism from the National Research Council, which has called for a full opposition process. Currently, Canada provides only a choice between a non-transparent and non-participatory re-examination process and full court proceedings.

In line with the Australian Law Reform Commission (ALRC) recommendations and Recommendation 13 of CBAC's report, *Patenting of Higher Life Forms*, Canada ought also to develop an opposition process that provides full transparency and participation but with firm constraints on time delays.

## **8. Development of Utility and Description Guidelines**

Like its homologue in the United States, the Canadian Intellectual Property Office ought to develop guidelines relating both to the application of the utility requirement in respect of biotechnological inventions and also to the non-obviousness and description requirements. CBAC called for similar action in Recommendation 10 of its report on the *Patenting of Higher Life Forms*. The recent recommendation by the National Research Council to toughen the non-obviousness standard, in addition to existing United States Patent Office guidelines on both the

utility and the description requirements, illustrate how Canada is behind its major trading partner.

## **Part I: Framework**

CBAC commissioned the CIPP and, through it, its Expert Group to undertake an analysis involving the following elements:

- a comparison of the current patent regimes and practices of Canada and its major trading partners as they relate to the field of human genetics and related technologies;
- an identification, review and analysis by country, of all available information on the impact of each patent regime on medical research and access to health services; and
- an identification, review and analysis of all available information, by country, on mechanisms for mitigating any negative impacts and/or maximising positive impacts.

The analysis thus involves four elements. First, it involves the selection of methodology with respect to the conduct of the analysis. Second, it involves a dissection of the patent regimes of Canada and its major trading partners in order to compare their various components. Third, it involves a review of existing empirical studies and research reports that identify and quantify the impact of particular country patent regimes on medical research and health services. Fourth, it requires the identification of particular mechanisms that Canada could adopt to ensure that it derives maximum social benefit from genetics research. Each of these elements presents dangers of inappropriate analysis if care is not taken to identify and respect limitations imposed both by theory and by fact. This Part identifies these limitations and their impact on this report.

## *Methodology*

By focusing on patent regimes and practices, the study requires the bringing together of expertise from a variety of disciplines (e.g., law, economics, management) and points of view (e.g., policy maker, scientist, health care administrator). Much of the IPMG's work is focused on questions of methodology, in particular how to bring people from different fields together to work on questions of intellectual property policy. It is this work in particular that has undergone significant peer-review and validation and thus stands as an essential starting point for any study in this field.

One of the main conclusions of the IPMG's work is that simply bringing people together from various disciplines and representing various stakeholders will not result in appropriate policy formation. A central problem with multi-disciplinary or interdisciplinary groups or expert committees is their lack of common concepts and methods to analyse policy issues. Experts, whether drawn from the ranks of legal practitioners or the industry policy communities, have failed to appreciate and address how patent systems interact with business and research practices, the health care system and science policy in general (Gold et al., 2002).

In response to this problem, the IPMG has formulated an approach that brings together experts from law, economics, management, ethics, philosophy, political science and the sciences together to address policy concerns relating to patent systems. This is relevant to the present study that involves a critical examination of both what is known about patent systems and what is left to be known. In particular, the methodology reveals certain flawed assumptions about the patent system and its functioning.

The first flawed assumption, often found in the literature, is that the patent system provides a necessary incentive to innovate. The argument usually takes the form that, but for the patent system, medications and medical procedures would never see the light of day. The argument is buttressed by anecdotal evidence of the form "without a patent, Company X would not have been able to develop and distribute this product." As with all anecdotal evidence, one must bring a healthy dose of scepticism to this claim. While it is undoubtedly true that without patents certain products would either not have been developed or only developed later, this does not mean that the existence of patent rights increases innovation in general. After all, we do not know whether the presence of patent rights has prevented other products from being developed (although there is some evidence of this with respect to clinical genetic services (Cho et al, 2003; Merz et al, 2002) or from having their development delayed.

A survey of the economics literature makes clear that this assumption has not been backed up with reliable empirical evidence. Empirical economic studies are still too few to draw any firm conclusions – for or against the incentive effect of patent rights. The research evidence that does exist shows both positive and negative effects on innovation due to the patent system. For example, the pharmaceutical industry, which needs to satisfy significant regulatory approval requirements, seems most likely

to have innovation increased by the patent system. Even here, the extent of the rights required by the pharmaceutical industry to innovate is highly contentious and not backed by any significant empirical evidence. There has also been some concern about the effect of DNA sequence patents on the cost of medication developed through genetic technologies or relying on pharmacogenomics (Eisenberg, 2002; Nunnally, 2003; Malinowski, 2002; Joly, 2003), but these have yet to be empirically verified. Lori Andrews has cited the example of one pharmaceutical company that seems to have patented a genetic test aimed at determining the effectiveness of one of its medications, but refuses to either license the test or use it, presumably out of fear that the test will lead some patients to avoid or stop using the medication (Andrews, 2002). In other industries, the empirical evidence provides too scant a basis to draw any clear conclusions.

Part of the problem with supporting or refuting the argument in favour of the incentive effect of patent rights is the difficulty of isolating the effect of patent systems on innovation. After all, even the most optimistic of studies suggest that factors other than patent rights are significantly more likely to influence the innovation potential of firms than is the patent system itself. These alternatives involve a mix of informal mechanisms such as licence arrangements, trade secrets, contracts or research agreements, as well as business practices such as lead time, complementary asset management (managing assets including other technologies, financing and goodwill that make the use of the patented invention more valuable), switching costs, clever marketing, and co-product diversification (Cloutier and Gold, forthcoming; Grandstrand, 1999; Winter, 2000). Trying to disaggregate the effects of patent rights is difficult because that process is dynamic and evolves quickly within firms and industries (Cloutier and Saives, 2002). For instance, firms may primarily use patents as an information coordination mechanism to attract investors, but will use other methods, such as acquiring rights to complementary assets and incorporating those assets in their products, to actually derive revenue.

A second problem with the assumption is that, even if patents have a positive influence on innovation rates, it is not clear how. The traditional approach is to argue that patent rights provide inventors with the opportunity to recoup their investment in research and development by exercising their rights to exclude others. That is, patents provide the necessary incentive (through the promise of future legal monopoly rights and, by implication, increased economic value for the firm) to conduct research today. Unfortunately, the economics literature puts this hypothesis in doubt (Cohen et al., 2000; Jaffe, 2000; Levin et al, 1987; Mansfield, 1986; Mazzoleni and Nelson, 1998; Baldwin and Hanel, 2003). A more likely scenario is that patents serve as an information coordination and identification mechanism in early negotiating stages (Rivette and Kline, 2000; Hall and Ziedonis, 2001, Reitzig, 2003) or perhaps to signal capabilities in certain technology spheres. Whatever the reality turns out to be, empirical research will suffer until we understand that reality and researchers design empirical studies to test it. Unfortunately, developing confirmatory empirical methods requires time as researchers must collect historical information, meaning that there will by definition be significant time lag between the phenomenon studied (e.g., award of a patent) and measurement (e.g., its effect on

research and development). Until then, we are likely to continue to suffer from a severe shortage of empirical analysis.

A second assumption, linked to the first, is that governments can best achieve the goal of developing a science and innovation economy by relying on the patent system. Again, success stories abound, but behind them, especially in the health biotechnology field, is significant and persistent government financing of both basic research (such as the Human Genome Project) and of the biotechnology industry itself. Basic government funding of research, as in the United States through the consistent and pervasive funding by the National Institutes of Health, has been a more important tool to stimulating R&D than the patent system.

Despite its severe problems, the assumption that governments can best promote health innovation through reliance on the patent system too often makes its way into policy arguments related to the patent system. For example, when people claim that patent systems need to be 'strong' to encourage biotechnological innovation, they inherently invoke this assumption. What 'strong' means is usually unstated but presumably means that the patent system provides inventors with more rights and technology users and the public with fewer rights than other systems. This presumes that a country can best maximise levels of innovation by giving inventors longer or broader rights – and users and the public fewer rights – over innovation.

This presumption is undoubtedly incorrect, for two reasons. First, the assumption upon which it is based – that the patent system is the best policy tool to achieve innovation – is unsubstantiated and probably false. Second, innovation is a dynamic process. Protecting first-generation inventors with broader rights impedes the activity of second-generation inventors – those whose research takes the first generation of research to new levels. Why a country should prefer first-generation inventors to second-generation inventors is never explained. In reality, a 'strong' patent system is one that best achieves the public good, one that includes all inventors and not simply the first ones to get there (Couter and Ulen, 1999). This skew towards first-generation inventors has distributional implications on the allocation of wealth and future income streams in society.

Two other assumptions relate to the claimed unfairness of creating patent haves and have-nots and to the claim that patents are ethically neutral. Both of these claims prove false on analysis, but are not relevant to the present study.

### *Comparison between elements*

Comparison between legal regimes requires care. Legal rules exist within a complex normative and cultural context. A comparison based on the strict reading of legal codes and statutes without an appreciation of the manner in which they are interpreted and enforced can be as inappropriate and uninformative as no comparison at all. This is particularly true when different legal regimes, understood in their entirety, may come to the same final result through a different combination of legal text, interpretative mechanism and institutional design. Still other concepts,

which may naturally fit within one legal regime, may be incoherent or unintelligible within other legal systems.

This danger of comparative analysis applies with particular force to intellectual property. As Gold has pointed out (Gold, 2003b), the same words in international treaties can mean entirely different things within different legal systems. Each system bases its interpretation of the words not only on legal concepts existing within those different systems, but also on different conceptions of the relationships involved in creative activity. For example, Anglo-American legal systems tend to view the relationship between creators and their creations in strictly economic terms while Franco-German systems see the creation as an intimate representation of the creator's being. This is especially evident in copyright laws (with Canadian copyright having elements of each) but also influences patent law. These different understandings of this relationship lead to vastly different interpretations of common texts (Gold, 2003b).

A second and related danger is to overemphasise the importance of one component as compared to others or to the entire system. By focusing on specific components of the patent system, one naturally tries to isolate the effect of that component on particular outcomes. This is dangerous at two levels. First, even within a particular regime, it is important to understand how a component is actually used. Consider, for example, recent Chinese copyright law. While the statute reads in a way that is similar to those in Canada or the United States, it operates quite differently. Chinese courts have, for the most part, not enforced the provisions nearly as stringently as courts in Canada or the United States would, awarding insignificant damages against infringers in comparison with similar proceedings in Canada.

