CENTRE FOR INTELLECTUAL PROPERTY POLICY

CENTRE DES POLITIQUES EN PROPRIÉTÉ INTELLECTUELLE

Biotechnology and Intellectual Property: Reinventing the Commons

Workshop Report

Montreal, Canada, September 25-27, 2005

Table of contents

I. INTRODUCTION 3

II. CONFERENCE BACKGROUND 4

1. The Beginning: Probes and Influence Diagrams 4
2. Current and Future Research Components 5

III. STRUCTURE OF THE WORKSHOP 6

PART I: GLOBAL IP POLICY INITIATIVES 6

1. The benefit of biotechnology 7
2. The Need to Protect Biodiversity and Traditional Knowledge 9
3. The Need to Regulate Biotechnology and Bio-safety 10
4. The role for Intellectual Property 11
   - *a. Role for intellectual property 11*
   - *b. Countries have different agencies that enforce and manage intellectual property law 13*
   - *c. Problems with intellectual property protection of biotechnological inventions 14*
     - i. Latin American Country Issues 14
     - ii. American, Canadian and Australian Issues 15
   - *d. Proposed policies to address these concerns 16*

PART II: MOVING IDEAS AND RESEARCH INTO THE POLICY REALM 18

1. Incorporating academic research into the policy process 18
   - *a. The researcher / policy-maker relationship is fundamental to accurate policy-making 19*
   - *b. Researchers must target all policy players when communicating research 19*
   - *c. In communicating research, researchers must adopt a language appropriate to the audience 20*
   - *d. Culture affects how research is incorporated into the policy process 20*
2. What aspects of IPMG's research would policy-makers find most beneficial 21
   - *a. Unbiased research 21*
   - *b. Provide practical policy tools 21*

PART III: OPEN SCIENCE: FROM IDEAS TO IMPLEMENTATION 22

CONCLUSION 24

APPENDIX I - LIST OF GUESTS 26

APPENDIX 2 - IPMG PROJECT TIME-LINE 30

I. Introduction

Biotechnology holds the promise of addressing significant human health and nutrition, agricultural and environmental concerns. When appropriately calibrated, the intellectual property (IP) system – the body of laws, business practices, governmental practices and institutions in a nation or region that creates or limits exclusive rights over new knowledge - can help to realize the benefits of biotechnology. It can do so by determining who has exclusive rights over what knowledge, how knowledge is distributed, at what cost, and who makes the decisions.

In making these determinations, IP systems try to manage the competing needs and desires of those who produce and make use of new knowledge as well as those who buy products and services made through the use of this knowledge. Balancing these conflicting interests is not easy: it requires constant review and analysis to keep up with changes in knowledge and new technology. Failure to manage conflicting interests may result in a system rife with inefficiencies, injustices and conflict. Furthermore, in attempting to achieve this balance, IP systems also interact with existing national and international polices for innovation, health and agriculture to produce certain economic and social outcomes. These interactions have not been well explored and are therefore poorly understood. As a result, policy makers do not have the information they need to adjust and implement IP systems so that they achieve desired social, scientific or economic outcomes in biotechnology.

The Intellectual Property Modeling Group (IPMG), an international and transdisciplinary team of researchers[1] based at the Centre for Intellectual Property Policy at McGill University, has undertaken a multi-year project to address the deficiency in understanding about IP systems. The ultimate goal is to help policy makers around the world calibrate IP systems to achieve desired policy goals in biotechnology that benefit society.

As part of this undertaking, the IPMG convened a workshop for policy makers of the Americas on September 25-27, 2005, in Montreal, Canada. The workshop explored creative approaches to IP systems such as open science initiatives and examined ways that the academic

[1] The research team covers the fields of law, management, philosophy, economics, ethics, biology, medicine, and political science.

and policy communities can work together in the area of biotechnology IP. The IPMG invited a distinguished group of international decision-makers from Canada, the United States, Latin America and the Caribbean who occupy positions of responsibility in the policy world, such as members of the judiciary, government ministry officials and science agencies. This diversity of background and opinions allowed for a conversation that moved beyond traditional discipline based assumptions that often characterize and skew discussions related to the IP system.

II. Conference Background

For the past three years, the IPMG has been developing an empirically grounded understanding of the IP system. The goal of the IPMG's research is to expand policy makers understanding of how the system actually functions, to help policy makers creatively use IP systems to achieve desired outcomes related to health and agriculture biotechnology and to provide strategic consultation on design and implementation of IP systems at the national and international levels. The project is unique in that it is a substantive, long term, transdisciplinary effort to understand how IP systems, it is based in empirical research and it aims at producing real tools to inform policy makers.

1. The Beginning: Probes and Influence Diagrams

The IPMG began by investigating inadequacies in the current understanding of how IP systems produce certain social, economic and scientific outcomes. The IPMG first identified assumptions found in the existing legal, management, ethics and economics literature about IP that could not be supported by data. They then developed research tools – called probes – that provide new vantage points from which to examine the IP system. Each probe – including distributive justice, innovation management, knowledge management, economic efficiency, integrity of living things, sovereignty and risk management – offers a new perspective that allows for the formulation of targeted research and policy questions that more fully capture the nuances of the IP system. In moving beyond discipline based analysis and traditional assumptions about the IP system that arise from these disciplines, the path is set for the

creation of a trandisciplinary framework through which to study and evaluate biotechnology patent systems.

