



PRACTICES, POLICIES AND POSSIBILITIES IN LICENSING IN HUMAN GENETICS

Prepared by
The Innovation Partnership for Health Canada

By Tina Piper & E. Richard Gold

April 21, 2008



TABLE OF CONTENTS

| | |
|---|-----------|
| EXECUTIVE SUMMARY | 3 |
| I. INTRODUCTION | 5 |
| II. BACKGROUND..... | 6 |
| THE LAST 5 YEARS | 6 |
| IS THERE AN ACCESS PROBLEM? | 9 |
| (a) <i>Introduction</i> | 9 |
| (b) <i>Telling Policy Stories</i> | 10 |
| III. THE TTO NEXUS..... | 14 |
| TTO POLICY FORMULATION..... | 15 |
| TTO METRICS | 16 |
| TTOs IN THE FUTURE..... | 17 |
| IV. ACCESS POLICY-MAKING AND INITIATIVES..... | 19 |
| TTO AND UNIVERSITY-BASED INITIATIVES | 19 |
| INTERNATIONAL POLICY-MAKING | 20 |
| LOCAL POLICY-MAKING | 22 |
| OPEN ACCESS INITIATIVES | 23 |
| V. MOVING FORWARD: CONCLUSIONS AND NEXT STEPS..... | 24 |



Executive Summary

The goal of this study and the accompanying workshop is to identify how technology transfer practices can optimize health outcomes in addition to yielding other social and economic returns to Canada in light of new genetic technologies. This report surveys a recent history of access-related policy developments and incidents. It concludes that while a range of policy initiatives have sought to ensure broad access to new health-related technologies through licensing terms, those policy initiatives have not necessarily been broadly adopted by constituents and this had led to continuing problems. We investigate and survey the practice and future of Technology Transfer Offices who are most directly responsible for licensing technologies. We conclude that TTOs sit within a web of policy-making organizations and that it is this web as an integrated whole of technology management, not just TTOs, that must be mobilized in order to overcome concerns of technology transfer and access. We then survey existing access initiatives at TTOs, universities, and non-governmental organizations as well as policy-making efforts internationally and domestically concluding that while a number of these initiatives are underway, we need to share information, best practices and enable integrated research to understand the efficacy of these endeavours. Finally, we suggest a number of points of intervention to enable the implementation of broad access principles in health related technology licensing. We point to the importance of revising the metrics that governments and institutions of higher education use to assess TTO performance; the leadership role that senior university administration and government departments can play in this transition; the importance of involving the researcher through requirements attached to grants of funding; an increased role for specialized legal assistance to preempt access problems from arising in complex contracting situations; the need for mechanisms to share experiences from civil society, international and other domestic organizations (including TTOs); and we propose the establishment of an independent broker in Canada who can mediate disputes that threaten to limit access to valuable health-related innovation. This final recommendation is reinforced by the results of the



workshop held by Health Canada where participants suggested the formation of a committee or working group to draft model licenses and/or licensing best practices for a Canadian audience



I. Introduction

The goal of this study and the accompanying workshop is to identify how technology transfer practices can optimize health outcomes in addition to yielding other social and economic returns to Canada in light of new genetic technologies. This report, as part of the study and workshop, aims at accomplishing four things: first, to identify policy issues and initiatives, as well as assess the status of ongoing research in the area of licensing innovative health care technologies; second, to evaluate the impact of licensing decisions and business models on healthcare delivery; third, to consider the identity, perceptions and plans of the key players involved in technology transfer; and finally, to identify and consider promising mechanisms to implement best licensing practices in the future.

This study blends a literature search identifying technology transfer concerns about health care research and access to it with empirical research by the authors and their research group (the Intellectual Property Modeling Group) that includes interviews of key actors. The study will be supplemented by the outcomes of a workshop of key actors from across Canada involved in technology transfer policy. The study is divided into four parts. First, we summarize key moments when the transfer of health technologies has affected health policy over the past five years. The report also considers in this part the evidence of ‘access’ barriers to those technologies caused by patents and licensing practices. Second, drawing from that foundation we identify the current issues linking technology transfer and health, discussing in particular the role of Technology Transfer Offices (TTOs) and other key actors in addressing those questions. Third, we survey the landscape of novel licensing initiatives to facilitate access at the level of TTOs, national and international bodies as well as open access licensing endeavours. Finally, we suggest steps available to those actors and other traditionally less involved parties to better adapt Canadian technology transfer practices to the needs of the health research and delivery sectors.



II. Background

The Last 5 Years

The transfer of health technologies has affected health policy over the past five years in a more reactive than proactive fashion. This situation arises because Canadian technology transfer has grown significantly in the last twenty years in tandem with rapid advances in biotechnology research that often have valuable applications for use in healthcare.