A second danger is that the construction of two different patent regimes may be so different that provisions with similar effects may not be noticed. Consider, for example, s. 19 of the Canada's *Patent Act*. Although it has never been invoked, some comparative economic studies count the very existence of a compulsory licensing provision as indicating that Canada's patent regime is less favourable to inventors than that of the United States. One of the principal patent indexes used by economists in comparative studies falls into this category (Park & Wagh, 2002). This is despite the fact that US law contains a provision (28 USC 1498) that not only permits the government to use a patent without permission, but that has actually been invoked many times. Because the US provision does not grant a compulsory licence, but only limits the recourse the patent holder has against the government when the government uses the invention, it is not understood as a compulsory licence. But the reality is that the Canadian compulsory licensing mechanism is more favourable to patent holders than is the US government use mechanism.

What the above discussion highlights is that, while one can arrive at interesting conclusions by breaking down patent systems into their component parts, one should not forget that it is the patent system as an entirety (including the cohesion of its interactive components) and the interaction between the patent system and other systems (e.g., health services) that should be the target of investigation and not individual components of the patent system taken in isolation.

## *Impact of Patent Systems on Medical Research and Health Services*

Just as the impact of any one component of a patent system can only be properly understood and analysed within the entire patent system, one can only evaluate the effect of the patent system on innovation within the entire innovation system. Innovation systems include education and universities, government grants, government research contracts, technology clusters, skilled management, the availability of venture capital, bankruptcy and creditor protection laws, entrepreneurship and so on. Within innovations systems, patent systems provide only a modest influence.

It is thus difficult to isolate the effect of the patent system on innovation in general. Trying to identify its effect on one particular industry – the biotechnology sector – is even more difficult, especially given the fast rate of change in that industry. Before this can be done, one needs to have a strong theoretical and empirical grounding, something which is currently missing in the literature.

This difficulty is only amplified when we try to determine the effect of the patent system not only on innovation, but also on the provision of health care services. So many factors beyond innovation policy come into play – from regulation of medicines, to provincial formularies, to tort law – any effort aimed at determining the effect of a small component of patent law on the delivery of health care services to Canadians becomes overwhelmed by other factors.

To this theoretical difficulty one can add the simple lack of empirical evidence. As noted earlier, economic empirical evidence on the patent system as a whole – not to mention biotechnology or health products – is thin and inconclusive at best. Drawing strong conclusions is not only impossible but irresponsible given the current level of empirical knowledge.

### *Identification of mechanisms for change*

Trying to identify mechanisms that exist in the patent regimes of the countries selected for this study that could be used to address particular socio-economic concerns that also exist in Canada must be undertaken with caution. As noted above, isolating one component of a patent regime and assessing its impact within the particular country in which that regime exists is difficult at best. Trying to assess the impact of that same component in a different patent regime interacting with other innovation systems is obviously even more difficult.

Given the scarcity of empirical data and the different settings in which patent components exist, the approach taken in this report is to examine trends in international patent law rather than to try to isolate bits and pieces of other countries' patent laws. We also recognise that some of the concerns raised about patents – as well as the responses to those concerns – are often based on opinion evidence rather than on more objective data. This means that some of the claims -- or responses to those claims -- may, in fact, not be correct. Nonetheless, opinion does shape behaviour, even if not based on fact. Thus, we conclude that, to the extent that the international trends we find address the concerns exemplified by opinion evidence, even if not supported by documented or theoretical concern, Canada ought to follow those trends.

One also needs to recognise that patent systems are general in nature, applying to all technologies. While particular provisions can and are included in patent statutes that apply to one or a limited number of technologies (for example, the ability to deposit biological material as part of the description requirement), one can only go so far in tailoring the patent regime to a particular set of technologies. Questions of patent claim construction, enforcement mechanisms and research exceptions are, by their nature, general in character. Thus, one must be cautious in making changes. In particular, one should consider the implications of those changes on other technologies. At the same time, a failure to appropriately adapt patent systems to particular technologies should lead one to the conclusion that this technology ought to be excluded from the patent system. Thus, while caution must be taken, caution should never be an excuse for non-action. As we describe below, Canada has generally placed too much emphasis on caution at the expense of creating an appropriate patent regime for human DNA sequences.

## Part II: International Trends

We surveyed the patent laws and related practices of nine countries: Canada, Australia, China, France, Germany, India, Japan, the United Kingdom and the United States. Seven of these countries represent Canada's major trading partners, three of these are members of the European Union (France, Germany and the UK), and two others are developing countries with a fast rising health biotechnology sector (China and India). China and India have recently substantially overhauled their patent systems to bring them into compliance with the *Agreement on Trade Related Aspects of Intellectual Property Rights*. The UK has brought its patent law into compliance with the European Union's *Directive 98/44 on the legal protection of biotechnological innovations* of July 2000 while France and Germany have not yet done so. France is, in particular, unlikely to implement the *Directive* in the foreseeable future given French national law on the ethics of patenting human DNA sequences.

We also surveyed the *European Patent Convention* (EPC) which deals with patent grants, but not enforcement or limits, for European countries including all Member States of the European Union.

As part of the IPMG's preparation of background material, it has and continues to develop a detailed survey of the patent systems of a variety of countries around the world, including those listed above (detailed comparisons are provided in Appendix A and online at the CIPP website: [www.cipp.mcgill.ca](http://www.cipp.mcgill.ca) ). The IPMG has developed a unique 'horizontal' approach to comparing patent regimes which takes into account 'hard' law (e.g., statutes, regulations and court decisions), 'soft' law (e.g., patent office practices, business practices, etc.) and institutions (e.g., patent offices, courts, competition offices). The IPMG has categorised the various elements of patent systems under the following headings each of which corresponds to a discrete part of the patent system as follows:

- **Subject-Matter** refers to the types of inventions covered by the particular patent regimes taking into account statutory and non-statutory exclusions from patent coverage; that is, it sets out those inventions which are patent-eligible.
- **Scope of Right** refers to the breadth of the patent right; that is, refers to how many different objects, methods or processes fall within the exclusive right of the patent-holder. It also refers to how judicial and administrative bodies construe patent claims.
- **Limits on Patent Rights** refers to specific limits on the scope of the patent right and includes exceptions such as research or medical use exceptions where these exist.
- **Criteria** refers to the criteria used by patent offices and then courts to assess whether a particular invention falling within the subject-matter of patent law is patentable.

- **Procedure for Obtaining a Patent** refers to the steps by which an inventor obtains a patent right and includes the institutions involved.
- **Invalidity** refers to the mechanism to challenge a patent post-grant and the criteria applicable to these challenges.
- **Methods of Enforcement** refers to the mechanism through which a patent holder can enforce a patent against a person using the invention without authority.
- **Regulatory Mechanisms** refers to regulatory mechanisms ancillary to the patent system (although sometimes included in patent legislation) to regulate the use, licensing or pricing of inventions.

Based on the above categories, IPMG has created a series of charts that provide a detailed overview of the patent systems of various countries. These may be accessed through the CIPP website at [www.cipp.mcgill.ca](http://www.cipp.mcgill.ca). As even a brief look at these charts will reveal, any detailed discussion of the components of the patent systems of the nine countries examined would be long. Instead, we provide an overview in this report of the trends that come out of such an examination. Any reader interested in further detail is encouraged to examine the charts themselves. It is worth noting the high degree of similarity between patent regimes, even including China and India. While there are differences in approach, as the discussion below reveals, the overwhelming conclusion one ought to draw is that patent regimes are very similar. Certainly the advent of TRIPs is one factor that has influenced this, but so too is the influence of economic pressure by developed countries imposed through bilateral trade agreements.

The following overview covers all nine countries and, where applicable, the *European Patent Convention* (specifically, Subject-Matter, Scope of Right, Criteria, Procedure for Obtaining a Patent and Invalidity). Figure 1 contains a chart summarising this text.

**FIGURE 1**

Country	Subject-Matter	Scope	Limits	Criteria	Procedure	Invalidity	Enforcement
Canada		Purposive	CL	Middle Grace		Re-exam (non-public)	
Australia		Purposive	CL	Middle Grace		Opposition	
China		Equivalents	CL; EX	Middle		Re-exam	
EPC				High Inventive Step		Opposition	
France		Intention	Health CL; EX	High Inventive Step		Opposition	
Germany		Intention	CL; EX	High Inventive Step		Opposition	
India	Only in 2005	Purposive	CL; EX	Middle		Opposition	
Japan		Equivalents	CL; EX	Middle Grace		Opposition	
United Kingdom		Purposive	CL; EX	Middle		Re-exam	
United States		Equivalents	CL	High Utility and Description; Grace		Re-exam	

**Glossary:**

Purposive: Patent scope determined according to the purposive approach (language of claims)

Equivalents: Patent scope determined using the doctrine of equivalents

Intention: Patent scope determined by looking at the language of the claim and using that as the basis for determining the intended scope (what the invention is, even if not strictly claimed)

CL: Compulsory licensing or government use provision

Health CL: Specific health-related compulsory licensing provision

EX: Experimental use exception permitting all research on subject-matter of invention

Middle: Average application of patent criteria

High: Higher than average application of patent criteria

Grace: A grace period exists with respect to disclosures by or through the patent applicant

Re-exam: A re-examination procedure exists

Opposition: A full opposition procedure exists

*Subject-Matter*

The international trend is to treat all inventions – understood as products or processes that would not exist in the form described in the patent claim but for

human intervention – as being patentable subject-matter, subject only to a limited number of exclusions.

For all countries examined (including Canada), except France and, for the time being, India, DNA sequences are patent-eligible (this should be contrasted with Brazil where DNA sequences are not patent-eligible unless they are completely artificial genes.) France's bioethics law of 1994 provides that "[t]he human body, its elements and products along with the partial or total knowledge of a human gene cannot as such be patented." As noted by Gold and Gallochat (2001), this provision violates European Union law and is thus invalid. Until a court rules on this, however, the French patent office will not award patents over human DNA sequences. In addition, anyone wishing to obtain patent protection in France over human DNA sequences need only apply for a patent through the EPC. Indian law will change in 2005 to provide that DNA sequences will be patent-eligible. How this will be interpreted in practice is still unknown.

International trade law, as codified in TRIPs, says nothing explicitly about whether DNA sequences must be patent-eligible. But as article 27(3) of TRIPs does explicitly require that microorganisms (although not plants and animals) must be patent-eligible and that DNA sequences are components of microorganisms, it is arguable that TRIPs implicitly requires countries to grant patents over DNA sequences. There is, however, no international consensus on this issue.

Canada is the only country that finds that entire animals or plants are not patent-eligible. However, this makes little difference in practice to the area of health care, since the Supreme Court of Canada has ruled that an inventor has *de facto* exclusive rights to an entire animal or plant where that animal or plant contains a patented DNA sequence or patented cell. We discuss this further under the Scope heading.