In addition to leading researchers to ask more directed questions about how IP systems function in respect of biotechnology, viewing the IP system from the vantage point of the different probes permits the identification of the various factors at play in the IP system and their interrelation. The IPMG was then able to map out how these different factors relate to one another, over what time period and how directly, by constructing an *influence diagram*. Influence diagrams are an especially useful tool to integrate disciplinary knowledge as they create a shared model of a problem and serve to build a common language and knowledge base in order for a group of people from different disciplines to form the same understanding of how the system works. In addition, influence diagrams capture tacit knowledge about different relationships and how these interact with one another.

The IPMG first presented its research at a workshop held in Raleigh, North Carolina in June 2004 and then in Florence, Italy, in October 2004. These workshops provided fora for international and national members of policy communities, academics, members of NGOs and industry to discuss current issues in biotechnology and IP. Whereas the Raleigh workshop concentrated on the workings of the IP system in relation to agricultural biotechnology, the Florence workshop explored health-related biotechnology. At both workshops, participants echoed the concerns that the IPMG identified about the present structure and functioning of the IP system, concluded that the probes were helpful in opening new ways to think creatively about old problems, and strongly supported the development of the influence diagram to better understand how the IP system worked in the biotechnology area.

2. Current and Future Research Components

The IPMG is creating a Domain Map of IP systems, concurrently with the *influence diagram*. The Domain Map classifies all the possible decisions to be made when designing legislation, institutions or in forming business and governmental practices and provides various options for making these decisions. Consequently, policy makers are provided with the different ways of making different decisions when, for example, developing patent law or constructing an institution.

The IPMG is also in the process of collecting empirical data to support the relationships mapped out in the influence diagram. Ultimately, the IPMG will produce a computer simulated model of IP systems in order to validate and predict policy outcomes founded on a number of set variables. Based on these simulations, the IPMG will provide three alternative policy strategies (APS) that show how to design an IP system that either: 1) maximizes the production of new knowledge, 2) helps to develop a scientific infrastructure, or 3) increases access to new products and services. The IPMG's final products will include a report describing the three APSs as well as rankings of how different countries IP systems rate with respect to certain features and comparative IP data across a variety of variable.

III. Structure of the Workshop

The goal of the Montreal workshop was to present the policy community with IPMG's findings to date, examine the state of IP policy in the Americas, discuss the most effective ways to turn ideas and findings into policy and explore open science approaches to biotechnology.

The workshop spanned two days. During the first day, all participants discussed the state of IP policy in the Americas, IPMG's work and how academic research can be turned into policy (focusing on the example of open science). During the morning, presenters discussed IP policy initiatives within their country. Following this session, IPMG presented its research and how it will contribute to current policy initiatives. In the afternoon, the workshop focus shifted to examining how decision-makers could best profit from academic research in IP systems and, more generally, how to foster the translation of ideas into policy. Finally, the day concluded with an example of how decision-makers and academics can work together to explore novel policy options such as the concept of open science and the *'commons'*.

During the second day, the IPMG held a special session for the Latin American and Caribbean participants that aimed at creating a partnership between Brazil, Argentina, Peru and Cuba with respect to biotechnology IP policy.

Part I: Global IP Policy Initiatives

The conference began with reports from Australia, Argentina, Brazil, Peru, the United States, Canada as well as a report on the International Polar Year, in order to provide participants with an overview of the current state of IP issues related to agriculture and biotechnology. The presentations revealed that all the countries represented see benefit in biotechnology and seek ways to promote and regulate it. Many of the countries also exhibit significant concern about the protection of biodiversity and traditional knowledge, particularly those from Latin America and those with a substantial indigenous population.

While all countries represented believe that IP systems play an important role in developing a strong biotechnology sector, many of these countries are concerned about the current structure of the IP system. In particular, Latin American countries identified problems related to technological dependency, inadequate capacity in areas of IP management, impeded access to patent databases, insufficient repositories as well as concerns about foreign patenting of inventions derived from local resources without any financial return to the country of origin. Meanwhile, Australia, Canada and the United States appear more concerned with problems of access to innovation and quality of patent examination and granting procedures. Countries also identified efforts to address these concerns. These ranged from examining alternative approaches to IP (e.g. patent pooling and open source initiatives), recommending patent law reform proposals, forming commissions to examine problems with the IP system and providing training in the area of IP.

1. The benefit of biotechnology

All of the countries represented have policies that seek to promote biotechnology. For example, Argentina's has built a strong biotechnology industry and has produced inventions such as a foot-and-mouth virus detection system that serves to distinguish between vaccinated and infected animals and genes for the multiplication of the Mal de Río Cuarto Virus (considered the most damaging to Argentina's corn crop leading to millions of dollars in losses). Argentina's private biotechnology agro-alimentary sector has also grown significantly. Genetically modified (GM) crops, in particular soy bean crops, are Argentina's main export. Although Monsanto originally developed these GM seeds, they are not patented in Argentina

and so the production costs are low. However, it was pointed out that Monsanto is currently trying to impose levies on all shipments of GM seeds to Argentina. There are approximately 85 nationally-based small to medium size biotechnology companies with a larger number of the large foreign companies. As there is very little venture capital available in Argentina, success is based on survival of the fittest. For example, vaccines for salmon, the production of growth hormones and cloned transgenic cows have all proved very lucrative innovations.

