DISCUSSION AND DEBATE

The Commercialization of Genomic Research in Canada

La commercialisation de la recherche en génomique au Canada

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Abstract

The commercialization of academic research has been promoted by North American policy makers for over 30 years as a means of increasing university financing and to ensure that promising research would eventually find its way to the marketplace. The following issues paper constitutes a reflection on the impact of the Canadian commercialization framework on academic research in the field of genomics. It was written following two workshops and two independent studies organized by academic groups in Quebec (Centre of Genomics and Policy) and Alberta (Health Law Institute). The full sets of recommendations are available upon request to the authors.

Résumé

Depuis 30 ans, en Amérique du Nord, les decideurs de politiques favorisent la commercialisation de la recherche universitaire comme moyen de financement et pour assurer que les recherches prometteuses se taillent éventuellement une place sur le marché. Cet article de discussion est une réflexion sur l'impact, au Canada, du cadre de commercialisation de la recherche universitaire dans le domaine de la génomique. Il a été écrit suite à deux ateliers et deux études indépendantes organisées par des groupes universitaires au Québec (Centre de génomique et politique) et en Alberta (Institut du droit de la santé). L'ensemble des recommandations est disponible sur demande auprès des auteurs.

This policy paper is intended to encourage policy makers and academic institutions to reflect on how commercialization, intellectual property (IP) and public–private partnerships in genomic research should be managed in the Canadian context. By way of IP rights and the creation of public–private partnerships, commercialization aims to convert academic research into a variety of commercial products. Commercialization could be viewed as the process of extracting economic value out of new products, processes and knowledge through the use of IP rights, the creation of spin-off companies or both (Gault and McDaniel 2005). In Canada, as in the United States and Europe, there has been a considerable push to commercialize university-based research in order to improve technology transfer,

facilitate economic growth, stimulate research collaboration and boost university financing (Joly et al. 2007). This activity has sparked debates on the impact of research commercialization within these countries/regions.

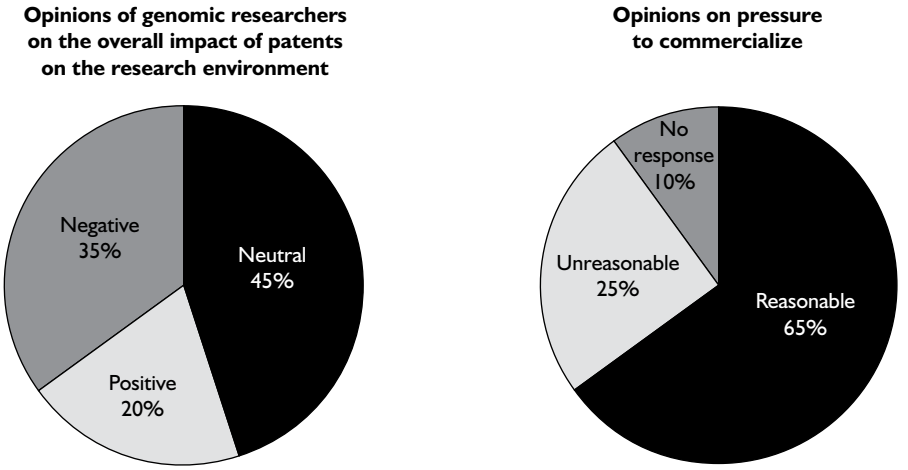
In late 2008, at the launch of the Centre of Excellence for the Commercialization of Research, Canada's Minister of Science and Technology, Gary Goodyear, stressed that in these times when many are concerned about the global economy, commercialization should become a greater priority. This commercial bent is no recent trend: the enabling legislation of the Canadian Institutes of Health Research (CIHR) stipulates that the objectives of the agency are to "encourage innovation, facilitate the commercialization of health research in Canada and promote economic development through health research in Canada." Likewise, many Canadian National Centres of Excellence projects have a strong commercial focus (e.g., the Stem Cell Network). To date, no real attempt has been made to situate the debate over commercialization in the broader context of academic research promotion.

Genomic research is an exciting new field of study that offers the prospect of new technologies and new cures. It aims to unravel the complexity of an organism's full complement of genes and how they interact – it links physiology with complete genetic make-up. By focusing on genetic networks rather than individual genes, genomic research has the potential to aid in the elucidation of the etiology of complex diseases or drug responses by surveying patterns of gene expression.

In 2000, the non-profit organization Genome Canada was established in order to develop and implement a national strategy in genomic research in areas such as agriculture, health and new technology development. Génome Québec, an investment arm of Genome Canada, has implemented specific measures to stimulate the integration of genomic research within industry. One example is the PRIVAC financing program of Génome Québec, which requires that at least a third of a project's funds be derived from the private sector. Given this shift to a more entrepreneurial approach, it seems essential to consider the effects of commercialization on genomic researchers, as well as on the organization and direction of genomic research in Canada.