Despite the growth in both technology transfer and research, the practical management of their intersection has not developed as quickly in Canada whether in the form of intellectual property management or licensing guidelines to ensure that public priorities in managing technologies are incorporated in technology transfer practices. In the recent past, this failure to implement policy has led to policy controversies that have fed reactive legislative and policy-making exercises that will be discussed below.

The earliest and best known Canadian case of patents limiting access to a technology with both research and health care uses is that of Myriad Genetics. This case is often cited in policy reports and academic literature as evidentiary support for the present unease over human gene patents. The Myriad story, as usually told, is that a private US company used its patent rights over breast and ovarian cancer genes worldwide to try to block outside research and prevent public health care systems from implementing a more cost and health-efficient genetic diagnostic test for breast cancer. Our own study of Myriad Genetics reveals a more subtle story that will be discussed below.

The controversies over Myriad Genetics' patents gave a significant boost to existing policy initiatives to ensure access to patented technologies by providing some proof and detail that an access problem existed. France amended its patent laws to permit the grant of a compulsory licence over diagnostics, the OECD studied the effect of human gene patents on research and access to medical products and the NIH prepared Research Tools Guidelines and new Best Practices for the Licensing of Genomic Inventions. Although



none of these documents is directly attributable to the Myriad dispute especially the Research Tools Guidelines which predate its start in 2000, most built on the momentum to which the Myriad controversy had given rise.

These international initiatives sought to remedy the perceived barriers to research and healthcare caused by patents. They generally encouraged the free flow of scientific information and ensured that patent rights were not used to prevent public health care systems from accessing innovations at a reasonable cost and in a manner that best accommodates the system's needs. In particular, the NIH Best Practices for the Licensing of Genomic Inventions targeted licensing practices that could curtail researcher access to genetic and genomic knowledge. The OECD Guidelines for the Licensing of Genetic Inventions (2006) (OECD Guidelines) went one step further, explicitly stating that patent holders had an affirmative obligation to license their genetic technologies in a manner that would increase access to medical treatment. Both the NIH and the later OECD Guidelines for the Licensing of Genetic Inventions (2006) called for non-exclusive licensing of genetic and genomic inventions whenever practicable, especially in respect of foundational inventions.

These activities at the international level have been reflected domestically. The Canadian government was a strong supporter of the OECD Guidelines and the Canadian Biotechnology Advisory Committee (CBAC) incorporated those guidelines in its analysis of patenting in the genetics field. In Human Genetic Materials, Intellectual Property and the Health Sector (2006), CBAC recommended that Canadian granting councils adopt licensing guidelines that grant recipients must follow, that Canadian public bodies use the OECD Guidelines as a basis of determining whether a patent holder has abused its patent rights and that Parliament institute a legislative research exception to ensure that health research was not stalled due to real or perceived fears over patent infringement.



These policy-making initiatives at the national and international levels were speaking largely to the constituency of TTOs at universities, colleges, teaching hospitals, private research institutes, government laboratories and funding councils engaged in scientific research in Canada. TTOs are critical to Canadian policy-making in this area as technology transfer and commercialization of innovation form an important pillar of Canada's Science & Technology Strategy. This is so even though Canada has not formalized the role of TTOs through legislation like the *US Bayh-Dole Act* which mandates the commercialization of federally-funded research in the US. However, the Government of Canada released a Federal Science and Technology Strategy in May 2007, entitled *Mobilizing Science and Technology to Canada's Advantage*. It identifies Canada's strength in public sector research and recognized that "it is essential to ensure that effective regulatory approaches are in place to tackle the increasingly important intellectual property, information-sharing and confidentiality issues that are part and parcel of the 21st century." The policy debates over the past five years have led to questions regarding the proper role of TTOs, metrics for TTO success and the role that TTOs can and should play in ensuring that the benefits of certain technologies remain broadly available to the public. This analysis of TTO practice has occurred in tandem with the growing professionalization of the corps of TTO officers through the AUCC, and the more recently formed Alliance for Commercialisation of Canadian Technology ("ACCT").

High-profile litigation complemented and reinforced the policy-making that arose from the interaction of the science of genetic engineering and the patenting process, namely the cases *Harvard College v. Canada* and *Monsanto v. Schmeiser*. The Canadian Intellectual Property Office (CIPO) is presently engaged in a process of revising its policy regarding biotechnology patents to take account of these decisions and others. While CIPO does not regulate licensing, it does determine what is or is not patentable. Its patentability guidelines are thus important to this discussion. While these guidelines may change, they propose to implement the SCC's *Harvard College* distinction of disallowing patents on



higher life forms – defined as plants, seeds, animals at any stage of development including fertilized eggs and totipotent stem cells (which have the inherent ability to develop into animals). Thus genetic technologies in the field of healthcare will likely remain patentable in the future, although with some restrictions.

