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Intellectual Property Management: Policy Issues and Options

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Intellectual Property Management: Policy Issues and Options



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Editor's Preface

Launched in 2009, *GPS: Where Genomics, Public Policy and Society Meet* is a series hosted by Genome Canada to facilitate a dialogue between federal policymakers and researchers exploring issues at the interface of genomics and its ethical, environmental, economic, legal and social aspects (or GE³LS).

Overarching themes for the series and specific topics are selected on the basis of their importance and timeliness, as well as the “ripeness” of the underlying scholarship. Accordingly, the first series focused on “Genetic Information,” whereas in year two, attention has shifted to “Translational Genomics.”

At the core of these exchanges is the development of policy briefs that explore options to balance the promotion of science and technology while respecting the many other considerations that affect the cultural, social or economic well-being of our society.

Co-authors of the briefs are leaders in their field and are commissioned by Genome Canada to synthesize and translate current academic scholarship and policy documentation into a range of policy options. The briefs also benefit from valuable input provided by invited commentators and a group of expert participants and other stakeholders convened at half-day events in Ottawa.

Briefs are not intended to reflect the authors' personal views, nor those of Genome Canada. Rather than advocating a unique recommendation, briefs attempt to establish a broader evidence base that can inform various policy-making needs at a time when emerging genomic technologies across the life sciences stand to have a profound impact on Canada.

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Executive Summary

Intellectual property rights, including copyrights, trademarks, trade secrets and patents, play an important role in innovation systems. While the *right* intellectual property policies and practices cannot, by themselves, catalyze innovation – other factors are equally if not more important – the *wrong* policies and practices can impede it. The focus of public policy debates should shift from the relative strength or weakness of legislative protection to the most efficient and effective models of managing intellectual property in practice. Options for policymakers include (1) encouraging as much acquisition and commercialization of intellectual property rights as possible, (2) supporting the public domain through free revealing of knowledge and technology, and (3) leveraging intellectual property rights through collaborative or “open” licensing models. Different resources in different industries involving different collaborators and different intellectual property rights can be managed using a mixture of approaches. Because the policy options are not mutually exclusive, policymakers' key role is not to choose among them but to articulate overarching principles that promote financial as well as non-financial returns on investments while taking into account the broad range of stakeholder needs.

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He currently co-leads the Canada-EU Trade Environment Technology Exchange funded by the European Commission and the “Open AIR” project, a large-scale research and training initiative on open innovation in Africa funded by Canada’s IDRC and Germany’s GIZ. His latest books include *Access to Knowledge in Africa: The Role of Copyright and Implementing the World Intellectual Property Organization’s Development Agenda*.

Richard Gold is a James McGill Professor in the Faculty of Law and an Associate Member of the Department of Human Genetics at McGill University. He is also President of The Innovation Partnership (TIP), a non-profit corporation dedicated to helping public and private actors in developing and developed countries better manage their innovation systems

Richard’s research centers on understanding the links between biomedical, agricultural and industrial innovation, intellectual property and development. He leads the Value Addition through Genomics and GE³LS (VALGEN) group of investigators in the theme of intellectual property management and technology transfer. He also conducts research with the Structural Genomics Consortium on open access innovation.

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I. The Context

Creating and implementing an effective science and technology strategy requires not only the right natural and social sciences research priorities, but also appropriate regulatory and governance choices, legal frameworks, competition policies, venture capital and business practices, education systems and much more. These will help scientific and technological research make a difference in solving major policy challenges such as food security, environmental sustainability, population health and economic growth.

One ingredient in the policy mix is intellectual property. This brief outlines the role that managing intellectual property can play in encouraging collaboration and partnership between research institutions, business, government and civil society. Elsewhere we and many others have addressed, and must continue to address, different aspects of innovation systems. We focus here on intellectual property not because it is the only or even the most important issue, but because it is one piece of a larger puzzle with which policymakers are struggling. While the *right* intellectual property policies and practices cannot, by themselves, catalyze innovation – other factors are equally if not more important – the *wrong* policies and practices can impede it.

The latest report card from the Conference Board of Canada gives Canada a “D” on innovation, influenced by, among other things, low scores for Canadians’ share of world patents, patents by population and cross-border trademarks (Conference Board of Canada 2010). In part because of such reports, much public discussion has assumed the characterization of Canada’s existing intellectual property framework as weak. Canada must provide higher levels, even “the world’s strongest” levels, of intellectual property protection, it is said, or risk losing investment in research and development, especially in the biotechnology industry (Canadian Council of Chief Executives; Coalition for Action on Innovation in Canada 2010). Others claim, to the contrary, that Canada already overprotects intellectual property rights to the detriment of the world’s poor in accessing essential medicines (Canada HIV/AIDS Legal Network 2011).

Discussing the relative strength or weakness of intellectual property protection in these ways, particularly given the very limited empirical basis for such opinions, distracts attention from concrete strategies to achieve the instrumental purposes of intellectual property policy or risks missing the broader policy picture (Gold 2000; Gold et al. 2008; de Beer 2008; Gold et al. 2009). Rather than extending a discourse that focuses on weak or strong rights, analysis should consider whether the intellectual property system is *effective* in achieving policy priorities (Patry 2009; Corbin 2010).