Most countries (other than Canada, Australia and the United States) and the EPC do not provide patent protection with respect to particular inventions that are determined to violate public order – usually understood to be inventions that would lead to public unrest – or morality – understood as the foundational norms of the jurisdiction (Gold, 2001). Some jurisdictions, such as the EPC, the UK and China, elaborate on this exclusion further by specifically excluding categories of biotechnological inventions from patentable subject-matter. These categories include processes to clone human beings, processes to modify human germ-lines, uses of embryos for commercial purposes, and processes to genetically modify animals where the suffering to the animal outweighs the medical benefits and the resulting animals.

Most countries have also determined that inventions relating to medical treatments, surgical methods or diagnostic procedures practiced on the human body or on animal bodies are not patent-eligible. Canada only applies this exclusion to medical treatments and thus diagnostic procedures are patent-eligible. The United States has no exclusion in this area but has created an exclusion from liability (discussed below under the Limits on Patent Rights heading). Australia has no such

exclusion in its patent laws. The remainder of the countries examined do have such exclusions from patentable subject-matter.

### *Scope of Right*

The scope of a patent claim determines how much third party activity is covered by the patent claim. The broader the scope, the more things the patent holder can prevent others from doing. The scope of a claim depends on both the manner in which the claim is drafted and the rules of interpretation that apply to patent claims. These rules of interpretation fall into three camps.

The first camp of countries includes France and Germany. While nominally courts ask how someone with technical skill in the particular discipline would understand the words of the claims; in practice, courts read the language of the claims sympathetically to the inventor so as to give the inventor what he or she invented, rather than what a strict reading of the claim language would give.

The second camp of countries includes Canada, the UK, Australia and India. In these countries, courts undertake a purposive analysis of the claims. Similar to the first camp, courts ask how someone with technical skill in the particular discipline would understand the words of the claims. Instead of giving the claims a sympathetic construction, however, courts limit the claim scope to the strict language used to define the claims. Where the same claim language is presented to a court in Germany and to one in the UK, the German court is more likely to find infringement for a similar device or process than one in the UK.

Courts in the third camp of countries (China, Japan, and the United States) interpret claims by breaking them down into their constituent components. The courts give each component a literal interpretation (based on the language of the claim), but then ask whether the equivalent component in the alleged infringing device or process has only insignificant differences. If the answer to this query in respect of all components is yes, the alleged infringing device or process is infringing. The United States will limit a claim to the literal terms, without asking about equivalents, if the patentee gave up a broader claim during the patent prosecution process.

The EPC deals with the question of patent scope in Article 69 and, more directly, in the Protocol to Article 69. It calls for harmonized patent claim construction that is neither restricted to “the strict, literal meaning of the wording used in the claims” nor expanded to protect what “the patentee has contemplated.” Despite this protocol, Member States of the EPC continue to construe claims very differently as described above.

While not specific to DNA sequence patents, it is worth noting that, in all jurisdictions examined other than Canada, China and India, the government will extend patent protection over pharmaceutical products for a period of up to 5 years (the exact amount depends on the jurisdiction) to compensate for regulatory delays.

This provision may be applicable to molecules developed using the DNA sequences and, if the actual therapeutic is the DNA sequence, the sequence itself.

### *Limits on Patent Rights*

Article 30 of TRIPs recognises the ability of countries to establish reasonable limits on the exclusivity provided by patent rights. The reasonableness of the limits is to be determined through an assessment of the significance of the curtailment of the rights and not on the basis of how many particular rights have been curtailed. There are clearly conceptual problems with this test (*Canada – Patent Protection of Pharmaceutical Products, WTO 2000*). First it is circular. You cannot know whether a right has been curtailed unless you have already determined how far a right to exclude extends. Second, it is difficult at best to determine the quality of the curtailment. Be this as it may, we can be clear that TRIPs recognises that States need not provide absolute exclusivity in respect of an invention.

In fact, every country in the sample recognises limits on patent rights in some way. All countries provide a mechanism through which the State can use an invention without the permission of a patent holder. In most countries, this takes the form of a compulsory licence or licence-as-of-right, as well as government-use provisions. In Canada, Australia and the United States, this only takes the form of a government use provision. In either case, the State may use a patented medication for public health purposes on payment of a fee.

Both France and India specifically provide for the grant of compulsory licences in respect of health products. While TRIPs requires that states do not discriminate among technologies (art. 27(1)), and while the meaning of discrimination is vague, neither France's or India's compulsory licensing provisions would most likely not be considered discriminatory. From *Canada – Patent Protection of Pharmaceutical Products (WTO, 2000)* case, we know that it is not discriminatory for a country to take into account legitimate differences between technologies. Given that article 8(1) of TRIPs and the *Doha Ministerial Declaration on TRIPs and Public Health (WTO, 2003)*, it would be very difficult to argue that a country taking particular measures in respect of health technology would be discriminating within the meaning of article 27(1).

All countries also provide a compulsory licence as a remedy for anti-competitive activity

The patent laws of countries other than Canada, Australia and the United States have exceptions for those conducting research on the nature of inventions or to improve upon them. All countries other than Australia (except when a patent benefits from a patent term extension) provide rights to satisfy regulatory requirements. The United States has the most generous right to conduct clinical trials, while in Germany they are more circumscribed. The status of the research exception in Canada (other than experimentation needed to satisfy regulatory requirements) is uncertain after the Supreme Court of Canada decision in *Harvard College (2002)*. It is worth noting that the Dispute Settlement Body panel in *Canada – Patent Protection of Pharmaceutical Products* recognised that research exceptions to patent law are almost universal and

thus would be examples of reasonable limits on the exclusivity offered to patent holders.

## *Criteria*

The TRIPs Agreement sets out the criteria to be used to determine which patent-eligible inventions gain patent protection. These are the novelty, inventive step (or non-obviousness) and industrial application (or utility) requirements. In addition, the inventor must fully describe the invention in the patent application. While there is overall agreement about the criteria and their meanings, the tests that different countries employ lead to differential application of the criteria.

The United States arguably has the strictest tests in respect of industrial application and description. It should be noted that the European Patent Office has recently indicated that it agrees with the US approach. How this will be reconciled with the language of the EPC, which sets out a much lower test, is yet to be determined.) To be patentable, an invention must have a specific, substantial and credible utility. This means that the invention must have a useful property that is specific to what makes it inventive; that is, the utility must be tied to what the inventor added to the prior art. That specific utility must be substantial, in the sense that it is not a trite use but something that someone would reasonably want. The claim of specific and substantial utility must be credible to people with expertise in the domain, based on the knowledge available when the application is filed. The US description requirement contains two elements: that the applicant fully describe all instantiations of the invention and how it operates and that the applicant explain how to make and use the invention. The first component means that an applicant cannot claim more than what he or she has described making claims over entire families of genes difficult. The second component means that, if a skilled person would need to experiment to figure out which of the molecules comprising the invention actually works, the invention fails the test.

All countries other than the US employ a much lower utility test: that the invention actually works or that it can be made. Description requirements in countries other than the US are also less rigorous, requiring a description sufficient to permit someone with technical skill in the field to make the invention without undue experimentation. Patent applicants are not required, however, to describe every instantiation of the invention as long as they describe a representative example.

The EPC establishes one of the strictest tests for inventive step, known as the problem/solution test. It has three components. First, one must compare the claimed invention with what existed before to identify the added value of the invention. Second, one must then determine, in light of this, the actual technical problem solved by the invention. Third, one must ask whether someone with technical skill in the field and starting with what was previously known would have arrived at the invention. This test effectively renders unpatentable claimed inventions that are interesting only as being the subject of subsequent research.

Non-European countries employ a less strict test for inventive step (or non-obviousness). Rather than requiring the invention to solve a technical problem, the test in these countries simply asks whether the invention would have been obvious to

someone with skill in the technical field who has knowledge of all information in that field. The US has the lowest test for inventive step with respect to DNA sequences. Whereas for most other countries, the mechanical search for a DNA sequence would not constitute an invention, as such a search would have been obvious to someone skilled in the technical field, the US courts have indicated that the sequence would be inventive as long as the sequence itself had non-obvious characteristics.

Most countries count any disclosure in the world as destroying the novelty of the invention. The US looks only to disclosures occurring in the United States as counting against novelty. This could have the result of permitting a US patent despite the existence of knowledge (such as traditional practices) known in another country but “unknown” in the US. United States, Canada and Australia (based on a recent amendment to the Patent Regulations) have one-year grace periods and Japan a six-month grace period which permits inventors to disclose inventions prior to filing a patent application. Under article 55.1, the EPC provides for a limited six-month grace period for disclosures of an invention that were the result of an abuse in relation to the applicant or as a result of being exhibited at an official international conference. Germany has adopted this same limited grace period. China also provides a six-month grace period where an invention is disclosed as a result of being exhibited at an international exhibition sponsored or recognised by the Chinese Government, being made public at a prescribed academic or technological meeting, or as a result of being disclosed by any person without the consent of the applicant.

#### *Procedure for Obtaining a Patent*

All countries require applicants to file an application prior to obtaining patent protection. While international mechanisms exist through which to obtain patent rights in a number of countries, patents are ultimately granted on a country-by-country basis except where regional agreements (such as the EPC) exist. Even there, the patent ultimately delivered by the patent office is a national patent right subject to national law.

In all countries, other than the United States, the first person to file a patent application with respect to an invention (in any country) obtains the patent. In the United States, it is the first person to invent the invention who obtains the patent regardless of the order of filing of patent applications.

Patent applications remain confidential for 18 months following first filing of the application.

#### *Invalidity*

Patents may be challenged in a variety of forums. Australia, the EPC, France, Germany, India and Japan provide for opposition processes through which third parties can challenge a patent on any ground through an administrative procedure within the patent office. The remaining countries, with the exclusion of Canada, provide for a public re-examination process in which a third party may challenge the

validity of a patent. In such cases, the patent office undertakes a review of the patent through a process open to the public. In Canada, the re-examination process may be initiated by any person but, once initiated, the re-examination process is conducted within the Canadian Intellectual Property Office, and does not include the person who initiated it. Nevertheless, the initiator is prevented from later challenging the patent on the same grounds as raised in the re-examination process, making the process unpalatable to most potential challengers.

With the exception of China, patents can also be challenged either before any infringement action is launched or in infringement actions through the courts. These are usually very expensive: it would not be unusual to spend over US\$2 million per side in the United States.

### *Methods of Enforcement*

Once a patent has been issued, a patent holder may enforce his or her rights against infringers by seeking either damages or injunctive relief. Damages are based on either the loss to the patent holder through the wrongful infringement of the patent or the benefits obtained by the infringer from the invention. An injunction is simply a court order not to engage in certain activity, such as selling a product.