Is There an Access Problem?

(a) Introduction

A central concern informing these debates over the past five years about patents, technology transfer and health continues to be that patents may impede or at least lessen research and the delivery of health services. Thanks to the traction of this debate, we now benefit from a number of studies and papers that provide significant, albeit inconclusive, data on the topic.

Recent data continues to be ambivalent as to the existence and extent of an access crisis in relation to patented genetic inventions. Caulfield et al thoroughly survey the evidence for and against an access crisis up to 2006. They suggest that fears over access were largely the result of abstract speculation in the academic and policy fields in the early part of the 21st century rather than being based on strong empirical data. A recent paper commissioned by BIO, the US-based biotechnology industry lobbying group, drew on this observation to conclude that “there is a lack of evidence that justifies overhauling the patent system in a way that could potentially disrupt the incentives of industries that rely on patents to innovate.” While there may be only little data about the effects of patents on access in general – and contrary to the selective evaluation undertaken in the BIO paper – the one empirical study of the issue concluded that there is a modest ‘anti-commons’ effect that becomes worse the longer an invention has been patented. References to the *US Bayh-Dole Act* in this respect are of limited utility to our current discussion as most studies suggest that the Act has had little effect on patenting and



licensing practices. US experience with the Act also has limited application to the distinct Canadian technology transfer context.

(b) Telling Policy Stories

As the quantitative data on technology transfer and health are limited and mixed, we supplement them with qualitative evidence that, while not providing a clear demonstration of the empirical significance of concerns, illustrates them concretely within practical contexts.

Myriad

Our research suggests that Myriad, contrary to the regular telling of its story as involving an attempt by a private patent holder/licensee to block further research or access to health services, simply took several poor business decisions. Chief among these is its failure to understand the markets in which it was entering, particularly those with public health care systems. Further, significant ill-will among researchers in the field and a lack of clear communications led researchers to believe that Myriad would sue those who continued to work on the two patented genes (BRCA1 and BRCA2) without the company's permission. This was not the case. Additionally, Myriad failed to communicate its intentions with respect to licensing its genetic tests to public health care systems in Canada and elsewhere. It asserts that it would have been willing to negotiate an arrangement that would have been mutually supportive of the company and of such public systems.

Perhaps our key finding, for present purposes, is that Myriad paid insufficient attention to ensuring that the consequences of its business practices had no negative impact on research and access to its test. Myriad simply entered into what it considered to be an ordinary business arrangement when it licensed its test in Canada to a private company on an exclusive basis. It was then surprised that this engendered so much resistance from academic and clinical researchers as well as public health administrators. Essentially,



Myriad failed to realise that its business practices had negative consequences on these actors working outside the marketplace who found that their responsibilities and activities were compromised because of Myriad's failure to broadly licence the BRCA1 and BRCA2 genes with few strings attached. This failure not only cost researchers and the health system money, but eventually led Myriad to lose most of its markets outside the US for its test as the reaction against Myriad's practices was so strong that its patents were challenged (successfully) in Europe and ignored in Canada.

The problem that Myriad reveals is several-fold. First, patent law does not operate in a vacuum but in a very real policy context. As Herder and Gold argue:

What is important to note, rather, is that effects (positive and negative) are not those that arise from a reading of applicable patent legislation, but rather from how real people actually react and deal with IP. Therefore, if IP rights are so confusing that people stay away from some research or if there is a miscommunication that leads people to not conduct certain work, that negative effect is, from a consequentialist perspective, accurately attributable to IP. Indeed, in hindsight, Myriad Genetics' main mistake appears to have been in failing to effectively communicate its business plans; it claims never to have intended to exercise its patent rights against health care providers. But because of how its actions were perceived, this instance is rightly characterized as a patent problem in our view.

Thus, it was critical that business practices account for how people actually work and understand the patent system. Myriad's business strategy failed to do this on several counts. First, Myriad did not, for example, fully appreciate researcher concerns that they might infringe patents nor how public health care systems integrate discrete health services as part of an entire suite of services. In Myriad's case, this suite of services included pre-testing and post-testing genetic counselling as well as surgical or medicinal care. Second, there was no honest broker to mediate the dispute between Myriad on the one hand and the research and public health communities on the other. No level of government had a mandate to play this role, for a variety of institutional reasons, and thus disputes festered. Third, there were no broadly accepted norms of behaviour in place at



the time, such as the OECD Guidelines. Myriad's statements to us that they agreed with these norms once they were articulated in the Guidelines, suggest that it might have been simpler than was thought at the time to overcome differences and engage in real discussion. Fourth, the parties did not trust one another largely due to a failure to communicate on all sides.