To repeat, intellectual property is one factor among many that influence direct investment, technology transfer and innovation systems (Maskus 1998; Phillips 2007; Castle 2009; Gold et al. 2008). However, some commentators such as Corbin (2010) suggest that shifting the analysis from innovation to intellectual property has the benefit of operationalizing broad concepts into “practical, unambiguous economic components” that are “potentially monetizable,” and offers the “seductive practicality of being able to count outputs.” Although focusing on intellectual

property outputs may be convenient, it is inherently risky, especially if the analysis depends on limited or inadequate metrics. For instance, the Conference Board of Canada (2010) recommends that policymakers “ensure incentives are in place to encourage more patenting of inventions at home, as well as more strategic patenting of inventions from elsewhere.” This advice fails, among other things, to appreciate that more patents will not necessarily cause more innovation, productivity or growth, and could possibly cause less by flooding the system with weak claims or incremental variations and potentially encouraging anti-competitive practices (Jaffe and Lerner 2006; Bessen and Meurer 2008).

What matters for science and technology innovation far more than counting outputs is leveraging the intellectual property system to better mobilize knowledge within a global economy. This more modern analytical paradigm stresses sharing and collaboration, not only the pursuit of protection (Gold et al. 2008). Moreover, it puts intellectual property in the context of increasingly distributed regulatory and governance systems that involve a dispersion of power over a wide variety of actors and groups (Phillips 2008). This paradigm is based on transdisciplinary understandings about the history of innovation (Johnson 2010), flowing information to solve problems (von Hippel 1994) and social production through networks of collaborators (Benkler 2006). For example, the Organisation for Economic Cooperation and Development (OECD)’s guidelines for licensing genetic inventions (OECD 2006) and its new “Innovation Strategy” depend less on protecting intellectual assets than facilitating “knowledge networks and markets” (OECD 2010). Such networks and markets involve deep interdependencies within the triple helix of innovation: university, industry and government (Etzkowitz 2008).

To benefit from new modes of production and innovation given the social, cultural, economic and technological realities of the 21st century, we need better legal strategies for managing intellectual property (de Beer 2008). This brief addresses the strategic options for policymakers – including especially research funding agencies, national and sub-national governmental departments, public sector institutional administrators and, to a lesser extent, private sector industrial partners. While policymakers are a diverse group, the nature of the information in this brief makes it a useful foundation for more specific discussions tailored to particular constituencies. It is not intended as policy advice, and does not advocate for any particular solution to the complex problems of intellectual property management. The objective is to synthesize ideas and proposals, and provoke critical reflection on available options.

II. The Issue

In considering strategic policy options, there are several facets of the intellectual property system to consider. The legislative frame-

work is one. During the past decade, the subject-matter and scope of patent protection has been at the forefront of debates about science, technology and intellectual property. The Supreme Court of Canada decisions in *Harvard College v. Canada* (2002), which interpreted the *Patent Act* to exclude higher life forms from protection, and *Monsanto v. Schmeiser* (2004), which effectively reversed course by broadly interpreting patent claims over genes and cells, were focal points for these debates in Canada. Such issues were in play, however, even before the much earlier American case of *Diamond v. Chakrabarty* (1980). The most current controversies about intellectual property in genomics involve ongoing litigation over the validity of gene patents such as those held by Myriad Genetics (*Association for Molecular Pathology v. USPTO*, 2011) and their enforceability in the agricultural biotechnology industry (*Organic Seed Growers v. Monsanto* 2011). While those matters are undoubtedly important, they may not be the highest priority issues for Canadian policymakers for at least three related reasons.

First, questions concerning the patentability of higher life forms, genes or gene sequences, and similar topics are extraordinarily sensitive, controversial and often politicized. Legislative or regulatory reform may be difficult or impossible in this current political context; gaps in the legal framework are inevitable. Second, constructive ambiguities will always be subject to interpretation by the institutions enforcing intellectual property rights, as happened in *Harvard College v. Canada* (2002) and *Monsanto v. Schmeiser* (2004), and is happening now in patent enforcement disputes in Canada (de Beer and Andrews 2009) and the cases going forward in the United States. Third, despite threats about moving capital elsewhere, biotechnology researchers and firms have adapted to Canada’s framework without any legislative reform. Of course Canada should comply with its obligations to the rest of the world, reflected in instruments like the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity (CBD) to name just two, but the fact is that Canada’s approach is mostly consistent with the international intellectual property governance framework. These obligations allow for a range of policy and practical options for intellectual property management, and this flexibility can be used to craft appropriate, context-specific solutions.

Consequently, policymakers’ attention is probably best directed toward more practical issues on which they can have real impact: *Managing* intellectual property in ways that facilitate innovation within the existing legislative framework.

III. Legal – Policy Background

Patents provide exclusive rights to make, use and sell inventions that are new (novel), not obvious (inventive) and useful (capable of industrial application), normally for 20 years from the date of an application for protection. Inventions can be products or processes, or

improvements to products or processes, in any field of technology. Trade secrets draw on general private law to prevent those to whom information has been disclosed from either using it or revealing it to others, for as long as the information remains secret. Although long considered a poor cousin to patents, which provide more extensive rights, plant breeders rights protect plant varieties in a complementary manner. Copyrights provide exclusive rights to copy, transmit, distribute or adapt original expression, generally for at least 50 years and often longer. Automatically protected expression can include among other things written outputs, computer code and in some cases compilations of data or other materials. Trademarks provide exclusive rights to use distinctive marks that identify goods or services. Others cannot use such marks to create confusion in the market for as long as the mark remains distinctive.