In France, users, sellers or holders of inventions are not liable for infringement unless they were also the wrongful manufacturer of the invention or they knew they were infringing. In Germany, the infringer must have acted either intentionally or negligently to be held liable. In Canada, a person who did not know and should not have been expected to know that he or she was using the invention and had no use for the invention may not be liable for infringement. This is also likely the law of the UK and India. For other countries, intention is not relevant to patent infringement.

### *Regulatory Mechanisms*

The regulatory mechanisms that apply to the exercise of an invention are so many and so varied as not to be subject to easy review. The principal mechanisms used to directly regulate the exercise of patent rights are competition law and price controls (particularly over pharmaceutical products).

Competition law aims at ensuring that the market for innovation and/or for products (there are differences between countries on the emphasis of competition law in respect of innovation) works fairly, that market actors do not unfairly exercise their power in the market. By itself, the decision to license or not to license a patented invention is not considered to be anti-competitive. However, when this decision is linked to a strategy to maintain market power, it can be challenged.

Price controls are designed to limit the price charged by product or service providers for their products or services.

### *Canada in Perspective*

Despite presumptions to the contrary, Canada's patent system is at least as favourable to patent holders as any in the world -- with two caveats. In some respects (such as lack of a clear research exception, lack of an opposition process and lower patentability criteria), Canada's system extends further in favour of patent holders than the other countries. The two caveats are that Canada does not provide patent protection over plants and animals and that Canada does not provide patent term extension for pharmaceutical products. The former caveat is minor, as patent agents should have the skill to claim DNA sequence patents in a way that will include the cells of the plant or animal in which that DNA is found. The latter is more important for those applications of DNA sequences that constitute pharmaceutical products. Nevertheless, the lack of patent term extension, particularly given that the pharmaceutical product market lies almost entirely outside of Canada, is, as accepted by pharmaceutical companies themselves (discussed in the next Part), less a problem of economics than of perception.

### **Part III: What is Known about Patents in Health Care**

Studies on the functioning of patent systems in particular countries or in regions are few at best and, overall, more qualitative than quantitative. That is, these studies are good at pointing out areas of concern but very limited in their ability to actually provide answers to those questions. We provide a survey of these studies in Appendix C. In this Part, we discuss these and other studies investigating the patent system and, in particular, highlight the impact of the patent system on health care, and reach conclusions that follow from this analysis. In most cases, the conclusions are consistent with policies developed through international organisations and in other countries.

#### *State of the Evidence*

As discussed in Part I, the current state of empirical knowledge about the functioning of patent systems in general is fairly low and of the interaction with the health care system almost non-existent. Apart from the types of anecdotal evidence used to support current patent law – which for the reasons given in Part I are inherently flawed – there is highly limited empirical evidence in economics and only some opinion-based evidence about the functioning of patent systems. As concluded in Part I, the economic evidence is contradictory and overall neither clearly supports nor undermines claims to the efficiency of patent systems to encourage innovation. Most of the opinion evidence surrounds questions of genetic testing, with less work done on other uses (e.g., therapeutic applications and pharmacogenomics) of DNA sequences.

The state of affairs in which we find ourselves is not, unfortunately, new. In his report to the Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary in 1958, Fritz Machlup noted as follows:

If one does not know whether a system ‘as a whole’ (in contrast to certain features of it) is good or bad, the safest ‘policy conclusion’ is to ‘muddle through’ either with it, if one has long lived with it, or without it, if one has lived without it. If we did not have a patent system, it would be irresponsible on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.

As CBAC noted in Recommendation 10 to its interim report on the *Patenting of Higher Life Forms*, supported by the OECD (OECD, 2002), the ALRC (ALRC, 2004) and the academic community, we need significantly more economic and similar empirical evidence about the functioning of the patent system, its interaction with innovation systems and with the health care system. Any review of the empirical literature amply demonstrates the need for such research. We therefore conclude as follows:

**1. Canada ought to support efforts at obtaining more empirical research** on the functioning of the patent system, the interaction between the patent system and innovation systems, and the effect of particular components of the patent system on the provision of health care services. Given the particular lack of empirical evidence with respect to non-clinical or diagnostic applications of DNA sequence patents, work ought to be conducted in this area.

### *Addressing Beliefs about the Patent System*

Opinion evidence, consisting of interviews with or questionnaires administered to either industry representatives (Straus, 2002; Walsh, Arora & Cohen, 2004; Nicol & Nielsen, 2004), clinicians (Merz, 2002; Cho et al, 2003; Nicol & Nielsen, 2004) or others represents the bulk of what is known about patent systems. This evidence must be approached with caution for a variety of reasons (Gold, 2000). First, it is based on the interviewee's beliefs about the patent system rather than the reality of the system or the economics behind it. Interviewing 20 expert sailors or cartographers 600 years ago would have led to the conclusion that the experts *believed* the Earth to be flat, not that the world *is* indeed flat. Similarly, 20 people believing that the patent system actually increases total amounts of innovation (or decreases innovation) does not demonstrate that the patent system actually has this effect. It simply demonstrates that people *believe* in this effect. But belief is one thing and empirical evidence another. The empirical evidence to date seems to support the conclusion that patent systems have some positive effects on innovation, but that they also have negative effects. Which of these effects prevails depends on a multitude of factors including levels of development, whether markets are mainly domestic or foreign, scientific infrastructure, availability of skilled personnel, availability of venture capital and so on. No strong conclusion can be drawn for or against the patent system in general, although the patent system seems to have a more positive effect in developed countries than in developing countries, particularly those developing countries with a developing scientific infrastructure.

Even positive conclusions about the effect of the patent system must be tempered by recognition that the best patent system is one adapted to the needs of a particular country, not one that simply tries to maximise the rights of first-generation inventors at the expense of those who follow. As discussed in Part I, a 'strong' patent system should not be confused with a patent system that expands patent scope (temporally or in the number of related instantiations covered) or makes patents easier to obtain and/or harder to invalidate. A truly strong patent system is one that is best tailored to the economy, research norms and scientific infrastructure of the country.

Opinion evidence is granular: questions are usually posed at a relatively high level of generality since most respondents are not expert in patent law and thus cannot be expected to fully appreciate the law's subtleties. Just because a large majority of industry representatives or of researchers believes that the patent system is critical to the development of health biotechnology or that the system undermines

research, one simply cannot draw the conclusion that one should either maximise the rights the State grants to patent holders or that one ought to hold biotechnological inventions unpatentable. The reality is simply much more subtle.

This does not mean that opinion evidence is not relevant to public policy making. Far from it: opinion evidence reflects the attitude of those working in industry, in the research sector and in health care and allows for the consideration of a broader set of facts. These individuals will act on their beliefs, attitudes and perceptions – whether those beliefs, attitudes and perceptions are right or wrong. Thus, policy makers must take into account beliefs, attitudes and perceptions. For example, the OECD recognised that many citizens of its member states believed that human DNA sequences were and ought to be held unpatentable, even though such patents have been granted since the mid-1980s (OECD, 2002). The OECD suggested that this attitude was due to a misunderstanding of the patent system and wondered how to educate the public about the benefits of the patent system. Similarly, policy makers may wish to address prevailing attitudes and perceptions about the patent system in regard to health biotechnology in industry, the research community or general public.

Consider, for example, the statement expressed by senior executives in the Canadian name brand pharmaceutical industry. These executives recognise that, because Canada represents only two per cent of the world's pharmaceutical market, even significant changes in Canada's patent law are unlikely to have a noticeable effect on incentives to conduct research into new medications (CBAC, 2000). Rather, these executives warned that if Canada failed to continue to modify its patent system to be more favourable to industry, those outside the country would believe that Canada was – wrongly – an unfriendly place in which to conduct research. These executives thus suggested that Canada modify its laws, not in order to increase total innovation, but to act as a symbol that would create a positive belief among industry representatives outside the country.

As noted in Part I, empirical evidence supports the conclusion that the clinical research community believes that patents stifle research in clinical genetics. Directors of clinical laboratories report that they have ceased to conduct research as a result of patent rights over human DNA sequences and of attempts by patent holders to enforce those rights by sending letters threatening legal action if the laboratories do not either stop research or buy a licence. What the empirical evidence demonstrates is a real fear on behalf of clinical laboratory directors and researchers based on the belief that patent holders can and will prevent them from conducting their research (Merz, 2002; Cho et al., 2003). It could be that these directors are wrong about whether patent holders could actually enforce their rights or whether they would actually do so. Nevertheless, regardless of the legal rules and business decisions, about which they may have limited knowledge, these directors act on their beliefs to stop existing research projects or not begin others.

While public policy cannot assume that patent systems either do or do not provide important incentives or serve to coordinate activity, until we obtain significantly better empirical evidence, it must take into account the beliefs, attitudes

and perceptions of both industry and the research community. This is the approach taken in this report. Where there is an absence of evidence, we ought to be cautious about making changes to the patent system except where there is good reason to do so. We have good reason to make changes when a demonstrable belief about the way the patent system functions or good empirical evidence suggests a change is needed.

A consideration of opinion leads to two fundamental conclusions. First, policy makers ought to take into account the symbolic value of the *Patent Act* in shaping international opinion about Canada's openness to biotechnological research and development. This leads to the following conclusion:

**2. Canada ought not to change its rules regarding the patent-eligibility of human DNA sequences.** Canada ought not to alter its rules regarding the patent-eligibility of human DNA sequences because the empirical evidence is not sufficiently strong to draw the conclusion that such sequences should not be patent-eligible and it is arguable that TRIPs requires that DNA sequences be patent-eligible. In addition, such a change might act as a symbol that leads the international business community to believe that Canada is unfriendly toward biotechnological research and development. Such a belief may have negative economic consequences for Canada.

Second, the opinion evidence from the research community demonstrates a significant fear that patents over human DNA sequence undermine health-related research and development, particularly in the field of human clinical genetics. While we concluded above that the economic evidence does not exist to support a decision to withhold patents over human DNA sequences, policy makers must take into account the fears and beliefs of the research community if Canada is to develop a strong domestic biotechnology industry. Just as the *Patent Act* may act as a symbol that leads international investors to invest or to withhold investment in Canada, the *Act* acts as a symbol to researchers that they can safely conduct research in Canada. Given the current fears over patent litigation, we conclude as follows:

**3. Canada ought to create a clear statutory research or experimental use exception within the *Patent Act*.** The clear international trend recognised by the OECD (OECD, 2002), the ALRC (ALRC, 2004) and other bodies is that countries have or are contemplating adopting research or experimental use exceptions within their patent laws to permit researchers to conduct basic research in genetics and related fields without fear of infringing upon a patent. Such an exception would be in addition to existing exceptions permitting research aimed at fulfilling regulatory requirement. Europe provides the clearest example of such a research exception. To date, no evidence exists to suggest that the European approach has a negative impact on research and development. To the contrary, fears over patent infringement by basic researchers in Europe are low in comparison with the United States and Canada, which have no such clear exceptions. Given that the state of a research exception in Canada is unclear at best after the Supreme Court of Canada decision in *Harvard College* and given CBAC's clear recommendation in its

report on *The Patenting of Higher Life Forms*, the failure thus far of the federal government to amend the *Patent Act* to address researcher concerns ought to be quickly remedied.