JAK2 Gene

Recently, Warnex Inc. of Laval sent out notifications to several laboratories across the country stating that the company has licensed the exclusive rights over a genetic test, this time in relation to the JAK2 gene and myeloproliferative disorders (affecting blood cells). The letter states, in part, as follows:

We would like to inform you that Warnex Medical Laboratories has obtained the exclusive Canadian operation rights for the intellectual property related to the V617F mutation of the JAK2 gene.

Included with this letter, you will find an information bulletin and you will shortly receive additional information about JAK2 and Warnex Medical Laboratories.

We are anxious to collaborate with you to provide you with quality testing for JAK2. For more information, we invite you to contact our Customer Service Department.

In some cases, Warnex followed up these letters with site visits.

While there is currently no patent over the JAK2 gene, a French public laboratory, the Institut Gustave Roussy (together with other French public institutions) has applied for a patent over the gene and related diagnostic methods. Given that there is only a single mutation in the gene for which testing is necessary, Canadian laboratories quickly developed genetic tests on publication of the initial scientific findings demonstrating that no significant development work was required to provide the test to Canadians. While the



NIH guidelines do not apply in France, they certainly caution against patenting such technologies.

Further, the Institut Gustave Roussy (one of the public institutions that had fought against Myriad Genetics' patents over BRCA1 and 2) exclusively licensed the JAK2 gene and associated test to Ipsogen, a French private company. This runs counter to the OECD Guidelines which state that exclusive licensing should be used sparingly and only where necessary. Given the rapid development in Canadian laboratories of a test for the JAK2 mutation, there was no obvious case of necessity here.

Warnex's notices to clinical laboratories failed to account for how the notices would be received by those laboratories. The Quebec government responded, for example, by sending Warnex a letter on March 20, 2008 saying it had instructed its laboratories to only obtain testing services from other public sector laboratories and not Warnex.

Warnex CEO Mark Busgang admitted at the workshop that, while he believed that they would be offering consistent service, a high level of quality, and a competitive price, he and Ipsogen may have been naïve in implementing their business strategy in Canada. Despite the fact that no Canadian patent has been issued, which was clear in supporting material sent by Warnex, laboratory directors may have understood the notice to mean that Warnex was threatening to sue them for infringement if they continued to provide tests or send their tests to other public laboratories. In actual fact, only if the patent is eventually granted could Warnex even contemplate suing for damages for tests conducted between the time of publication (which has passed) and the actual grant of the patent. In any event, it would not likely be in Warnex's interest to bring such a suit since the legal costs would likely be more expensive than the damages that would be awarded and such a lawsuit could be a public relations disaster for the company.

In personal discussions between one of the authors of this report and Warnex and Ipsogen, it became clear that both companies support broad licensing of genetic tests in principle. At the workshop, Busgang stressed that Warnex made every effort to



encourage research and that its long-term goal is to develop links with the hospital community as part of its business strategy. Busgang was also frustrated at the way that provincial governments used their superior bargaining position to disregard and on occasion trample the businesses that actually develop new tests. Given this, it seems that, as in Myriad, the real problem may be one of communication.

This first part has considered policy-making, controversies and research of the last five years to flesh out the nature of the debate over access by researchers and public healthcare systems to patented genetic technologies. We conclude that while a range of policy initiatives have sought to ensure broad access through licensing terms, those policy initiatives have not necessarily been broadly adopted by constituents and this had led to continuing problems. We now move to consider the critical role that TTOs play in implementing policy and the challenges they face in doing so.

III. The TTO Nexus

Research has come to focus on the TTO as the site of inquiry for resolving many of the concerns discussed above. As a result, a body of recent research, including the 2007 study by Herder and Johnston for Health Canada, provides invaluable insights into the role of TTOs in this larger policy debate. The following will discuss the key features of TTO practice relevant to this debate, discussing first, TTO policy-making practices, second, challenges posed by TTO metrics and finally some predictions about the institutional evolution of TTOs. It will conclude with the observation that while TTOs remain important players, they sit within a web of policy-making organizations. It is this web as an integrated whole of technology management, not just TTOs, that must be mobilized in order to overcome concerns of technology transfer and access. The final parts will highlight on-going initiatives and possible further avenues for effecting better integration. There remains, however, a pervasive concern that technologies are not put to



use or commercialized as broadly, rapidly or usefully as they could be and TTOs form a central focus of these debates that we will now consider.

TTO Policy Formulation

TTOs are separate units at institutions of higher learning that are responsible for transferring technology developed in the university, college or hospital to commercial and other purposes. Their underlying goal is one of ensuring access to technology. In practice, however, this goal is mediated by pressures to commercialize, bring revenue to their institutions and the metrics TTOs must meet.