Argentina created the National Commission for Agricultural Biotechnology (CONABIA) in 1991 to promote agricultural biotechnology in the country. The Commission, made up of public and private sector representatives, engages in both local initiatives and regional cooperation with other Latin American countries, for example, by extending training to countries in the region. Other international efforts include the Argentinean-Brazilian Center for Biotechnology (1986), Bilateral Cooperation with India (2004), the European Union-Mercosur Agreement on Biotechnology (2005), the Argentinean-Algerian Center for Biotechnology (2005) and the Bilateral Spanish-Argentinean Center for Plant Biotechnology 2005.

Similarly, Peru has placed considerable emphasis on promoting biotechnology. For example, Peru's National Long Term Agreement of Governability includes biotechnology as one of its seven policy priorities and CONCYTEC – the government science funding agency – established biotechnology as one of the five strategic science and technology areas to promote and to fund. In particular, the country has focused on using modern biotechnology techniques such as cell/tissue culture, DNA handling and transformation, molecular markers, stem cell manipulation and cloning. The country also encourages use of its rich biodiversity in biotechnological research. CONCYTEC, the Ministry of Production and the National Center for Strategic Planning have joined forces to prepare a National Plan of Biotechnology and Genetic Engineering in order to focus and foster R&D in biotech-based enterprises. Furthermore, the National Plan of Biotechnology and Genetic Engineering includes the creation of a National Centre of Biotechnology and Genetic Engineering as the central pivot of a research system supplying services, technical and training support. The National Centre will operate through a foundation with private sector participation and will provide logistic support to companies and to the biotechnology regulatory system.

Recently, Peruvian representatives from industry, agriculture, export, the legislature, health, universities and regional governments held public meetings to discuss the biotechnology plan, the law promoting biotechnology and the biosafety regulatory framework. It seems that a significant number of scientists, high level governmental decision-makers and private sector leaders support the proposed law for the promotion of modern biotechnology. The main opposition to the law appears to come from environmental organizations connected with Greenpeace and other international non-governmental organizations (NGOs) that oppose GM crops.

However, while the growth of GM crops in Argentina, Peru and Cuba is widespread and growing, the experience of the United States over transgenic wheat – for which regulatory approval has not been granted for use – may be important to watch. Australia faces a unique situation in that while there is a rich resource base, from the 1970s with IBF technology to stem cell technology and genetic research, the market for these technologies is far away and so capacity for growth is limited.

2. The Need to Protect Biodiversity and Traditional Knowledge

A second policy concern is the protection of biodiversity and traditional knowledge. Brazil, Argentina and Peru are all rich in biodiversity and traditional knowledge. Australia – unique among industrialized countries in this respect - also possesses considerable biodiversity. In Canada, First Nations also hold a great deal of valuable traditional knowledge.

In 2001, the Brazilian government adopted a provisional measure aimed at establishing a public, as opposed to a private, law approach to protecting traditional knowledge and biodiversity. As part of this initiative, the government defined "genetic patrimony" as information of genetic origin that belongs to the State under the *Convention on Biological Diversity*. The government created a Council for the Administration of the Genetic Patrimony to administer Brazil's genetic patrimony with the mandate of 1) elaborating guidelines on benefit-sharing, 2) authorizing commercial and non-commercial contracts as well as research using genetic patrimony, and 3) authorizing material transfers of genetic patrimony.

Brazil's approach is designed to provide Indigenous communities and local communities with the assurance that the origin of their traditional knowledge will be

recognized in all publications, uses, exploitation and dissemination. A party that does not have authorization from the originators of the knowledge may not a) use, test, research or make commercial use of traditional knowledge, b) disseminate, transmit or forward data on traditional knowledge, or c) receive benefits from the economic exploitation of the traditional knowledge. Unfortunately, there has been a general lack of commitment to protecting local genetic resources, as the Brazilian patent office apparent failure to comply with the rules illustrates.

Peru similarly has a rich biological diversity that is being largely exploited by private firms and public R&D centers in developed countries without official permits (e.g., alpaca, ayahuasca, yacon, maca, others). Native Peruvian plant species and their components have been patented in developed countries without acknowledgment of the indigenous and traditional knowledge's origin. Peru is thus moving on expanding Decision 391 of the Andean Community[2] – which deals with sovereign rights and fair and equitable sharing of benefits derived from access to biodiversity resources and native knowledge – to regulate the use of indigenous knowledge. This law has yet to be put into place.

In Canada, First Nations and Inuit hold significant traditional knowledge. The importance of protecting this traditional knowledge will be examined through the International Polar Year (IPY), an international programme of coordinated, interdisciplinary, scientific research and observations in the Earth's Polar regions and their peoples. The IPY has prepared a data policy that respects and safeguards traditional knowledge and cultural heritage, encourages timely, free and unrestricted exchange, assures quality control, assures ease of access to data and preserves data in perpetuity.

3. The Need to Regulate Biotechnology and Bio-safety

The consideration for exploiting biodiversity is its protection through biosafety legislation. Several countries have enacted regulations to control biotechnological research and end products.