Health care providers have indicated that they fear, not only in Canada, but in Australia, Europe and the United States, that some – even if they turn out to be few in number – patent holders of important human DNA sequences may withhold licensing of their inventions on terms affordable by health care systems. Whether this concern will eventually be addressed by the simple action of the market – although many doubt that market forces function this way in the health care sector – both health care administrators and the public at large are fearful about the short- and medium-term effects of such holdout problems. This fear, as noted by the OECD (OECD, 2002) can seriously undermine the public's confidence in the patent system. Failure to address this concern may deepen public cynicism of this system. We therefore conclude as follows:

**4. Canada ought to amend the *Patent Act* to include a compulsory licensing or government use provision aimed specifically at health care services such as genetic diagnostic tests.** The current *Patent Act's* section 19 provides governments with the right to seek a compulsory licence in respect of any health care service provided (directly or indirectly) by any government (Gold & Lam, 2003) without prior negotiation with the patent holder. It could thus in theory be invoked by provincial governments to provide diagnostic services at a reasonable cost. Unfortunately, section 19 is so broad in scope that its invocation by any province will likely cause substantial fear from the pharmaceutical and medical equipment manufacturers that all pharmaceuticals and this equipment will be used without their having the opportunity to enter into licence agreements. What Canada needs is a compulsory licensing provision that is targeted to the the particular areas of concern to the health care system including, but not necessarily restricted to, genetic diagnostic services. The scope of the compulsory licence provision needs further investigation but, at the least, it must provide governments with the ability to correct market problems without threatening the entire Canadian health care industry. Other countries, such as France and Australia, have recommended these changes. In addition, the change would seem to be compliant with TRIPs, as it recognises the legitimate policy differences between health and other sectors.

## *Technology Transfer*

Most health-related biotechnology products and services have their origin in university-based research. This research is largely funded by the public sector through research grants and government support of university infrastructure. In order to ensure that basic university research makes its way to the physician and hospital, researchers and universities must find ways to transfer their knowledge to the private sector that will use the basic knowledge to develop a useful product or service.

While research publications provide a significant way to transfer knowledge and innovation from the university to industry, researchers and universities are increasingly licensing technology developed at the university to the private sector. Through specialised offices at the universities, generically called technology transfer offices (TTOs), the university finds a private-sector licensee of university research in return for licence fees.

Recent work in Canada, the United States and Australia has examined appropriate ways in which universities ought to transfer knowledge and innovation to industry, given both the public nature of universities and the fact that the research originated in government-funded work. Debates continue over whether universities should licence out their technology in such a way as to maximise their own revenues or whether universities should simply act as a conduit to permit local industry to use the technology to create employment in the country. What is clear is that we cannot expect universities to do both simultaneously (CIPP, 2004a). This leads us to the following conclusion:

- 5. Canada ought to adopt a technology transfer strategy.** This strategy should be national in scope and ought to set out whether universities ought to seek their own benefit or the province's or country's benefit in licensing their technology to industry. A strategy requiring universities to maximise revenue requires a significant investment in TTOs so that they have the resources to fully negotiate licences in respect of those technologies most likely to provide a monetary return to the university. A strategy aiming at the public good requires the development of standard licence agreements that favour non-exclusive over exclusive licences and a focus on those technologies most likely to help society than on those that are most lucrative. Industry Canada is best placed, in conjunction with federal granting agencies and universities, to develop such a strategy.

## *Licensing Guidelines*

As noted earlier, both the NIH in the United States and the OECD internationally have developed or are developing guidelines on the appropriate licensing of human genetic inventions. These guidelines aim at providing a legally non-binding, but morally persuasive, set of principles and best practices that will assist industry and universities to negotiate licence arrangements that will serve both the interests of industry and the public at large, including the health care sector. These

guidelines provide a useful supplement to any reform of the *Patent Act* that encourages industry participation in solving perceived problems with current patent arrangements. We thus conclude as follows:

- 6. Canada ought to adopt and adapt best-practice guidelines developed at the OECD and elsewhere.** Canada should work with industry associations such as BIOTECanada and the universities to encourage adoption of these best practices.

#### *Patent Process Reform*

In its report on the *Patenting of Higher Life Forms*, CBAC recommended that Canada institutes two reforms of the patent process: the creation of an opposition process within the Canadian Intellectual Property Office and the development of guidelines on the patentability criteria as they apply to biotechnological innovations. So far, Canada has failed to implement these recommendations.

Since CBAC's call for these improvements, the Australian Law Reform Commission has come to the same conclusion. The United States has amended its re-examination process to be much more transparent and fair to those opposing granted patents. The United States utility and description requirements have substantially clarified US patent law for inventors. Canada now stands significantly behind its major trading partners without any sound reason. We thus conclude as follows:

- 7. Canada ought to develop an opposition process within the Canadian Intellectual Property Office.** Such a process would provide an administrative mechanism through which to challenge issued patents without having to suffer the costs and time delays caused by having to ask a court to invalidate a patent. Such a process not only reduces costs and time delays, but renders significantly more valuable and clear to the patent holder issued patents that have survived the opposition process. Being able to challenge a patent quickly and economically will reduce any negative effect that the issuance of patents of uncertain validity causes. As current US statistics indicate that approximately one-third of issued patents challenged in court are held invalid, reducing costs and delays provides a significant advantage to industry, researchers and the health care system. Every country examined in this study has adopted a procedure that is significantly more transparent and fair than is the Canadian re-examination procedure.
- 8. The Canadian Intellectual Property Office ought to develop utility and description guidelines to aid patent applicants.** Canada ought to follow the lead of the United States Patent and Trademark Office in developing guidelines that set out how the CIPO will evaluate patent applications relating to biotechnological inventions. These guidelines would assist the development of strategies for industry in filing patent applications and those considering whether to challenge the validity of a patent.

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## **APPENDIX A BIOGRAPHIES OF CIPP EXPERT GROUP AND RESEARCHERS**

### **CIPP EXPERT GROUP**

Gold, E. Richard

Dr. Richard Gold is the Director of the Centre for Intellectual Property Policy and teaches in the area of intellectual property and technology at McGill University's Faculty of Law as the Bell Chair in e-Governance. His research centres on the nexus between technology, commerce, and ethics, particularly with respect to biotechnology in the international context. He is the Principal Investigator of the Intellectual Property Modelling Group. He has published widely in legal and scientific journals on this topic and is the author of *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington: Georgetown University Press, 1996). Dr. Gold holds an S.J.D. and LL.M. from the University of Michigan, a LL.B. (Honours) from the University of Toronto and a B.Sc. from McGill University. Professor Gold was Senior Advisor, Intellectual Property, to the Canadian Biotechnology Advisory Committee, Legal Policy Consultant to the Ontario Ministry of Health and Long-Term Care and is a consultant to the Organisation for Economic Cooperation and Development on biotechnology intellectual property issues. He is a Research Associate at the Health Law Institute at the University of Alberta and an Associate Fellow at CIRANO (Centre for Interuniversity Research and Analysis on Organisations).

Knoppers, Bartha M.

Dr. Knoppers, Canada Research Chair in Law and Medicine, is Professor at the Faculty of Law, Université de Montréal, Senior Researcher at the Centre for Public Law (C.R.D.P.) and is an *Officer* of the Order of Canada. Currently, Chair of the International Ethics Committee of the Human Genome Organization (HUGO), she is Co-Founder of the International Institute of Research in Ethics and Biomedicine (IIREB) and a Co-Director of the Quebec Network of Applied Genetic Medicine (RMGA). She was named to the Board of Genome Canada in 2000. In 2003, she became Director of the international Public Population Project in Genomics (P<sup>3</sup>G).

Caulfield, Timothy

Timothy Caulfield has been Research Director of the Health Law Institute at the University of Alberta, since 1993. He recently received a Canada Research Chair in Health Law and Policy. He is also an Associate Professor in the Faculty of Law and the Faculty of Medicine and Dentistry. His research has focussed on two general areas: genetics, ethics and the law; and the legal implications of health care reform in Canada. Over the past several years he has been involved in a variety of interdisciplinary research endeavours which have allowed him to publish numerous

health law articles and book chapters. He is the recipient of an Alberta Heritage Foundation for Medical Research Health Research Scholarship entitled "Regulating the 'Genetic Revolution"; an Alberta Law Foundation funded project on Health Care Reform in Alberta; a Genome Canada project on the regulation of genomic technologies and is an associated theme leader in the recently created Stem Cell Network (National Centres of Excellence). He was recently a visiting scholar at the Hasting Center for Bioethics in New York, and has been a Visiting Fellow at Stanford University's Program in Genomics, Ethics and Society and is a Senior Fellow with the Einstein Institute for Science, Health and the Courts. In November 2000, he was awarded the University of Alberta's Martha Cook Piper Research Prize. Professor Caulfield is a member of the Canadian Biotechnology Advisory Committee; The Health Canada's Expert Advisory Committee on Xenograft Regulation; the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology (2001); and the Institute Advisory Board, Institute of Health Services and Policy Research, Canadian Institute of Health Research. He also serves on a number of research ethics boards, is an editor of the *Health Law Journal* and the *Health Law Review*, teaches Law and Medicine in the Faculty of Law, and provides health law lectures for other faculties.

Cloutier, L. Martin

L. Martin Cloutier is an Associate Professor in the Department of Management and Technology, University of Québec at Montréal; and the Director of the Research group on the management of biotechnology enterprises ([www.mateb.uqam.ca](http://www.mateb.uqam.ca)), and his area of expertise includes the development of simulation models, and of systems of performance indicators, for use as decision support systems; applied to biotechnology issues and university-industry technology transfer. He holds B.Sc. and M.Sc. degrees from McGill University; and has obtained his PhD from the University of Illinois at Urbana-Champaign. He is the faculty representative on the board of the *Institut santé et société* at the University of Quebec at Montreal.