TTOs tend not to be integrated within the broader enterprise of their institution and often exercise a relatively high degree of decision-making autonomy, particularly in developing their own policies with respect to licensing. TTOs operate in a fluid policy environment in which policy is continuously evolving, involving a mix of formal policy principles and less formal practices that develop as new technologies and relationships emerge. Canadian TTO officers decide whether and how to license their patented inventions based on “rules of thumb” (e.g., in favour of licensing research tools nonexclusively), “useful strategies” (e.g., in favour of only patenting inventions for which exclusive licenses can be obtained), or “special rules” for specific cases (e.g., only executing nonexclusive licenses for a particular kind of invention).

Given the level of autonomy enjoyed by TTOs and the strength of their internal policy-making process, four key factors must be considered when attempting to influence or change TTO policy. First, attempts to micro-manage relationships between external bodies (e.g. funding agencies) and TTOs are generally unsuccessful. The best role for those outside of TTOs wishing to influence TTO practice is to facilitate discussions in policy areas of concern to TTOs (e.g. a health funding body could facilitate discussions on access issues to cardio-vascular research between various TTOs commercializing



research in that area) or to provide complementary skills and services (e.g., a specialist in a particular research domain could help TTOs understand the patent and the industrial ecology). Second, preserving TTO flexibility on some issues is more important than on others, for example, flexibility on exclusive versus non-exclusive licensing decisions may be more important than on decisions to reserve research and educational uses of the technology. Third, any policy directed to TTOs should be sensitive to the multi-layered policy context in which they operate and the goals or metrics they must attain in order to demonstrate the success of their operations. Fourth, TTOs may be bound by requirements of many national funding agencies, such as Genome Canada, that applicants seek co-funding, often from industry. This collaboration limits a TTO's ability to license in a manner that maximizes broader health goals.

TTO Metrics

Inspired by examples from the United States, Statistics Canada, AUTM and universities primarily judge Canadian TTOs as successful based on their ability to generate patents, licenses, start-up companies, and dollars through sponsored research. This quantitative approach seeks to maximize the number and value of transactions that transfer technology from Canadian research institutions to the private sector, and rests on the perspective that cash-strapped research institutions have adopted towards their TTOs as a resource for generating revenues in the short-term.

The continued usefulness of these transactional markers, however, has been increasingly doubted by TTOs and others, and this is given weight by recent research from the US suggesting that, for many universities, “the net effect of licensing is negative.” Thus, growing questioning of the appropriateness and effectiveness of existing markers creates opportunities for creative solutions. Inquiries into how to accurately assess TTO performance are increasingly engaging with the view that the greatest benefits of technology transfer may be poorly measured by short-term quantitative markers. Existing markers often provide counter-productive incentives to produce short term



financial gain instead of unlocking the competitive potential of a sector of the economy. Thus existing metrics of success push TTOs to maximize the element being measured rather than the fundamental benefit to Canada. One gets, in effect, what one measures. If metrics count the number of patents held, then TTOs seek to patent more inventions, even if such patenting runs counter to larger and more desirable socio-economic outcomes such as enhanced access to healthcare innovation. TTO managers have noted the gap between what they think they ought to do – benefit the Canadian public and, in respect of health innovation, ensure access to new health interventions – and what they are measured for doing – obtaining short term revenues and licences for their institutions. Further, existing metrics may not be aiding the high quality disclosures that sustain a TTO's operations. Disclosure of important innovations by talented faculty remains a key concern of TTO officers.

Given this recognition, TTOs are at the forefront of arguing that broader, more subtle metrics are required in order to achieve more diverse goals such as access (or even disclosure). TTOs agree that if an organization's goal is to have a beneficial effect on society more broadly, then current methods of measuring knowledge transfer (number of patents, licenses, or revenue) are not only insufficient but counter-productive. Focusing on indicators, such as industry inputs into research, grants of doctoral degrees, numbers of graduate students, disclosures and/or useful clinical applications (regardless of patent status), may enhance the activities of TTOs and their beneficial effect on the Canadian economy. There is a sense amongst some TTO officers, however, that government and institutional policy-makers have yet to recognize the problem with existing metrics.

TTOs in the Future

Several trends are likely to shape TTO practice in the future and may give a sense of the likelihood that these organizations will eventually serve broader goals.



First, TTO professionals have increasingly moved towards a greater understanding of their academic mission, the goals of publicly-funded research, and the objectives of patent legislation. They are also increasingly of the view that adopting technology transfer practices that maximize social benefit is complementary to the goals of their host institutions. This development has been facilitated by the increasing professionalization of TTO staff.

Second, while Canadian TTOs may adopt either a university-owns or inventor-owns IP policy, there is little push for a uniform Canadian IP policy from TTOs since there is no evidence that one type of policy is better than another. Each has its advantages and disadvantages. Further what is good for one institution – with its own particular research focus and culture – may very well not be good for another. Even in the US after the *Bayh-Dole Act*, there are substantial differences as to IP policies at different institutions.