Patents tend to dominate intellectual property debates around science and technology policy, but patents are not the only, nor necessarily the most important, intellectual property right to consider.

Patents may be relevant for the underlying science and technology: research tools, diagnostic tests, modified genes and chemical or biological compounds. Copyrights, however, affect the accessibility of equally important bioinformatic software, scientific publications, original compilations of data, and possibly even synthetic DNA sequences. Trademarks are used for branding genomics research enterprises or particular technologies. A holistic view of *all* forms of intellectual property rights, and also classic tangible property rights over biological materials (de Beer 2005), is especially important in areas such as synthetic biology, which lies at the confluence of information technology and biotechnology.

Most public and private sector organizations involved with genomics are generally aware of the importance of these intellectual property issues. The challenge for policymakers is to help build further awareness and, more importantly, translate awareness into coherent intellectual property management policies that effectively and efficiently facilitate continuous circulation of knowledge.

Policymakers recently began hearing opinions that the legal tactics of the open source software movement can do that best, by providing a partial solution to the social and economic problems that intellectual property can cause for biotechnology (Joly 2007). While more empirical work is needed, research does suggest that in some cases “thickets” of overlapping intellectual property rights can make it impossible to negotiate the right to actually make or sell anything (Shapiro 2001). Similarly, a “tragedy of the anti-commons,” in which many independent rights result in “gridlock,” may threaten the circulation of knowledge or impede the discovery or distribution of valuable technologies (Heller and Eisenberg 1998; Heller 1998; Heller 2008). While some are of the view that stronger rights will best overcome these problems (Kieff 2011), the broad consensus is that developing clear pathways to partnership offers a better solution (OECD 2010). The question, then, is how best to fa-

cilitate collaborative partnerships and exploit networked knowledge (Phillips 2005).

IV. Policy Options

Option 1 - Acquisition toward commercialization

Since – or perhaps because of – the United States Supreme Court decision in *Diamond v. Chakrabarty* permitting patents for “anything under the sun that is made by man,” and the American *Bayh-Dole Act* permitting universities to hold patents arising from federally funded research, a culture of intellectual property acquisitiveness has arisen in the field of genomics. This culture of acquisitiveness in both private and public sector organizations is most apparent through the expectations placed upon technology transfer offices and the metrics used to evaluate their success. Bubela and Caulfield (2010) report evidence that technology transfer offices are increasingly pressured to advance and implement the commercialization agenda of the organization to which they belong, especially in the life sciences, and are rewarded for obtaining patents, granting licenses and creating spin-offs. Smyth (2011) describes a variety of policy measures in Canada that have contributed to the expectation that research institutions should acquire intellectual property rights in order to commercialize them.

This model rests on a simple view of innovation: Researchers disclose promising inventions to technology transfer offices, technology transfer offices evaluate and protect the commercially promising ones, industrial partners or affiliated spin-offs acquire rights to the intellectual property, normally on undisclosed terms, and technology transfer offices occasionally receive royalties or remuneration for commercialized research. Inverted from industry’s perspective, the process looks similar: research is essentially outsourced to academic partners that are sometimes given use or royalty rights to new technologies in exchange for their services (Weigelt 2009).

In implementing this model, the vast majority of technology transfer offices at best either break even or lose money for the institutions involved. And they are not effectively stimulating research productivity or innovation. Smyth’s (2011) analysis of Canadian data from 1998 to 2008 shows that while the total investment in university research has increased sevenfold, the proportion of patents actively licensed by universities is declining, and the number of spinoffs has fallen to half what it was a decade ago. Intellectual property management costs of technology transfer offices are nearly equal to the licensing revenues they generate, and more concerning, costs are trending upward – particularly in respect of litigation – while revenues are relatively flat. These data likely understate the problem, as they fail to account for the probable increases in costs of enforcement over the entire life-cycle of organizations’ intellectual

property portfolios. Also, they do not account for other rights holders' potential anti-competitive uses of intellectual property portfolios, or the transaction, licensing and other costs that are likely to increase in the future, as the intellectual property landscape becomes more crowded, in part because of these institutions' own policies and practices.

This disappointing picture may be partly attributable to the metrics being used for evaluation. But also, the model fails to recognize that innovation is messy, circular and dispersed (von Hippel 2005). Innovation occurs in networks, not lines (OECD 2010). The actual or perceived shortcomings of the acquisition model might also reflect the possibility that innovation coming from research institutions may simply lack sufficient economic value to make commercialization worthwhile. The lack of success might therefore be attributable to unattractive innovation rather than inappropriate intellectual property management. Nevertheless, this strategy seems especially ill-suited for mobilizing innovation with high social, but not necessarily commercial, potential.

Not all current efforts at intellectual property management in genomics research are without merit and never achieve positive outcomes. Universities, governments and companies have made considerable investments in establishing technology transfer and liaison offices. The resulting qualified personnel and institutional relationships are likely to be integral to any intellectual property management strategy, whether based on acquisitiveness and commercialization or any of the other options presented in this brief. They are often in the best position to see opportunities to develop networks, despite being hampered by policies, metrics and funding models that prevent them from taking full advantage of their knowledge.