## **CIPP RESEARCHERS**

Carbone, Julia

Julia Carbone is a Researcher at the Centre for Intellectual Property at McGill University. She is currently finishing her LL.B.-B.C.L at McGill Faculty of Law and has a B.A. in Philosophy from McGill. She is conducting comparative analyses of intellectual property law in respect of biotechnology for the IPMG.

Joly, Yann

Yann Joly is a lawyer and a member of the Barreau du Québec since April 2003. He is currently completing a graduate degree in law (specialisation in biotechnology law) at the Université de Montréal. Yann works as a research associate for the Genetics and Society Project and is the editor of the team's newsletter GenInfo. His research interests are primarily in the fields of pharmaceutical law and intellectual

property. Yann is also the coordinator of the HumGen database and, a member of both the Centre for Intellectual Property Policy (CIPP) and the International Institute of Research in Ethics and Biomedicine. Yann is the Coordinator of the Young Researchers' Network of the Association for Research in Medical Law for North-America (ARFDM).

Sheremeta, Lori

Lori Sheremeta joined the HLI in October 2001. She is a graduate of the University of Alberta and was called to the Bar in 2001. Lori articulated at Oyen Wiggs Green & Mutala, a Vancouver law firm specialising in intellectual property. Lori is employed by the Health Law Institute as a Research Associate. Her work is focussed on the legal, ethical and social issues surrounding genetic technologies (Genome Prairie), stem cell technologies (Stem Cell Network) and nanotechnology (National Institute for Nanotechnology). Lori has a particular interest in the intersection of intellectual property law and health policy both in Canada and abroad. Lori has co-authored background papers for Genome Canada, the Canadian Institutes of Health Research and the Canadian Biotechnology Advisory Committee on various issues relating to genetic research in Canada. In addition to her research duties, Lori sits on the University of Alberta Hospital Clinical Ethics Committee, the Cross Cancer Institute Animal Care Committee and on the Scientific Advisory Board of the Hereditary Breast and Ovarian Cancer Society. Lori is currently enrolled in the LL.M. programme at the University of Alberta and is the recipient of the Alberta Law Foundation Scholarship in Health Law and Policy. She is also a student participant in the Canadian Institutes of Health Research (CIHR) Training Program in Health Law and Policy. Lori's LL.M. thesis is focussed on the legal, ethical and policy considerations of large scale population genetics studies and associated databanks.

**APPENDIX B**  
**DETAILED COMPARISON CHARTS OF NATIONAL PATENT LAWS**

The charts in this Appendix are reproduced with the permission of the Centre for Intellectual Property Policy. To date, they are available only in English. Please see the CIPP website, [www.cipp.mcgill.ca](http://www.cipp.mcgill.ca), for these and other country charts.

## **APPENDIX C**

### **COUNTRY STUDIES ON PATENT SYSTEM AND HEALTH CARE**

#### **United States**

In the United States, a variety of studies have been performed which attempt to assess the effects of genetic patents on research and access to healthcare. In 1996, in response to the EST patenting controversy, the U.S. National research council held a workshop to assess the impact of patents on research tools in molecular biology. The published workshop summary outlines five case summaries to illustrate various IP protection and licensing strategies (NRC, 1997). Two main conclusions were drawn by the workshop participants: (1) the patenting of uncharacterised cDNA sequences is not appropriate as it has the potential to reward the routine discoverer whilst penalizing those who determine biological function; (2) research tool claims should not be so broad as to block discoveries outside the patent. With respect to research tool patenting this report asserts that it is important to consider whether a delay in disclosure that results from patent application filing unduly inhibits scientific progress, whether access to research tools is broad enough to facilitate scientific progress and whether the benefits of a protected environment for further development outweigh the costs of excluding others from the research tool. No single policy option exists that will address all of the relevant issues raised. Rather, a balance must be sought through the close and continued scrutiny of people that are concerned with the science and the application of molecular biology.

In 2001 Isaac Rabino published results of a survey aimed at elucidating the opinions of human geneticists on a variety of issues that had appeared in the literature including patenting, academic secrecy, duplication of efforts and over attention paid to commercialisation of genetic technologies rather than on high quality genetic research. 1229 scientist members of the American Society of Human Geneticists responded to a questionnaire mailed to them.

- 49% reported that a DNA patent or patents had limited their research;
- 46% reported that patents had never limited their research;
- 74% of respondents disapproved of DNA patenting;
- 90% of respondents (and 86% of industry respondents) viewed excessive gene patenting as a problem.

Although generally optimistic about human genetics, respondents were concerned about the impact of commercialisation and specifically of patenting. Surprisingly, opposition to patenting of DNA was strong, even amongst industry scientists and those whose work had never been negatively impacted by patents. If DNA patents are granted, a large majority of survey respondents felt that they should be narrow in scope.

In two survey studies, Jon Merz and Mildred Cho and colleagues evaluated the impact of gene patents on research and the clinical delivery of genetic testing services in the U.S.. The first survey (Merz, 2002) specifically posed questions concerning HFE testing for hemochromatosis. In that study, 119 telephone surveys directed to genetic

testing facilities were conducted. Thirty percent (30%) of respondents reported that they had either discontinued testing or ceased test development because of the relevant HFE patents. The authors concluded that HFE patents had a measurable impact on HFE test delivery and availability in the U.S. In addition, because HFE testing was commenced by a number of labs before the first U.S. patent issued, the authors question whether patents are necessary for the rapid translation of gene discovery to the provision of genetic testing services. Other concerns raised, but not definitively answered, by this study include the role of patents in: delaying scientific publication; preventing the development of new tests and tests for specifically relevant genetic mutations responsible for a give phenotype; increasing the cost of testing; increasing the potential for laboratory errors; royalty stacking; and the creation of administrative bottlenecks arising from the need to negotiate license agreements.

In an expanded second study, the authors reported the results of a survey of genetic testing laboratories (Cho *et al*, 2003). Of 122 respondents, 53% reported that they had opted not to develop a test/service for clinical research purposes because of an existing patent. The survey revealed that 12 specific tests were subject to stoppage by at least one respondent lab because of an existing patent. The survey demonstrated that, in general, respondents held a negative view of the impact of patents on cost, access, test development and data sharing amongst researchers. The authors conclude that "patents and licenses have a significant negative effect on the ability of clinical laboratories to continue to perform already developed genetic tests." Further to the HFE study, the findings of this survey support the notion that labs are able to quickly translate published data into clinical tests without patent incentives and that labs are prevented from performing such tests after patents issue. This suggests that patent incentives may not be critical for the development of an invention into a commercially viable service when the invention is the finding of an association between a genetic variant and a particular condition. This study does not, however, provide insight into whether the described problem translates into decreased patient access; the data do not reveal whether patients are able to access testing services elsewhere. Though there exists a sense amongst respondents that costs to labs and to patients have increased as a result of patents there exists no data that specifically speaks to this issue. The authors of this study presume that a cost increase necessarily translates into decreased access. While logical, this assertion remains to be proven. In addition, the authors assert that the effect of fewer labs performing tests may result in lesser test quality, diminished innovation and less clinical research. Again, these assertions remains to be proven. In conclusion, the authors assert that "[a]lthough patents may have provided incentives to conduct the basic research underlying the genetic tests, the reported inhibition of clinical testing and research does not bode well for our ability to fully and efficiently use the results of the Human Genome Project and related work" (at 8).

Recently Walsh *et al* (2004) published the results of a U.S. survey aimed at determining the effects of research tool patents and licensing on biomedical innovation. This same data was presented to the OECD meeting in January 2002 and reported in the 2002 OECD Report (OECD, 2002). Through the survey, the authors sought to answer the following questions: (1) Has there been a proliferation and

fragmentation of patent rights? (2) If so, has this caused a failure to realise beneficial licensing agreements as predicated by Heller and Eisenberg (i.e. does the “tragedy of the anticommons” exist?); (3) Can examples be found where restricted access to upstream discoveries has hindered research? (4) Has the nature of IP negotiations substantially changed? (5) What strategies have firms adopted to overcome the challenges associated with the accrual and exploitation of IP? Importantly, the authors conclude that although certain pre-conditions for an anticommons appear to exist (there has been a proliferation and fragmentation of patent rights) the drug discovery process appears not to have been adversely affected to any great degree by gene patents. There appeared to be little evidence that research was being impeded by concerns over patents on research tools in the U.S. Although there exists a real potential that holders of patents on research tools may limit access, there exists no systematic data showing that projects have been passed up or abandoned due to patent issues. Firms commonly redirect research projects to “invent around” various research tools but it is not common for firms to redirect their research into an entirely new field (i.e. another disease or an entirely new approach to the same disease). Importantly, the vast majority of respondents cite no cases in which research projects were stopped because of IP problems relating to research inputs. Though royalty stacking is a real issue this study suggests that research projects are not unduly impeded by licensing costs. With respect to the research environment, there is concern that the 2002 CAFC decision of *Madey v. Duke University* 307 F 3d 1351 (2002) may have a chilling effect on potentially “offending” biomedical research conducted in universities. The authors of this study therefore recommend that policymakers “seek to ensure an appropriate exemption for research intended for the public domain.”

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## Germany

A survey, of German pharmaceutical companies, small and medium sized biotech firms, and publicly funded research institutes was performed between July 2001 and January 2002 (Straus, 2002). The study results were presented to the BMBF and OECD Workshop on January 24-25, 2002 and are reported in the 2002 OECD Report (OECD, 2002). The survey sought to clarify whether German bio-pharma research and development is adversely affected by: (1) dependency of patents on earlier patented inventions as a result of the proliferation of DNA patents and overly broad patent claims; (2) avoidance by researchers or firms, to enter fields of research in which genes have already been patented; (3) reach through royalty claims; (4) royalty stacking and increased transaction costs; (5) delayed publication of research results due to the novelty requirement under patent law; and (6) a proliferation of lawsuits related to genetic patenting.

In summary, the following conclusions were drawn from this survey:

### ***Economic and financial value***

- To biotech firms, patents are a critically important indicator of a company's financial value.
- Large pharmaceutical firms require a robust patent portfolio to ensure that they can continue R&D in a particular field. Patents are also important in negotiations with potential collaborators.

### ***Research cooperation***

- At present, research cooperation is not "unduly harmed by intellectual property issues".
- Pharmaceutical companies are rarely reluctant to grant non-exclusive licenses to their IP except in the context of research tools where exclusive licenses are used to give the licensee a period of exclusivity to recoup his or her investment.

### ***Dependency and product development***

- Companies are reluctant to pursue fields of research that will likely lead only to dependent patents.
- In a field where R&D is advanced and an invention is likely to be dependent, firms may try to license, cross-license or purchase the dominant patent.

### ***Research tools***

Patents on research tools have not had a discernable effect on the cost or pace of research in Germany.