Third, there is a growing trend amongst TTOs to support and pursue a more transversal or specialized commercialization. It is therefore likely that TTOs may change in the future to be less dependent on an affiliation with a particular institution in a given province and more closely tied to activity in a certain technical field, e.g., heart disease, breast cancer or SARS. This trend will be dependent on TTOs obtaining more information about research conducted in different units of their own institution and finding ways to share that information with other institutions to develop synergies.

Fourth, researchers (particularly at universities) are increasingly demanding more involvement in determining how the technology they have developed is to be commercialized and how revenues derived from the invention will be distributed. This is true even at universities with institution-owns IP policies. Thus researchers are likely to grow as an important voice in technology transfer that will need to be informed and heard.



Finally, licenses as opposed to spin-offs are likely to remain a key tool of commercialization at Canadian TTOs due to the limited financial investment required.

Ultimately, an inspiring conclusion from this research is that successful TTOs are nimble organizations that bridge the gap between academic culture, with its view of knowledge as a public good, and firm culture, where knowledge is proprietary. Social networks between academic researchers and industry researchers, as well as university administrators and TTOs, can build important social capital for information exchange and broad diffusion of technologies. The TTO may be the key to the policy puzzle introduced in the first part of this report.

IV. Access Policy-Making and Initiatives

Various initiatives are already underway to implement improved control of access to health care products, principally through licensing. These include TTO and university based initiatives, international policy-making, local policy-making and open access initiatives developed by a range of NGOs. We will survey these in turn.

TTO and University-Based Initiatives

In a recent attempt to redefine TTO metrics, the University of British Columbia's (UBC) Global Access Principles articulate an institutional commitment to measuring societal impact as a key indicator of the success of technology transfer activities at the university, alongside standard throughput, financial and economic measurements. UBC's University Industry Liaison Office (UILO) is developing and implementing metrics to capture these larger goals. Angus Livingstone, who heads the UILO, presented results from a study that his organisation had conducted on their licensing practices. The study of 237 active license and assignment agreements measured academic, societal, economic, financial and political impacts of UBC's IP portfolio. Impact scores were assigned through reference to



a series of benchmarking descriptions generated for each impact category. The study's results were instructive for future policy-making at the UILO as they concluded that 68% of licenses have a minor or negligible overall impact while 4% have a good or better overall impact. Livingstone observed that Research Tools and Software licenses and that individual non-exclusive licenses (as opposed to individual exclusive licenses) have a lower impact score. The licenses with the most potential to increase impact with time are those in the life sciences. We also note that McGill University is currently contemplating a wider set of metrics than the traditional but this work is still underway and not yet public.

Internationally, broad coalitions and initiatives have coalesced to address specific access issues to healthcare products. Universities Allied for Essential Medicines (UAEM) is a coalition of students and faculty at 25 universities across North America. UAEM focuses on universities as the locus for closing the research and funding gap in the areas of access to essential medicines in developing countries and research into neglected diseases. At the workshop, Louis Fazen of UAEM introduced the UAEM Access Metrics Initiative (AMI). UAEM has put forward what they call 'process metrics' that capture the value of technology transfer using criteria that go far beyond the number of licences issued and licensing revenue. UAEM also proposes that universities adopt a metric of the percentage of due diligence clauses included in licensing agreement. According to them, universities should aim for 80% of their exclusive licences and 40% non-exclusive licenses to contain such terms. This initiative highlights the creative solutions that institutions funding and incubating innovation can take to ensure that access objectives are met.

International Policy-Making

A round of international policy-making is tackling issues relating to access to medicines for neglected and emerging infectious disease. One such initiative, led jointly by the OECD and WHO, is the Noordwijk Medicines Agenda. Its stated goal of accelerating innovation and access to medicines accepts that intellectual property rights do not provide



the only rewards that incentivize health-related innovation. It advocates, therefore, for the use of complementary reward systems as well as sustainable collaborative mechanisms (such as patent pools) to increase needed research and the delivery of health products. In particular, the Agenda calls on governments and policy-makers to facilitate the development and operation of a sustainable architecture for the sharing and exchange of knowledge, data and research tools necessary for the discovery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases. Such efforts likely include mechanisms that go well beyond non-exclusive licensing, to include ways to create a knowledge ‘market’ that would allow companies to profit from the knowledge they share, to pooling and even open science platforms.

Also on the international front, although operating more at the political rather than practical level, are discussions both at the World Intellectual Property Organization on the implementation of its Development Agenda and at the World Health Organization’s Inter-governmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). While the WIPO initiative seeks to increase the priority given in particular to access issues with respect to health care within the policy and training work of the organization, the IGWG seeks to build a consensus about ways that countries around the world can better ensure that developing countries gain access to and can use existing and future technology. While the IGWG also has ambitions to examine mechanisms to enable developing countries to carry out more of their own research, this remains a long term goal since the bulk of the world’s scientific and technological innovation takes place in developed countries.