To improve the existing, dominant model, policymakers could consider two possibilities. One is to reformulate technology transfer offices' mandates to be more consistent with institutional missions and employ evaluation metrics that account for academic, societal, economic, political *and* financial impacts more holistically. The University of British Columbia's industry liaison office has led this effort by developing new metrics (Bubela and Caulfield 2010) but has only had funding to assess its work once. Another possibility is to increase the efficiency of operations by using new tools for licensing the intellectual property portfolios that technology transfer offices are encouraged to acquire. For instance, the OECD Working Party on Biotechnology (2010) describes why model agreements might help to simplify licensing transactions by eliminating the need to negotiate all but the most contentious issues. It cites the success of the "Lambert Toolkit," a set of model agreements developed in the United Kingdom by representatives from academia, government and large and small companies in order to reduce the financial and human resources required to negotiate intellectual property agreements. The University of Glasgow has similarly simplified its tech-

nology transfer processes through a dedicated online portal that clearly lists "Easy Access IP" available for free as well as "Commercial Deals" for licensing and co-development.

Option 2 - Free-revealing to build the public domain

One reason for disappointing financial returns on investment in acquisition-oriented intellectual property management strategies is the significant expense of acquiring and enforcing rights, especially patents. These costs can be entirely eliminated by choosing to forego any intellectual property protection, instead freely revealing knowledge and technology directly into the public domain.

There is a possibility of confusion in differentiating this approach from other putatively "open" models of intellectual property management. The open source approach taken by some software developers, the Creative Commons system of licensing copyright protected works and several examples of open source biotechnology described below all depend, fundamentally, on acquiring intellectual property protection. The novelty of such open source systems is that intellectual property is then licensed to *require* rather than *restrict* access to the protected content or technology. The free-revealing approach is distinct because it sidesteps the intellectual property system altogether. It not only involves foregoing intellectual property rights; it also develops strong community norms that ensure what is publicly revealed not be appropriated by others.

Perhaps the best example of an unrestricted public domain model of intellectual property management is the Structural Genomics Consortium. Its access policy *prohibits* affiliated scientists or collaborators to seek patents that would grant exclusive rights over its research outputs, and encourages funders from government, industry or civil society to similarly forego patent rights. Unlike some other models that use the intellectual property system itself, through licences, to enforce such conditions, the Structural Genomics Consortium relies on a combination of contracts and social norms such as trust. The organization's non-proprietary philosophy is a key reason cited for its success (Edwards 2008; Edwards et al. 2009; Weigelt 2009).

A good illustration of an intellectual property management model on the border between the public domain and open source is PLoS, the Public Library of Science. While everything published in its repository is publicly available for free, some copyright restrictions still apply. Specifically, content remains copyright-protected and is licensed on one of the standard terms of the Creative Commons system, which permits use and reuse on the condition of attribution of source and authorship. Sage Bionetworks, a nonprofit biomedical research organization, takes a similar approach to providing data, tools, analysis and models.

While the orthodox approach rests upon acquisition and commercialization of intellectual property, Boyle (2008) argues: “the opposite of property’ is a concept that is much more important when we come to the world of ideas, information, expression, and invention. We want a lot of material to be in the public domain, material that can be spread without property rights.” Rai and Boyle (2007) apply this principle in the specific context of synthetic biology, and in the process explore tensions among different ways to create openness, including both public domain and open source models. As a promising example of the public domain model, they mention the Registry of Standard Biological Parts created by the Massachusetts Institute of Technology (MIT), which indexes biological parts, offers assembly services to construct parts, devices and systems, and could grow into a repository of information and specifications to facilitate synthetic biology. Such public disclosure makes the parts and trivial improvements unpatentable by others.

Free revealing may in some cases, however, leave open the possibility that others will attempt to acquire intellectual property rights over public domain knowledge or technologies. Therefore, some organizations, such as the British Columbia Cancer Agency (BCCA), seek patents for defensive reasons -- to guarantee freedom to operate for themselves and their constituencies.

Option 3 - Open collaborative licensing

Recognizing that current models of technology transfer have proved less successful than desired, and pursuing the ethos of publicly accessible science, a number of organizations have begun to experiment with middle ground models of intellectual property management. These models rely on intellectual property protection, but leverage protection to implement creative licensing practices that encourage co-operation and facilitate collaboration.

Their common feature is that they help to facilitate multilateral intellectual property transactions, either through the creation of centralized or decentralized structures. The OECD Working Party on Biotechnology (2010) explains how in centralized systems, like a patent pool, an agent (a rights holder or third party) bundles intellectual property rights and provides standard licenses covering that bundle, while in decentralized systems, like a clearinghouse, an agent merely provides a mechanism through which rights holders and licensees can efficiently interact.

Historically, agreements among patent holders to bundle rights in a pool have been controversial for their potential anti-competitive impacts; similar issues about their misuse have been raised around open source biotechnology (Feldman 2004). Such concerns are alleviated when patent pools are used to develop common technological standards for an industry, but that context is more applicable to information and communications technologies than biotechnologies.