In spite of two decades of commentary on the impact of commercialization on the field of genetic/genomic research, evidence on the trade-offs inherent in the push towards commercialization and the entrepreneurial university paradigm, specific to the Canadian context, is still lacking (Herder and Gold 2007). Outside of the general ethical framework of the *Tri-Council Policy Statement* (TCPS), no practical guidance exists for Canadian researchers or policy makers. In 2008, two groups of Canadian researchers, one based at the Centre de recherche en droit public in Montreal and the other at the Health Law Institute in Edmonton, undertook a series of in-depth qualitative interviews of genomic researchers concerning the commercialization environment (Silverstein et al. 2009; Murdoch and Caulfield 2009). Their research was financed by Génome Québec, Genome Alberta and Genome Canada.

FIGURE 1. Opinions of genomic researchers on the impact of patents and commercialization (based on results from Murdoch and Caulfield 2009)



Although the survey was conducted on a small sample of researchers (30 Canadian researchers), the results do not suggest that commercialization has had an overwhelmingly negative impact on their work or has created overt conflicts of interest. While interviewees mostly viewed patents in a neutral light, they identified secrecy, the proliferation of material transfer agreements (MTAs) and publication delays as causes for concern. Moreover, researchers often felt disconnected from the imperatives of the commercialization agenda. The results of these two qualitative studies, as well as additional evidence from the literature, inform the points to consider listed in Table 1.

Conflicts of Interest

Conflicts of interest (COIs), arising from undue influence of industry, call into question the objectivity and trustworthiness of research (Bekelman et al. 2003). The 2008 federal government's draft second edition of the *Tri-Council Policy Statement* notes that "[a]lthough the potential for such conflicts has always existed, pressures to commercialize research or suspend dissemination of research outcomes heighten concerns" (Panel on Research Ethics 2010). With genomic research, it has been suggested that the need to commercialize new research findings and to secure private partners could conflict with more traditional values of scientific integrity, academic freedom and the vocation of the academy (Joly et al. 2007; Bekelman et al. 2003). According to this position, traditional academic values are being neglected in favour of new commercial imperatives: it has been suggested that commercial agreements could negatively affect the mentorship of graduate students by faculty researchers and reduce the ability of these students to publish their research results (Behrens and Gray 2001). This pessimistic vision of the academic–industrial relationship thrives owing to a lack of trans-

parency, accessibility, harmonization and readability of institutional policies on COIs (Williams-Jones and MacDonald 2008). Furthermore, public trust can be eroded by highly publicized commercial controversies or theoretical arguments stressing the potential for conflicts in the fields of genetics and genomics, irrespective of the actual evidence (Caulfield et al. 2007).

TABLE 1. Commercialization of genomic research: Points to consider

Conflicts of interest Ethics committees should require a declaration of COIs from principal investigators whose research projects involve the private sector before approving their protocols.
Secrecy Researchers should conduct additional studies to pinpoint the sources of secrecy in the context of genomic research and to clearly delineate the respective roles played by MTAs, public–private partnerships and IP in this problematic area.
MTAs Canadian institutions should consider moving towards a simple standardized model of MTAs for non-commercial genomic research.
Intellectual property Funding bodies should encourage comprehensive empirical studies on the direct and indirect effects that the patent system has on academic genomic research in Canada.
Harmonization Canadian research institutions should promote transparency in three ways: (a) provide standard MTA forms online, (b) facilitate public access to COI and commercialization policies via websites and (c) develop open science data-sharing practices.
Overall Policy makers should recognize the structural limits of the commercialization framework and begin discussions on the promotion of university-based research in a broader context.

Secrecy

One of the most disturbing claims concerning the commercialization of genomic research is that it could possibly contribute to an increase in secrecy among university scientists and administrators. According to a growing body of evidence, researchers are not sharing data, materials and research tools as freely as they used to and are often publishing at a later stage in the research process (Blumenthal et al. 2006; Campbell et al. 2002). It has so far been difficult to attribute this problematic situation to a single element, although the proliferation of MTAs in academic research is believed by many to be a contributing factor. As recently suggested by Hong and Walsh (2009), it would be beneficial to "unpack the various dimensions of commercialization, sharing and secrecy to see what aspects are affected by what." If allowed to develop, the climate of secrecy in genomic research could limit the capacity of researchers to review and validate the work of other research groups by reproducing it independently. It

could also restrict the academic freedom of researchers in two ways: first, in pursuing research in the direction of their choosing, and second, in choosing their collaborators, and so hindering collaboration and delaying scientific progress. However, in limited circumstances a certain degree of secrecy could be justified by the need to protect the personal information of research participants.