Many groups act as if an "informal research exemption" exists that covers the use of patented research tools.

Fear of patent infringement litigation is low in the public sector – many researchers are unaware of potential liability and research often yields little incentive for patent holders to sue.

### ***Reach through claims***

- Opinion is split on the impact of reach-through claims. Some feel that they are invalid, others believe that the question of validity must be determined by the courts.
- Reach through claims for licenses have the potential to make negotiations cumbersome.

### ***Royalty stacking***

- The need to enter into license agreements with a numerous patent holders is a reality. It can, however, be overcome by the mutual realisation of parties to the agreement that royalties must be reflective of the commercial reality.
- Royalty stacking clauses can be incorporated into license agreements that reduce the amount of individual royalties such that the cumulative royalty does not exceed a certain amount (i.e. 10% of the turnover of the final product).

### ***Reform Options***

- All respondents agree that no special patent law is necessary for genetic inventions and that there is a need for increased harmonisation at the international level (i.e. patent examiners in different countries should use the same examination criterion).
- Pharmaceutical firms perceive that absolute protection of inventions is essential; biotech firms are more willing to accept that patents claims reflect only the inventor's contribution to the state of the art.
- No consensus exists amongst respondents on the need for a grace period to facilitate publication of research results, though research institutions generally favour adoption of a grace period.
- Survey respondents did not feel that patent pools, consortia and cross-licensing arrangements are effective solutions to the problem due to the difficulties in assessing the relative contribution of the parties.

### **References:**

Straus, Josef "GENETIC INVENTIONS AND PATENTS – A GERMAN EMPIRICAL STUDY", presentation to the BMBF & OECD Workshop entitled "Genetic Inventions, Intellectual Property Rights and Licensing Practices", Berlin, January 24-25, 2002, online: OECD <[www.oecd.org/document/57/0,2340,en\\_2649\\_34537\\_2743225\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/57/0,2340,en_2649_34537_2743225_1_1_1_1,00.html)>.

Organisation for Economic Cooperation and Development, GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS & LICENSING PRACTICES, 2002, online: OECD <[www.oecd.org/dataoecd/42/21/2491084.pdf](http://www.oecd.org/dataoecd/42/21/2491084.pdf)>.

## Australia

A survey, of Australian pharmaceutical companies, biotech firms, research institutes and diagnostic testing facilities was performed (Nicol & Nielsen, 2004). Forty semi-structured interviews were undertaken with participants from all of the above-named sectors. The study results were presented to the Australian Law Reform Commission and they comprise a substantial component of the data considered by the ALRC in preparation of its Report "Genes and Ingenuity: Gene Patenting and Human Health" (ALRC, 2004). The survey was conducted to assess the impact of patents in the Australian medical biotech sector. A key finding of this study is that "a very delicate balance exists between the role played by patents in encouraging innovation and the potential for patents to impact negatively on research into, and the development of, new drugs, therapies and diagnostics." Legal reform is recommended to occur "only at the margins" to ensure that the delicate balance is not unduly disturbed.

In summary, the following conclusions are drawn from the Nicol-Nielsen survey:

### ***Research and Patent Issues***

- Participants in research institutions and industry agree that patenting is an essential part of the commercialisation process.
- Concerns exist about the breadth of patents being granted by the Australian Patent Office and the impact of patents on downstream research, and the potential for patents over research tools.
- There are questions as to the degree of legal immunity that Australian research institutions enjoy from patent infringement liability. An express research exemption should be considered though the appropriate scope of such an exemption is unclear.

### ***Transfer of Technology***

- There is a need to streamline technology transfer in Australia. Statutory licensing and/or collective rights arrangements may be helpful to those industry participants seeking to license out widely.

### ***Restrictions on Access***

- Clear evidence of exclusionary practices were identified in Australia though respondents describe little difficulty accessing broadly applicable research tools and technologies.
- Respondents report being able to access needed technology or redirect research efforts though access to technology was frequently gained at both a monetary and a time cost.
- Open science should be protected in Australia while simultaneously ensuring that innovation is adequately rewarded.
- Consideration of competition law, compulsory licensing, clearinghouse

mechanisms and/or use of a research exemption may be warranted.

### ***Anticommons Issues***

- The Australian biotechnology industry appears to be avoiding an unworkable anticommons situation though the potential exists that one may emerge.
- For any given research project, the number of problematic patents is typically less than five.
- Although not quantified in this study research project abandonment due to patent crowding it is considered a problem.
- Industry participants recognise that royalty stacking can be a problem. Attempts are made to minimize the problem when in-licensing technologies.
- Study respondents did not report significant problems associated with the attempted enforcement of research tool patents. It may, however, become more of a problem in the future. At present, a number of the most aggressively enforced research tool patents do not exist in Australia or, if they do, they are not enforced.
- Legal options, including statutory licensing, collective rights arrangements, improved standards for the granting of patents and a clearly defined research exemption may help to avoid the problem in Australia.

### ***Impact on the Provision of Diagnostic Services***

- In contrast to a recent U.S. survey, this study did not find evidence of patent enforcement in the area of diagnostic genetic services, aside from Roche's PCR patent.
- The report notes that GTC's junk DNA patent is being enforced, or is expected to be enforced in Australia in the near future. Access terms may, however, be available.
- Respondents that provide genetic testing services are concerned about the impact of patents to a far greater degree than respondents from other industrial areas or academia.
- The authors suggest that options for law reform should be more closely scrutinized in this area (i.e. in the provision of genetic testing services) than in other areas.
- In addition to the previously mentioned legal options, exempting methods of diagnostic testing from patent infringement may be worth exploring.

### ***Market Solutions***

- The importance of patenting, maintaining freedom to operate, and avoiding encumbrances on patent rights is widely recognized across all sectors of the Australian biotech industry.
- There remains a laissez faire attitude in Australia with respect to patent enforcement and the avoidance of patent infringement liability through the use of others patented technologies. In order to avoid patent infringement liability, industry players utilise a variety of techniques including: (1) inventing around patented technologies (2) ignoring granted patents; (3) negotiating license agreements (including cross-licenses); (4) relying on the existence of an

informal (practice-based) research exemption; (5) challenging the validity of blocking patents.

- Growth of the Australian biotech industry may increasingly come to depend on the strategic exploitation and use of patented technologies.

### **Reform Options**

- Law reform should be cautiously considered and implemented so that the momentum of the Australian biotech industry is sustained.
- Options for law reform are of two main types – either the granting or the use of patents can be regulated:
- Regulation of the grant of patents:
  - The addition of an industrial applicability/utility requirement at the examination stage and crafting of more biotechnology-specific guidelines for assessing the description criteria;
  - Consider excluding methods of diagnostic testing from patentability (clear recognition that a decision to do this would require further analysis);
  - Creation of an express research exemption.
  - **Note:** adoption of a gene sequence exclusion or an ordre public/morality clause are problematic and may create undue uncertainty (at 258).

#### Regulation of the Use of Patents:

Relax the conditions under which compulsory licenses may be granted (though not to devalue patent grants)

Utilise mechanisms to reduce the onerous demands of patent searching and infringement tracking in situations of non-profit research, diagnostics and research tools.

Given the confidential nature of many IP transactions, consider the appropriate role of competition law with respect to exclusionary licensing practices.

***In December 2002, the ALRC was asked by the Australian Government to conduct an inquiry into intellectual property issues raised by genetic information. A comprehensive Discussion Paper entitled “Gene Patents and Human Health”, (DP 68) was published in June 2004 (ALRC, 2004). The final report (DP 99) was publicly released in August 2004 (ALRC, 2004). Specifically, the ALRC was to examine the impact of patent laws and practices as they relate to genes and genetic-related technologies in the following three contexts: (1) the conduct of research and its subsequent application and commercialisation; (2) the Australian biotechnology sector; and (3) the cost-effective provision of healthcare. The ALRC was asked to report on what changes may be required to address any problems identified in current laws and practices, “with the aim of encouraging the creation and use of intellectual property to further the health and economic benefits of genetic research and genetic and related technologies”.***

***Chapter 13 (Patents and Human Genetic Research), Chapter 20 (Gene Patents and the Healthcare System) and Chapter 21 (Gene Patents and Healthcare***

**Provision) of DP 68 are particularly relevant to this present review. In these specific areas, the ALRC concludes:**

#### **Patents and Human Genetic Research**

- There is limited evidence to suggest that gene patents have had any significant adverse effect on the conduct of research in Australia to date. However, as the Australian biotech industry develops an international presence, it may attract more attention from patent holders.
- The ALRC takes a cautious approach towards recommending major changes to patent law in the area of human genetics.
- Whilst recognising that the situation requires monitoring and may change, the ALRC is of the opinion that a more detailed consideration of reform options are warranted. Specific options include:
  - Implementing changes to Patent Office practice;
  - Enacting a new experimental use defence;
  - Encouraging health departments or other agencies to challenge questionable gene patents that may impact adversely on medical research;
  - Developing model license agreements to encourage access to genetic inventions;
  - Amending the Crown Use and compulsory licensing provisions of the Australian Patents Act.
  - Developing a government initiative directed towards using the government's research funding leverage to reduce transaction costs and to encourage and maintain widespread access of research tools.

#### **Gene Patents and the Healthcare System**

- Concerns about the implications of gene patents for public healthcare funding has arisen primarily in relation to medical genetic testing.
- The extent to which increased expenditure on medical genetic testing will challenge overall healthcare funding is unclear. It is also not clear what role gene patents will have on increased expenditure.
- There is a need to develop processes for: (a) economic evaluation of medical genetic testing; and (b) examination of the financial impact of gene patents on the delivery of healthcare services in Australia.
- There is a need to examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and are used in the provision of healthcare. For example, medicare funding of a medical genetic test could be made conditional on wide licensing of the test.
- Where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, appropriate government departments should actively consider whether to: request re-examination of a patent; initiate proceedings to oppose a patent; apply for revocation of a patent; apply for the grant of a compulsory license; or exploit or acquire a patent under the Crown use and acquisition provisions of the *Patents Act*.

- Government should establish offices to monitor and manage intellectual property issues relating to genetic materials and technologies. The offices should be staffed by qualified individuals who are capable of giving specialist legal and policy advice about intellectual property, biotechnology and human health. Health departments should also establish mechanisms to enable them to draw on expertise in other government departments and agencies to advise and assist them in dealing with intellectual property issues arising from gene patents.
- The application of intellectual property laws to genetic materials and technologies should be monitored, where these may have implications for medical research or human health.

### ***Gene Patents and Healthcare Provision***

This chapter focuses on the impact of patent laws and practices on medical genetic testing.