Biotechnology patents pools (or ponds, as some call them) have been most used so far by social entrepreneurs for philanthropic purposes. In the case of the Medicines Patent Pool, for example, a partnership has formed under the auspices of UNITAID to provide a “one-stop shop” for clearing patent rights related to antiretroviral medicines for treating HIV (Gold et al. 2007; Childs 2010; Bermudez and t Hoen 2010). Similarly, the OECD Working Party on Biotechnology (2010) describes the important steps taken by Syngenta, in partnership with the researchers who genetically modified rice to produce β -carotene (provitamin A), to establish the Golden Rice Humanitarian Board with authority to license a large number of patents for free to subsistence farmers. (That Golden Rice has, despite this licence, still not achieved its promise because of regulatory barriers related to the deployment of genetically modified organisms reinforces the point that intellectual property management is simply one of many issues in translating genomics into practical impacts.)

Some commentators have highlighted the potential of patent pools in the field of gene-based diagnostic testing (Ebersole, Guthrie and Goldstein 2005; Verbeure et al. 2006), but nearly ten years of discussions about a pool to deal with patents around the severe acute respiratory syndrome (SARS) corona virus genome have so far failed to yield a tangible outcome, although this may be simply because SARS has not reappeared (Simon et al. 2005; Correa 2009). It remains to be seen whether these models can work successfully outside of the humanitarian context, where there are fewer incentives for firms to voluntarily pool intellectual property rights with other organizations.

Clearinghouses, on the other hand, have had some modest success despite relying on non-financial incentives for participation. Van Zimmeren’s (2009) conceptual typology of clearinghouses includes some that provide only access to intellectual property information and some that also aim to facilitate use through standard licensing or royalty collection.

Probably the most famous example of a clearinghouse is Cambia, a non-profit institute creating new technologies, tools and paradigms that enable innovation in agricultural biotechnologies through biological open source, or BiOS (Jefferson 2006; Berthels 2009). Its “Patent Lens” project and the related “Initiative for Open Innovation” provide cyber-infrastructure to access key legal, scientific, technical and business data. Another good illustration of an intellectual property rights clearinghouse is the Public Intellectual Property Resource for Agriculture (PIPRA), which supports the broad application of agricultural biotechnologies developed in public and non-profit institutions (Bennet and Boettiger 2009). Such tools are especially valuable for creating and modeling best practices (Kratzinger et al. 2009), and useful in the context of intellectual property landscaping -- a key part of effective and efficient intellectual property management (Lewensohn and Gold 2011).

Clearinghouses and other open source licensing models for tools and materials, not just information, have proven more difficult to sustain. The BioBricks Foundation is one example of an enterprise making biological parts available through open source style licenses. Cambia attempted to do so with a “TransBacter” plant transformation system to bypass the patent-stacked *Agrobacterium*-mediated gene transfer technology, and “Diversity Array Technology” to analyze genomes (Berthels 2009). Intellectual property rights related to DArT are currently being licensed by a privately held company on non-exclusive and reportedly fair and equitable terms that the technology’s proprietors describe as open source (Kilian 2009).

One of the major challenges in even considering the possibilities of open source models is the lack of consensus around a precise definition or even conceptual framework for analysis. Promising work is emerging from the management research on open innovation in general (Dahlander and Gann 2010) and analyses of open source biotechnology and genomics in particular (Hope 2008; Van Overwalle 2009; July 2010). But there are still major gulfs in the discourse and framing of concepts like openness and accessibility (compare, for example, Chesbrough (2005) with Kapczynski and Krikorian (2010)).

For Jefferson (2006), the key features of the open source model include full disclosure of enabling information and accessibility of technologies, and legal mechanisms that confer permissive rights as well as responsibilities to “share alike,” *i.e.* license improvements or subsequent innovations back to the source community. In the most thorough analysis of open source biotechnology to date, Hope (2008) elaborates on the general objectives of open source, which are enforcing intellectual property protection to avoid opportunistic exploitation, granting standard licenses that permit competition and technological improvements or “forks,” and often but not always imposing on licensees reciprocal obligations to share their improvements on similar terms.

The core challenge with these models, explains Hope, is to create relatively standard licenses that can accommodate the complexity and variety of biotechnology transfer agreements, yet remain faithful to the underlying logic of open source. We would add another key issue, which is identifying a viable business model to profit from substantial capital investments in scientific and technological research. Without economic sustainability, open source models are unlikely to enter the mainstream. Whether these challenges can be overcome remains an open theoretical and practical question.

V. Practical Application and Considerations

In very general terms, policy option #1 directly or indirectly encourages acquisition and commercialization of *all* possible intellectual property rights. Policy option #2, on the other hand, favours *no* intellectual property protection, supporting strong norm development to ensure a vibrant public domain. Policy option #3 promotes the acquisition of *some* intellectual property protection, but does so to

facilitate collaboration rather than (or in the process of) exclusive rights to commercialization. While there is an understandable, perhaps inevitable, instinct to gravitate toward this middle ground in the search for consensus, the theoretical and practical considerations discussed in this brief suggest that one or the other more clear-cut management strategies may, in many cases, be more efficient and effective.

It is important to realize that an increased focus on enriching the public domain does not ignore the importance of commercialization; it simply puts responsibility for pursuing and measuring that outcome on other actors in the innovation system. For example, the Structural Genomics Consortium builds the public domain for pre-competitive research, in effect pushing the role of intellectual property rights further down the supply chain of commercializable science and technology. Conversely, the acquisition toward commercialization model is not meant to devalue the dissemination of knowledge. It is based on the good faith belief that the pursuit and use of intellectual property rights is an effective means to that end. For example, the requisite disclosure of innovations through patents creates an almost immediately accessible body of technical literature that anyone may rely upon, initially subject to the legal rights of the patentee but eventually for free.