Material Transfer Agreements

As genomic projects expand in size and ambition, researchers increasingly depend on the use of research tools and materials from outside their institutions to carry out research. However, because of the promise of obtaining IP rights, materials are often transferred by means of detailed agreements delineating the precise rights and obligations applicable to the transfer. Such MTAs are a direct consequence of the commercialization of academic research and of the rapid development of new scientific fields. These private legal agreements, variable in scope and complexity, are now extensively used in academia to clarify the rights of providers and recipients of genomic materials, tools or data. In fact, one could even argue that MTAs are used in situations where there is no real necessity for them (e.g., when the material to be transferred is of little commercial value or is meant to be openly disseminated). MTAs are a growing source of secrecy, reach-through rights and communication delays. They are also perceived as creating a significant hurdle to open collaboration among researchers (Bennett et al. 2007; Campbell et al. 2002). Conversely, it could also be argued that MTAs have become a necessary evil in protecting the potential of genomic research at a time when patenting research tools and private–public partnerships have become common practice.

Intellectual Property

IP gives power to an individual or entity (the IP holder) to control how knowledge will be used. In the field of genomics, IP protection is usually ensured through the patent system. Patents are exclusive IP rights, granted on eligible inventions for a period of 20 years. The patenting of genetic "inventions" has generated a considerable amount of controversy in recent years. It has been criticized for slowing down the pace of innovation, fostering secrecy, biasing the choice of research projects and obstructing the clinical uptake of valuable research (Joly 2009). Emerging evidence questions the veracity of many of these critiques (Walsh et al. 2003). Nevertheless, it is still possible that the growing importance of securing patent rights within academia is, directly or indirectly, encouraging the proliferation of MTAs, publication delays, secrecy and other sources of conflicting interests among genomic researchers. Patenting practices may exacerbate these concerns in the future (Mills and Tereskerz 2007). OECD member countries have taken the position that licence agreements that give licensors

exclusive control over human genetic information should be avoided. The OECD guidelines on good licensing practices are a proactive mechanism to streamline the patent system (OECD 2006; Canadian Biotechnology Advisory Committee 2005).

Harmonization

The new era of "big science" genomics involves the collaboration of multiple centres, often across national boundaries, and the creation of large biobank projects, such as the International Cancer Genome Consortium and the Canadian Partnership for Tomorrow Project. However, a major obstacle to achieving interoperability, large-scale collaboration and database networking is the dearth of socio-ethical or legal norms at the global and national levels that could guide such endeavours. Discrepancies in the policies that apply at the institutional level also impede the success of networking efforts. If commercialization remains a priority, some level of policy harmonization is necessary. Otherwise, policies meant to alleviate some of the potentially adverse effects of commercialization could end up doing more harm than good, leaving researchers mired in conflicting obligations, the reconciliation of which will require time and effort. Arguably, some of the issues associated with commercialization may derive from the difficulty of researchers and administrators to navigate through the numerous diverging institutional policies and identify a clear and comprehensive picture of trends, obligations and obstacles in policy work on this topic.

Conclusion: Towards a More Coherent Framework?

The issues associated with commercialization would be better managed if we were to view commercialization as one of many vectors in the broader context of the promotion of genomic research. In its 2001 *Policy on Science and Innovation*, the government of Quebec decided to avoid the general use of the term commercialization, replacing it instead by the French word *valorisation*. This word is sometimes translated in English as "development" or "promotion." This expression would seem to convey a much richer content than the word *commercialization*. The *Policy on Science and Innovation* confirms this by specifying that *valorisation* "refers globally to a group of activities that introduces the world of research to the economic and social sphere" and by adding the following:

> All research results will not produce commercial applications and lead to financially profitable businesses. Obviously, the promotion of research cannot be limited to the commercial exploitation of research results; generally, it rests on the demonstration and exchange of knowledge, and this, in all fields of knowledge development. (Translated from the French)

Nevertheless, in more recent documents – for example, in its *Action Plan: Managing Intellectual Property* – the Quebec government seems to have increasingly equated *valorisation* with *commercialization* alone and forgotten the other meanings conveyed. This is regrettable; the time has now come for policy makers to recognize the structural limit of the commercialization framework and to begin discussions on the promotion of university-based research in a broader context. This new framework should go beyond commercialization to consider also the implementation of research knowledge (the conversion of knowledge into tangible applications) along with its impact on health services. By better linking research with action, *valorisation* could enable stakeholders to bridge the pervasive disconnect between discovery and application in genomic research, thus finally enabling the population to enjoy concrete health benefits from the "genomic revolution."

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