

Title: Evaluating Alternative IP Mechanisms in Genomic Research

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Abstract:

This paper offers a preliminary review of alternative intellectual property (IP) approaches for results produced by the MORGEN project team which is funded by Genome Canada and centered at the British Columbia Cancer Agency in Vancouver, B.C. The aim of the paper is to summarize results from our research thus far, as they relate to our broader study of the relationship between open science, commercialization and technology transfer offices. The role of technology transfer offices (TTO) is central to our analysis and is viewed as a key factor in implementing Genome Canada policies and principles associated with IP and commercialization.

Keywords: Commercialization, open science, technology transfer

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## **1. Introduction**

This paper offers a preliminary review of alternative intellectual property (IP) approaches for results produced by the MORGEN<sup>1</sup> project team which is funded by Genome Canada and centered at the British Columbia Cancer Agency (BCCA) in Vancouver, B.C. The aim of the paper is to summarize results from our research thus far, as they relate to our broader study of the relationship between open science, commercialization and technology transfer offices. The role of technology transfer offices (TTO) is central to our analysis and is viewed as a key factor in implementing Genome Canada policies and principles associated with IP and commercialization.

## **2. MORGEN – The Science Project**

MORGEN is an extension of a previous project, the Mouse Atlas of Gene Expression<sup>2</sup>, which was also funded by Genome Canada. Funding by Genome Canada is administered by regional units, Genome British Columbia in this case. Among the objectives of the MORGEN team is the characterization of gene regulatory mechanisms governing organogenesis with a special focus on the heart, liver and pancreas. The project is involved in upstream, basic research with possible relevance to human development and disease. The MORGEN team has identified potential useful results of research to include, organogenesis genes/products, biological targets, and tools for Stem cell therapies.

## **3. Balancing the Agenda**

One challenge associated with Genome Canada funded work relates to the maintenance of open science norms. Open science refers generally to the effort to widely disseminate results and preserve broader access to science research or results, according to accepted academic practices of releasing them to the public domain. The challenge is to maintain these norms while also honoring the mandate of Genome Canada, which is to ensure that the results of research, such as discoveries contributing to medical products, benefit Canadians. This mandate is generally understood to involve patenting at some stage of research. Thus Genome Canada recipients are in a complex situation in which they are expected to deposit research to the public domain but need to remain mindful of intellectual property and commercialization. Hence, in some measure aims and values clash, and the sophistication of patenting and licensing techniques is becoming increasingly important.

Genome Canada has a number of policies and statements regarding their own perspective on this somewhat complex situation. The publicly funded Genome Canada requires matching funds.<sup>3</sup> That is, Genome Canada funds only half the cost of a project, while the other half must come from other agencies or from private sector donors.<sup>4</sup> This practice is clearly part of an effort to enlist potential commercial

partners in research. Genome Canada explicitly asks in its funding Guidelines/Evaluation Criteria, for details surrounding social and economic benefit to Canada, including a proposal for the transfer, dissemination, use or commercialization of proposed research results.<sup>5</sup> Some of Genome Canada's communications have explicitly stated that they don't require commercialization, while simultaneously stating that Genome Canada intends to promote translation to useful applications.<sup>6</sup> Ultimately, the conflicted goals of open science in academia and commercialization make entertaining the alternatives in genomics a challenging and intricate process, and provide an impetus for entertaining licensing schemes that integrate private and public players.

#### **4. Theoretical Background**

The controversies over gene patenting provide a backdrop to the current calls for alternative IP mechanisms and efforts to engage in practices consistent with open science. After 1980, legislation such as the Bayh-Dole Act in the United States gave universities, small businesses and non profits control over inventions resulting from federal funding.<sup>7</sup> Subsequently, patenting of genomics became more prevalent, and U.S. Supreme Court decisions, such as *Diamond v. Chakrabarty*<sup>8</sup>, that deemed some human made microorganisms patentable, furthered such practices. Tensions over the appropriate extent of gene patenting erupted into the public forum with the well publicized race between the public human genome project and the private company Celera to complete the map of the human genome. One of the most coherent expressions of concern over these developments came in a seminal 1998 paper<sup>9</sup>, by Heller and Eisenberg, expressing concern over a "Tragedy of the Anticommons".<sup>10</sup> Little empirical support has emerged for this theory in subsequent years. However, the publication of the paper marked renewed interest in alternative forms of IP. It is in this context that we consider creative licensing strategies used in concert with patenting, open source and patent pools for upstream genomics research.