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[2] Andean Community Commission, DECISION 391: Common Regime on Access to Genetic Resources on line at: http://www.sice.oas.org/trade/JUNAC/decisiones/DEC391e.asp

Brazil recently enacted legislation regulating biotechnological research and release of GM Organisms[3] that replaced its earlier 1995 law. This regulation provides that two governmental bodies have exclusive jurisdiction over biosafety-related issues. The first of these is the National Bio-safety Council which is in charge of: 1) establishing the principles and guidelines for federal agencies with jurisdiction on the matter, 2) analyzing, on the request of the National Bio-safety Technical Commission (CTNBio), the social and economic impact of the commercial use of GMOs, and 3) making decisions about the permissibility of activities that involve the commercial use of GMOs. The second body is the CTNBio, a branch of the Ministry of Science and Technology. CTNBio is a multidisciplinary expert panel providing the federal government with technical assistance in respect of Brazil's National Bio-safety Policy for GMOs and is responsible for establishing technical safety norms in respect of research and commercial use of GMOs. It should be noted that, despite being required by its constitution, Brazil's biosafety framework does not require any environmental impact study prior to release of GMOs.

Like Brazil, Peru has a biosafety regulatory system for biotechnology that it implements through its CONAM (the National Environmental Commission) with funding from GEF-PNUMA. Peruvian Bio-safety Law[4] and Regulation[5] set out the relevant regulation of the safety of GMOs. Regulatory regimes are similarly being established for agriculture, food, and fisheries.

4. The role for Intellectual Property

a. Role for Intellectual Property

Each of Australia, Argentina, Brazil, Peru, Cuba, the United States and Canada has IP laws that protect biotechnology to varying degrees. Some countries, such as Peru and Australia, have also entered into Free Trade Agreements with the United States that contain provisions above and beyond was is required by the World Trade Organizations' Agreement on Trade Related Aspects of IP Rights (TRIPs), thus limiting flexibilities in designing and implementing their IP laws.

[3] Law 11.105/2005
[4] Law 27104 of May 1999 *On the prevention of risks derived from the use of biotechnology*
[5] D.S. 108-2002-PCM

Brazil's legal framework for IP protection consists of three primary laws: the Industrial Property Law[6], the Plant Varieties Act[7] and the Provisional Measure of 2001 that regulates access to genetic resource and associated traditional knowledge. On the International stage, Brazil is a member of the Paris Union, the UPOV 1978 Act and TRIPs. Brazil's IP law is also now TRIPs compliant, ending a fifty-year prohibition of the patentability of pharmaceuticals, food and chemical products. Plant varieties and animals are not patentable but transgenic microorganisms are patentable.

While Brazil is a member of the 1978 UPOV Act, it has not set up a genuine "sui generis" regime of protection of plant varieties, as India has done. Brazil protects corporate-originated cultivars, "stant" varieties (landraces) and, despite not yet being a member of UPOV 1991, protects essentially derived varieties.

Biotechnological innovations are largely unpatentable, at least in practice, in Peru. While Decision 345 of the Andean Community[8] permits the patenting of new plant varieties, the Peruvian Patent Office nevertheless excludes GM varieties from patentability. According to Article 15.b of Andean Decision 486[9], genes and nucleotides are also not patentable.

Peru's laws are nevertheless likely to soon change as a result of the negotiations of a Free Trade Agreement between Peru, Colombia, Ecuador and the United States. Nevertheless, Andean countries remain firm in rejecting United States' requests to extend patent protection to plants and animals, human or animal diagnostics and surgery or therapeutic procedures. Additionally, Andean countries also resist providing patent protection over new uses and new methods of using known products, in particular pharmaceuticals. On the other hand, the United States has agreed to consider the use of an Andean biodiversity information database in the Patent and Trademark Office's examination of patent applications.

Australia, Canada and the United States also provide patent protection over biotechnology innovations. The Supreme Court of Canada has largely developed the law in

[6] Law n.9279/1996
[7] Law n. 9.456/1997

[8] Decision 345 Common Provisions on the Protection of the Rights of Breeders of New Plant Varieties, on line: http://www.comunidadandina.org/ingles/treaties/dec/d345e.htm

[9] Decision 486 of the Andean Community on Common Intellectual Property Regime, on line: http://www.sice.oas.org/Trade/Junac/Decisiones/DEC486ae.asp

Canada in two recent cases; *Harvard College*[10] and *Monsanto*[11]. Although initially the Court held that plants and animals are not patentable (*Harvard College*), it provided cell and DNA sequence patent holders with *de facto* rights over whole plants and animals (*Monsanto*).

It is interesting to note that Australia is the first developed country to enter into a Free Trade Agreement with the United States that contains a TRIPs plus provision (that is, provides for higher minimum standards than does TRIPs). To date (having only entered into force on January 1, 2005), the main impact of the Australian-United States agreement has been to reduce TRIPs flexibilities. For example, the agreement only allows for exclusion of patentability for public order, morality and methods of medical treatment. Consequently, it will no longer be possible to exclude plants and animals from patentability and compulsory licensing provisions will only be available on grounds of anti-competitive conduct, public use and national emergency. Although the United States and Canada are part of a free trade agreement, the chapter on IP is similar to the requirements contained in TRIPs.

b. Countries have different agencies that enforce and manage intellectual property law

In order to enforce these IP laws, different countries use different agencies. In Argentina, the National Institute of Intellectual Property (INPI) and in particular, the Agency for the Promotion of Science and Technology, deals with these issues. While the INPI grants patents, the Agency focuses on the financing of patent applications in public institutions and SMEs, the training of experts in IP management and the providing of access to patent databases. The use of public databases is particularly important in order to perform thorough examinations that permit inventors and their sponsors to assess the likelihood of obtaining a patent. The agency administers two funds to promote innovation: the FONCyT[12], which funds innovation in public institutions, and the FONTAR[13], which focuses on funding enterprises and start-ups.