Delineating the boundaries of control over innovation is not merely a matter of timing, either in terms of the stage in the innovation process at which intellectual property becomes important, or the duration of the term of intellectual property protection. It also depends upon other factors, such as the nature of the research (basic or applied) or the source of funding (public or private). Not least among other factors are issues of race and culture (Amani and Coombe 2005). In particular, the traditional knowledge of indigenous and local communities – including Aboriginal Peoples of Canada – has been conceptualized outside of the intellectual property system. A team of researchers working on Aboriginal anti-diabetic medicines is working to put principles of prior informed consent, joint or collective ownership, access and benefit sharing, and stewardship and responsibility into practice (CIHR-TAAM, n.d.). There is, however, an interesting but unexplored parallel between the values underlying indigenous perspectives on control of knowledge and the principles animating open source communities.

Despite the illustrations provided, it is unlikely that any single intellectual property management strategy would or should be applied rigidly within or across organizations. There is no need for policymakers to choose only one of these options because they are not mutually exclusive, despite their convenient presentation in this brief as distinct. Degrees of openness can be characterized on a continuum reflecting the porosity of boundaries separating public and private rights, and the emphasis on osmosis between them. Moreover, different resources at different stages of development in different industries in different places involving different collaborators and different intellectual property rights can be managed using a mixture of approaches. Perhaps most importantly, the appropriate blend of intellectual property management models will depend on

the essential nature of the commercial or non-commercial value to be created and shared among stakeholders.

At present, key policies of certain organizations are not neutral toward intellectual property management strategies. For example, most granting agencies' implicit or explicit criteria for evaluating and funding research proposals normatively establish the acquisition and commercialization of intellectual property as a prescriptive requirement, particularly as an expected economic benefit of the funded project. They tend not to encourage outside-the-box thinking or experimentation. While institutional cultures can be difficult to change, serious consideration should be given to the appropriateness of such policies in light of policymakers' objectives for financial and non-financial returns on investments and the instrumental purposes of managing intellectual property. Intellectual property's functions should be to create knowledge networks and markets that facilitate access to and use of knowledge, provide incentives to invest in knowledge creation and dissemination, ensure equitable distribution of commercial and social benefits and take account of the broader needs of stakeholder communities.

Policymakers have a key role to play in articulating the overarching principles that drive an organization's intellectual property policy. While the details can and should be left to those actually designing and implementing a particular intellectual property management scheme, statements of principle, effective funding mechanisms and training programs provide starting points for discussions and negotiations between actors.

VI. Future Research Questions

As stated earlier in this brief, we have provided a general synthesis and concise evaluation of various intellectual property management models, and an overview of some practical considerations for policymakers. Obviously, much more could be said about all of these issues. We believe that three points in particular warrant attention in the immediate future. First, we have identified the need to determine more precisely which actors could or should take responsibility for action. Who, specifically, are the policymakers best positioned to address each of the many distinct issues highlighted in this brief? Second, there is a need to establish a forum in which such actors can convene to consider the instrumental purposes of intellectual property and the specific tools available to actors for influencing management strategies. How can policymakers best make a difference? Third, if there is experimentation with new management models, it will be necessary to develop and test new metrics to measure the success of these models based on their objectives. What might such evaluation mechanisms look like? Underlying all of these points is the need for further research exploring the conceptual and practical challenges associated with each of the intellectual property management models we have introduced. Here, we have provided a starting point for further study of such issues.

Moreover, this brief on intellectual property management has, by necessity addressed only one of many issues relevant to science and technology innovation policy. That is not because we intend to overstate the importance of intellectual property, but is simply because other research in the past and future has addressed and will address other key issues, including consent and privacy, science and technology entrepreneurship, regulation and governance and much more.