#### **5. Legal Framework**

When funding is awarded by Genome Canada to a researcher in British Columbia, collaborative agreements are set up involving researcher's institutions, researchers, and Genome BC. According to those agreements, control of IP is placed entirely in the hands of researchers and their institutions, although an advisory body, including members appointed by Genome BC, is appointed. In effect then, a primary voice in making decisions about IP is the TTO of the researchers' institution. As such, we have focused our research efforts on governance considerations in technology transfer. Technology Transfer Office's are the center of the process of patenting and commercialization and an essential consideration as we seek to identify the role of alternative IP mechanisms on the research continuum.

The Canadian innovation landscape is a system of devolved governance. There is no parallel in Canada to the U.S. Bayh-Dohl Act of 1980, and there is uncertainty associated with Canada's policy framework. So what policy measures do affect how Genome Canada research moves through the university system? Canadian

universities implement a variety of practices. Policies may specify whether the ownership of IP is with the university or its researchers and resultantly whether the investigator must disclose.<sup>11</sup> There are some universities where there are no explicit policies, hence IP ownership is with “creator” and these individuals are thus “not required to disclose IP to their university”.<sup>12</sup> The difference in IP approaches make specific collaborative endeavors and partnerships with industry challenging.<sup>13</sup> For example, in B.C., the ownership policies of three lower mainland institutions have differing assignments of ownership and disclosures and serve as a good case example for use in further empirical work.<sup>14</sup>

Although Genome Canada places management of IP squarely in the hands of researchers and their institutions, Genome Canada policies nevertheless can impact management of research results. The Genome Canada funded Principle Investigators (PIs) must sign a Data Release policy when accepting their funding contract.<sup>15</sup> This policy allows both open release, for instance on a publicly available website, and patenting as forms of data release. The Genome Canada commercialization policy is far from definitive. One example of guidelines to commercialize is those from Genome BC on which no signature is required.<sup>16</sup> Hence, in an attempt at balancing these competing policies a variety of alternatives are under consideration.

The IPPRG<sup>17</sup> has been considering how Open Source mechanisms could be adequately developed given the governance context. Innovative legal mechanisms are necessary as we seek solutions to balance the conflicting agendas present in governing policies and procedures. In the MORGEN context, we consider the current implementation of a Creative Commons license.<sup>18</sup> However, we are interested in other models such as the CAMBIA BIOS type license.<sup>19</sup> A version of this could be used if research results are already of a patentable quality. Some academics have raised objections based on the technical and logistical difficulties such license development would create. Further work on the issue is needed.

## **6. Interim conclusions on alternative intellectual property and upstream genomics research**

Against this contextual and legal backdrop our group is trying to identify alternative IP mechanisms that might preserve open science while acknowledging Genome Canada and Genome BC as well as technology transfer office aims. As all are aware, alternative forms of IP are varied and complex. Part of the research process is the development of actual positions on alternatives with which we can move forward. On March 9, 2007, in Vancouver, British Columbia the IPPRG held a interdisciplinary workshop, which allowed for development of research themes within this project.<sup>20</sup>

First of all, emerging from this workshop were overwhelming indications that within a public health care system there is a need to separate health care delivery issues from upstream research issues. Genome Canada mandates delivery of products of benefit to Canadians. Therefore, key to the alternatives debate, is when and where an alternative mechanism encourages access for upstream researchers while at the same time promotes investment towards development of a commercially viable product.

This includes the need for further investigation into research management protocols that adequately represent the public interest. We found that the commercialization policy and the academic norms are hard to balance in practice making the academic – industry interface challenging to manage. This is true particularly when we look at the legislative landscape against which we must perform basic and applied research. The worm model described by the C. Elegans<sup>21</sup> project was a specific, perhaps special place that ignores the commercialization drive and yet thrives in its methods of dissemination and collaboration.

Secondly, we found that TTOs play a critical role in determining what types of IP are applied, and what science is the subject matter of IP protections. Part of our research is looking into how alternative IP may actually be explored and implemented by TTOs. While the consistency of patent protections within TTO's is largely related to the commercial values associated with the research, the use of alternative licensing schemes may be a key factor in the actual translation of research with public/private interests attached. Central to this debate then, is the effectiveness of traditional TTO patenting and licensing models in transferring viable products to market. Given that there are many more good ideas than there are funds for product development alternatives are of primary consideration when we talk about translating research from bench to bedside.