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[10] *Harvard College* v. *Canada* [2002] 4 SCR, on line : http://www.lexum.umontreal.ca/csc-scc/en/pub/2002/vol4/html/2002scr4_0045.html
[11] *Monsanto Canada Inc.* v. *Schmeiser* [2004] 1 SCR, on line : http://www.lexum.umontreal.ca/csc-scc/en/pub/2004/vol1/html/2004scr1_0902.html
[12] Fondo para la Investigacion Cientifica y Tecnologia, on line : http://www.agencia.secyt.gov.ar/foncyt.php
[13] Fondo Tecnologico Argentino, on line : http://www.agencia.secyt.gov.ar/fontar.php

In Brazil, the Brazilian Patent and Trademark Office (INPI) is responsible for the granting of trademarks, industrial designs, patents and for the registration of technology transfer, licensing and franchising agreements. INPI is also in charge of examining and granting patents for all inventions, including transgenic microorganisms. Furthermore, it maintains a database of patent applications in Brazil. Interestingly, this database reveals that the majority of biotech-related patent applications filed since May 1996 are held by foreign corporations and entities.

c. Problems with intellectual property protection of biotechnological inventions

While countries assert the importance of IP, they also identify problems with the system that result from having to adapt it to new technologies and, in the case of the Latin American countries, from applying a system developed by industrialized countries to countries that are in the midst of developing.

i. Latin American Country Issues

Argentina and Peru identified similar concerns with the IP system. These problems include the high costs of patenting, lack of awareness about the patent system that has an economic impact on public research institutions, lack of harmonization in IP regulation between institutions, limited access to patent databases, the absence of a repository for microorganisms and lack of evaluation of potential markets for new innovations.

These problems are evident when one examines the fact that in 2000, Argentinean residents filed 1,062 patents but the patent office granted only 145 applications. This can be compared to Brazil's issuance of 3,022 patents to Brazilian residents out of 8,807 applications in Brazil and the United States' grant of 85,070 patents to United States residents out of 164,795 patent applications in 2001. One of Argentina's problems in the biotechnology area is the lack of repositories for biological material. To patent a biotechnology innovation, a sample of the organism must be deposited in a repository but these repositories are difficult to come by in Argentina and so samples must be sent abroad. This increases the cost to Argentinean inventors of patenting their inventions.

Similar statistics exist in Peru. The number of patent applications filed by Peruvian residents for each 10,000 inhabitants has decreased from 0.07 to 0.01 between 1978 and 2002, while neighboring countries like Ecuador and Chile have increased their numbers during the same period. Meanwhile the number of patents requested by non-Peruvian residents compared to patents requested by residents has increased from 4.78 to 26.6 between 1977 and 2002.

In Brazil, problems with the IP system relate to the burdensome structure for obtaining patents and the contradictory nature of the rules that apply to patents. These problems work against a more general lack of a consolidated industrial policy based upon the sustainable use of the Brazilian biodiversity and associated traditional knowledge. In fact, the regulatory framework largely stimulates misappropriation of local biodiversity, limits Brazilian research in the field of biotechnology and protects foreign biotechnological asset holders. In addition, many of these issues are still very new and civil society is not involved in discussions, to the point that IP is not even studied in law school.

In general, these countries also encounter problems in exporting products that, although inexpensive to produce within the country due to lack of patents, are patented in other countries. For example, Argentina uses Monsanto's genetically modified seeds but faces problems in exporting its crops.

ii. American, Canadian and Australian Issues

Developed country issues with the IP system focus on questions of access to patented inventions for further research and development and adapting current laws to respond to the challenges that new technologies present.

Gene patents pose the greatest concern in many developed countries because a gene patent can give broad monopoly control over a wide range of research tools and diagnostic tests. The issue of gene patents was most recently the centre of a report that the Australian Law Reform Commission published in June 2004 (although to date there has been no governmental action). The Report's main conclusions are that 1) any reform to patent law should be nuanced, 2) there is a fundamental need for an experimental use exemption, and 3) direct regulatory issues ought to be addressed, for example, the improvement of IP management at public sector organisations and funding agency.

Gene patents have also been at issue in Canada where there have been calls for Parliament to clarify and modify the *Patent Act* to address gene patents. The current approach taken in Canada is that a DNA sequence can only be patented if it has an evident (to one skilled in the art) or described function.

A related issue is that of patent licenses and access to these licenses in order to prevent research and development from being blocked. In Australia, much research has been conducted through a series of surveys and interviews, which revealed that industry finds working solutions to access problems and tends to ignore patents that they believe are invalid. Public sector organizations also tend not to enter into a great number of licenses.

d. Proposed policies to address these concerns

Countries have responded to these concerns in various ways. In Argentina, the Office for IP management (OPI) and, in particular, the Agency for the Promotion of Science and Technology, has been charged with handling the IP system. In Peru, the government organized public meetings with representatives from industry, agriculture, labour, physicians, universities and regional governments to discuss the government's biotechnology plan, its promotional law, the biosafety regulatory framework and IP. However, Peru is reluctant to alter its IP legislation because of its membership within the Andean Community that requires the consensus of its 5 members before any change can be brought about. Likewise, in Brazil, any change will take a significant amount of time. Interestingly, Cuba has taken measures to encourage education about IP that even extend to publishing children's books about IP.