Even if countries agree with the goals of the Development Agenda and the IGWG and presuming that the WIPO and WHO institutions have the capacity and skill to promote their realization, there remains significant doubt about the willingness of countries, including some of the most vocal developing countries on the issue, to actually take measures that implement them. Brazil, for example, while calling for greater flexibility in



international rules relating to intellectual property, not only does not exercise many of the existing flexibilities, but almost passed legislation in 2007 to further restrict the use of these flexibilities in its national patent law.

Local Policy-Making

In addition to policy-making at the international level, institutions have also been engaged in developing local principles and guidelines. The best example of this are the UBC Global Access Principles which express a commitment to building on the values of access and dissemination, promoting non-exclusive licensing and considering field-of-use and jurisdictional limitations in exclusive licenses to exclude developing countries. Further, those principles allow developing world access ‘at cost’ to relevant technologies that are licensed on a world-wide exclusive basis (required for technology development). UBC has committed to designing patent strategies with its development partners that ensure quality product delivery to those most in need, while promoting sustainable, local infrastructure.

Various new institutions and initiatives have also been created in conformity with the OECD and other guidelines and discussions at the international level. In Canada, the West Coast Licensing Partnership brings together nine West Coast research institutions and bundles technologies in four areas: animal models, biomarkers, medical imaging and medical devices. A single license covers all the research institutions and all licenses issued are non-exclusive with the goal of “increasing global access to research tools by promoting and enhancing non-exclusive licensing.” The partnership has the advantage of facilitating inter-institutional collaborations and providing standardized terms to begin creating new norms of practice and behaviour.



Open Access Initiatives

Similarly, organizations such as PIPRA (the Public Intellectual Property Resource for Agriculture), Cambia/BiOS, Science Commons and the Tropical Disease Initiative seek to modify the complex ecology of patent behaviour. In particular, PIPRA is developing a humanitarian license clause that facilitates material transfers with developing countries. It is also mapping the complex ecology of certain technologies through establishing patent clearinghouses and databases of licensing information from public and private institutions. Cambia/Bios is engaged in a similar project, while also explicitly developing an open source licensing community. Science Commons combines standardized licenses for access to written materials, biological material transfer agreements as well as using the semantic web to enhance access to and processing of valuable scientific information. These collections of information to map patent landscapes should ideally be collected at the national level, as in Japan, for example, which is centrally collecting information related to patent licenses. These collections provide invaluable information about the breadth and strength of existing patents, terms of control and who exercises control, and suggest zones of 'freedom to operate'. Federally, the Canadian Institutes of Health Research, Genome Canada and the Social Sciences and Humanities Research Council have developed, or are in the process of formulating, open access to research output policies that will affect all grantees in relation to publications, software, materials and data.

Thus a broad range of national and international initiatives are both developing policy to enhance access goals and implementing it in creative new ways. The goal of this final part is to suggest the actors and practices based on the foregoing that may stimulate discussion about the best way to implement the goal of enhanced access in the Canadian healthcare context.



V. Moving Forward: Conclusions and Next Steps

After considering the multiple facets of the question, we now propose in this concluding section to identify the set of actors and areas of practice that must be implicated to attain the goal of increasing access to health-related innovation. This follows the thread of Herder and Johnston's study which surveyed the actions of TTOs themselves, emphasizing the variability of TTO practice, the need for TTO buy-in, and the importance of sensitivity to TTO expertise and operational culture. We start with TTOs but move significantly beyond them.

Both the Herder and Johnston study and our own analysis point to the importance of revising the metrics that governments and institutions of higher education use to assess TTO performance beyond simply the number of patents, licenses and revenue generated. If an organization's goal is to positively influence society more broadly – such as through the development of new health products and services for Canadians – then those methods of measuring knowledge transfer are insufficient. There is an immediate need to develop metrics that TTOs could readily use (and for which they have expressed a need): for example, if an organization's goal is broad dissemination of knowledge and the development of useful clinical tools, an organization could measure the number of students trained, disclosures and/or clinical applications developed or implemented (regardless of patent status). These metrics need to include or even comprise criteria such as facilitating access and soft measures such as gauging a TTO's contribution to the public benefit on relevant health markers. These metrics may also vary depending on whether a TTO has a core expertise in one technology area or in another.

Institutionally, developing new metrics could be coordinated at several stages of the technology transfer 'food chain'. The TTO's host institution can take the lead at a senior management level. In particular, we suggest that the VP Research or similar officer take a leadership position in developing new metrics, thus allowing TTO practice to evolve to



accommodate access concerns. In order to accomplish this, senior university management needs to be informed about its role in achieving access goals and the kind of support it can provide to its TTO support in achieving greater access.