Finally, in the MORGEN context, one can see the complexity of the situation and observe that the type of technology and the timing are critical to thinking through IP. Illustrative is the debate that continues to surround the use of an open source model for genomics. Of interest, is MORGEN's implementation of a license based on open source philosophies. That is, a Creative Commons license requiring attribution of the original source of website data, if the data is used or published. It is far harder than many imagined, to develop an open source licensing approach that would be the basis for further development. One possibility is the development of open source models such as CAMBIA BIOS license, allowing for a merger of public and private interests in furthering commercial potential and the public good. Notable of course is the difficulty in creating such a license. In essence, it would be very demanding of time and resources. In fact, it may be too complex and an Open Source type approach may have to depend on other arrangements, for instance, encouraging development of IP governance, and community building as the proper course of action. For instance, the formation of collaborative networks involving both academics and industry partners can allow for a creative melding of interests in IP models. The question remains as to how and when TTO's would implement such approaches.

## **7. Points to Consider**

In keeping with the mission of the GE<sup>3</sup>LS<sup>22</sup> program, the next focus of our project is to identify some of the conditions that have hindered or promoted the successful evolution from research to commercialization. The study will begin with institutions in British Columbia.<sup>23</sup> We aim to understand how TTOs might use IP depending on the type of technology, the stage and potential ends of the research, as well as the

funding source. Hence, the following are key points when making decisions about alternative IP.

### **7.1. Type of technology**

An important element for evaluating the applicability of alternative IP is the type of technology or research result under consideration. In patenting, alternative choices will be affected by the nature of the invention, whether it is the basic genomic data, intermediate research tools, genomics databases, (associated software and hardware) or late stage platform technologies such as therapeutics, diagnostics, and vaccines. The type of IP to be applied will also vary on a determination of whether a technology has human, environmental or other industrial applications.

### **7.2. The stage of research**

The stage of research is also a relevant consideration in making IP decisions. With earlier stage research, there is less ability to determine its economic value and a less stringent form of IP is likely applied. As such, timeline divisions are necessary as we separate the upstream research issues from the health-care and delivery side issues. Essentially, timelines are important in research commercialization as we consider how, and when, research results are openly released or protected by some form of IP.

### **7.3. Technology research funding**

Finally, the nature and source of research funding can shape the potential application of IP and commercialization by universities, collaborators, and funding agencies. Some of this will depend on contractual terms relating to IP that are tied to funding, as well as how the funding is set up and who is making the IP decisions. When funding comes through a combination of sources the scenario is more complex and the challenge is again in balancing conflicting aims.

## **8. Conclusions: What are MORGENS alternatives?**

The IPPRG at the CAE – UBC is considering a number of alternative mechanisms to full scale traditional patenting. Concepts under consideration include patent pools, public domain, open source and mixed mechanisms. It may be productive for early stage research consortia such as MORGEN to focus their efforts on unique forms of IP application, specifically tailored to individual research products. While seemingly complex, the development of individual licensing schemes based on open source philosophies may be possible. Our research will continue to evaluate whether a TTO would implement such approaches. The conflicting agendas remain and the development of novel schemes to license, not necessarily for free, but in order to preserve access warrants consideration. Following from this, the role of the TTO in future IP management may be best served by industry/academic pooling aiming for an accessible end product. In sum, the actual applications of alternative IP mechanisms are case specific. Given the wide variety of products seen in such a project, varying from basic facts and data, databases, and certain forms of software

and hardware, licensing schemas will vary as will the type of IP appropriate to a variety of products. Mechanisms may include a unique blend of the philosophies of copyright, patenting, and contract law, a diversification of ideals, aiming ultimately for balance and a productive social and commercial end.

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<sup>1</sup> Dissecting Gene Expression Networks in Mammalian Organogenesis Project, Online:

<<http://www.mouseatlas.org/>> Retrieved Aug 24, 2007

<sup>2</sup> Mouse Atlas of Gene Expression Online: <<http://www.mouseatlas.org/>> Retrieved Aug 24,2007

<sup>3</sup> Tim Caulfield, “Commentary: An Independent Voice?: Conflicts of Interest and Research on Ethical, Legal and Social Issues, (2005) 13 Health Law Review 114-116 at 114.

<sup>4</sup> Paul Wells, “Our Mad Scientists” *Macleans*, (23 June 2005); Library of Parliament, Online: <http://www.parl.gc.ca/information/library/prbpubs/prb0627-e.htm>

<sup>5</sup> Online: <<http://www.genomecanada.ca/xresearchers/competitions/c3/GuidelinesFinal.pdf>> Retrieved Aug 24,2007

<sup>6</sup> As per Genome Canada website, “Genome Canada is not a venture capital firm. We do have an objective to ensure the translation of research into useful applications, but we are not required to promote commercialization and generate financial returns on our investments.”