In Australia, concerns about gene patents and blocking patents led to calls for the creation of compulsory licensing provisions, research exemptions and for exploration of alternative or parallel ways of protecting inventions. The Australian Law Reform Commission suggests that the creation of such an exemption would make research tools and basic scientific research more accessible. The Commission also supported a compulsory licensing provision that would help prevent the use of patent rights to undermine health. Canada and the United States have such compulsory licensing provisions. Compulsory licensing in this context aims to provide a credible threat that can be used to discipline patent holders who would otherwise use their rights against the public interest. Other developed countries have similar provisions. For

example, the United States has a broad governmental use provision upon which it often relies whereas Canada's s.19 of the *Patent Act* provides for compulsory licensing even though it has never been invoked.

Recently, Canada also enacted a compulsory licensing provision to encourage the supplying of essential medicines to developing countries. Following the Doha and Cancun agreements at the World Trade Organization (WTO), Canada responded relatively rapidly to implement changes that would "facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries". The amendments stipulate the conditions under which the government can issue a compulsory licence to a pharmaceutical manufacturer for the manufacture and export of a patented drug to developing and least-developed countries.

Apart from these formal means of addressing the series of concerns set out earlier, some organizations have developed alternative or parallel ways of protecting inventions. For example, CAMBIA, a BIOS Initiative (Biological Innovation for an Open Society), is developing and validating a new means for cooperative invention, improvement and delivery of life sciences technologies by drawing inspiration from the open source software movement. It does so through the creation of a protected commons whereby owners provide licenses to their technologies within a framework of reciprocal licensing. A second response has been to create patent pools in the biotechnology field. In Canada, the British Columbia Cancer Association has been a leader in this effort through the licensing of its patent over the SARS genome to Health Canada. Health Canada in turn is to bring in other patents to create a pool to support research and development related to SARS. Health Canada is currently establishing the pool.

There have also been several policy initiatives in the United States to deal with questions of access and inefficiencies in the patent system. The Public Intellectual Property Resource for Agriculture (PIPRA), an organization based at the University of California at Berkeley works to ensure access to IP in order to facilitate the development and distribution of improved staple crops that can satisfy developing country needs. The development of new crop varieties through biotechnology research in agriculture depends on access to multiple technologies that are often protected by IP rights, fragmented across many institutions in the

public and private sector. To address this, PIPRA is creating a clearinghouse for patents in the agricultural sector through a collaboration of public and private sector actors.

The United States has recently introduced legislation to reform its patent law. The original proposal for reform included a third party submission procedure for prior art, a post-grant opposition process with two windows for launching opposition (one, immediately after issue and a second at any time later), limitations on the availability of preliminary injunctions, adoption of a first-to-file rule (as opposed to the current first-to-invent rule), the requirement that all applications be published after 18 months (starting from the priority date) and a reinvigoration of the duty of candour. Despite the introduction of the legislation, it remains to be seen whether the proposed reforms will actually pass into law. The sub-committee evaluating the proposed reforms recommended dropping the provisions dealing with injunctive relief and with the proposed second window for post-grant oppositions. There is a feeling that the reform bill will likely be set aside for the moment due to other pressing issues in the United States.

Likewise, it remains to be seen whether the Canadian Parliament will heed the pleas of the Supreme Court of Canada, academic and public-policy commentators and others to explicitly address the issue of biotechnology patenting, particularly patents over human genes and over plants and animals, in a comprehensive manner. The issues are likely to become increasingly challenging as genetic technologies enter into the health system in a more significant manner and as Canada grapples with its regulation of embryonic stem cells in research.

Part II: Moving ideas and research into the policy realm

1. Incorporating academic research into the policy process

The overview of biotechnology IP policy in various countries clearly reveals that many different organizations and researchers, from both within specialized governmental institutions (e.g., the Australian Law Reform Commission and the European Commission and National Academies of Science) and academia, have conducted research on patent policy. The workshop participants therefore asked how decision-makers could make use of this knowledge and what

researchers and decision-makers can do to facilitate knowledge translation. During discussions, participants identified several factors, discussed below, that facilitate knowledge transfer.

a. The researcher / policy-maker relationship is fundamental to accurate policy-making

Participants agreed that the relationship between the researcher and decision-maker is fundamentally important and goes two-ways. That it, researchers should not only concentrate on informing decision-makers of current issues and approaches in biotechnology IP, but should be open to input from decision-makers on which questions to research and on which methodologies are acceptable to decision-makers. Such a relationship builds on the respective strengths of researchers, who conduct research that decision-makers see as free of bias (or at least, as free of inherent bias as is possible), and decision-makers who understand the policy environment within which IP policy is made. Communication is critical to the functioning of this relationship. For example, if academic research is restricted to technical journals, filled with jargon, poorly or tediously presented, takes to long to read or makes no clear recommendation, then decision-makers will not be able to draw upon it in forming policy. Such research is essentially 'lost' within the decision-making process.

This does not mean, however, that all academic research must be aimed at decision-makers. There is much merit in academic work that pushes the boundaries within the particular field of knowledge. Nevertheless, institutional rules and practices ought to facilitate knowledge translation for researchers desiring to see their work translated into policy. For these researchers, the ability to communicate their research, particularly by providing practical policy recommendations that flow from the research, is essential.

b. Researchers must target all policy players when communicating research

Several different governmental institutions affect policy in the area of biotechnology IP. For example, in the United States, Congress, the judiciary, the executive and several administrative agencies (such as the National Institutes of Health and Department of Agriculture) all have jurisdiction over aspects of IP policy. Some participants noted that the

best way to bring about policy change is to address research questions in a way that captures the interests of as many of these different institutions as possible.