In March 2003, GTG advised public sector labs in Australia and New Zealand that they would need to negotiate licenses over the non-coding gene patents which are infringed by medical genetic testing for a range of genetic conditions. (In the US, Applera Corp. is facing an infringement suit for refusing to obtain a license to use GTC's non-coding patents for, among other things, a diagnostic test for CF.)

The ALRC's preliminary view is that there is limited evidence to date to suggest that gene patents and licensing practices have had any significant adverse impact on the cost of healthcare provision in Australia: there is no firm evidence of any impact of patents on access to medical genetic testing, the quality of testing or on clinical research and development.

Concerns raised about gene patents by health authorities, health consumer groups, health professionals and others have largely been based on assumptions about the future development of the market in medical genetic testing and about the intentions of patent holders with regard to the exploitation and enforcement of gene patents—in particular, the assumptions that patent holders will use exclusive licenses as their business model and that such licensees will charge monopoly prices. The extent to which this business model will be adopted in Australia is unclear and it is problematic to extrapolate from the experience in other countries such as the United States, which have very different healthcare systems.

Concerns about the cost of, and access to, medical genetic testing are influenced by broader concerns about Australian healthcare policy, applicable to all new medical technologies. These concerns include the future of Medicare, the respective roles of tax-financed healthcare and private health insurance, and the mix of public and private healthcare provision generally. For example, Dr Amanda McBratney and others observed, in relation to the cost of genetic health technologies, that: "The issue is more about equity in welfare payment and in how the health care burden should be distributed in Australia rather than the price of an individual 'gene based' technology" (at 21.130).

While there is limited evidence that gene patents are having any present impact on the cost-effective provision of healthcare, genuine concerns are held

about the potential for future negative effects on access to medical genetic testing, the quality of such testing, and clinical research and development. As a result, more detailed consideration of options to address the impact of gene patents on healthcare is justified (21.133).

Elsewhere in this Discussion Paper, the ALRC has proposed reforms that address the potential for future harm, including with respect to healthcare provision. Some of these reforms are intended to ensure that problems are identified at an early stage, for example, through monitoring of anti-competitive conduct and informal prices surveillance by the Australian Competition and Consumer Commission.

In August 2004, the ALRC's Report 99 entitled "Genes and Ingenuity: Gene Patenting and Human Health" (ALRC, June 2004) was released. Though this report has not yet been comprehensively reviewed, the following recommendations have been extracted from the executive summary available online at <[http://www.austlii.edu.au/au/other/alrc/publications/reports/99/\\_3.html](http://www.austlii.edu.au/au/other/alrc/publications/reports/99/_3.html)>.

Specifically, the ALRC recommends reforms directed at:

- Improving patent law and practice concerning the *patenting* of genetic materials and technologies, including through amendments to the *Patents Act* and changes in the practices and procedures of IP Australia, patent examiners and the courts.
- for example, the ALRC recommends specific reforms to this requirement to increase the burden of proof on applicants and require that 'usefulness' be assessed during the examination of an application for a standard patent. Greater scrutiny of applications during examination should lead to patents that are more likely to withstand challenge. The ALRC also recommends that IP Australia develop guidelines to assist patent examiners in applying the revised usefulness requirement. The Inquiry does not recommend that social or ethical concerns should be added as explicit grounds for excluding an invention from patentability. The ALRC recommends that the *Patents Act* should *not* be amended to exclude genetic materials or technologies from patentability; or to provide a new medical treatment exclusion; or to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.
- Improving patent law and practice concerning the *exploitation* of gene patents, including in relation to a new defense to claims of patent infringement, Crown use, and compulsory licensing of gene patents;
- the Inquiry recommends that the Australian *Patents Act* should be amended to provide for an experimental use exemption. The ALRC recommends that the new exemption be limited to protecting study or experimentation on the subject matter of a patented invention—that is, research with a focus on discovering more about the invention and its properties.
- Ensuring that publicly funded research, where commercialised, results in appropriate public benefit, including through the adoption of appropriate patent practices;
- Encouraging universities and other research organisations to raise the

awareness of researchers about patenting issues and the commercialisation of research;

- Ensuring that Australian research organisations and biotechnology companies are adequately skilled to deal with issues concerning commercialisation and the licensing of patented inventions;
- Establishing mechanisms for monitoring the implications of gene patents for research and healthcare so that governments have the ability to intervene where gene patents are considered to have an adverse impact, either in specific cases or systemically;
- for example, the ALRC recommends that where particular gene patent applications, patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, health departments should consider whether to exercise any of the existing legal options to facilitate access to the inventions.
- Clarifying the application of competition law to the exploitation of intellectual property rights, including patented genetic materials and technologies; and
- the ALRC also recommends that health departments and other stakeholders should make use of the existing complaint procedures under the Trade Practices Act where evidence arises of anti-competitive conduct that may have an adverse impact on medical research or the cost-effective provision of healthcare.
- Clarifying the scope and practical application of exceptions to copyright infringement in relation to research.

Two additional Australian reports – one dealing with the experimental use, the other with Crown use -- are expected to be released by the Advisory Council on Intellectual Property in late 2004. The inquiries leading to these reports overlapped with aspects of the ALRC's Inquiry but given the ALRC's reporting schedule, it has not been possible to take ACIP's recommendations into account in formulating the final recommendations in Report 99, although the ALRC has discussed common issues with ACIP.

#### **References:**

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## OECD

The 2002 OECD report entitled "Genetic Inventions, Intellectual Property Rights and Licensing Practices (OECD, 2002) considers a variety of issues associated with IPRs and genetic inventions. The study was initiated by the German government in response to political concerns arising from the implementation of EU Directive 98/44 EC on the protection of biotechnological inventions. In formulating its report, a questionnaire approach was avoided. Rather, studies of published literature were performed followed by a two-day workshop held in Berlin on January 24-25, 2002. Over 100 experts from 18 OECD countries attended the workshop. Specifically, OECD member countries sought to identify systematic problems encountered by researchers, firms or clinical researchers in their attempts to gain legal access to genetic inventions and to address public concerns about systematic gene patenting. There is reason to believe that the public's lack of trust in the patent system and to its application to genetic inventions is spreading to the actions of scientists, doctors, universities and government agencies. The purpose of this report is to inform OECD member countries about:

- challenges raised by the proliferation of patents on genes and gene fragments and by the licensing strategies of firms, research bodies and others;
- studies and empirical data to shed light on the economic impact of the IP system and how patenting and licensing practices influence the research process, new product development and the clinical diffusion and use of novel treatments and diagnostics (Walsh *et al*, 2004; Merz *et al* 2002; Cho *et al* 2003; See also, Straus *et al*, 2002).
- the advantages and disadvantages of various policy measures within and outside the patent regime that could be used to address any systematic breakdowns in access to genetic inventions.

In general, the OECD concludes that the patentability of genetic inventions is not fundamentally in question. The available evidence does not support that there exists a systematic breakdown of the licensing of genetic inventions. The few examples cited to illustrate the theoretical economic and legal concerns related to the potential for the over-fragmentation of patent rights, blocking patents, uncertainty due to dependency and abusive monopoly positions appear anecdotal and are not supported by existing economic studies.

A review of the existing literature reveals that there are potential problems associated with the numbers and breadth of gene patents now being issued. Despite a lack of reliable statistics on DNA patents, there is concern that the numbers are rapidly rising and that patent thickets and royalty stacking are real potential problems. In addition, the increased number of patents containing reach-through claims may ultimately require government attention. Empirical studies suggest that there are problems arising over access to diagnostic genetic tests –and there is evidence of broad consensus on the problems encountered by genetic testing laboratories -- although the extent and exact cause of the problems has not been fully elucidated.

Laboratories aim to rapidly adopt new testing methods and improve testing services but are concerned about patents that they find out about after they have implemented new testing methods. Governments are concerned about licensing fees associated with diagnostic tests. The OECD recommends that continued monitoring of the patenting and licensing of genetic inventions should be carried out. Robust economic data must be collected so that it may be used as a basis for action if access issues become more problematic.

Policies may be directed at the IP regime itself, the way patents are administered, or the post-grant behavior of patent holders. There are divergent opinions on which route (or combination of routes) is best. Solutions need to be carefully tailored to rectify problems whilst involving as few unintended consequences as possible. Generally, it was agreed that policy measures should not discriminate against a specific technology or unduly jeopardize incentives to innovate. Questions concerning the appropriate response(s) to the specific challenges raised by genetic patenting persist. Though industry does not favor altering the present protection afforded to genetic inventions, the perceived problem of overly broad patents may be resolvable within existing IP regimes, through reforms of patent administration or simply through opposition procedures (where available) or the courts. Other issues that bear consideration include: the appropriate scope of a research exemption, the role of competition law or compulsory licensing provisions within the patent regime, the role of licensing practice guidelines, the role of patent pools, clearinghouses or collective licensing organisations.

Importantly, the OECD recognizes that **“there is a conspicuous absence of rigorous economic studies that explore the impact of present patenting licensing practices on industry and public research. The literature on patenting relies heavily on case studies and on theoretical legal arguments. OECD countries should address this lacuna” (at 82)**. In addition, there is a clearly recognised need to engage public opinion – especially in areas relating to ethics and access to health care – to facilitate the rebuilding of public opinion in the patent system and its application to biotechnology.

The OECD suggests that future work is needed “to elucidate further the economic impact of the present system of protection, to understand the advantages and disadvantages of various policy solutions and to rebuild public trust. More work at international level might be done in the following areas:

- The collection of data on biotechnology patenting and licensing practices would be an invaluable resource for policy makers. Further monitoring of licensing practices in particular would help to understand, for example, how research delays and transactions costs affect biomedical research. The OECD will conduct a targeted study of the impact of patents and licensing practices for genetic inventions on the availability of genetic testing services in 2002-03.
- The development of a guide for policy makers on the indicators that could be used when performing economic impact studies of patenting and licensing practices for biotechnology inventions would be useful.

- The development of good practice licensing guidelines by and for public research organisations involved in biomedical research. Such guidelines could ideally be developed in concert with industry players.
- A comparative review of possible policy measures being developed to enhance legitimate access to information and technologies would be useful. What are their advantages, disadvantages, and side effects? How likely are they to be used or effective?
- Rigorous economic studies should be undertaken to explore the actual impact of present patenting licensing practices on industry and public research.
- A study of research exemption use and litigation might help to determine the extent to which the current system should (or should not) be reformed (at 83).

**Reference:**

Organisation for Economic Cooperation and Development, GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS & LICENSING PRACTICES, 2002, online: OECD <[www.oecd.org/dataoecd/42/21/2491084.pdf](http://www.oecd.org/dataoecd/42/21/2491084.pdf)>.