References

Literature

- Amani, Bita and Rosemary J. Coombe. "The Human Genome Diversity Project: The Politics of Patents at the Intersection of Race, Religion, and Research Ethics." *Law and Policy* 27 (2005): 152-188.
- Bessen, James and Michael A. Meurer. *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk*. Princeton: Princeton University Press, 2008.
- Benkler, Yochai. *The wealth of networks: How social production transforms markets and freedom*. New Haven: Yale University Press, 2006.
- Bennet, Alan B. and Sara Boettiger. The Public Intellectual Property Resource for Agriculture (PIPRA). In *Gene Patents and Collaborative Licensing Models*. Cambridge: Cambridge University Press, 2009.
- Bermudez, Jorge, and Ellen t Hoen. "The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good." *The open AIDS journal* 4 (2010): 37-40.
- Berthels, Nele. CAMBIA's Biological Open Source Initiative (BiOS). In *Gene Patents and Collaborative Licensing Models*. Cambridge: Cambridge University Press, 2009.
- Boyle, James. *The Public Domain: Enclosing the Commons of the Mind*. New Haven & London: Yale University Press, 2008.
- Bubela, Tania M, and Timothy Caulfield. "Role and reality: technology transfer at Canadian universities." *Trends in biotechnology* (September) 28 (9) (2010): 447-451.
- Canada HIV/AIDS Legal Network. 2011. "Key Documents," <http://www.aidslaw.ca/EN/camr/index.htm#Documents>.
- Canadian Council of Chief Executives. "Innovation and Competitiveness: Intellectual Property," <http://www.ceocouncil.ca/en/innovation/intellectual.php>.
- Coalition for Action on Innovation in Canada. 2010. "An Action Plan for Prosperity," http://www.actiononinnovation.ca/en/media/ENG_Plan.pdf.
- Castle, David. *The role of intellectual property rights in biotechnology innovation*. Chetelham: Edward Elgar Publishing, 2009.
- Chesbrough, Henry William. *Open Innovation: The New Imperative for Creating And Profiting from Technology*. Boston: Harvard Business Press, 2005.
- Childs, Michelle. "Towards a Patent Pool for HIV Medicines: The Background." *The open AIDS journal* 4 (2010): 33-36.
- CIHR Team in Aboriginal Anti-diabetic Medicines. n.d., <http://www.taam-emaad.umontreal.ca/>.
- Conference Board of Canada. 2010. "How Canada Performs. A Report Card on Canada." Conference Board of Canada, <http://www.conferenceboard.ca/HCP/Details/Innovation.aspx>.
- Corbin, Ruth. 2010. "Intellectual Property in the 21st Century." Conference Board of Canada, <http://www.conferenceboard.ca/documents.aspx?did=3452>.
- Correa, Carmen E. The SARS case: IP Fragmentation and patent pools. In *Gene Patents and Collaborative Licensing Models*. Cambridge: Cambridge University Press, 2009.
- Dahlander, Linus, and David M Gann. "How open is innovation?" *Research Policy* 39 (6) (July 1) (2010): 699-709.
- de Beer, Jeremy. "Reconciling Property Rights in Plants." *Journal of World Intellectual Property* 8 (1) (2005): 5-31.
- de Beer, Jeremy. "Legal Strategies to Profit from Peer Production." *Canadian Business Law Journal* 46 (2008): 269-291.
- de Beer, Jeremy and Kurtis Andrews. "Accounting of Profits to Remedy Biotechnology Patent Infringement." *Osgoode Hall Law Journal* 47 (2009): 619-662.
- Ebersole, Ted J, Marvin C Guthrie, and Jorge A. Goldstein. "Patent pools and standard setting in diagnostic genetics." *Nature Biotechnology* 23 (8) (August) (2005): 937-938.
- Edwards, Aled. "Open-source science to enable drug discovery." *Drug Discovery Today* 13 (17-18) (September) (2008): 731-733.
- Edwards, Aled M, Chas Bountra, David J Kerr, and Timothy M Willson. "Open access chemical and clinical probes to support drug discovery." *Nature Chemical Biology* 5 (7) (July 1) (2009): 436-440.
- Etzkowitz, Henry. *The Triple Helix: University-Industry-Government Innovation in Action*. New York: Routledge, 2008.
- Feldman, Robin. "The Open Source Biotechnology Movement: Is It Patent Misuse?" *Minnesota Journal of Law, Science and Technology* 6(1) (2004): 117-168.
- Gold, E Richard. "Finding common cause in the patent debate." *Nature Biotechnology* 18 (11) (November) (2000): 1217-1218.
- Gold, E Richard, Tina Piper, Jean-Frédéric Morin, L. Karen Durell, Julia Carbone, and Elisa Henry. *Preliminary Legal Review of Proposed Medicines Patent Pool*. The Innovation Partnership, 2007,
- Gold, E Richard, Wendy Adams, Tania Bubela, Luc Cassivi, David Castle, Ghislaine Cleret de Langavant, L Martin Cloutier, et al. "Toward a New Era of Intellectual Property: From Confrontation to Negotiation." The Innovation Partnership, 2008.
- Gold, E Richard, JC Kohler, J Orbinski and JF Morin. "Beyond access to drugs is access to knowledge" *The Hill Times*, June 22 (2009): 16.
- Heller, Michael. *The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives*. New York: Basic Books, 2008.
- Heller, Michael A. "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets." *Harvard Law Review* 111 (3) (January 1) (1998): 621-688.