Simply engaging different governmental institutions is not sufficient to translate knowledge. What is equally important is to address the various forms of conversation surrounding biotechnology IP within these institutions. There are, after all, many different target audiences within government decision-making processes: civil servants, politicians, appointees, staff, other interest groups, citizens, and the press, to name but a few. In focusing on these different target audiences, one must consider their characteristics, specifically, their knowledge base, their objectives and whether they are repeat players. One must also take into account the intersection of discourses and how to resolve the different and sometimes contradictory interests of actors within those different discourses. For example, if the computer industry seeks one policy and the pharmaceutical industry lobbies for the opposite policy (for example, with respect to the structure and timing of an opposition process), research needs to investigate how best to balance and in some cases trade-off interests between these actors.

c. In communicating research, researchers must adopt a language appropriate to the audience

Workshop participants noted the importance of communicating research in a language that can be understood by the various target audiences. This involves providing background information that illuminates an existing concern or raises a new concern, explains the context in which the concern arises and sets out possible policy outcomes. The researcher needs to also create a link between the information provided and the values underlying the particular concerns so as to enable decision-makers to understand and evaluate the differing claims put forward and the rationale behind the researcher's proposed solution. Researchers should, at bottom, answer the following question: what is the incremental benefit, the hurdles facing reform and the basis for opposition to compromise?

d. Culture affects how research is incorporated into the policy process

Cultural traditions also dictate the ways in which research may be incorporated into policy. For example, in Brazil, it is difficult for researchers examining the IP system to be

viewed as neutral, particularly since NGOs generally see IP as a negative force and thus view groups researching IP as working contrary to the public interest. Similar views exist throughout Latin America whereas NGOs in Canada and the United States tend to be less homogeneous in respect to their views of IP systems.

In order to maximize the chances that those involved with policy making accept the results of academic research, it is vitally important that researchers not only are, but are perceived as being, independent of any institutional or financial bias. For example, the IPMG has gone to great effort to ensure that its researchers represent a variety of views, that it engages government departments with differing interests, consults with different non-state actors from industry to public-interest NGOs, uses a peer-reviewed methodology and does not rely on direct industry or NGO financing. Consequently, IPMG, as an independent research community, has more traction in presenting solutions and trade-offs, especially when it presents information in a way that is accessible and useful to all participants.

2. What aspects of IPMG's research would policy-makers find most beneficial

a. Unbiased research

Participant decision-makers clearly stated that the IPMG's research will provide them with significant benefit. Generally, decision-makers do not have the time they would like to conduct research themselves and thus appreciate having access to unbiased, well substantiated research. There is also often a gap between what information and studies decision-makers need and what is available. Participants agreed that IPMG can play a significant role in filling this gap with respect to biotechnology IP systems.

b. Provide practical policy tools

Decision-makers stated that they benefit most from research that is not only theoretically grounded but that also provides them with practical tools. The IPMG's Domain Map that lays out different policy options and case-studies that provide insight into acceptable trade-offs, are most desirable as they increase the capacity and the speed of the decision-making process. These tools focus on what is key to decision-making: not on what *should* be

the policy result but on *how* to arrive at an acceptable result. Research that indicates which questions to ask and the frameworks within which to answer those questions enriches the decision-makers' understanding and appreciation of issues and trade-offs.

There was significant interest in case studies, particularly if supported by qualitative and quantitative data. Case studies provide insight into the possible policy implications of a given approach.

Part III: Open Science: From ideas to implementation

In order to more deeply focus on knowledge translation between the research and policy communities, workshop participants focused on one particular example, that of open science initiatives. As discussion of open science mechanisms has started to appear in the academic literature, the question arises about how these academic discussions can be shared with decision-makers.

Open science involves a method of disseminating the results of scientific research that permits for simple and low-cost access to scientific work in order to not only expand knowledge but to translate that knowledge into concrete products and services. Open science initiatives build on the ideas of the open source movement in which software is made freely available to programmers who build and expand upon it and who agree to distribute the results of their efforts to others on the same basis. Similarly, an open science initiative – CAMBIA being an early-stage example of such an effort – would develop mechanisms through which to distribute biotechnology to the research community in an efficient and inexpensive manner that requires researchers drawing on that technology to contribute resulting technology back in the same manner.

Both open science and open source initiatives build on the notion of the 'commons' or 'public domain'. The commons was originally developed as a complement to the market. The commons is a regime for creating and managing value through non-market means in which information and knowledge are made available for use by all takers. It constitutes a community of people that agrees to abide by a common set of rules over the sharing of resources and the allocation of benefits deriving from the use of those resources.

According to David Bollier, discourse surrounding the public domain originally envisioned an open, non-commercial space of activity with materials freely available to all. Individuals could obtain protection over their own creative efforts despite using information from the public domain. Thus, the public domain divided the world into two. First were those new ideas with commercial value over which creators had proprietary rights. Second were the older ideas that fell within the public domain. This was viewed as something of a junkyard filled with works of little value.