Further, government departments and research agencies could facilitate a process of developing more effective metrics in conjunction with TTOs. This could be achieved through workshops or targeted Requests for Proposals by agencies such as the CIHR or Genome Canada. Scholars experienced in the area could be mobilized to synthesize and investigate possible metrics that would benefit TTO operations and to collect data and information about experiences in other countries.

Second, at the level of the researcher rather than the TTO, CIHR and other funding agencies could require that when applying for funds, applicants must explain how any resulting plan for commercialization accords with the OECD Guidelines and other guidelines. This would be consistent with the CBAC recommendations on implementing the OECD Guidelines.

Third, TTOs often rely on generic or in-house legal expertise to address licensing questions (although they rely on large firms for their patenting work). Given that TTO professionals generally have little time, let alone experience with, complex contracting, they generally wait for access problems to present themselves (as apparently did the Institut Gustave Roussy with respect to the JAK2 gene) instead of proactively contracting to prevent them. Further, TTOs may perceive that proactive licensing (for e.g. including humanitarian clauses in licenses) lies outside of their mandate, further highlighting the importance of ensuring that the institution's administration is involved. They may also fear that industry will resist changes although this too is likely more apparent than real as even the pharmaceutical industry is recognizing the importance of actively promoting access to health. Waiting for access problems to arise does little service to either the public goals of their host institutions or the goals set out in the OECD Guidelines and



elsewhere. Instead TTOs should consider encouraging and taking advantage of specialized and high quality legal and professional support from those with both a commitment to the public goals of the institution and experience in complex contracting.

Fourth, there are a range of practical approaches drawing from methods developed by civil society, international and other domestic organizations (including TTOs) that could be adopted by TTOs. Examples include developing a collaborative organization such as the West Coast Licensing Partnership, adopting statements of principles, developing humanitarian clauses or other access provisions for licenses as well as drafting standard commercial and non-commercial terms for licenses. Each TTO will need to determine which approach best suits its culture and objectives and at what level within the institution these types of initiatives need to be implemented. Discussions are further needed with TTOs to identify which tools are necessary to support these initiatives and to build them. Finally, there is a need for TTOs to share information with other civil society, research and international initiatives.

A final method to implement the OECD and other Guidelines is to establish an independent broker in Canada who can mediate disputes that threaten access to valuable health-related innovation. At present, as illustrated by the examples of both Myriad Genetics' patents over BRCA1 and 2 and Warnex's exclusive Canadian licence over JAK2, there are no established processes of communication to address concerns over health access. Our research in other instances has identified that parties, in these circumstances, quickly resort to legal mechanisms that appear heavy-handed, punitive and provocative. In such cases, the law may be the only language left to the parties in which to communicate. This is so even though the parties' underlying interests may both lie in avoiding public conflict and legal posturing: industry wishes to avoid bad press and public health providers wish to resolve the dispute as quickly as possible in order to continue providing services. An independent broker would manage a dispute resolution process that could mediate unanticipated conflicts between public sector institutions and



private sector parties. The broker may also adopt a role in educating parties as to the proper extent of their patent rights. As the JAK2 situation demonstrates, often parties may poorly appreciate the extent of patent rights held; this misunderstanding may disproportionately chill behaviour.

Such a broker likely cannot be from within government. Technology transfer and health cut cross too many federal and provincial departments to give any of them a lead role in resolving disputes. Thus, outside, independent experts are needed who are trusted and knowledgeable.

Thus as a prerequisite to advancing on any of the issues discussed in the first section we must consider the various nodes of decision-making on each aspect of the access question (for example, decisions about licensing at the governmental, legislative, institutional and TTO level), the importance of responding to current trends with respect to open licensing as a business model, the necessity merging with access to knowledge initiatives within public funding bodies and policy making initiatives to the same effect at the international level, and the importance of clear and consistent guidance from governments, funding bodies and other key stakeholders in this debate.

One particularly intriguing proposal that certain of the workshop's participants suggested was the formation of a committee or working group to draft model licenses and/or licensing best practices for a Canadian audience. For example, Health Canada could create such a committee in order to advise it on the IP policies that it ought to attach to the projects it funds.

While initially, this committee would concentrate specifically on health and genetic licensing, participants at the workshop suggested that the committee's output should be seen as a chapter in a book, rather than as an entire book in itself. The entire book would focus on technology transfer practices in general rather than simply on the health sector.



The committee could be asked to draft the table of contents of this book, but it will be up to the technology transfer community to move the project forward.

By taking a comprehensive approach that examines the role of each actor involved in technology transfer policy – government, granting councils, senior university administrators, TTOs and industry – we can formulate an appropriate set of policies that will better manage university technology for the better health of Canadians.