Online:<http://positionpapers.genomecanada.ca/en/information-meeting-february-2007.php?q01> Retrieved Aug 10, 2007

<sup>7</sup> Online: <[http://en.wikipedia.org/wiki/Bayh-Dole\\_Act](http://en.wikipedia.org/wiki/Bayh-Dole_Act)>

<sup>8</sup> *Diamond v Chakrabarty*, 447 U.S. 303 (1980)

<sup>9</sup> M.A.Heller & R.S. Eisenberg, “Can Patents Deter Innovation? The Anticommons in Biomedical Research” 280 *Science*, 698 – 701.

<sup>10</sup> See Caulfield et. al. for further discussion of issues, Caulfield, T. et. al, “Evidence and anecdotes: An analysis of human gene patenting controversies”(2006) 24 *Nature Biotechnology*, 1091-1094 at 1091.

<sup>11</sup> Afshin, Afshari, “ The Academic Technology Transfer Landscape in Canada and Quebec in Particular” (The 7<sup>th</sup> National Congress on Government-University-Industry Relations for National Development, Iran, December 2003) at 12. Online: < <http://www.ea-sciencepark.org.ir/PDF%20Files/44.pdf>> Retrieved Aug 2007.

<sup>12</sup> *Ibid* at 12.

<sup>13</sup> Andrew F. Christie et. al, Commonwealth Department of Education, Science & Training, Commonwealth of Australia, 2003, *Analysis of the Legal Framework for Patent Ownership In Publicly Funded Research Institutions* (Commonwealth of Australia, 2003) at 53.

<sup>14</sup> For example, differing policies on ownership are summarized as follows: UBC UILO-All staff, students, faculty, or anyone associated with the university who used university funds or facilities must assign all rights to the university → the university can then chose to reassign back to the inventor, undertake patenting and licensing arrangements through UILO; Online:<  
<http://www.universitycounsel.ubc.ca/policies/policy88.pdf>>

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; SFU-There is no obligation to assign rights to the university. There is, however, an option to do so. All patents belong to the inventor unless there is a written contract that says otherwise; Online:

<<http://www.sfu.ca/uilo/researchers/property.html>>

BCCA- All inventions by BCCA/BCCF employees or associates which result from the use of BCCA/BCCF funds or facilities are the property of the BCCA/BCCF unless there is a prior arrangement with the sponsor of the research. The BCCA can then chose to keep the rights or assign them to the inventor or a university; Online:< <http://www.bccancer.bc.ca/NR/rdoonlyres/E60548DF-7BBC-4DA1-8166-656B9EE9BF2C/3102/BCCAPatentPolicy.pdf>> Retrieved Aug 30, 2007.

<sup>15</sup> Genome Canada Data Release Policy,

Online:<<http://www.genomecanada.ca/xcorporate/policies/DataReleasePolicy.pdf>> Retrieved Aug 30, 2007.

<sup>16</sup> Among the principles that are iterated in *Genome BC's Ethical Principles for Commercialization of Genome BC funded research*, is the obtaining of patents where “strategically advisable” with the financial aid of GBC/GC; GBC funded institutions manage IP within their own and GBC guidelines; non-exclusive and exclusive licensing will be applied where “appropriate”; and IP that comes from GBC funded research “must be developed/commercialized for the maximum public good”.

<sup>17</sup> Intellectual Property Policy & Research Group, Center for Applied Ethics, University of British Columbia

<sup>18</sup> Creative Commons, Online:<<http://creativecommons.org>> Retrieved Aug 30, 2007.

<sup>19</sup> BIOS(Biological Open Source)Licenses , Online:<<http://www.bios.net/daisy/bios/licenses/398.html>> Retrieved Aug 30,2007.

<sup>20</sup> The speakers included (Speaking order) Cheryl Power – Lawyer & Research Associate – Center for Applied Ethics, University of British Columbia, Kate Murashige – Partner – Morrison & Foerster, San Diego, CA, Tania Bubela – Assistant Professor, Dept of Marketing, Business Economics and Law, University of Alberta, Olaf de Jager – Legal Counsel/Business Consultant –Viroscope., Netherlands, Don Moerman – Professor – Department of Zoology, University of British Columbia, Robert Cook-Deegan, M.D. – Director – Center for Genome Ethics, Law & Policy, Duke University and Tina Piper – Assistant Professor of Law – McGill.

<sup>21</sup> Efficient Identification and Cloning of Single Gene Deletions in the Nematode *Caenorhabditis elegans* Online:<<http://ko.cigenomics.bc.ca>> Retrieved Aug 30, 2007.

<sup>22</sup> Ethical, environmental, economic, legal and social issues related to genomics research

<sup>23</sup> University of British Columbia, Simon Fraser University, British Columbia Cancer Agency