This view has increasingly come under attack in academic scholarship and among NGOs as researchers come to see the public domain as containing valuable ideas and knowledge for ongoing research. Thus, the division of the world into ideas with value and those without is highly artificial. There is value not only in the knowledge that exists in the public domain but also in the fact that this knowledge is freely accessible by current researchers. Thus, there is value in protecting the public domain as something separate and apart from the market. The grant of excessively broad property rights and monetarization of resources within the public domain can be expected, over time, to lessen innovation, competition and public access by removing the facultative capacity of the public domain to encourage research.

The commons or public domain can thus be understood as standing beside the market in providing incentives to innovate. This idea was given life with respect to the Internet and through the creation of such initiatives as open source software, listservs and collaborate websites, instant messenger, peer-to-peer file sharing, wikis, weblogs and open repositories of public domain materials like Internet Archive.

Currently, some universities, scientific disciplines and academic journals have adopted a commons approach in the natural and life sciences to further values that they hold dear: sharing, collaborating and open debate. New software architecture (e.g. websites and web logs, such as NASA's Click workers, invites Internet users to identify and classify craters on Mars based on satellite images), innovative legal structures (e.g. open source licenses such as the General Public License for software development) and institutional mechanisms (academic institutions and independent organizations that take the initiative to create their own commons) open up the possibility of a commons approach in the sciences.

Researchers have examined various forms of open science in the biological sciences such as patent pooling, open source journals and licenses similar to the General Public License used in the open source movement. So far, relatively little work has been done on the actual implementation of these mechanisms as most research has looked at their general structure and compatibility with legal frameworks such as IP and competition law.

For decision-makers, this level of analysis is not sufficient. They require more knowledge about the form, consequences and implementation of science commons. The analysis they seek needs to contextualise the commons. For example, in examining the role of the commons and its relationship with scientific progress and with the market, they need research that makes clear the variety of interests and motives involved in biotechnology research and development. For many actors, IP rights may provide the necessary motivation either for conducting research or in developing and commercializing the results of that research. One should not assume that either a commons or a market-based approach works equally well in areas of basic and of applied science. It may be that each plays an important role in different areas of the value chain.

Before relying on any method to provide the incentives necessary for scientific progress and dissemination, there is a need for a greater empirical understanding of how the market and the commons actually function. It is important to understand whether market-based and commons approaches are mutually supporting or whether one displaces the other, whether market forces work well to support basic research and whether commons approaches facilitate dissemination. Further work is also necessary to understand whether thinking about open source can easily be translated to science given significant differences in investment, technology life-spans, the areas upon which the technologies act, ethics and institutional structures between the Internet and biotechnology.

Even assuming that it should be adopted, decision-makers asked for guidance on how to implement a science commons. Should it be created through a change to IP legislation, government funding policies, or the creation of new institutions? Any successful knowledge translation between decision-makers and researchers would need to address these issues.

Conclusion

Both researchers and decision-makers play critical roles in advancing policy-making in the IP field. Decision-makers need to be open to developments in academia while academic researchers need to understand the policy-context in which decision-makers act. Working collaboratively, academic researchers and decision-makers can better specify questions that require investigation, develop methodologies through which to answer those questions and propose contextually-appropriate policy recommendations.

The research community must acknowledge that research can take different forms. While some researchers engage in developing fundamental knowledge that is shared within their community, others aim at translating their academic knowledge into policy. These latter researchers must place importance on not only communicating their work in a manner that is understandable to decision-makers, but must also actively engage decision-makers to help determine questions that require investigation and to structure their research products to meet decision-makers' needs for context, trade-offs and recommendations.

The IPMG research team benefits from continued discussion with decision-makers within a variety of governmental institutions to find ways to share its knowledge and research tools. In the short term, IPMG's Domain Map and case studies will provide decision-makers with contextual and empirically grounded tools to assist in policy formation. In the longer term, the expertise of the IPMG and its more general research platform offers significant potential to decision-makers working in the field of biotechnology IP.

APPENDIX I

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APPENDIX 2
IPMG PROJECT TIME-LINE

Conceptualisation of Project	Fall 2001
Building common vocabulary, challenging existing disciplinary assumptions	Spring/Summer 2002
Publication of Trends in Biotechnology (article on assumptions)	Summer 2003
Identify 7 probes to cut across disciplinary silos	Summer/Fall 2003
First workshop in Raleigh on Ag-Biotech; review methodology and probes	Summer 2004
Complete case studies based on 1) farmer growing patented canola and 2) on patents on breast cancer genetic test	Summer 2004
Publish articles in Public Affairs Quarterly. Identify assumptions and propose probes	Fall 2004
Complete influence diagram map	Spring 2005
Commence empirical work	Spring 2005
Complete case study on plant derived vaccines	Summer 2005
Policy-Makers from the Americas workshop	September 2005
Publish plant derived vaccines case study	Fall 2005
Commence Bill C-9 case study	Fall 2005
Workshop on APS1 (maximizing short to medium-term innovation levels)	Fall 2005
Commence internal allocation of research funds case study	Spring 2006
Complete Domain Map	Spring 2006

Complete empirical work	Summer 2006
Workshop on APS2 (Developing a scientific infrastructure)	Summer 2006
Test APS1 through Dynamic Simulation Model	Fall 2006
Test APS2 and APS3 through Dynamic Simulation Model	Winter 2007
Workshop on APS3 (Maximizing access to existing and future innovations)	Spring 2007
Draft Report	Fall 2007
Final Report	Spring 2008