- Heller, Michael A., and Rebecca S Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research." *Science* 280 (5364) (May 1) (1998): 698-701.
- Hope, Janet. *Biobazaar: The Open Source Revolution and Biotechnology*. Boston: Harvard University Press, 2008.
- Jaffe, Adam B. and Josh Lerner. *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*. Princeton: Princeton University Press, 2006.
- Jefferson, Richard. "Science as Social Enterprise." *innovations* (fall) (2006): 1-32.
- Johnson, Steven. *Where Good Ideas Come From: The Natural History of Innovation*. New York: Putnam, 2010.
- Joly, Yann. "Open Source Approaches in Biotechnology: Utopia Revisited." *Maine Law Review* 59 (2) (2007): 385-406.
- Joly, Yann. "Open biotechnology: licenses needed." *Nature Biotechnology* 28 (5) (2010): 417.
- Kapczynski, Amy, and Gaelle Krikorian. *Access to Knowledge in the Age of Intellectual Property*. Cambridge: Zone Books, 2010
- Kieff, F. Scott. "Removing Property from Intellectual Property and (Intended?) Pernicious Impacts on Innovation and Competition." George Washington University Law School Legal Studies Research Paper Series and Public Law & Legal Theory Research Paper Series, 2011. <http://ssrn.com/abstract=1797287>.
- Kilian, Andrzej. Diversity Arrays Technology Pty. Ltd. (DArT). In *Gene Patents and Collaborative Licensing Models*. Cambridge: Cambridge University Press, 2009.
- Krattiger, Anatole, Richard T. Mahoney, Lita Nelsen, Jennifer A. Thomson, Alan B. Bennet, Kanikaram Satyanarayana, Gregory D Graff, Carlos Fernandez, and Stanley P. Kowalski. *Intellectual Property Management in Health and Agricultural Innovation*. Second edition. Centre for the Management of Intellectual Property in Health Research and Development and Public Intellectual Property Resource for Agriculture, 2009.
- Lewensohn, Danielle, and E Richard Gold. "Methods for Patent Landscaping." VALGEN Working Paper, 2011.
- Maskus, Keith. The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer. *Duke Journal of Comparative and International Law* (1998): 109-161.
- OECD. "Guidelines for the Licensing of Genetic Inventions" Organisation for Economic Co-Operation and Development, 2006 <http://www.oecd.org/dataoecd/39/38/36198812.pdf>.
- OECD. "The OECD Innovation Strategy: Getting a Head Start on Tomorrow." Organisation for Economic Co-operation and Development, 2010.
- OECD Working Party on Biotechnology. "Collaborative Mechanisms for Intellectual Property Management in the Life Sciences." Organization for Economic Co-operation and Development, 2010.
- Patry, William. *Moral Panics and the Copyright Wars*. Oxford: Oxford University Press, 2009.
- Phillips, Peter. The challenge of creating, protecting and exploiting networked knowledge. In E. Einsiedel and F. Timmermans (eds) *Crossing Over: Genomics in the Public Arena*, 7-32. Calgary: University of Calgary Press, 2005.
- Phillips, Peter. *Governing Transformative Innovation: Who's In Charge?* Cheltenham: Edward Elgar, 2007
- Phillips, Peter. Technology, ownership and governance: an alternative view of IPRs. In E. Einsiedel (ed), *Foresight on Emerging Technologies*, 307-326. Calgary: University of Calgary Press, 2008.
- Rai, Arti, and James Boyle. "Synthetic biology: caught between property rights, the public domain, and the commons." *PLoS biology* 5 (3) (March) (2007): e58.
- Shapiro, CarlAdam B. Jaffe, Josh Lerner, and Scott Stern. Navigating the Patent Thicket: Cross Licences, Patent Pools and Standard Setting. In *Innovation Policy and the Economy*, Adam B. Jaffe, Josh Lerner, and Scott Stern ed., 119-150. Cambridge: The MIT Press, 2001
- Simon, James H M, Eric Claassen, Carmen E. Correa, and Albert D M E Osterhaus. "Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling." *Bulletin of the World Health Organization* 83 (9) (September) (2005): 707-710.
- Smyth, Stuart. "Working at the intersection of ego and greed: A Canadian assessment of university technology transfer offices." VALGEN Working Paper, 2011.
- Van Overwalle, Geertrui. *Gene Patents and Collaborative Licensing Models*. Cambridge: Cambridge University Press, 2009.
- van Zimmeren, Esther. Clearinghouse mechanisms in genetic diagnostics: Conceptual framework. In *Gene Patents and Collaborative Licensing Models*. Cambridge: Cambridge University Press, 2009.
- Verbeure, B, E van Zimmeren, G Matthijs, and G Van Overwalle. "Patent pools and diagnostic testing." *Trends in biotechnology* 24 (3) (2006): 115-120.
- von Hippel, Eric. "Sticky Information' and the Locus of Problem Solving." *Management Science* 40 (4) (April) (1994): 429-439.
- von Hippel, Eric. *Democratizing innovation*. Cambridge: The MIT Press, 2005
- Weigelt, Johan. "The Case for Open-Access Chemical Biology." *European Molecular Biology Organization Reports* 10 (9) (September 1) (2009): 941-945.

Legislation

Bayh-Dole Act (University and Small Business Patent Procedures Act), 35 U.S.C. § 200.

http://www.law.cornell.edu/uscode/html/uscode35/usc_sup_01_35_10_II_20_18.html

Copyright Act, R.S.C. 1985, c. C-42, <http://laws-lois.justice.gc.ca/fra/lois/C-42/>

Patent Act, R.S.C. 1985, c. P-4, <http://laws-lois.justice.gc.ca/fra/lois/P-4/>

Trade-marks Act, R.S.C. 1985, c. T-13, <http://laws-lois.justice.gc.ca/fra/lois/T-13/>

Case law

Association for Molecular Pathology et al. v. U.S. Patent and Trademark Office et al., No. 09-cv-4515, 94 USPQ2d 1683 (S.D.N.Y. March 29, 2010), Rev'd 2010-1406 (July 29, 2011), <http://www.aclu.org/files/assets/2010-3-29-AMPvUSPTO-Opinion.pdf>.

Diamond v. Chakrabarty, 447 US 303 (1980), <http://supreme.justia.com/us/447/303/case.html>.

Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, 2002 SCC 76, <http://scc.lexum.org/en/2002/2002csc76/2002csc76.html>.

Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 2004 SCC 34, <http://scc.lexum.org/en/2004/2004csc34/2004csc34.html>.

Organic Seed Growers and Trade Association et al. v. Monsanto, No. 11-cv-2163, (S.D.N.Y.),

<http://www.pubpat.org/assets/files/seed/OSGATA-v-Monsanto-Complaint.pdf>



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